

**AN EXAMINATION OF CRITICAL ISSUES IN
TRADITIONAL CHINESE ACUPUNCTURE RESEARCH**

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TABLE OF CONTENTS

	<i>page</i>
ABSTRACT	xvi
DECLARATION	xvii
PRELIMINARY NOTES ON TERMINOLOGY, FORMAT AND STYLE	xviii-xx
ACKNOWLEDGEMENTS	xxi
LIST OF TABLES	xiv
LIST OF FIGURES	xv
 <i>Chapter</i>	
1 INTRODUCTION	1
1.1 Background of the Study	1
1.1.1 Research: A path to Traditional Chinese Acupuncture (TCA) knowledge	1
1.2 The Aim of the Study	3
1.3 The Objectives of the Study	4
1.4 The Methodology of the Study	6
1.5 An Overview of the Structure and Format of the Dissertation	7
1.6 The Postmodern Context of the Study	11
1.7 The Importance of Significant Research Questions in the Field of TCA	15
1.7.1 The evaluation of the therapeutic effectiveness of TCA	16
1.8 The Significance of the Study	19
1.9 Limitations and Delimitations of the Study	22
1.9.1 Declaration of the author's position as researcher	22
1.10 The Determination of the Role of Traditional Chinese Acupuncture in Future Health Care Systems	25
1.10.1 The need to review health care in the light of the 'crisis' in Western health care systems	26
1.10.2 The declining effectiveness of biomedicine	28
1.10.2.1 The economic consequences of biomedicine	28
1.10.2.2 The effectiveness of biomedicine	28
1.10.2.3 Medical iatrogenesis	29
1.10.3 The challenge of the complementary therapies	30

2	DEFINING THE TERRAIN OF TRADITIONAL CHINESE ACUPUNCTURE PRACTICE AND RESEARCH	35
	SECTION 1 The Nature and Practice of Traditional Chinese Acupuncture	35
2.1	The Nature of Traditional Chinese Medicine (TCM)	36
2.2	Cultural and Philosophical Influences on TCA	37
2.3	Core Concepts and Themes of TCM that Underpin TCA Practice	41
2.3.1	The TCM paradigm is broad and can tolerate diverse schools of thought and practice	41
2.3.2	<i>Dao</i> and the limits of knowledge	42
2.3.3	Ontology: The Chinese concept of <i>qi (chi)</i>	42
2.3.4	The concept of <i>yin/yang</i>	46
2.3.4.1	The interdependence of opposites	47
2.3.4.2	The interpenetration of opposites	48
2.3.4.3	The unity of opposites	48
2.3.5	No mind-body dualism in TCM	50
2.4	The Practice of Acupuncture	51
2.4.1	The acupuncture needling technique	51
2.4.2	The different forms of acupuncture	52
2.4.3	Traditional Chinese acupuncture therapy	54
2.4.4	TCA therapy is dynamic and not static	55
2.4.5	TCA therapy is more than the application of the acupuncture needling technique	56
2.4.6	The TCA practitioner-client encounter	57
	SECTION 2 The Domain of Traditional Chinese Acupuncture Research	62
2.5	Appropriate Research Methods for TCA	62
2.6	The Purpose and Role of Basic Research, Applied Research, and Evaluation	65
2.6.1	The role of basic research in TCA	65
2.6.1.1	Types of basic research	66
2.6.1.1.1	Descriptive research	66
2.6.1.1.2	Exploratory research	67
2.6.2	Applied research and evaluation	67
2.6.2.1	The evaluation of the effectiveness of TCA therapy	70

<i>Chapter</i>	<i>page</i>
2	
2.6.3 The improvement of TCA clinical practice and TCA teaching programs through 'action' research	71
2.7 The Flaws of Contemporary Acupuncture Clinical Research	72
2.8 Priorities for Traditional Chinese Acupuncture Research	75
2.9 TCA Research Questions and Issues	76
2.10 The Need for a Variety of Research Approaches and Designs to study TCA	78
2.11 TCA and Social Research Methods	79
2.11.1 Health care research is interactive	80
2.11.2 TCA research is reflexive	81
2.12 Desirable Characteristics of TCA Researchers	82
2.13 Desirable Characteristics of TCA Research	83
2.14 Summary	83
3	
PHILOSOPHICAL AND SOCIOCULTURAL ASPECTS OF MEDICAL SYSTEMS	85
3.1 Introduction	85
3.2 Sociocultural Considerations of Medical Systems	87
3.3 Models of Health, Illness and Disease	88
3.4 The Different Discourses of Traditional Chinese Medicine and Biomedicine	91
3.5 Philosophical Underpinnings of Biomedicine	92
3.5.1 Mind-body dualism	92
3.6 Holism and Holistic Health Care	96
3.6.1 Assumptions of holism	96
3.7 A Holistic Definition of Health	98
3.8 The 'Systems' Perspective of Health Care	99
3.8.1 Characteristics of 'systems' theory	101
3.9 The Nature of the Human Being: Levels of being	107
3.9.1 Emergent properties	110
3.10 Perspectives of the Body	112
3.10.1 The nature of the human being in TCM and Biomedicine	113
3.10.2 The 'lived body'	115
3.11 Health can be Something More Collective than Individual	118
3.12 Holistic Models of Health Care	119
3.12.1 The tenets of holistic forms of medicine	122
3.13 Traditional Chinese Acupuncture: An example of holistic and humanistic health care	122
3.14 Holons ('wholes' that are simultaneously 'parts')	125
3.15 Implications of the TCM Model of Health Care for Research	129
3.16 Summary	131

<i>Chapter</i>	<i>page</i>
4	AETIOLOGICAL MODELS OF HEALTH, ILLNESS AND DISEASE 132
4.1	Oriental and Western Understandings of the Causes of Illness and Disease 133
4.2	Disease Entities 134
4.3	The Concepts of Determinism and Causality in Health Care Research 136
4.3.1	In TCM it is not always possible to identify the 'causes' of illness and disease 138
4.4	Aetiological Models Used to Explain the Presence of Illness and Disease 140
4.4.1	Supernatural/magical aetiological models 140
4.4.2	Naturalistic/systemic aetiological models 141
4.5	Aetiological Factors Involved in Health and Disease According to TCM 141
4.5.1	Imbalances of <i>yin/yang</i> 142
4.5.2	Disturbances of <i>shen</i> 142
4.5.3	The quality of a person's <i>zheng qi</i> ('right' or antipathogenic <i>qi</i>) and resistance to pathogenic <i>qi</i> 143
4.5.4	The <i>bu nei wai yin</i> 143
4.6	Sociocultural Factors of Health and Disease 143
4.6.1	The role of beliefs in the production of health, illness and disease 145
4.6.2	Research that supports a sociocultural model of health and disease 145
4.7	Psychological Determinants in Health and Disease 146
4.7.1	Implications for TCA research 153
4.8	'Mind-body' and TCM Research 154
4.9	Summary 155
5	PARADIGMS OF RESEARCH 157
5.1	Paradigms of Research 157
5.2	Paradigms and the Postmodern Context 159
5.3	The Languages of Paradigms 161
5.4	Research Paradigms and TCA 163
5.4.1	Realism 164
5.4.2	Positivism 165
5.4.2.1	Objectivity and the avoidance of subjectivity 168
5.4.2.2	Criticisms of positivism 170
5.4.3	Postpositivism and neopositivism 173
5.4.4	The naturalistic paradigm 173

<i>Chapter</i>		<i>page</i>
5	5.4.5 The humanistic paradigms	174
	5.4.6 The interpretive paradigms	176
	5.4.7 Constructivism	177
	5.4.8 Critical Social Theory	178
	5.4.9 Phenomenological approaches to obtaining knowledge	180
	5.4.9.1 Phenomenology and the language of consciousness	179
	5.5 Research Paradigms and their Different Conceptions of the Human Being	182
	5.6 The Relative Value of a Paradigm's Approach to Knowledge	183
	5.6.1 The 'voices' of the various paradigms	183
	5.7 Summary	184
6	WAYS-OF-KNOWING IN TRADITIONAL CHINESE ACUPUNCTURE	185
	6.1 Chinese Philosophical Concepts of Knowledge	186
	6.2 Modes of Thought in the Traditional Chinese Medicine	188
	6.3 Thought Processes and Reasoning in TCA	189
	6.3.1 Logistic reasoning	190
	6.3.2 Inductive and deductive reasoning	191
	6.3.3 Dialectical reasoning	192
	6.4 Thought Processes Used in Clinical Reasoning	194
	6.4.1 Pattern recognition	195
	6.4.2 Hypothetico-deductive reasoning (HDR)	196
	6.4.3 Systematic scanning	196
	6.4.4 The role of introspection and intuition in clinical reasoning	198
	6.5 Ways of Acquiring TCA Knowledge	199
	6.5.1 Authority and tradition	199
	6.5.2 The study of classical Chinese texts	200
	6.5.3 Role-modelling	201
	6.6 Types of Knowledge	202
	6.6.1 Propositional knowledge	202
	6.6.2 Non-propositional knowledge	203
	6.6.2.1 Professional craft knowledge	203
	6.6.3 Personal Knowledge	204
	6.6.4 Knowledge from personal experience though 'trial and error'	205
	6.6.4.1 Practical knowledge	207
	6.7 Appropriation of Research Methods from other Disciplines	208
	6.7.1 Clinical trials, naturalistic inquiry and qualitative research	209
	6.8 Summary	209

<i>Chapter</i>	<i>page</i>
7	THE EPISTEMOLOGICAL ORIENTATIONS OF TRADITIONAL CHINESE ACUPUNCTURE PRACTICE: IMPLICATIONS FOR RESEARCH 210
7.1	Research and the Health Professions 210
7.2	Epistemological Orientations to Practice 212
7.3	Reasons for the Neglect of the Epistemologies of Practice 213
7.4	Epistemological Orientations of Health Care Practice 213
7.4.1	The traditional epistemological orientation to practice 213
7.4.2	The disciplinal epistemological orientation to practice 216
7.4.3	Neopositivism 219
7.4.3.1	The fundamental body of knowledge of the neopositivistic orientation to practice 220
7.4.3.2	The applied body of knowledge of neopositivism 221
7.4.3.3	Professional practice of neopositivism 221
7.4.3.4	Advantages of the neopositivist orientation 222
7.4.3.5	Possible disadvantages of the neopositivist epistemological orientation to practice 222
7.4.4	The phenomenological epistemological orientation 224
7.4.4.1	Advantages and disadvantages of the phenomenological orientation 226
7.5	Summary: The Epistemological Orientations of TCA Practice and the Implications for Future Research 227
8	SCIENTIFIC INQUIRY AND TRADITIONAL CHINESE ACUPUNCTURE 230
8.1	TCA and Scientific Inquiry 231
8.2	Science and the Scientific Method 231
8.3	Implications of Quantum Physics and the Emerging New Sciences 234
8.3.1	Quantum physics 234
8.3.2	Chaos theory 236
8.4	Is TCM Scientific? 238
8.5	Typologies of Science 239
8.6	Truth and the Methods of Science 241
8.7	Philosophical Bases of Experimental and Clinical Research 242
8.8	The Role of Theory in TCM 242
8.9	Theory in TCA Practice and Research 244
8.10	Types of Quantitative Research Designs that can be used to examine TCA 248

<i>Chapter</i>		<i>page</i>
8	8.10.1 Correlational research	248
	8.10.2 Experimental-type research	249
	8.10.2.1 Prospective and retrospective research designs	252
	8.10.2.2 Pragmatic randomised controlled trial (PRCT)	253
	8.10.3 Quasi-experimental research	253
	8.10.4 Single subject experimental design (n=1 trial or n of 1 trial)	254
	8.10.5 Surveys	256
	8.10.6 Epidemiology	257
	8.10.7 Meta-analysis and systematic review	257
	8.10.8 The limitations of quantitative research methods	258
	8.11 Summary	259
9	APPROACHES TO THE MEASUREMENT OF HEALTH OUTCOMES IN TRADITIONAL CHINESE ACUPUNCTURE RESEARCH	260
	9.1 Measuring Health Outcomes in TCA Research	260
	9.2 The Measurement of Data in TCA Research	262
	9.2.1 Assessment of data in the three realms of body, mind and spirit	263
	9.3 Quality of Life (QOL) Measures	263
	9.3.1 The reasons for considering 'health-related quality of life'	265
	9.3.2 When should 'quality of life' not be measured?	268
	9.4 The Purposes of Outcome Measurement in TCA Research	268
	9.5 Definition of a Therapeutic Outcome	268
	9.6 The Distinction Between the Management of Chronic Illness and Disease and the Treatment of Acute Disease	269
	9.6.1 Chronic disease and TCA therapy	270
	9.6.2 Treatment of acute conditions by TCA	270
	9.7 Deciding on which Domains and Parameters to Measure in TCA Research	271
	9.8 Possible Domains and Parameters to Measure in Research to Establish TCA Efficacy	272
	9.9 Research Instruments for TCA	274
	9.9.1 'Weighted' and 'Unweighed' Parameters in 'Quality of Life' Instruments	274
	9.9.2 Safety Parameters in TCA Efficacy Research	275
	9.9.3 Parameters that measure both efficacy and safety	275
	9.10 Research Instrument Validity and Reliability	275
	9.10.1 Content, face & construct validity	276
	9.11 Advantages of Creating an Original Instrument for a TCA Study	276
	9.12 Disadvantages of Creating an Original Instrument for a TCA Study	277

<i>Chapter</i>	<i>page</i>	
9	9.13 Creating New Instruments by Modifying or Combining Sections of Other Research Instruments	277
	9.14 Methods and Instruments for Measuring Outcomes in TCA	278
	9.14.1 MOS 36-Item Short Form Health Survey (SF-36)	278
	9.14.2 The World Health Organisation Quality of Life Group research instrument	279
	9.14.3 The Patient Generated Index (PGI): A way of measuring quality of life	280
	9.14.4 Measure Yourself Medical Outcome Profile (MYMOP)	281
	9.15 Summary	282
10	THE EVALUATION OF THE EFFICACY OF TRADITIONAL CHINESE ACUPUNCTURE THERAPY	283
	10.1 Evaluating the Efficacy of TCA Therapy: Some Preliminary Observations	284
	10.2 The Randomised Controlled Trial (RCT)	286
	10.3 The Placebo Effect in Traditional Chinese Acupuncture Research	288
	10.4 The Double-blind Randomised Controlled Trial	288
	10.5 The Single-blind Randomised Controlled Trial	290
	10.5.1 'Sham' acupuncture controls in TCA clinical research	291
	10.5.2 Possible problems associated with the 'sham' acupuncture control	293
	10.6 Are the Therapeutic Effects of the TCA Needling Technique and the Non-specific (placebo) Effects of Therapy Additive?	295
	10.7 Problems of Adapting the Randomised Controlled Trial Methodology to Evaluate the Efficacy of TCA Therapy	296
	10.8 Other Issues in the Evaluation of the Effectiveness of TCA	300
	10.9 Overcoming Clinical Research Problems Associated with the Different Languages of TCM and Biomedicine	300
	10.10 Which Diseases and Syndromes Should the TCA Profession and Researchers Consider for Research?	304
	10.11 'Non-specific' (placebo) Factors in TCA Clinical Trials	305
	10.12 The Mega-placebo Effect	306
	10.13 The Importance of the Mind and Psychological Factors in Health and Disease	308
	10.14 Understanding the Placebo Phenomenon	308
	10.14.1 Placebo effects on illness and disease	309
	10.14.2 Theories of placebo action	310

<i>Chapter</i>	<i>page</i>
10	
10.14.3 The placebo effect: A psychological phenomenon	312
10.14.4 The placebo is not psychotherapy	312
10.14.5 The 'meaning model'	314
10.15 Care and Cure: The effect of the physician in the healing of human illness and disease	316
10.16 Placebo Healing in Randomised Clinical Trials	318
10.17 The Therapeutic Effect of Individual Health Care Practitioners is Not Always the Same	319
10.16.1 The role of practitioner intention in TCA practice	319
10.18 Pragmatic Trials that Use Active Controls	321
10.19 Two-arm and Three-arm Pragmatic Trials that Use Active Controls	322
10.19.1 Does TCA therapy result in better therapeutic outcomes than 'formula' acupuncture or standard biomedical treatment?	325
10.20 The Quest for Certainty: Problems associated with the randomised controlled trial	327
10.20.1 'Helplessness' in research	329
10.21 Could the RCT Reduce the Effectiveness of Complementary Therapies such as TCA?	330
10.22 It is Impossible to Eliminate All Possible Explanations by Using the Randomised Controlled Trial	331
10.23 Further Difficulties of Accounting for Non-specific (placebo) Effects in Randomised Controlled Trials	332
10.24 All New Medical Procedures Should be Evaluated, Not Only the Complementary Therapies	333
10.25 Summary	334
11	
ETHICS AND TRADITIONAL CHINESE ACUPUNCTURE RESEARCH	335
11.1 The Conflicting Obligations between the TCA Practitioner's Roles of Therapist and Clinical Researcher	335
11.2 Ethics in TCA Practice	336
11.3 Ethics in Clinical Research	337
11.4 Therapeutic and Non-therapeutic Research	338
11.5 Informed Consent in Clinical Research	340
11.6 Other Ethical Issues Associated with TCA Clinical Trial Designs	342
11.7 When Should Placebo Controls Not be Used in Clinical Research	343
11.8 The Monitoring of TCA Clinical Trials	344
11.9 Summary	345

<i>Chapter</i>	<i>page</i>
12 QUALITATIVE METHODS AND OTHER RESEARCH APPROACHES FOR TRADITIONAL CHINESE ACUPUNCTURE	346
12.1 Naturalistic Inquiry and Qualitative Research Methods	346
12.2 Similarities between the Patton's Themes of Qualitative Research and TCA Theory and Practice	348
12.3 The Roles of Qualitative Methods in TCA Research	351
12.4 Data Collection and Analysis in Qualitative Research	352
12.4.1 The qualitative research interview	353
12.4.2 Common features of qualitative data analysis	354
12.5 The Role of Theory in Qualitative Research	355
12.6 Types of Qualitative Research that can be Employed in the Field of TCA	357
12.6.1 Grounded Theory	357
12.6.2 Phenomenological Research	357
12.6.3 Hermeneutics	360
12.6.4 Case Study	362
12.6.4.1 Intrinsic and instrumental case studies	364
12.6.4.2 Forms of generalisability	365
12.6.5 Etymological Studies	366
12.6.6 Ethnography	366
12.6.7 Critical Social Theory	367
12.6.8 Focus groups	368
12.7 The Role of Qualitative Research Methods in the Improvement of TCA Clinical Practice	368
12.8 Other Research Methods for TCA	370
12.8.1 Clinical Audit	370
12.8.2 Philosophical Inquiry	371
12.8.3 Historical Research	372
12.8.4 Primary Prevention and Health Promotion Studies	372
12.9 Summary	373

<i>Chapter</i>	<i>page</i>	
13	CRITERIA FOR EVALUATING THE QUALITY OF TRADITIONAL CHINESE ACUPUNCTURE RESEARCH	374
13.1	Modern and Postmodern Understandings of Validity	374
13.1.1	Validity and positivism	375
13.1.2	Validity and constructionism	376
13.2	Knowledge Validation: Conviction, Truth and Evidence	377
13.3	Evaluating Competing Knowledge Claims	378
13.4	Verification Principles for the Collection of Data in the Three Realms of Body, Mind and Spirit	380
13.5	Pragmatic Validity and TCA	381
13.6	Criteria for Evaluating the Quality of TCA Research	382
13.7	The Validity of Quantitative Research	384
13.7.1	Validity and bias in TCA clinical research	385
13.7.2	Maintaining internal validity in TCA clinical research	386
13.7.3	Maintaining external validity in TCA clinical research	387
13.7.4	The evaluation of the quality of clinical evidence	387
13.7.5	The criteria for the evaluation of TCA clinical trials	388
13.8	Maintaining Validity in Naturalistic Inquiry and Qualitative Research	393
13.9	Summary	397
14	SUMMARY AND CONCLUSIONS	398
14.1	A Summary of Research Findings	398
14.2	The Implications of this Study for Future TCA Research	405
14.3	Priorities for Future TCA Research	407
14.4	Towards an Integrated Model of Health Care	410

APPENDICES

A	The Therapeutic Techniques of the Contemporary Practitioner of Traditional Chinese Acupuncture	412
B	What Respondents Said Chinese Medicine Care Does and Why they Liked It	413
C	National Health and Medical Research Council (NHMRC) (1995) Quality of Evidence Ratings	414
D	The Mitroff and Kilman Typology of Scientists	415
E	Threats to Internal Validity (Cook and Campbell, 1979)	416
F	Domains and Facets of the World Health Organisation Quality of Life Instrument	417
G	Instruments that Could be Used in Research of Traditional Chinese Acupuncture	418
H	Types of Triangulation	419

BIBLIOGRAPHY	421
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LIST OF TABLES

<i>Table</i>	<i>page</i>
2.1 General Examples of Phenomena Classified According to <i>Yin/Yang</i>	47
2.2 Examples of <i>Yin/Yang</i> as Applied to the Human Being and TCM Diagnostic Phenomena	47
3.1 Levels of Being	109
3.2 Dualisms to Avoid	128
5.1 The Contrasting Axioms of Positivism and the Naturalistic Paradigm	174
6.1 Major Differences Between Naturalistic Inquiry and Experimental-type Research	192
7.1 Comparison of the Characteristics and Features of the Technical-rational View and the Professional Artistry Model of Professionalism	211

LIST OF FIGURES

<i>Figure</i>	<i>page</i>
2.1 <i>Tai qi (tai chi)</i> Symbol	46
3.1 The Heuristic Model of the Stress Process that Integrates the Environmental, Psychological and Biological Levels	105
3.2 The Effects on the Individual by Changes in the Various Units of a Systems Hierarchy	106
3.3 The Chinese Philosophical Concept of ‘Heaven, Earth & Man (Humanity)’	118
3.4 Abraham Maslow’s Hierarchy of Needs	123
8.1 The Role of Theory in Quantitative/Experimental-type Research	247
8.2 The Pretest-postest Control Group Design	250
8.3 Single Subject (ABAB) Experimental Design (n=1)	254
8.4 Treatment of Meniere’s Disease by Acupuncture (Chell, 1997)	255
10.1 A Selection Procedure for a TCA Clinical Efficacy Trial	302
12.1 The Role of Theory in Naturalistic Inquiry/Qualitative Research	356
12.2 A Schematic Representation for the Development, Refinement, and the Assessment of the Adequacy of Sets of Guidelines for TCA Practice	369
12.3 The Audit Cycle	371

ABSTRACT

This dissertation examines the critical issues associated with inquiry and research in the field of Traditional Chinese Acupuncture (TCA), one of the treatment modalities of Traditional Chinese Medicine (TCM). TCM can be understood to constitute a distinct health care paradigm in the Kuhnian sense of having its own ontology, fundamental tenets, assumptions and practices. As TCA is practised within the framework of the TCM paradigm with its associated concepts of the person, health, illness and disease, it is argued that appropriate modes of inquiry and research methods for TCA can only be determined if one has a comprehensive understanding of the nature, philosophy, theory and practice of TCM and TCA.

Philosophical inquiry is used in this study to examine and determine the forms of inquiry, research designs and methodologies which are appropriate for increasing the understanding of TCA, and for the further development of TCA knowledge and practice. This study is predicated on the understanding that the various research methods of biomedicine, primary health care and sociology cannot be utilised without consideration of, and in some cases adaption to, the nature and practice of TCA.

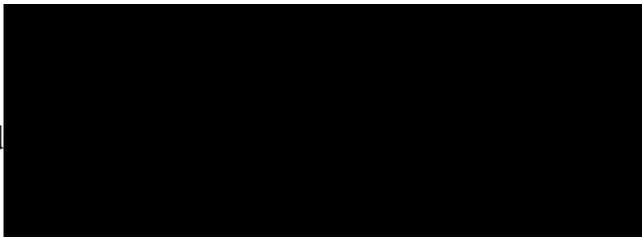
While some health care professions have an affinity with, and tend to utilise particular research methods, it is argued that it is the nature of the TCA research question that should direct the selection of an appropriate research design for any particular study. The various research paradigms and associated research methods examined in this dissertation can produce different types of knowledge, all of which can be of value and useful for particular TCA research goals. Considering the common features and themes of TCA and qualitative inquiry (both hold a holistic perspective and are case oriented where contextuality is emphasised), qualitative research methods should have a more important role in the future development of TCA knowledge.

This foundational study provides a firm basis for future researchers wanting to conduct sound and worthwhile studies in the field of TCA utilising appropriate forms of inquiry and research methods.

DECLARATION

I certify that this dissertation does not incorporate any material previously submitted for a degree or diploma in any university. To the best of my knowledge, this dissertation does not contain any material previously published or written by another person, without acknowledgement, and where due reference has not been made in the text.

signed



date 22 December 1999

Barry Wayne Nester

PRELIMINARY NOTES ON TERMINOLOGY, FORMAT AND STYLE

The term, 'Traditional Chinese Medicine' (TCM), that is used in this dissertation is defined broadly and encompasses the extensive range of traditional ideas on health and illness, and of practices that have been used by practitioners, healers and lay people in China over the past three millennia. The term TCM is used rather than 'Chinese Medicine' (a translation of the Chinese term *zhong yi*) to emphasise the traditional nature of this form of medicine.

It should be noted that many medical concepts and terms are paradigm specific. There are many instances where a particular term or concept of one system of medicine does not have an equivalent in another. For example, the TCM term *fei* is often translated into English as 'lung'; however, it should be noted that the functions of *fei* (lung) in traditional Chinese medicine (TCM) are *not* the same as the functions of the lungs as they are understood in Biomedicine (orthodox medicine). While respiration is the essential role of the lungs in Biomedicine, the functions of *fei* in TCM include the functions of controlling *qi* and respiration, dispersing *qi* throughout the body and keeping the water passageways unobstructed (see Zhiya, 1995).

It should also be noted that some Traditional Chinese Acupuncture (TCA) practitioners refer to the people whom they try to help as *clients* rather than as *patients*. The use of the term *client* by some TCA practitioners acknowledges the idea that a person can be *partly* responsible for their own health through their decisions, actions, and lifestyle. This position could be understood to stem from an altered health care provider relationship from that of Biomedicine. The term *patient* can connote a passive receiving of therapy by a dependent person; the term *client* in contrast, suggests a person who is essentially independent and capable of making judgments on the advice given to them by their health care practitioner. In this dissertation the term *client* is the term that is generally used to refer to a person who consults a TCA practitioner; however, it should be noted that some TCA practitioners prefer to use the term *patient*.

Researchers also use a variety of terms to describe those individuals studied in research. Often researchers that use experimental/quantitative research designs refer to those people studied as 'subjects'; whereas researchers who utilise qualitative research methods prefer the terms 'informant' or 'participant'.

Romanisation of Chinese Characters

In this dissertation, the *pin yin* style of Romanisation of Chinese characters has been used, except on occasion for terms and names that are well known in spellings based on the Wade-Giles system of Romanisation. The first time a Chinese term appears in this dissertation, it is given in both styles of Romanisation, the *pin yin* first, followed by the Wade-Giles in parentheses. The following list includes some of the more commonly used Chinese terms that occur in this dissertation in both the *pin yin* and the Wade-Giles systems of Romanisation:

<i>Pin Yin</i>	<i>Wade-Giles</i>
<i>Dao</i>	<i>Tao</i>
<i>Dao De Jing</i>	<i>Tao Te Ching</i>
<i>Daoism</i>	<i>Taoism</i>
<i>Laozi</i>	<i>Lao Tzu</i>
<i>Qi</i>	<i>Chi (Chi)</i>
<i>Kongzi</i>	<i>Confucius</i>
<i>Tai ji</i>	<i>Tai chi</i>
<i>Yi Jing</i>	<i>I Ching</i>
<i>Tai Ji Quan</i>	<i>Tai Chi Chuan</i>
<i>Qi Gong</i>	<i>Chi Kung</i>

The author has decided to italicise Chinese medical terms so that the reader can clearly differentiate between the terms of Traditional Chinese Medicine (TCM) and Biomedicine.

The system of referencing used in this dissertation is that of the American Psychological Association (APA). The thesis is double spaced and is set in 12 point 'Times' typeface to enhance readability. The spelling of words in this dissertation is in accord with *The Macquarie Dictionary* (3rd. ed.) (1997) which is a standard reference of Australian spelling. Technical terms are as a rule defined when first used in the text. The author has endeavoured to use gender neutral (inclusive) language throughout the dissertation.

ABBREVIATIONS USED IN THIS DISSERTATION

ACES	Active Control Equivalence Study
CHM	Chinese Herbal Medicine
EBM	Evidence-based Medicine
ERCT	Explanatory Randomised Controlled Trial
HDR	Hypothetico-deductive Reasoning
HRQOL	Health-related Quality of Life
NHMRC	National Health and Medical Research Council
NIH	National Institutes of Health
PRCT	Pragmatic Randomised Controlled Trial
QOL	Quality of Life
RCT	Randomised Controlled Trial
TCA	Traditional Chinese Acupuncture
TCM	Traditional Chinese Medicine
WHO	World Health Organisation

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New ideas and knowledge are seldom born fully formed from a vacuum. New knowledge is usually developed from the ideas and efforts of others. It is for this reason that I wish to acknowledge all of those authors, scholars, academics and thinkers who are listed in the bibliography of this dissertation, whose thoughts and insights have influenced the development of my own.

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CHAPTER 1

INTRODUCTION

“As disciplinary boundaries and the line between science and nonscience blur, as claims to universal knowledge lack credibility, as knowledges are viewed as interlaced with rhetoric power, the very meaning of knowledge is changing.”

- Seidman (1994, Introduction, p. 2)

1.1 Background of the Study

1.1.1 *Research: A Path to Traditional Chinese Acupuncture (TCA) Knowledge*

Research can be understood as a process in which people conduct inquiry in an attempt to gain knowledge and understanding of a particular phenomenon or subject of interest. Research, if conducted in a systematic manner, can validate old knowledge and generate new knowledge (Burns and Grove, 1993). It is the view of many people, including researchers, that research is a worthwhile human pursuit since it can increase humanity's knowledge of worldly phenomena and enhance our understanding of the nature and activities of human beings. Implicit in this view is the Humanist¹ assumption that knowledge can be applied to change and improve the world in which human beings live.

One of the aims of health care research has been to improve the lives of human beings by determining which health programs, medical interventions, and therapies can effectively prevent and treat illness and disease and thereby reduce human pain and suffering. Many acupuncture practitioners also believe that further research in the field of acupuncture will be

¹ Humanism is an idea-system of the mid-twentieth century. According to Julian Huxley, 1962, p. 14 humanism “affirms that knowledge and understanding can be increased, that conduct and social organisation can be improved, and that more desirable directions for individual and social development can be found.”

beneficial for the acupuncture profession and the health of society as a whole (Fitter and Blackwell, 1993). It is now evident that health care practitioners who maintain a 'holistic' orientation to practice, including many traditional acupuncturists, have come to the realisation that the interface between holistic principles (see chapter 3) and conventional research methods has not been ideal (Guzzetta, 1989).²

This dissertation examines the critical issues associated with inquiry and research in the field of Traditional Chinese Acupuncture (TCA).³ TCA is one of the treatment modalities of Traditional Chinese Medicine (TCM)⁴ which has been derived, in part, from Chinese philosophical concepts and TCM theory and practice. During clinical encounters, TCA practitioners use acupuncture and associated traditional adjunctive practices to influence the *qi*⁵ of their clients who are ill, in an to attempt to restore their health and wellbeing.⁶

While academics involved in TCM research and education generally embrace the idea of increasing the knowledge base of TCA through the process of research, the means by which this can, and should be achieved has been a contentious issue. Volker Scheid (1993) has suggested that researchers need to consider carefully whether all of the research methods that are used in the West are suitable for the examination of TCM, since TCM is an Eastern system

² M. Little (1995, p. 182) states that an important assumption of *holism* is that "the totality of entities and systems is more than the simple sum of their parts." It is often claimed by holists that it is the 'whole' which determines the nature of its parts, and that the parts reflect the whole in its totality. A consequence of such an understanding is that any 'system' (whether it be a human or a society) can only be fully understood in relation to larger systems of which it is a part.

³ According to N. Wiseman and F. Ye (1998, pp. 5-6), the term acupuncture comes from the Chinese term *zhen jiu*, *zhen* meaning 'needle' and *jiu* meaning 'moxibustion'. Acupuncture is "the practice of puncturing the body with metal needles (steel, gold, or silver) at specific points in order to regulate construction, defense, qi, and the blood." The nature and practice of TCA is described in detail in chapter 2.

⁴ The broad definition of the term Traditional Chinese Medicine (TCM) that is used in this dissertation is presented in chapter 2.1.

⁵ *Qi* is a concept that is central to TCM. According to Chinese Daoists, all manifestations in the universe are understood as configurations of *qi* generated by the dynamic interplay of the two archetypal complementary polar opposites termed *yin* and *yang*. See chapter 2.3.3.

⁶ See Appendix A: The Therapeutic Techniques of the Contemporary Practitioner of Traditional Chinese Acupuncture.

of medicine with different premises and assumptions than those of Western Biomedicine.⁷ A claim that is often made by members of the TCA profession is that TCA is not just another medical technique but is in fact a unique system of medicine that has been derived from Oriental ideas and understandings (Guilluume, 1991). It has also been noted that the epistemology of the TCM world view is “synthetic, relational and associative, rather than deductive and analytical” as is the case in Western science and medical research (Ryan, 1995, p. 74). Scheid (1993) has suggested that the study of TCM using inappropriate research methods could even be detrimental to the system of TCM, possibly signalling the beginning of its demise. Scheid (1993, p. 28) states that, “[t]he scientific re-evaluation of traditional systems of medicine is, from an objectivist point of view, a thoroughly legitimate enterprise. For traditional ways of thought, however, it amounts to acts of epistemological violence.” This statement suggests that occidental epistemology and its ways of obtaining knowledge might be dissonant with the ontology and associated epistemology of paradigms of medicine such as TCM. Scheid (1993, p. 28) has also expressed a concern that research into TCM using Western research approaches could possibly draw attention and resources away from the methods of inquiry characteristic of its own tradition.

It should be realised at the outset that the concept of *research* is not a foreign concept to practitioners of TCA. As Scheid (1993, pp. 27-28) has noted, practitioners of TCM (many of whom are acupuncturists) are always simultaneously both clinicians and researchers in the sense that their knowledge increases with continued practice. With Scheid’s concerns in mind, it is crucial that the research methods used by researchers to investigate TCA and related phenomena are appropriate and not incongruent with the perspective of TCM.

1.2 The Aim of the Study

The aim of this dissertation is to examine the critical issues associated with inquiry and research in the field of Traditional Chinese Acupuncture (TCA). One major focus of this study is to critically examine the various approaches of inquiry that have been used in research of TCA,

⁷ Biomedicine (or orthodox medicine) is the dominant form of medicine that is now practised in the developed world. Biomedicine is practised by medical practitioners who assert its legitimacy by reference to its claims to scientificity.

Biomedicine, primary health care and the social sciences, so as to be able to determine which types of inquiry and associated research methods are appropriate for, and which can be adapted for the further development of TCA knowledge and practice. This will require the examination of the ontology and epistemological perspectives of several paradigms of research (chapter 5) and their associated research methods, so as to be able to assess which could be useful and congruent with the traditional Chinese medical perspective. It is argued in this dissertation that appropriate approaches of inquiry and research methods for TCA can only be determined if one is cognizant of the ideas, assumptions, theories and philosophy of TCM, the Oriental world view from which TCM has been derived, and the way TCA is actually practised by members of the TCA profession.

It is hoped that this foundational study will provide a basis for future researchers who will desire to conduct sound and useful studies in the field of TCA utilising appropriate forms of inquiry and research methods.

1.3 The Objectives of the Study

The objectives of this study are as follows:

- (1) To determine some guiding principles for the development of appropriate research designs and methodologies that can be utilised in research of TCA.
- (2) To make explicit the nature of TCM and the core philosophical and theoretical concepts, features and recurring themes that underpin TCA practice (chapters 2, 3 & 4). This analysis is a prerequisite for the determination of the types of research methods that are congruent with the philosophy, theory and practice of TCA.
- (3) To examine the roles that sociocultural factors and psychological determinants play in the process of human health and disease from the perspective of TCM so as to determine the implications of these for TCA research (chapter 3 & 4).
- (4) To examine several research paradigms and perspectives of health care that have relevance for the determination of appropriate forms of inquiry and research methods for TCA (chapter 5).

- (5) To identify the forms of TCA knowledge and the means by which this knowledge has and can be obtained (chapters 6 & 7).
- (6) To determine the methods that have been used by members of the TCA profession to generate knowledge so as to make explicit the epistemological orientations of these various approaches (chapter 7).
- (7) To explore issues related to the utilisation of the methods of science to examine and evaluate TCA (chapter 8).
- (8) To determine the uses of quantitative research designs for the production of TCA knowledge (chapters 8, 9 & 10).
- (9) To examine issues that are critical to the evaluation of the efficacy of TCA therapy. This will include:
 - (i) ascertaining the domains and parameters that are most relevant to research that attempts to determine the efficacy of TCA therapy (chapter 9);
 - (ii) identifying the reasons for which conventional randomised clinical trial methodologies need to be adapted so as to be able to evaluate the efficacy of TCA (chapter 10);
 - (iii) the exploration and implications of the 'placebo' phenomenon in relation to its role in TCA therapy and TCA clinical research (chapter 10).
 - (iv) the examination of the limitations of quantitative research designs such as the randomised clinical trial in evaluating the effectiveness of TCA therapy (chapter 10).
- (10) To examine some of the ethical issues that should be addressed when designing and conducting TCA research involving human beings (chapter 11).
- (11) To determine the roles of naturalistic inquiry and qualitative research methods in the field of TCA research. Consideration will be given to the various qualitative and interpretive methods of inquiry for generating TCA theory, understanding the nature of TCA,

increasing TCA knowledge, and improving TCA practice (chapter 12).

(12) To determine ‘quality criteria’ by which the quality of TCA research can be assessed (chapter 13).

1.4 The Methodology of the Study

The aim and objectives of this dissertation are to be addressed primarily by *philosophical inquiry* (Ellis, 1983; Burns & Grove, 1993, pp. 79-81), *via* an extensive examination and analysis of relevant literature. Relevant literature for this study includes texts and research articles from the disciplines of TCM, primary health care, sociology, Oriental philosophy, the philosophy of science, and health care research methods. Literature and information has been obtained by manual and database searches and through citation tracking. Data bases accessed include MEDLINE, AMED (Allied and Alternative Medicine), CINAHL, HEALTHSTAR and EMBASE.

The form of philosophical inquiry that has been used by the author draws on *constructionist* understandings of knowledge production (see Guba & Lincoln, 1994). According to Guba and Lincoln (1994, p.114), constructionists hold the position that “knowledge accumulates only in a relative sense through the formation of ever more informed and sophisticated constructions”. The research methodology of this study also draws on the approach of *critical social theory methodology*⁸ as outlined by Burns and Grove (1993, pp. 595-597). The thrust of critical social theory is that social phenomena can only be understood when examined within an historical context. Some critical social theorists contend that most societies are based on ‘closed systems’ of thought that can lead to constraints that impede the free and uncoerced participation in, and the personal growth of individuals in that society (Burns & Grove, 1993, p. 83). It is maintained in this dissertation that the current ‘crisis’ in health care in Western societies is in part due to the dominance of Biomedicine with its limited philosophical premises and conceptions of health, illness and disease.

⁸ Critical social theory started in the 1920s and has been influenced by the writings of the philosopher Karl Marx [1818-1883] and later by Habermas (1971). For accounts of critical social theory, see J. Cheek *et al.*, *Society and Health: Social theory for health workers*, 1997 and also T.A. Schwandt, *Qualitative Inquiry: A dictionary of terms*, 1997, pp. 24-25.

Philosophical inquiry provides a means to access knowledge. It allows intellectual analyses to clarify conceptual meanings and to identify and make explicit the values, premises and assumptions of theories, paradigms and world views. Such an approach allows the ontology and epistemological perspectives of paradigms of research and their associated research methods to be examined, so as to be able, in the present instance, to determine appropriate forms of inquiry that are congruent with the TCM perspective for the generation of TCA knowledge.

The author, throughout this dissertation, upholds a postmodernist position which claims that no one discourse, whether it be positivism, science, or TCM has the sole claim to authoritative knowledge.⁹ As Laurel Richardson (1994) states:

The core of postmodernism is the *doubt* that any method or theory, discourse or genre, tradition or novelty, has a universal and general claim as a 'right' or the privileged form of authoritative knowledge. Postmodernism *suspects* all truth claims of masking and serving particular interests in local, cultural, and political struggles. ... postmodernism does not automatically reject conventional methods of knowing and telling as false or archaic. Rather, it opens those standard methods to inquiry and introduces new methods, which are also subject to critique.

A postmodernist perspective therefore permits this dissertation to proceed, by allowing the various methods of conventional inquiry to be examined and subjected to scrutiny.

1.5 An Overview of the Structure of the Dissertation

The content of this dissertation is organised into chapters. The first, introductory chapter, provides a background for the study that explains the context for the research topic. The aims and objectives of the thesis are outlined, as is the methodology by which the aims and objectives are to be achieved. The significance of this study for researchers and the TCA profession is made explicit. Other factors and issues that have contributed to the need for more research in the field of TCA are also outlined.

⁹ For an insightful account of the postmodernist movement, see Ken Wilber, *The Marriage of Sense and Soul: Integrating science and religion*, 1998, pp. 116-136.

In the first section of chapter two, the nature of Traditional Chinese Acupuncture (TCA) and the core philosophical concepts, characteristics and recurring themes of Traditional Chinese Medicine (TCM) that underpin TCA practice are identified. Through this examination and analysis of the nature and features of TCA, it then becomes possible to determine the types of research methods that are congruent with the philosophy, theory and practice of TCA. This preliminary examination of TCM and TCA is necessary to fully appreciate why conventional biomedical and health science research methods cannot be simply transposed to investigate TCA without a comprehensive understanding of the nature of TCM.

In the second section of chapter two, the domain of TCA research is outlined. An overview of contemporary acupuncture research, from a TCM perspective, is provided so as to make explicit the flaws in contemporary acupuncture research that have made this study necessary. Attention is also given to how a researcher of TCA can identify and determine what is an appropriate research design or method of inquiry for any given research question in the field of TCA. It is argued that the research design selected for any particular TCA study will be dependent upon the nature of the research question that is to be addressed.

In chapter three, sociocultural and philosophical aspects of medical systems and their implications for research are examined. TCM and its associated conceptions of health, illness and disease are compared and contrasted with Biomedicine. Although the focus of this dissertation is on TCA, it becomes clear through the comparison that the concepts of different medical systems have implications for how they are to be evaluated, and how research of them is to be conducted. What constitutes health and disease in each system of medicine has a direct bearing on which domains and parameters are assessed and measured, and how the effectiveness of the therapies informed by these systems is to be evaluated. Since many of the existing research approaches, designs and methodologies have been developed for Biomedicine, it is necessary to consider the system of Biomedicine to determine if its research methods can be adapted to the needs of TCA research.

The focus of chapter four is on aetiological models of health and disease. The concepts of

determinism¹⁰ and causality are examined in relation to TCM. Implications of these concepts for TCA research are explored. Much contemporary biomedical research has relied upon the randomised controlled trial (RCT)¹¹, which assumes a determinist and linear understanding of cause and effect. In contrast, it could be argued that the TCM model of health, illness and disease is more holistic and maintains a 'systems' orientation¹² that does not assume the same linear causal links. It has been noted by Laura and Heaney (1990) that in recent years there has been a transition from a bioreductionist model of disease to a 'systems' orientation. TCA would appear to be 'systems' based, and this needs to be taken into consideration when attempting to decide how TCA is to be studied. The TCM model of health, illness and disease is examined in the light of the ideas that permeate 'holistic' models of medicine¹³ and other models based on 'systems' theory.

In chapter five, several research paradigms are examined that are relevant for any investigation of the methods of inquiry for TCA. It could be expected that researchers within a discipline would attempt to utilise research approaches that are thought to be congruent with the ontology and epistemological understandings of their paradigm. It is argued that appropriate research approaches for TCA would need to be congruent or compatible with the TCM paradigm if they

¹⁰ According to G. Vesey and P. Foulkes (1990, p. 84), *determinism* is the "view that events, including people's actions, do not occur by chance, but are caused to occur, usually with the implication that they could not be otherwise than they are. ...The implication is absent in the case of self-determinism (meaning that an agent is the cause of his own actions) since he could have decided to act otherwise than he did."

¹¹ J. Filshie and A. White (1998, p. 4) claim that in Biomedicine, the randomised controlled trial (a quantitative experimental design) has become the 'gold' standard in medical research to determine a medical intervention's effectiveness.

¹² The 'systems' perspective is based on the pioneering work and concepts developed by the biologist Ludwig von Bertalanffy (1968) in his 'general systems theory' (Capra, 1997). Capra (1983, p. 26) states that "[s]ystems theory looks at the world in terms of the interrelatedness and interdependence of all phenomena" In this framework, a system is an integrated whole whose properties cannot be reduced to those of its parts. Living organisms, human beings, societies, and ecosystems can all be regarded as systems. Capra (1982, p. 27) notes that systems theory understands living systems as organised in such a way that they form multilevelled structures, each level consisting of subsystems which are wholes in regard to their parts, and parts with respect to larger wholes." See also chapter 3.8.

¹³ P.T. Wolpe (1990, p. 915) has defined holistic medicine as, "a philosophy of practice that generally emphasises the primacy of the doctor-patient relationship, the importance of psychological, social, and spiritual factors in health and illness, the acceptability of nonconventional modalities of treatment, and the responsibility of the patient for participation in the health process."

are to be acceptable to both TCA practitioner-researchers and the TCM profession.

In chapter six, the nature of TCA knowledge is examined. This is accomplished through determining the forms of knowledge that are held by members of the TCA profession and those that can be identified in TCM literature. Consideration is also given to how TCA practitioners can transform their clinical experiences into knowledge. It is argued that knowledge in the discipline of TCA has accumulated using a variety of methods, including authority and tradition, trial and error, personal experience, as well as through the utilisation of methods that have been appropriated from other disciplines. The relations between TCA theory, practice and research are also explored.

Chapter seven builds on the analysis of chapter six by examining the various 'epistemological orientations to practice' that have been identified in the health professions so as to determine the epistemological orientations to practice that are being used by practitioners of TCA. This analysis provides an overview of the ways knowledge has been obtained by practitioners and researchers of TCA.

Chapter eight considers several issues related to the utilisation of the methods of science to examine and evaluate TCA. The nature of science is examined to determine if TCM *is*, or *can* be scientific. It is argued that the methods of science can be utilised to investigate particular TCA research questions, as long as a broad definition of science is adopted. The second part of chapter eight examines the roles that quantitative research designs can play in the production of TCA knowledge.

Chapter nine examines the purposes of therapeutic outcome measurement in research aimed at establishing the efficacy of TCA therapy. Various philosophical and technical issues associated with therapeutic outcome measurement in TCA research are examined. Domains and parameters that are appropriate to assess in TCA clinical research are identified.

Chapter ten develops the ideas introduced in chapter nine. A major focus of the chapter is an examination of a number of critical issues related to the evaluation of the efficacy of TCA. One important issue explored in the chapter is the significance and implications of the 'placebo'

phenomenon in relation to TCA clinical research. The limitations of the randomised clinical trial for evaluating the therapeutic effectiveness of TCA are also examined.

Chapter eleven outlines a number of ethical issues that need to be considered when designing TCA clinical research which involves human beings. Chinese humanist notions of the person are considered in relation to research design. It is argued that ethical issues cannot be divorced from TCA clinical research design and methodology.

In chapter twelve, the role of 'naturalistic' inquiry and qualitative research methods for developing TCA knowledge are examined. A number of research methods are identified for generating TCA theory, understanding the nature of TCA and improving TCA practice.

Chapter thirteen identifies a set of 'quality criteria' by which the quality of TCA research can be assessed. While positivist and constructionist paradigms (chapter 5) and their associated quantitative and qualitative research methods may have different evaluative criteria, some general guidelines are given for judging the quality of TCA research.

Chapter fourteen consists of an integrated summary of the findings from chapter one through thirteen. The implications of this study are summarised and priorities for future TCA research are stated.

1.6 The Postmodern Context of the Study

Postmodernism is an intellectual perspective which has become influential in the social sciences since the 1970s. Postmodernism is a movement that is not easily defined since there would appear to be diverse understandings of what postmodernism is.¹⁴ It is often suggestive of the relativity of all knowledge. From the postmodernist perspective, knowledge cannot be absolute and is always conditioned by the historical situation. According to West (1996, p.190), postmodernists are often critical of many of the characteristic assumptions of the

¹⁴ S. Kvale (1996, p. 41) argues that postmodernism constitutes a broad movement in current art and philosophy which has been expressed in different form by thinkers that include Baudrillard, Derrida, Foucault, and Lyotard.

Enlightenment.¹⁵ Lyotard (1984) claims in *The Postmodern Condition: A report on Knowledge*, that the postmodern age in which we now live is characterised by a disbelief in universal systems of thought. Lyotard contends that there is a lack of credulity toward meta-narratives of legitimation, including the Enlightenment belief of progress through knowledge and the methods of science.

From a contemporary postmodernist perspective, it has been convincingly argued that there is *no single* method of inquiry that has a privileged status (Richardson, 1994, p. 518). Human beings seek knowledge of the world, themselves and other people in many different ways. Few people, after being exposed to the arguments of postmodernism, would attempt to claim that there is *only* one valid approach to obtaining knowledge. One only has to peruse the various academic disciplines to find that there are many forms of inquiry and research methods that are utilised to generate knowledge. This fact alone supports the idea that there is a need for a plurality of research methods to generate different types of knowledge. According to Kvale (1996), postmodern thought has long been influential in the humanities and is now influencing the social sciences. The author would suggest that postmodern thought is now becoming influential in health care research where there is an increasing use of different research methods.¹⁶

Fay (1996, p. 72) claims that *perspectivism* has replaced positivism¹⁷ as the dominant view

[p]erspectivism is the dominant epistemological mode of contemporary intellectual life. *Perspectivism* is the view that all knowledge is essentially perspectival in character; that is, knowledge claims and their assessment always take place *within* a framework that provides the conceptual resources in and through which the world is described and explained. According to perspectivism knowers never view reality as it is in

¹⁵ Vesey and Foulkes (1990 p. 98) state that the *Enlightenment* is the name given to an intellectual movement that occurred in 18th century Germany, France and Great Britain that was “informed by reason and the power of scientific research and discovery.”

¹⁶ For example, in recent years there has been an increase in the use of qualitative research methods to address particular research questions in health care that cannot be answered by using quantitative research methods.

¹⁷ R. Audi (1995, p. 445) notes that *positivism* began in the 1920s and became an influential philosophy on the sciences. It has been criticised over the second half of the twentieth century in terms of its metaphysical assumptions. It is a philosophic doctrine which claims that inquirers must confine themselves to what is provided to them by sense-experience. Positivistic clinical research designs tend to emphasise control of variables, quantification and objectivity (see also chapter 5.4.2).

itself; rather they approach it from their own slant, with their own assumptions and preconceptions.

Health care research involves the study of human beings who are complex, and because of this it could be expected that different forms of inquiry would be required to study the many facets of the human being while experiencing health, illness and disease. From the TCM perspective, the human being is not only a biological entity but is also a social being with a spiritual dimension.

Human beings appear to inhabit a number of interconnected 'realms' which differ in complexity and display different properties. Ken Wilber (1990) suggests that each of these 'realms' may require its own methods by which it can be investigated. This is not a new idea, as Wilber (1990, pp. 2-3) explains

St. Bonaventure, the great *Doctor Seraphicus* of the Church, ... taught that men and women have at least three modes of attaining knowledge - "three eyes," as he put it (following Hugh of St Victor, another famous mystic): the *eye of flesh*, by which we perceive the external world of space, time and objects; the *eye of reason*, by which we attain a knowledge of philosophy, logic, and the mind itself; and the *eye of contemplation*, by which we rise to a knowledge of transcendent realities.

In simple terms, Wilber claims that St. Bonaventure was talking of the three realms of matter, mind and spirit. In 'holistic' conceptions of the human being, these three realms are said to manifest as body, mind and spirit. While in TCM these three realms are not understood to be intrinsically different, they might nevertheless require different methods of inquiry to examine and understand them. As Schumacher (1977, quoted by Wilber, 1990, p. 5) has noted

we 'see' not simply with our eyes but with a great part of our mental equipment as well [the eye of the mind]... With the life of the intellect [the *lumen interius*] we can see things which are invisible to our bodily senses. ... The truth of ideas cannot be seen by the senses.

For example, the truths of logic and mathematics rest on their own internal axioms which can be examined and determined only by the mind rather than through reference to sensory objects.¹⁸

¹⁸ Plato argued in the *Phaedo* along similar lines that the human being's understanding of the concepts of geometry and mathematics can be grasped only through the mind (through the *forms*) and not by merely observing any number of physical examples (see Hamilton & Huntington, 1961).

Wilber (1990, p. 47) claims that, in mental-phenomenological inquiry, the 'things' examined in the mind are *thoughts*, with their structure and their form being immediately displayed to the inward mental eye. Wilber (1990, p. 48) states that

[a]ccording to phenomenology, if one directly inquires into a mental act - an image, a symbol, a word, as one actually uses it - one will find that it intrinsically possesses *intentionality* or *meaning*; it has a native form of structure; and it is semiotic or symbolic. For, unlike the objects of *sensibilia* - rocks, photons, trees, and so on, which do not themselves possess meaning (in the sense that they do not symbolically represent or point to something other than themselves) - the objects of *intelligibilia* intrinsically possess meaning, value, or intentionality (i.e., a mental symbol or act always carries the power to represent or point to some object or act). And the way you discover such *meaning* is via mental inquiry, apprehension, or interpretation, not sensory impact.

Wilber (1990, p. 39) claims that directly apprehended experiences can occur in each of the three realms of the 'flesh' (empiric/sensory), 'mind' (mental), and spirit. Wilber has termed the 'objects' of the three realms of the 'flesh', 'mind' and 'spirit' as *sensibilia*, *intelligibilia*, and *transcendelia* respectively.

Wilber (1990, p. 9) claims that 'category error' can occur when an inappropriate 'eye' usurps the roles of the other two, that is, "when one of the three realms is made to wholly substitute for another realm" - or, when things (flesh) are confused with thoughts (mind) and transcendental insights (contemplation). Wilber (1990, p. 46) suggests that scientism¹⁹ can result when empirical scientists commit 'category errors' and refuse to accept data other than that of *sensibilia*.

It is the view of Whitehead (1967) that the empiric-scientific method is effectively incapable of dealing with *quality*, and that science is primarily *quantitative* in nature in that it deals in quantities and numbers. Wilber (1990, p. 26), commenting on Whitehead's (1967) claims that "the empiric-scientific world view is unbelievable because it is partial, and in pretending to be total, it lands itself in incredulity." Wilber (1990, p. 29) suggests that some scientists, who are

¹⁹ Ken Wilber (1990, p. 7) claims that scientism can result when empirical scientists restrict the data that can be used to understand or explain phenomena to the one realm of 'sensibilia'. Scientism is an example of what Wilber terms 'category error'.

really scientists, do not merely make the claim that the collection of empiric data is the best method for obtaining information in the sense realm: they make the greater claim that only propositions that can be empirically verified can be demonstrated to be true. Wilber makes the important point that there are limits to empiric knowledge. There is in fact no empirical proof to demonstrate that empirical proof alone is real: that is, the proposition itself cannot be verified empirically. Wilber suggests (1990, p. 31) that “[t]o escape from scientism or exclusive empiricism is simply to realise that empiric knowledge is not the only form of knowledge; there exists beyond it mental-rational knowledge and contemplative-spiritual knowledge.” In Wilber’s analysis, if people are not prepared to consider realms other than the physical (that is the eye of the flesh) they will be limited to the philosophy of positivism and the psychology of behaviourism.²⁰ However, if a person is prepared to see beyond the purely physical, then one can use other forms of inquiry such as phenomenology, intersubjective psychology and proper speculative philosophy (Wilber, 1990, p. 33) (see chapters 5 & 12).

In this dissertation, the term *research* will be defined in its broadest sense as a kind of systematic inquiry or investigation that can validate and refine existing knowledge and generate new knowledge. What constitutes *research* will not be restricted to the empirically based positivist approaches that have dominated the physical sciences and Biomedicine. From a postmodernist perspective it will be argued that different research paradigms provide a variety of means by which different types of knowledge in the field of TCA can be generated.

1.7 The Importance of Significant Research in the Field of TCA

Priority should be given to those research questions in the field of TCA that are significant, rather than to those questions that can be easily answered but which are not useful or important to the TCA profession and to society as a whole. Schon (1983) has noted that the dilemma of ‘rigour or relevance’ often arises in the professions. Schon (1983, p. 42) states that in professional practice

²⁰ Audi (1995 p. 67) notes that in the doctrine of *behaviourism*, there is the notion that “behaviour is fundamental in understanding mental phenomena. The term applies both to a scientific research program in psychology and to a philosophical doctrine.”

there is a high, hard ground where practitioners can make effective use of research-based theory and technique, and there is a swampy lowland where situations are confusing 'messes' incapable of technical solution. The difficulty is that the problems of the high ground, however great their technical interest, are often relatively unimportant to clients or to the larger society, while in the swamp are the problems of greatest concern.

Schon (1983, p. 42) asks two important questions that have relevance for researchers of TCA:

Shall the practitioner stay on the high, hard ground where he can practice rigorously, as he understands rigor, but where he is constrained to deal with problems of relatively little social importance? Or shall he descend to the swamp where he can engage the most important and challenging problems if he is willing to forsake technical rigor?

Researchers of TCA should be mindful of Schon's comments, since to ignore them could result in research that might be of little value to TCA practitioners, their clients or society. Cheek *et al.* (1997, p.166) have also suggested that "as a consequence of viewing contemporary Australian health practices from the 'high hard ground' of scientific certainty" that there has been "the relentless pursuit of answers or 'truths' rather than of questions or issues in health research."

1.7.1 *The evaluation of the therapeutic effectiveness of TCA*

A large proportion of contemporary acupuncture research has been devoted to the admirable aim of evaluating the clinical effectiveness of acupuncture. The motive for this, in part, has been to establish the clinical legitimacy of acupuncture in terms of Western research criteria. Vincent (1993, p. 292), in his review of acupuncture clinical research, concluded that, "[m]any studies of acupuncture treatment are seriously flawed by methodological problems. Poor design, inadequate measures and statistical analysis, lack of follow-up data and substandard treatment are all too common." The misfortune for the TCA profession is that much of the clinical research that has been conducted to determine the therapeutic effectiveness of acupuncture has been of poor quality by being methodologically flawed (Lewith & Machin, 1983; Vincent, 1993; Vincent & Furnham 1997; Ernst & White, 1997).

In pharmaceutical drug evaluation, the 'double-blind' randomised controlled trial is considered

to be the 'gold standard' or benchmark in clinical evaluation (Pocock, 1993; Lewith, 1994, p. 44; Kiene, 1996a; Kiene, 1996b).²¹ Many of the research design and methodological flaws in the acupuncture trials noted by Vincent (1993) and Ernst & White (1997) have arisen because researchers have attempted to use the same clinical research methods for acupuncture as have been used to evaluate pharmaceutical drugs. Vincent and Richardson (1986a, pp.10-11) claim that the standard double-blind randomised controlled trial (RCT) design that was developed in the 1940s from Western scientific premises for pharmaceutical drug evaluation cannot be used in its usual form to evaluate the efficacy of acupuncture therapy. The reason for this, they claim, is that the method does not truly consider the 'hands on' nature of TCA therapy and other peculiarities of the TCA therapeutic system which have been derived from Oriental philosophical tenets and assumptions. There would appear to be some dissonance between the actual practice of TCA and the usual form of the randomised controlled trial design.

There have been few acupuncture clinical trials conducted in which traditionally trained acupuncturists have been allowed to treat people in a way that is in accord with traditional acupuncture practice (Watson, 1991; Kaptchuk, Edwards and Eisenberg, 1996, pp. 49 & 56; Birch & Hammerschlag, 1996; Birch, 1997a). In many of the clinical trials that have been conducted to determine the effectiveness of acupuncture, the sets of acupuncture points that have been used in treatments have been kept constant, as is routinely done in conventional biomedical research, and not 'tailored' to the specific and unique health problems of the client as is done routinely in TCA practice.²² As a result, much of the published literature on the efficacy of TCA may not be truly indicative of the actual effectiveness²³ and therapeutic value

²¹ The 'double-blind' Randomised Controlled Trial (RCT) is a quantitative research design used for data collection and evaluation to control for potential experimenter and subject bias. In a properly conducted 'double-blind' RCT, the researchers do *not* know if they have administered a real therapy or a placebo. In addition to this, the 'subjects' in the clinical trial are not told if they have received the 'real' drug or therapy that is being evaluated or a placebo. The research method is commonly employed in pharmaceutical drug evaluation studies (the RCT is examined in more detail in chapters 8.12.2 & 10).

²² Vickers (1996, p. 199) correctly notes that the treatment being evaluated in randomised clinical trials does not have to be standardised. For example, in the evaluation of surgery, surgeons are required to 'tailor' the treatment to the particular characteristics of each individual patient.

²³ Roth and Fonagy (1996, p. 13 cited in Horton with Varma, 1997, p. 168) note a distinction between the terms *efficacy* and *effectiveness*, the distinction being that "efficacy demonstrates achievable results in the setting of a research trial, whilst effectiveness demonstrates the outcomes of treatment in routine practice".

of TCA therapy.²⁴ While meta-analyses of acupuncture trials such as those of Patel *et al.* (1989) and ter Riet, Kleijnen and Knipschild (1990) suggest that acupuncture may be efficacious for particular conditions, Kaptchuk, Edwards and Eisenberg (1996, p. 48) believe that the findings of acupuncture trials to date that have involved ‘sham acupuncture’ controls²⁵ are “inconclusive, doubtful or too contradictory for a clear interpretation.”

To rectify this situation, there is the need for the determination of appropriate research approaches, designs and strategies that will enable researchers to further enlarge the knowledge base of TCA and to evaluate and improve the effectiveness of TCA therapy. These methods of inquiry would need to be congruent with the TCM paradigm and at the same time acceptable to the TCA profession, researchers, and research funding bodies.

It has been suggested by Mike Fitter (cited in Gould, 1996, p. 55) that research into holistic systems of medicine such as TCA has the potential to influence the development of conventional medicine in “significant and valuable ways”. Conventional medicine’s preoccupation with the physiological processes of the biological body might be transformed so that due recognition is given to understanding health and healing through the balance and integration of body, mind and spirit. More productive research could then be conducted which acknowledges and respects this perspective. TCA therapy could have an important role in future government health care systems that are based on more comprehensive, ‘holistic’, or ‘systems’ models of health and illness such as the biopsychosocial model of Engel (1977; 1981) and those of the World Health Organisation (see World Health Organisation Quality of Life Group, 1994).²⁶

²⁴ Birch (1997a, p. 148) notes that practitioners of traditionally based acupuncture systems (TBASs) believe that better clinical results can be obtained by using TBASs where the treatment is individualised to the specific needs of the patient as compared to ‘formula acupuncture’ approaches.

²⁵ A ‘sham acupuncture’ control involves the needling of points in the skin with acupuncture needles at loci on the body other than those of classical acupuncture points. Points adjacent to known acupuncture points that are not on acupuncture channels (meridians) are often used for this purpose. It has been used in randomised controlled trials to control for the placebo effect of TCA (see chapter 10 of this dissertation and also Vincent & Furnham, 1997, pp. 182-183).

²⁶ TCA as it is practised in the occident could be regarded as a holistic form of medicine since it attempts to treat the whole person - body, mind and spirit. This is also the perception of many clients of TCM practitioners, see Appendix B: What Respondents Said Chinese Medicine Care Does and Why they Liked It (from Cassidy, 1998).

For TCA to be integrated into any government funded health care system, government health departments would require sound research to be conducted to determine its therapeutic and cost-effectiveness. TCA has the potential to enhance future systems of health care; therefore, it is important that TCA should not have its utilisation as a form of health care curtailed by having to legitimate itself solely through the research methods that are commonly used to evaluate new pharmaceutical drugs and which might be inappropriate for TCA.

Surveys conducted to determine the perceived effectiveness of the complementary therapies in general and TCM in particular (see Vincent & Furnham, 1994; Cassidy, 1996; Vincent & Furnham, 1997; Cassidy, 1998) would suggest that acupuncture is perceived as an efficacious form of therapy for some medical conditions by those who have tried the therapy. A number of reviews of controlled clinical studies (Birch & Hammerschlag, 1996; Bensoussan & Myers, 1996; Ernst & White, 1997; National Institutes of Health Consensus Development Panel on Acupuncture, 1998) also suggest that acupuncture is an efficacious therapy for some health disorders and that more quality research is required to determine the full range and extent of the applications of TCA.

1.8 The Significance of the Study

This study is timely and significant for a number of reasons:

(i) The Victorian Ministerial Advisory Committee on TCM (1998, p. xvi) claims that there is a need for further research in the field of TCM. In their thirty-first recommendation, the committee advised that “targeted funding be made available from the Victorian Department of Human Services Health Research Initiatives for research into the risks and benefits associated with the practice of TCM, its effectiveness or lack of in treatment of specific conditions, and the detection and evaluation of opportunities for health intervention.” In the thirty-second recommendation, the committee suggested that the National Health and Medical Research Council (NHMRC) consider the allocation of targeted funding for the same purpose. This followed a similar recommendation of the Bensoussan and Myers (1996, p. 47) report into the practice of TCM in Australia that “national funding bodies such as the National Health and

Medical Research Council (NHMRC) be encouraged to allocate funding for sound methodological investigations of the clinical efficacy of Chinese herbal medicine and acupuncture, including cost-effectiveness studies.”²⁷ Bensoussan and Myers (1996, p. 46) concluded in their summary of findings that there is a “sufficiently strong case for the clinical use of acupuncture in the management of pain, nausea and vomiting” and that, in other clinical areas “acupuncture shows significant promise and warrants a greater research focus.”²⁸ The U.S. National Institutes of Health (NIH) has also recently endorsed acupuncture for the treatment of postoperative pain from dental surgery and nausea and vomiting from chemotherapy and anaesthesia.²⁹ The NIH suggests that acupuncture may also be effective for migraine, arthritis, menstrual cramps, low back pain and tennis elbow.³⁰ Further well designed and conducted research could determine the potential uses and limitations of TCA therapy in a broad range of clinical applications.

Although there are many recipients of TCA therapy who would testify to its benefits (Cassidy, 1996; Vincent & Furnham, 1997; Cassidy, 1998), and an increasing number of positive clinical trials, there is still the need for further well designed and conducted clinical trials to convince particular groups such as health policy makers and research funders of the therapeutic effectiveness of TCA therapy.

(ii) Bensoussan and Myers (1996, p. 300) suggest that further research is warranted in the field of acupuncture because the greater use of acupuncture could result in a considerable reduction in health care expenditure.

²⁷ This report was commissioned by the Victorian Department of Human Services, the New South Wales Department of Health, and the Queensland Department of Health.

²⁸ It should be noted that A. Bensoussan and S. Myers (1996) in their evaluation of acupuncture clinical trials used the grading system of the National Health & Medical Research Council (1995) to assess the quality of clinical evidence. See Appendix C: National Health and Medical Research Council (NHMRC), Quality of Care and Health Outcomes Committee, 1995. Guidelines for the development and implementation of clinical practice guidelines.

²⁹ See National Institutes of Health (NIH) Consensus Development Panel on Acupuncture, 1998, 1518-1524.

³⁰ A summary of controlled acupuncture clinical trials by S. Birch and R. Hammerschlag (1996) would also suggest that there is a broad range of medical conditions that respond positively to acupuncture and that would warrant further research.

- (iii) The introduction of TCA degree programs into Australian universities in the 1990s has resulted in a need for appropriate research designs and methodologies to allow both post-graduate students and researchers to further develop knowledge of TCA.³¹
- (iv) Funding from organisations such as the World Health Organisation (WHO) and the NHMRC will only be granted to acupuncture research projects that use research designs and methodologies that are regarded as appropriate, rigorous and sound. Therefore, a case needs to be made for research designs and methodologies for the development of the TCA knowledge that would that would be deemed suitable by such research funders.
- (v) The European Advisory Committee for Medical Research (EACMR) was created in 1977 in response to the concern that there was a relatively weak structure for the development of public health and health services research compared with biomedical research. One of this group's recommendations was that

research should be developed using paradigms, methodologies and organisations that have so far found little or no application in the field of health but, by their nature, promise a better understanding of health issues than those that historically and traditionally have been in the forefront of health research (Nizetic, Pauli, and Svensson, 1986, p. 1)

TCM is one such paradigm that could provide a better understanding of health, illness and disease. TCM is one system of medicine that has the potential to improve health care outcomes in both developed and undeveloped countries. It is for this reason that appropriate research designs and methodologies are now required to study and evaluate it.

- (vi) The findings of this study as to what constitutes appropriate research methods for TCA could have relevance for researchers of Biomedicine. The biomedical model appears to be becoming more 'holistic' and is now beginning to place a greater emphasis on psychological and sociological factors involved in disease processes, as has always been the case in TCM. Consequently, modifications might have to be made to existing biomedical research designs and methodologies to accommodate this change in perspective.

³¹ In 1992, a four year degree program in Traditional Chinese Acupuncture began at the Victoria University of Technology, an Australian government university. Presently, there are four Australian universities that offer degree programs in TCM.

(vii) The TCA research issues that are addressed by philosophical inquiry in this dissertation are important ones and have not been previously addressed to any significant extent in TCM literature. This study, through its critical analyses, provides a firm foundation for researchers to better understand the nature of TCA so as to be able to develop appropriate research methods to further the development of TCA knowledge.

1.9 Limitations and Delimitations of the Study

1.9.1 Declaration of the author's position as researcher

The word 'thesis' comes from the Greek word for 'place', which suggests that the author of a thesis or dissertation must take up a position. The author's position, or perspective, has been influenced by his background as a TCM practitioner and educator over the past fifteen years. While the arguments that are advanced in this thesis are based on philosophical analysis, it must be acknowledged that the analyses made will have no doubt been influenced by the author's own personal encounters and experiences with TCM as a practitioner of TCA.

The arguments put forward by the author rest on the postmodern assumption that *no* method of inquiry has a privileged status in obtaining knowledge. The various academic disciplines often use different research methods to generate knowledge and this fact alone suggests that there is a requirement for a plurality of research methods to examine different domains. It is the aim of the specific TCA research question that should guide the researcher to select the most appropriate type of research design and methodology for any particular study.

One difficulty of this study has been to define the essential characteristics and features of TCA practice. The reason for this is the actual practice of TCA is not homogeneous (see Seem, 1992; Birch, 1997c; Birch and Felt 1999; Birch and Kaptchuk, 1999). Individual TCA practitioners tend to place different degrees of emphasis on particular TCM ideas, theories and practices that have developed in different historical periods in China (see Unschuld, 1985). Also, as TCA has spread from country to country, it has been observed to change and adapt to the needs, ideas, philosophies and culture of the local people (Papier, 1988; Birch and Felt 1999). As a consequence, the discussion in this dissertation will generally be limited to TCA as it is

practised in the Australian context (see chapter 2). It should be noted, however, that the TCA literature suggests there are many traditionally trained acupuncturists in Europe, the United States and other countries who practise in a way that is similar to those practitioners in Australia. The author has attempted to outline and articulate the core tenets, ideas, theories and philosophies that many TCA practitioners would accept as underpinning their practice (chapter 2); however, any such attempt must be a simplification when one considers the many different schools of thought that have influenced the practice of acupuncture over its two thousand year history. With this acknowledged, it is hoped that the author's exposition is respectful of the diverse views of the various members of the TCA profession.

The interpretation and meaning that any researcher in the human sciences gives to their data and results will always be dependent upon their own belief system with its various assumptions. It is now generally acknowledged by philosophers of science and other academics involved in the sociology of knowledge, that the way a researcher conducts research is dependent upon the world view that the researcher holds (chapter 5). For example, one's understanding of the nature of the human being will influence the forms of inquiry that a researcher will regard as being appropriate and ethical for the study of human beings.

Research methods are often derived from ones preferred ontology³² or world view which is linked via the ontology's associated epistemological assumptions. Therefore, the level of analysis of any study of research methods is ultimately linked to one's perception and understanding of ontology. Since questions of ontology will probably never be resolved to the satisfaction of all researchers through either consensus, science or research, the most that can be achieved is to consider the implications for TCA research if a particular ontology is assumed to be true. The author would hope that the analysis would lead to the formulation of more sophisticated understandings by researchers in the future.

The TCA profession in China, Australia, Europe, the United States and many other countries is now experiencing rapid change. For example, the systematisation and rationalisation of TCM in post revolutionary China has resulted in the restructuring of TCM educational and professional

³² Ontology is a branch of philosophy concerned with the essence of 'reality' and the nature of being.

organisations (Scheid, 1993, p. 30). In Australia, the introduction of TCM courses into government funded universities will no doubt impact on the TCA profession in Australia and in other countries. Scheid (1993, p. 30) also suggests that in the United Kingdom, the TCM profession is attempting to imitate conventional forms of professionalisation. If this is the case, then it is possible that the TCA profession will attempt to adopt conventional health care research methods rather than those that are more in keeping with its own tradition.

The discussion of specific research methods in this study has been limited to their essential features, such as the ontology and associated epistemological perspective from which they are derived and the methods *via* which data is collected and analysed. A comprehensive examination of any one of these research approaches would constitute a book in itself. Therefore, what the author has endeavoured to do is to examine and analyse several paradigms of research in broad terms, and to consider the implications and consequences that would follow if the theory of the paradigm were to be acted upon by researchers when examining TCA.

The author, like many others, believes that there is indeed a place for TCA therapy in government subsidised health care systems.³³ The reason for this belief stems from the effectiveness of TCA therapy as perceived by both TCA practitioners and their clients (Cassidy, 1996; 1998). When TCA is practised by well trained practitioners, TCA therapy appears to be a relatively safe therapy when compared with biomedical pharmaceutical therapies and procedures. Bensoussan and Myers (1996, p. 83) state that “[i]t is highly unlikely that the practice of TCM poses as great a risk to public safety as the practice of western medicine.”³⁴

³³ There is now a growing interest by many groups in determining the future role of complementary and alternative medicine in an integrated system of healthcare. As an example, see J.R. Coates and K.A. Jobst (eds.), *Integrated Healthcare: A Way Forward for the Next Five Years? A Discussion Document from the Prince of Wales's Initiative on Integrated Medicine*, 1998, pp. 209-247.

³⁴ A. Bensoussan and S. Myers (1996, pp. 49-95) have outlined some of the risks associated with the practice of TCM. See also C. Vincent and A. Furnham, 1997, pp. 242-246 and H. Rampes and R. James, 1995.

1.10 The Determination of the Role of Traditional Chinese Acupuncture in Future Health Care Systems

Most people who live in the developed world are familiar with, and predominately use, what medical anthropologists call Biomedicine or orthodox medicine. Biomedicine is that system of medicine practised by medical practitioners, who assert its legitimacy by reference to its claims to rationality and scientificity. Biomedicine's orthodoxy is derived from both political authorisation and cultural acceptability (Sharma, 1992, p. 2).

Over the last three decades, there has been a significant increase in the types of therapies that have been used to treat human health problems in Australia and other countries of the developed world. In addition to the pharmaceutical treatments and surgery of Biomedicine, there is now a plethora of 'complementary' or 'alternative' therapies³⁵ such as TCA, Chinese herbal medicine (CHM), western herbalism, osteopathy, and homeopathy.³⁶ These so called 'complementary' therapies are most often practised by people who have been trained in these various therapies but who are often not registered medical practitioners.³⁷ Many complementary health care practitioners claim that these 'complementary' therapies are part of a growing holistic health movement.³⁸

³⁵ The terms 'alternative therapies' and 'complementary therapies' are used by some authors as synonyms. These therapies refer to treatment systems other than those that are usually employed in conventional biomedicine (*i.e.* allopathic medicine). The term *complementary therapies* is perhaps the better term since it suggests that these new and traditional therapies can complement mainstream Biomedicine rather than be an alternative to it. Many people access *both* Biomedicine and the complementary therapies. Perhaps a more appropriate term for the complementary therapies is *natural and traditional medicines* rather than the terms 'alternative' or 'complementary' therapies, since these two latter terms suggest that all of the natural and traditional medicines only complement mainstream Biomedicine. This can be misleading, since there are a multitude of different forms of medicine and health care operating in the world, with Biomedicine being only one of the many forms. To classify all of the natural and traditional medicines into one group which are then understood to complement Biomedicine could suggest that Biomedicine is the only 'real' medicine, with the other systems of medicine being viewed as either supplementary, inferior or unscientific ethnomedicines.

³⁶ For an examination of the complementary therapies, see S. Fulder, *The Handbook of Complementary Medicine*, 1984.

³⁷ It should be noted that there is an increasing number of biomedical practitioners who are using the 'complementary' therapies.

³⁸ For an account of the basic concepts and features of alternative medicine see S. Fulder, 1998, pp. 147-158.

One large representative population survey (n=3004) on the use of alternative medicines in South Australia (Australia) conducted by MacLennan, Wilson and Taylor (1996) found that 48.5% of respondents used at least one non-medically prescribed alternative medicine during 1993, and that 20.3 % of respondents had visited at least one alternative health care practitioner. Extrapolation to the Australian population for the year 1993 would suggest an expenditure (assuming that the South Australian usage is representative of the Australian population) on alternative medicines of \$AUD 621 million and for alternative therapists of \$AUD 309 million per annum. This amount would exceed patient contributions of \$AUD 360 million for all pharmaceutical drugs purchased in Australia during 1992/93. Other studies on the prevalence of 'unconventional medicine' in the United States also revealed the wide-spread use of alternative therapies and medicines (Eisenberg *et al.*, 1993; Eisenberg *et al.*, 1998).³⁹ In Europe, one survey has suggested that approximately one third of the population have used a type of alternative medicine (Fisher and Ward, 1994).

1.10.1 *The need to review health care in the light of the 'crisis' in Western health care systems*

During the 1980s criticisms of Western health care systems had become prevalent. Gremy (1986, p.142), in a World Health Organisation (WHO) publication, claimed that it had become a truism to speak of the 'crisis' in modern medicine (biomedicine) and the health care systems of the Western world. Gremy argued that the criticism of Biomedicine came from numerous and varied sources, including philosophers (Foucault, 1973), sociologists (Illich, 1975; Willis, 1989), consumers of health care, nurses, epidemiologists, and even medical practitioners themselves (Taylor, 1979; Little, 1995).

The criticisms of health care systems in developed countries could be seen to stem from a crisis

³⁹ Eisenberg *et al.* (1998, p. 1569) estimate that from 1990 to 1997 there has been a 47.3% increase in the total visits to alternative medicine practitioners in the U.S. (from 427 million in 1990 to 629 million in 1997). This number of visits to alternative medicine practitioners exceeds the total visits to all US primary care physicians.

in the paradigm, or the 'received view' from which Biomedicine has been derived.⁴⁰ This crisis could be understood to have two principal sources: first, its epistemological position (with its various assumptions) and secondly, at a more pragmatic level, its failure to lift the health of individuals in society to the levels promised by the advocates and proponents of Biomedicine (Gremy, 1986).⁴¹

The Chinese term for 'crisis' is *wei-ji*. This Chinese term comprises the conjunction of two Chinese characters meaning 'danger' and 'opportunity' (Capra, 1982, p. 7). This has particular significance in the context of the current discussion of Western health care, since without a change of direction in the delivery of health care there is the *danger* of the present health care system collapsing. If, however, the warnings are heeded, there is the *opportunity* for a renewal of Western health care systems. Renewal is only possible by reflecting on the weaknesses of the existing system and then acting to improve that system (Laura and Heaney, 1990, p. 57). One possible way Western health care could be improved is by the introduction of complementary therapies into mainstream government subsidised health care systems. Before this could be done however, it would first have to be determined if the complementary therapies are efficacious, safe, and cost effective. Further research is the means by which the efficacy, safety and cost effectiveness of complementary therapies, including TCA, can be evaluated.

If Biomedicine adequately treated all of the illness and diseases of humanity there would be little need to evaluate the effectiveness of complementary therapies such as TCA, since to do so would amount to wasting valuable financial resources by attempting to duplicate an already effective health service. This, however, does not seem not to be the case (Moynihan, 1998). The reality is that health care in Western countries is in a state of crisis because of the high cost of technologically based Biomedicine with its apparent decline in effectiveness. The deficiencies of modern Biomedicine, which have necessitated further research into the efficacy of the complementary therapies such as TCA, will be outlined below.

⁴⁰ The 'received view' is a term that refers to the understandings of the paradigm of positivism. E.G. Guba and Y.S. Lincoln (1994, p.108) claim that the 'received view' has dominated the formal discourse in the physical and social sciences for some 400 years.

⁴¹ See also R. Moynihan, *Too Much Medicine: The business of health-and its risks for you*, 1998 and M. Walton, *The Trouble with Medicine: Preserving the trust between patients and doctors*, 1998.

1.10.2 *The declining effectiveness of biomedicine*

The health care systems found in most Western countries are based in part on the concepts, philosophy and ideas of Flexner that can be found in two reports that he wrote for the Carnegie Foundation in the 1920s (Flexner, 1910, 1912 cited by Gremy, 1986). Flexner promoted a model of medicine based on a 'scientific foundation'. This biomedical model of medicine has been contested in recent times on three fronts: its economic consequences; its effectiveness; and its social implications (Gremy, 1986, p.142).

1.10.2.1 *The economic consequences of biomedicine*

Laura and Heaney (1990, pp. 57-58) argue that Biomedicine utilises high technology which has resulted in a form of health care that is not cost-effective. They cite numerous examples that support this claim. For example, in the twenty-five year period from 1965 to 1990 in the USA, the cost of medical care increased 330% in comparison with a 74% rise in the cost of living, yet this high technology health care does not seem to have resulted in better health for its citizens at the population level. Adverse drug events have been costly in both social and financial terms, with drug related morbidity and mortality having been estimated to cost more than \$136 billion a year in the United States (Johnson & Bootman, 1995).

1.10.2.2 *The effectiveness of biomedicine*

Laura and Heaney (1990, p. 51) claim that the effect of medical interventions on the improvement of community health has been "negligible and in the large irrelevant". Rene Dubos (1959, p. 89 cited in Laura and Heaney, 1990, p. 58) exploded the myth of medical 'progress' when he argued convincingly that most significant changes in health at the population level have resulted from advances in nutrition, economic and social factors, rather than from the technological innovations of contemporary Biomedicine. Illich (1975) argued along similar lines, and concluded that environmental factors rather than clinical interventions are the primary determinants of advancements in public health. Improved sanitary conditions, safe drinking water, better housing and good nutrition: all impact on the virulence and incidence

of infectious disease. Porter (1972, p. 95 cited in Laura and Heaney 1990, p. 58), in his presidential address to the British Association for the Advancement of Science, announced that between 1860 and 1965 nearly 90% of the total decline in mortality in children to the age of fifteen who suffered from scarlet fever, measles, whooping cough and diphtheria had occurred prior to the introduction of immunisation programs and antibiotics. This type of evidence does not deny the legitimate place of antibiotics and other pharmaceutical drugs in the treatment of disease; however meta-analyses now suggest that their value in terms of health at the population level has been overstated by proponents of Biomedicine. Nevertheless, regardless of Biomedicine's deficiencies and limitations, it is still a powerful and influential force in Western societies, even though at least part of its influence rests on perceived effectiveness rather than actual clinical evidence.

1.10.2.3 *Medical iatrogenesis*

Paradoxically, biomedical interventions in their attempts to advance community health have inadvertently contributed to the production of illness and disease (Illich, 1975; Taylor, 1979; Black, 1988; Laura and Heaney, 1990). This phenomenon has been termed 'iatrogenesis', a term derived from the Greek word for 'physician', *iatros*, and *genesis*, meaning 'origin' (Illich, 1975, introduction, xi). Iatrogenic diseases are a relatively new category of diseases which are caused directly from physician, medical or hospital interventions. It should be noted that iatrogenic diseases are *not* the result of malpractice⁴² by medical practitioners: they are in fact the outcome of biomedical interventions that have been implemented 'correctly' by the protocols of Biomedicine.

Over twenty-four years ago, Jick (1974) reported the seminal work of the Boston Collaborative Drug Surveillance Project that estimated that approximately 30% of hospitalised patients experience adverse events that are attributable to drugs and that from 3% to 28% of all hospital admissions are related to adverse drug effects. In 1975, Ivan Illich claimed that iatrogenic disease had reached epidemic proportions (Illich, 1975, introduction, p. xi). Lazarou *et al.* (1998, p. 1204) in a meta-analysis of hospital patients claims that adverse drug reactions

⁴² Malpractice results from a physician acting negligently, or being ignorant of standard medical procedures or protocols.

(ADRs) could constitute the sixth leading cause of death in the in the United States after heart disease, cancer, stroke, pulmonary disease and accidents. O'Hara and Carson (1997) have reported that 19% of adverse events in hospitals in Victoria (Australia) between 1994-1995 were due to adverse drug effects. This was the same rate that was reported by the Harvard Medical Practice Study II that involved a sample of 30,195 randomly selected hospital records (Leape *et al.*, 1991). Taylor (1979, p. 47) makes the claim that iatrogenic disease can be self-perpetuating, with many iatrogenic complications requiring more medical treatment, further exposing the patient to 'second level' iatrogenic disease.

Laura and Heaney (1990, p. 65) also suggest that technologically orientated Biomedicine has been iatrogenic in the sense that it has depersonalised health care. They claim that Biomedicine has been, "covertly *iatrogenic* in respect of the process of healing". They state that

biomedicine has had the tendency to depersonalise the fundamentally social aspects of health care by the progressive substitution of technological innovation for the phenomenon of human exchange. This aspect of the degradation of health is seldom, if ever, classified as iatrogenic, though we believe a more perspicacious picture of the crisis in health care emerges from doing so.

This brief overview highlights that the 'crisis' in Western health care has resulted in part from the biomedical approach to health care with its use of expensive high technological medical interventions. Biomedicine has promised so much, but on analysis its benefits would appear to have been exaggerated. In reality, Biomedicine has not delivered the level of health at the population level that it promised. In many cases, it has even led to a reduction in community health through iatrogenic diseases.

1.10.3 *The challenge of the complementary therapies*

There is a growing acceptance of the complementary (alternative) therapies (including TCA) by people in some Western countries as evidenced by the expenditure on them by private individuals (see MacLennan, Wilson & Taylor, 1996; Eisenberg *et al.*, 1993; Eisenberg *et al.*,

1998).⁴³ This response might be due in part to the perceived weaknesses of conventional biomedical practice.⁴⁴ The complementary therapies are often perceived as being less technological, more natural, 'holistic', and less invasive.

The increasing popularity and use of the complementary therapies in many developed countries not only presents a challenge to the authority of Biomedicine, but also raises important issues related to government health policy. The question could be asked: If people living in the developed world no longer see biomedical practitioners as having a privileged role in primary health care, then should not governments acknowledge this and provide a choice for people in national health schemes? The Victorian Ministerial Advisory Committee (1998, p. xii) argues that there is now a need for more research "to explore opportunities to improve the health status of the Australian community through the application of TCM in concert with Western medicine, to ensure adequate protection of the public, and to determine the place of TCM within the health care system."

With the complementary therapies quest for legitimacy, and a growth in their use by the public, it is inevitable that government authorities will call upon the practitioners of the complementary therapies to provide evidence of their therapies' efficacy. It is perhaps not surprising that some academics are now also asking for complementary health care practitioners to prove the effectiveness of their therapies by subjecting their therapies to the same testing and controls as Biomedicine in order to protect people from possible unsafe medicines and practices (Jonas, 1996) and from ineffective therapies (Resch & Ernst, 1996).

It should also be noted that the acceptance of a therapeutic system is not entirely based on its objective successes. As Foster (1989) notes:

⁴³ For example, A. Bensoussan and S. Myers (1996, p. i) claim that in Australia, TCM is increasing in popularity and estimate that there are over 2.8 million TCM consultations each year. Also, according to D.M. Eisenberg *et al.* (1998), in the United States "[e]stimated expenditures for alternative medicine professional services increased 45.2% between 1990 and 1997 and were conservatively estimated at \$[US] 21.2 billion in 1997, with at least \$12.2 billion paid out-of-pocket. This exceeds the 1997 out-of-pocket expenditures for all US hospitalizations. Total 197 out-of-pocket expenditures to alternative therapies were conservatively estimated at \$27.0 billion, which is comparable with the projected out-of-pocket expenditures for all us physician services."

⁴⁴ For an examination of this point, see A. Furnham, 1996, pp. 71-88.

the strength of a healing system in society rests only partly on objective successes; equally important for its continuing acceptance and support is the anchoring of its medical notions in the world view and, especially, in the socio-theoretical concepts of a population or individual political groups.

In a similar vein, Wiseman (1998, p. vii) in the foreword of *Chinese Medicine* suggests that, “a medical system develops its theories, and gains and maintains the acceptance of the community it serves not by its clinical effectiveness but by the acceptability of its underlying ideas.”⁴⁵ If this is correct, practitioners of TCA will eventually be required to convince the public and other stakeholders of the worth of the philosophical and theoretical bases of their health care paradigm, in addition to proving that the therapy itself is efficacious in the treatment of illness and disease.

Now that there is a variety of complementary therapies, including TCA, being used for a whole range of human health disorders, it would seem reasonable and socially important to ask two questions: (i) Which therapies are the most effective for ameliorating particular illnesses and diseases? and (ii) Which therapies can promote health and wellbeing? These two questions need to be answered so that the funds allocated to health care by government authorities and funding bodies are spent wisely for the benefit of the public, rather than to appease and benefit the practitioners of any one system of medicine. Research is one means by which the previously posed questions can be answered.

TCA has different theoretical tenets, assumptions and philosophical underpinnings when compared with Biomedicine. These would need to be considered before appropriate research designs and methodology for TCA could be determined. One of the flaws of the biomedical paradigm from the perspective of TCM is its dualist ontology that separates mental phenomena and social events from the physical realm of the body. In the case of Biomedicine, many researchers have decided (whether consciously or unconsciously) to focus their attention on phenomena of the ‘physical’ biological domain of the body at the expense of the other levels of the human being (*i.e.* the psychological, social and spiritual). The tragedy for health care is that the desire for certainty and ‘objective’ knowledge has required that psychological and social

⁴⁵ This statement was made in relation to the author’s work by the translator in the translator’s foreword of P.U. Unschuld, *Chinese Medicine*, 1998.

determinants of health and disease be understated, and in some cases jettisoned, to maintain internal paradigm consistency. As a result, the evaluation of therapeutic outcomes by biomedical researchers has often been restricted to the measurement of domains and variables that 'fit' the biomedical paradigm and which are possibly limiting when applied to TCA clinical research. Proponents of TCM claim that TCA therapy is able to enhance and balance vital life energies (*qi*) and bring about improved states of wellbeing. These parameters, however, have seldom been measured by researchers when conducting acupuncture clinical studies. The reason for this is that in many cases the researchers who conducted the studies did not have comprehensive training in TCA and hence had only a limited understanding of TCA theory and practice. In many TCA clinical trials, researchers have attempted to measure therapeutic outcomes by measuring changes in variables and parameters that are thought to be relevant, but which are often too narrow from the TCM perspective (see chapter 9). TCA therapy could be better understood in the context of more comprehensive models of medicine such as the 'biopsychosocial' model (Engel, 1977), transpersonal medicine⁴⁶ and holistic medicine⁴⁷ (see chapter 3).

It should be noted that since 1946, the World Health Organisation (WHO) has defined health as "a state of complete physical, mental, and social well-being, and not merely the absence of disease and infirmity" (WHO, 1958). In acknowledgement of the WHO's more comprehensive definition of health, there is now the need for researchers to develop new research instruments that can assess the efficacy of TCA therapy by the measurement of parameters from the biological, psychological, social, and spiritual domains that are in accord with the ideas of both the World Health Organization Quality of Life (WHOQOL) Group (1994) and the TCM paradigm.

⁴⁶ Transpersonal medicine understands health in terms that go beyond the reductionistic/mechanistic model of Biomedicine. Health is defined in more spiritual terms. S. Krippner (1998, foreword, ix cited in D. Rothberg and S. Kelly 1998) states that 'transpersonal studies' refer to the study of "observed or reported human behaviours and experiences in which an individual's sense of identity appears to extend beyond its ordinary limits to encompass wider, broader, or deeper aspects of life or the cosmos-including divine elements of creation." G. Lawlis (1996) claims that disease in transpersonal medicine is often understood as a breakdown of the relationship between body, mind, and spirit.

⁴⁷ Medicine or therapy that attempts to treat the 'whole' person: body, mind and spirit.

Spilker (1991, p. 377) claims that the types of parameters that can be measured in medical research include not only clinical signs and symptoms, and laboratory data, but also wellbeing and 'quality of life' information (see chapter 9). Ernst and Resch (1996, p. 27) claim that modern science has been "criticised at times for choosing to evaluate what is measurable rather than what is relevant". The same criticism could be levelled at much biomedical research.

The majority of contemporary acupuncture research in the Western world has focused on two areas: firstly, the evaluation of the clinical effectiveness of acupuncture, and secondly, the translation of Chinese medical texts. There are also other qualitative research methods available to researchers which can be utilised to obtain knowledge and understanding of TCA phenomena and generate theory; however, these approaches have not been used to any significant extent by researchers of TCA. There would appear to be a strong argument for the greater use of qualitative and interpretive research approaches when one considers the similarities of themes found in qualitative inquiry and TCA practice (see chapter 12).

An important focus of this dissertation is the examination of the forms of inquiry, research designs and methodologies that are appropriate for increasing the understanding of TCA and for the further development of TCA knowledge and the improvement of TCA practice. It is crucial that the research methods used by researchers to investigate TCA and related phenomena are appropriate and not incongruent with the TCM perspective. It is also important that significant research questions in the field of TCA are addressed and not merely those questions that can be easily answered. Finally, it should be the specific TCA research question or research aim that dictates the type of research design and methodology that is deemed appropriate for any particular TCA study.

CHAPTER 2

DEFINING THE TERRAIN OF TRADITIONAL CHINESE ACUPUNCTURE PRACTICE AND RESEARCH

“The Western mind seeks to discover and encounter what is beyond, behind, or the cause of phenomena. In the Chinese view, the truth of things is immanent; in the Western, truth is transcendent. Knowledge, within the Chinese framework, consists in the accurate perception of the inner movement of the web of phenomena. The desire for knowledge is the desire to understand the interrelationships or patterns within the web, and to become attuned to the unseen dynamic.”

- Ted Kaptchuk (1983, p.15)

Section 1: The Nature and Practice of Traditional Chinese Acupuncture

In this chapter some key terms, concepts and practices of Traditional Chinese Acupuncture (TCA) that will enable an examination of the critical issues in TCA research are defined. In the first section of this chapter, the nature of Traditional Chinese medicine (TCM) is examined so as to be able to understand why some research methods need to be modified if they are to be utilised for the further development of TCA knowledge. Through this examination and analysis of the nature and features of TCM and TCA, it will then become possible to determine the types of research methods that are congruent with the philosophy, theory and practice of TCA. In section two of this chapter, the domain of TCA research is outlined. An overview of contemporary acupuncture research, from a TCM perspective, is provided so as to make explicit the flaws in contemporary acupuncture research that have made this study necessary. Attention is also given to how a researcher of TCA can identify and determine what is an appropriate research design or method of inquiry for any given research question in the field of TCA. It is argued that the research design selected for any particular TCA study will be dependent upon the nature of the research question that is to be addressed.

2.1 The Nature of Traditional Chinese Medicine (TCM)

The research methods adopted by a health care profession could be expected to be determined in part by the beliefs, philosophy, and the epistemological orientations to practice⁴⁸ of its members. Research aims are often discipline dependent and emerge from the nature and goals of the discipline. In the first section of this chapter, the nature and core philosophical concepts, characteristics and themes of TCM that underpin many forms of TCA practice will be explicated. With this completed, and the essential characteristics of TCA practice described, it then becomes possible to determine appropriate types of research questions and methods that are congruent with the underlying philosophy and theory of TCA practice. This explication is necessary to fully appreciate why some conventional health care research methods cannot be simply transposed without adaption for the purpose of investigating TCA.

The Chinese term *zhong yi* (translated as Chinese Medicine) is a general term which can encompass all forms of traditional Chinese medical practice (see Beinfield & Korngold, 1991). The term *zhong yi* has in recent times also been translated as 'Traditional Chinese Medicine' (TCM) by some authors (Birch, 1997c, p. 8). It is important to note at the outset that there are at least two uses of the term *Traditional Chinese Medicine* that can be identified in Chinese medical literature. The first use of the term *Traditional Chinese Medicine* is used to describe a school of Chinese medicine called *ba gang bian zheng* that gained popularity in China in the 1960s and which has been practised since then in China and the occident.⁴⁹ This *ba gang bian zheng* approach to treatment is based on the discrimination of *patterns* of clinical phenomena collected by the 'four diagnoses' (*si zhen*), which can be analysed by the 'eight principles' (*ba gang*) (Flaws, 1972). The second use of the term 'TCM' encompasses a broad range of traditional ideas on health and illness, and of practices that have been used by physicians, healers and lay people in China over the past three millennia. Contemporary TCM

⁴⁸ The term 'epistemology of practice' was coined by D. Schon (1983) and defined by A. Mosey (1992, pp. 4-5) as the "investigation of the origin, nature, forms of inquiry, and organisation of knowledge in the science based professions and the use of such knowledge in practice. It also includes the study of how professions describe their ideology and its relationship to scientific knowledge."

⁴⁹ See Birch (1995, p. x) for a brief account of the historical development of this school of TCM.

practitioners now draw on a variety of theories and traditional practices. These include acupuncture, moxibustion, Chinese herbal medicine, *tui na* (Chinese therapeutic massage), meditation, *yangsheng* (health maintenance), orthopaedic manipulations and Oriental health counselling (Watson, 1995, p.13; Bensoussan & Myers, 1996, pp. 19-20). In this dissertation, the term TCM will be used in the second broader sense unless otherwise stated.

It should also be noted that diverse views of professionalism and different epistemological orientations to practice can be found amongst contemporary TCA practitioners which could result in different notions of what constitutes appropriate research in the discipline of TCA (chapter 7).

2.2 Cultural and Philosophical Influences on Traditional Chinese Acupuncture

To understand how the concepts and practices of TCA have developed, one needs to have an understanding of how cultural and philosophical influences have influenced the intrinsic nature of TCM. Confucianism, Daoism (Taoism) and Buddhism are three major philosophical systems that have substantially influenced the practice of TCM and therefore the practice of TCA. Maciocia (1997, foreword p. x) claims that, “the greatest influence on Chinese medicine is still essentially Confucian”. De Bary and Hurvitz (1972, pp. 126-27) note that Confucianism has been the most dominant ethical and intellectual tradition in China and has contributed to its strong secular orientation. It is partly due to the influence of Confucianism that the Chinese are said to be ‘this-worldly’ and pragmatic in their outlook to life. De Bary and Hurvitz (1972, pp. 126-27), in an examination of Confucianism, state that

the ultimate destiny of the individual, for Confucius, is inseparable from the personal fulfilment attained through facing the immediate needs and responsibilities of human life. It is “this” life-man in his concrete situation, in his normal relations - that Confucius’ thought centres around. Yet such an attitude does not make him irreligious, because it is precisely in the human order that Confucius recognizes the workings of Heaven and man’s obligations to serve Heaven. His lofty moral idealism is based not on a supernatural revelation, but rather on the natural revelation of the Heavenly order in man’s moral sense and reason.

Thus, Confucius’ affirmation of life can be considered ‘this-worldly,’ but only if we recognise that for him ‘this world’ was not opposed to Heaven.

From the Confucian perspective, harmonious and healthy societies can be achieved if individuals recognise their proper relationship to other members of society. This would amount to 'Heaven-on-Earth'.

The second major philosophy of China that has influenced the development of TCA is *Daoism* (*Taoism*). De Bary and Hurvitz (1972, pp. 126-28) claim that Daoism departs from the human-centeredness of Confucianism insofar as it defines human life in relation to a transcendent, all-pervading Way (or *Dao*) which is the ultimate principle of life, rather than in ethical and social terms as is the case in Confucianism. Larre and Rochat de la Vallee (1986, p. 2) in their examination of *Dao* state that:

The Tao [*Dao*] is nameless, formless, invisible and unknowable, yet it holds the essences, the designs, the beginning and ending of everything that has existed or ever will exist. The initial productions of the Tao are Heaven and Earth, the two basic energies in the universe, which through their interaction create and support everything else that exists. Man [humanity] is the meeting place and the channel for the joining of these two primary entities, and he [humanity] is the most precious of all beings in which their interplay is revealed.

Daoists, from this fundamental understanding, developed a philosophy, a system of medicine and related practices to support their lives. Daoism might have differed on the proper methods of self-cultivation and the governing of society, and might dispute the high position the Confucianists gave the human being in the scheme of the universe; however Daoists, like the Confucianists, agreed that life is worth living and hence Daoism is fundamentally life-affirming. Daoism, in contrast to Confucianism, encourages a more spontaneous enjoyment of life, which it is said can be achieved through an awareness and cultivation of *Dao*. Daoists tend to support a less structured form of government which they consider permits a greater freedom of human activity and the possibility of a serene life. Transcendence of the world is implied by the actions of some Daoists by their desire to rise above change in the world through meditation and self-cultivation. However, in Daoism, there is no disgust with life or the world, nor a

focus on 'sin' as can be found in some other world philosophies and religions.

An important concept of Daoism, termed *wu-wei*, has profoundly influenced the way TCM is practised (Garvey, 1996, p.10). *Wu-wei* has been translated as 'taking no unnatural action'.⁵⁰

The Daoist concept of *wu-wei* is suggestive of the natural and innate healing capacity of the human being. Kaptchuk (1997, preface p. xv) claims that many contemporary acupuncturists would accept that "healing is not primarily the outcome of an external mechanical stimulus-response nexus. Rather, healing comes from what the ancient tradition calls *resonance* [*gan ying*], an eliciting of inner potential to recreate balance." This is the idea that human beings have the potential within them to restore harmony themselves, and that it is the role of the healer to evoke this potential.⁵¹ In the context of medical practice, the concept of *wu-wei* is suggestive of the notion that minimal medical intervention is preferable to highly invasive interventions and procedures.

In Buddhism, the third major philosophy to have influenced TCM, there can be found an explanation for the suffering of life, a problem which Confucianism and Daoism perhaps do not adequately address. De Bary and Hurvitz (1972, p.128) remark that in Buddhism certain contrasts to the native Chinese tradition can be found in the formulation of the 'Four Noble Truths', "[t]aken together, these Truths express succinctly both Buddhism's initial pessimism about life and its final optimism." The way of salvation for the Buddhist is to first realise the 'truth' that 'life is indeed suffering' and that the cause of this suffering is *desire*. According to the Buddhist tradition, freedom is gained when one follows the path that leads to the cessation of desire and therefore the cessation of suffering (Yogi Ramacharaka, 1930, p. 199). Gautama (the Buddha) held that

⁵⁰ *Wu-wei* has often been translated as *inaction*, however according to W. Chan (1963, p. 491) "wu-wei is not simply 'inaction' but "taking no unnatural action".

⁵¹ Ted Kaptchuk (1997, p. xx) in the preface of H. MacPherson and T. Kaptchuk (eds.), *Acupuncture in Practice: Case History Insights from the West*, 1997 remarks in the second footnote that the "notion of resonance is rarely mentioned in the English language or modern Asian language discussion of causality in Oriental Medicine. Modern practitioners of Asian medicine seem to prefer to make Oriental medical causality resemble the proximal mechanical causality of classical Western science."

the Fundamental Cause of Suffering and Unhappiness in Samsara [52] was the Sense of Separateness by which the 'I' was deluded or hypnotized. This sense of Separateness brought in its train Selfishness, Strife, Conflict, and all the other evil manifestations that make of life in *Samsara* a nightmare of suffering. In other words Separation is the root of Evil, and all manifestations of evil may be traced back to its common source. And therefore all of Gautama's teachings were directed toward escape from this illusion of Separateness, by means of killing out the desire which was its very life energy. (Yogi Ramacharaka, 1930, p. 197).

A similar sentiment can be found in the first chapter of one of the classics of Chinese medicine, the *Huang Ti Nei Jing Su Wen* (hereafter referred to as the *Nei Jing*)⁵³:

one should live a quiet life with few desires so that one can preserve one's Qi and guard one's Mind in order to avoid disease. Thus if emotions are absent and craving is curbed, the Heart is peaceful and there is no fear (People's Health Publishing House, 1979, quoted in Maciocia, 1994, p. 278).

Buddhist philosophy emphasises the notion that the root of human suffering is the misconception of seeing oneself as completely separate, independent and self-sufficient, that is, forgetting one's true place and connection to the greater 'whole' of which one is a part. For the Buddhist, seeing one's true relationship to the 'whole', or one's true nature, requires spiritual insight. Like Daoism, the insights of Buddhism are practical and down-to-earth. Hagen (1997, p. 4) notes that the insights of the Buddha deal with the *here and now*, rather than with theory, speculation or belief.

It is important to understand that the 'holistic' Oriental perspective sees human health as being dependent on physical, psychological, social and spiritual factors. Consequently, in TCM, the health of the human being is understood to involve the interplay of these same factors. From the Chinese philosophical perspective, the universe has a unity, in which all things and processes are interconnected.⁵⁴ This traditional Chinese world view foreshadowed

⁵² J. Snelling (1996, p. 94) notes that *samsara* is the cycle of death and rebirth.

⁵³ This primary source of TCM is also known as *The Yellow Emperor's Classic of Internal Medicine* [c. 200 B.C.]

⁵⁴ While there have been many schools of philosophical thought in ancient China, a recurring concept in many of them is the idea that the manifest universe consists of *one* field of *qi*. It follows that all phenomena are ultimately interconnected. This perspective is similar to some early Greek schools of thought, e.g. Plato's idea of the 'one' in the *Parmenides* (see E. Hamilton and C. Huntington, *Plato: The Collected Dialogues*, 1961).

contemporary holistic philosophies (*e.g.* the ‘general systems theory’ of von Bertalanffy, 1968). Without acknowledging and understanding the philosophical perspectives of Confucianism, Daoism and Buddhism, it is not possible to comprehend how TCM notions of health, illness and disease have developed and how they continue to influence TCA theory and practice.

2.3 Core Concepts and Themes of TCM that Underpin TCA Practice

2.3.1 *The TCM paradigm is broad and can tolerate diverse schools of thought and practice*

TCM has never been an homogeneous medical system: throughout its long history there have been numerous schools of thought, each with its own associated theories and practices (see Maciocia, 1982; Unschuld, 1985, 1987; Birch & Felt, 1999; Birch & Kaptchuk, 1999). As a consequence, it is not possible to make a comprehensive list of all of the tenets and theories of TCM that underpin TCA practice; however, what is possible is to outline some of the core ideas, concepts and themes that constantly recur in the TCM discourse.

Ryan (1995, p. 74) claims that it is *tradition* that has set the parameters for the maintenance of TCA’s theoretical coherence as it has developed and responded to changing health needs. Ryan (1995, p.75) notes that the TCA paradigm has always been open to change and development with the boundaries of the paradigm being “broad enough to tolerate diverse schools of thought and practice.” As a result, additions to the TCA ‘paradigm’ are possible by considering the ideas and concepts of other philosophies and disciplines. It could also be noted that the relatively new scientific theory known as *chaos theory* suggests *both* order and disorder in all phenomena. Chaos theory posits that there *are* laws but that the outcomes of these laws are not completely predictable in actual practice (Goerner, 1995, p. 22).⁵⁵ Such an understanding suggests possible limits to knowledge.

⁵⁵ For an account of the ideas of Chaos see J. Gleick, *Chaos: Making a new science*, 1988.

2.3.2 *Dao and the limits of knowledge*

The concept of *Dao* is fundamental to *Daoism*. Tu Wei-Ming (1992, pp. 88-89) states that as “a root metaphor in Chinese medical thought, *Dao* suggests an approach, a path, and a process of becoming.” Blofeld (1978 in Govinda 1981, p. xiv) claims that *Dao* is “the formless ground from which all forms emerge.” *Dao* is understood by Daoists to be formless and essentially unknowable by the mind. This has important implications for traditional Chinese medical concepts of knowledge. Ryan (1995, p.74) has remarked that, “[traditional] Chinese medicine has been shaped by a philosophy which holds that there is a level at which reality is unknowable, ambiguous and contradictory.” As a consequence, TCA theory does not tend to posit laws but rather attempts to identify the patterns, motifs and tendencies of reality. From the Daoist perspective, there are limits to knowledge regardless of the form of inquiry used. According to the writings of Chinese sages, the true nature of the *Dao* will not be revealed through logic or reason. This idea relates to Wilber’s (1990) notion that the ‘eye of reason’, and the methods by which we attain knowledge of philosophy, logic and the mind itself, cannot be used to uncover transcendental realities.⁵⁶

2.3.3 *Ontology: The Chinese concept of qi (chi)*

For Daoists, all manifestations in the universe are understood as configurations of *qi* (*chi*, *ch’i*) generated through the dynamic interplay of the two archetypal complementary polar opposites termed *yin/yang*. TCM practitioners understand all ‘matter’, ‘energy’ and other phenomena of the universe, regardless of whether they be inanimate or living, to be manifestations of this one *qi*. According to Daoist tradition, everything is composed of *qi* and all movement involves *qi* (Manaka, Itaya & Birch, 1995, p. 5). It could also be noted that contemporary quantum physicists hold an understanding of the universe that is congruent with Chinese philosophical thought, as Capra (1983, p. 70) explains

⁵⁶ C. Chung-yuan (1975, p. 19) states that, “[t]he understanding of *Tao* is an inner experience in which distinction between subject and object vanishes. It is an intuitive, immediate awareness rather than a mediated, inferential, or intellectual process. *Tao* does not blossom into vital consciousness until all distinctions between self and nonself have disappeared.” This statement suggests that a phenomenological approach might be required to understand *dao* (see chapter 5).

modern physics reveals the basic oneness of the universe. It shows that we cannot decompose the world into independently existing smallest units. As we penetrate into matter, nature does not show us any isolated basic building blocks, but rather appears as a complicated web of relations between the various parts of a unified whole.⁵⁷

The concept of *qi* is fundamental to TCM philosophy and theory, and yet no single English word or phrase can capture its essential meaning. Ted Kaptchuk (1983, p. 35) states that, “[q]i is not some primordial, immutable material, nor is it merely vital energy, although the word is occasionally so translated. Chinese thought does not distinguish between matter and energy.” The TCA practitioner usually perceives *qi* functionally by what it *does*, rather than what it *is*. Capra (1983, p. 344) states that *qi* (*ch'i*)

is not a substance, nor does it have the purely quantitative meaning of our scientific concept of energy. It is used in Chinese medicine in a very subtle way to describe the various patterns of flow and fluctuation in the human organism, as well as the continual exchanges between organism and environment. Ch'i does not refer to the flow of any particular substance but rather seems to represent the principle of flow as such, which, in the Chinese view, is always cyclical.

Maciocia (1989, p. 36) suggests that the reason that the term *qi* is so difficult to translate correctly “lies precisely in its fluid nature whereby it can assume different manifestations and be different things in different situations.” The central role and significance of the concept of *qi* in TCM is indicated by its prevalence in TCM literature. For example, in one of the primary classical texts of TCM, the *Nei Jing* [c. 200 B.C.], over eleven hundred of the fifty thousand characters of the book are characters for the term *qi*: that is, approximately one in fifty characters (Manaka, Itaya & Birch, 1995, p. 5).

In TCM literature, the ‘body-mind’ complex of the person with its various properties and processes is understood to be a manifestation of *qi*. Birch (1995, p. xxii), in an introduction to the research of Manaka, explains that *qi* can be thought of as *information*. According to *information theory*, “[i]nformation is any pattern of events in time and space ... The form or

⁵⁷ It might be fruitful to compare the Chinese concepts of *dao* and *qi* with David Bohm's (1980) theory of *implicate order*. Newman (1986, p. 12) explains that “[a]ccording to Bohm, there exists in our universe an unseen, multidimensional pattern that is the ground, or basis, for all things. This is the implicate order. Arising out of the implicate order is the explicate order, a kind of precipitate of the implicate order. The explicate order includes the tangibles of our world.”

structure of the body has informational content.” (Cunningham, 1986 quoted by Birch, 1995, p. xx). This perspective would seem congruent with that of TCM. For example, in TCA practice TCA practitioners obtain diagnostic *information* from their clients through observation and palpation of bodies (see Zhiya, 1995).

It could also be noted that TCA practitioners understand the spoken word to be *qi*. In the practice of TCA, it is believed by some practitioners that *qi* can be transferred between the TCA practitioner and the client. Now if *qi* has informational content, it follows that the words spoken by a TCA practitioner to a client could affect the configuration of a client’s *qi* and hence changes in states of health and wellbeing. Cunningham (1986 cited in Manaka, Itaya & Birch, 1995, p. xx) has suggested that it is the *information* content of energy that brings about change in organisms.

Capra (1983, p. 343), in a discussion of the Chinese conception of the human being, has noted that

the idea of the body has always been predominantly functional and concerned with the interrelations of its parts rather than with anatomical accuracy. Accordingly, the Chinese concept of a physical organ refers to a whole functional system, which has to be considered in its totality, along with the relevant parts of the correspondence system.

In TCM theory, human attributes and natural phenomena can be related through the Chinese system of *wu xing* (five phases) correspondences (Maciocia, 1989; Zhiya, 1995).⁵⁸ For example, the concept of *xin* (heart) does not refer specifically to the heart organ, but rather to an entire system which includes other related phenomena such as the tongue, the colour red, joy, the complexion, the blood vessels and the *shen*⁵⁹, all of which are associated with the ‘fire

⁵⁸ *Wu xing* has been translated by Wiseman and Ye (1998, pp. 205-206) as ‘five phases’. This is a more apt term than the more commonly rendered term of ‘five elements’. *Xing* means ‘move’ or ‘movement’ which is suggestive of the dynamic and cyclic nature of the five Chinese concepts of *fire, earth, metal, water* and *wood*. The term ‘element’ of Western philosophy and science connotes something that is more static in nature.

⁵⁹ According to Ted Kaptchuk (1983, p. 45), “human consciousness indicates the presence of Shen. Shen is associated with the force of human personality, the ability to think, discriminate, and choose appropriately”. G. Maciocia (1989;1993) associates *shen* with the mind.

element' (or phase) through correspondence.⁶⁰ Capra (1983, p. 343) argues that the Chinese conception of the human body as an indivisible system of interrelated components is more similar to modern 'systems' approaches following von Bertalanffy (1968) than to the classical Cartesian model (see chapter 3.3). The holistic TCM model of health, illness and disease continually emphasises the interrelatedness and interaction of all phenomena. Tu Wei-Ming (1992, p. 91) claims that the Confucian conception of the body as a modality of *qi* is congruent with the notion of the lived experience of the body, and as a consequence, the body might be better understood as "a flowing stream constantly responsive to the vicissitudes of the changing environment" rather than as a static structure.

The Daoist conception of *qi* suggests a single differentiated field of *qi*, punctuated by centres that have no clear boundaries. Each human being can be thought of as a whole, an embodied self, that can be perceived as an aspect of the great field of *qi*. This understanding combines aspects of Lincoln and Guba's (1985) *perceived* and *constructed* realities. A *perceived reality* is the ontological position that asserts that "there is a reality, but one cannot know it fully. ... It is partial and incomplete only because each perception yields experience of only a limited number of *parts* of the whole" (Lincoln & Guba, 1985, p. 83). It follows from this idea that knowledge can be limited and that reality can only be known from one's particular vantage point. A *constructed reality*, in contrast, is the idea that there is no objective reality and that reality is constructed by individuals through cognitive processes. For the 'constructive realist', reality is constructed, multiple and holistic (Lincoln & Guba, 1985, pp. 83-85). From a Daoist perspective, there can be multiple 'perceived realities' at the human level, which is nevertheless compatible with the ontological concept of a single *qi*.

While the Daoist ontological conception of the one *qi* might seem similar to the one substance monism of materialism⁶¹, where the term 'matter' is substituted by the term *qi*, there are

⁶⁰ Helms (1995, p. 59) notes that fractal mathematics suggests the possibility of a fractal resonance between the interactions represented in the 'five phases' of acupuncture theory and the dynamics of fractal structures. This is suggested from the relationship between activated acupuncture points and their inactivated symmetrical points. See M. Kuman (1991) for an account of chaotic dynamics, fractals and the acupuncture channel system.

⁶¹ M. Little (1995, p. 183) notes that *Materialism* is a view that all phenomena can be explained in mechanical terms. G. Vesey and P. Foulkes (1990, p. 182) state that materialists are people who believe in "the existence of material things over and above the sensory IDEAS [*sic*] we have of them".

important differences. Materialism cannot easily account for mental states. The mind in materialist accounts is usually thought of as an epiphenomenon of the brain, and its importance is usually understated since it cannot be fully explained solely in terms of known laws and physical processes. In contrast, *qi* is a more fluid concept and does not produce the same dichotomy between 'mind' and 'body' as is found in some Western philosophies and in orthodox Biomedicine.

2.3.4 *The concept of yin/yang*

Larre and Rochat de la Vallee (1986, p.11) state that "[t]ao [*dao*] is essentially a rhythmic pace of alternating *yin* and *yang*." From the perspective of TCM, *yin* and *yang* are viewed as polar aspects of a single whole (that is of the one *qi*) and not as intrinsically different categories. According to TCM theory, no phenomenon can be said to be absolutely *yin* or *yang* in nature. All things and beings are aggregates of *qi*, oscillating between the two poles of *yin* and *yang*. From this perspective, the phenomena and processes in the world can be classified as being predominately *yin* or *yang* in nature (see Tables 2.1 and 2.2 on p. 47 below for examples of phenomena and processes classified as predominately *yin* or *yang*).

The concept of *yin/yang* can be traced back to mythical antiquity and was referred to in the early Chinese classic, the *Yi Jing (I Ching)* (Wilhelm, 1967, introduction, xlvi). The concept of *yin/yang* is ancient and pervades the whole of early Chinese thought and culture.⁶²

Kaptchuk (1983, p.7) suggests that *yin/yang* theory can be called *synthetic* or *dialectical* since it is assumed that a part can only be understood in relation to the whole. The Chinese *tai qi (tai chi)* symbol represents diagrammatically several related *yin/yang* concepts (see Figure 2.1).

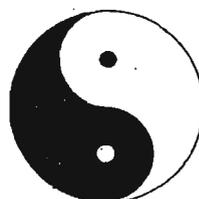


Figure 2.1 *tai qi (tai chi)* symbol

⁶² See Z. Zhiya (1995, pp. 164-173) for a comprehensive account of the concept and theory of *yin/yang*.

Table 2.1

General examples of phenomena classified according to *yin/yang*

Table 2.2

Examples of *yin/yang* as applied to the human being and TCM diagnostic phenomena

<i>yin</i>	<i>yang</i>
darkness	light
night	day
moon	sun
negative	positive
water	fire
material	immaterial
quiescence	movement
contraction	expansion
descent	ascent
matter	energy
space	time
below	above
producing form	producing energy
order	chaos
destiny	freedom

<i>yin</i>	<i>yang</i>
structure	function
medial aspects of body	lateral aspects of body
internal aspects of body	superficial aspects of body
inferior	superior
anterior aspects of body	posterior aspects of body
muscles	skin
body	mind
<i>zang</i>	<i>fu</i>
<i>xue</i> (blood)	<i>qi</i>
cold	hot
slowness	rapidity
soft	hard
chronic disease	acute disease
hypoactivity	hyperactivity
feeling hot	feeling cold
(as in <i>yin qi xu</i>)	(as in <i>yang qi xu</i>)
red complexion	pale complexion
empty pulse	full pulse

2.3.4.1 *The interdependence of opposites.*

The black and white 'tadpoles' of the *tai qi* symbol (Fig. 2.1) symbolise two aspects (*yin/yang*) of a whole, with each aspect requiring the presence of its polar aspect for its own existence. For example, light is understood by contrasting it with its opposite, darkness; beauty is appreciated in comparison with ugliness. In the context of TCM, health can only be understood in relation to illness and disease. Kaptchuk (1983, p.13) notes that the dynamic curve dividing *yin* and *yang* in the *tai qi* symbol indicates that "Yin and Yang are continuously merging. ...Yin and Yang create each other, control each other, and transform into each other."

2.3.4.2 *The interpenetration of opposites.*

Chinese philosophers claim that ‘polar opposites’ can be found within any identified phenomenon; that is, *yin* can be found within the *yang*, and *yang* within the *yin*. This is represented in the *tai qi* symbol by a small circle of the opposite colour within each of the ‘tadpoles’. This suggests that if one looks hard enough at any phenomenon, its opposite can be found within it. For example, within any work of art or beautiful object can be found aspects that could be seen as flaws from another perspective: this is the *yin* within the *yang* in Chinese philosophical terms. Another example given by Rowan (1981b, p. 130) at the human level of experience is the presence of hate in any great love, and some love in every hate. It follows from *yin/yang* reasoning, that in TCM, health and disease are not understood as two discrete categories by which human health status can be categorised. Human beings experience *relative* states of health, illness and disease. For example, while a person may claim to be in good health, that same person may experience minor signs and symptoms of illness and/or disease.

2.3.4.3 *The unity of opposites.*

The concept of *yin/yang* stresses that ‘polar aspects’ are not of intrinsically different ontological categories. In Daoist philosophy, *yin* and *yang* are regarded as *complementary* ‘polar’ opposites that make up *one* whole. According to Chinese Daoists, the manifested world and all phenomena are but aspects of the one *qi*. The inseparable nature of the two polar aspects is emphasised by the ability of one aspect to turn into its opposite if one pole is taken to an extreme. This idea is expressed poetically in the Lao Tzu’s classic of Chinese literature the *Dao De Jing (Tao Te Ching)* (trans. Feng and English, 1972, chapter 9), “[b]etter stop short than fill to the brim. Over sharpen the blade, and the edge will soon blunt.” Carl Jung (1983, p. 245) termed this process, or law of change, *enantiodromia* (reversal *in extremis*). As a simple example of this idea, consider exercise. While some exercise is generally regarded as being beneficial for the health of the human being, too much over long periods might be detrimental to the body.

From the Daoist perspective, the world (the macrocosm) can be understood to be in a state of harmony when there is a dynamic balance between *yin* and *yang*. This idea is alluded to by Larre and Rochat de la Vallee (1986, p. 8) when they state that, “[t]he working of Heaven/Earth is wonderful in its rhythm and silence. Occasional departures from its regular pattern are only temporary ... Health is the natural state of the universe.” From this perspective, the health of the environment requires a dynamic balance of *yin* and *yang*, with imbalances manifesting in the form of natural disasters such as floods and earthquakes. In a similar way, the health of the human being (the microcosm) is also believed to be dependent on a dynamic equilibrium between *yin* and *yang*. For example, from the perspective of TCM, a person with a deficiency of *yang qi* might have the signs and symptoms of feeling cold, a pale complexion, frequent urination and low vitality.⁶³ The aim of TCA therapy in this case would be to restore health by reinforcing (or tonifying) the *yang qi* by needling specific acupuncture points or using moxibustion⁶⁴ to restore the dynamic equilibrium between *yin* and *yang*.

Larre and Rochat de la Vallee (1986, p. 8) note that in Chinese texts the states of *health* and *illness* are represented by two Chinese characters that are nearly homophonous. The Chinese character transliterated as ‘*ping*’ can represent “regularity, balance, tranquillity and therefore health”, while the character transliterated as ‘*bing*’ can be rendered as “defect, alternation, malfunction, illness.” This again emphasises the notion that health and illness, from the TCM perspective, are relative terms and do not constitute intrinsically different categories. Health is associated with ‘dynamic balance’, while illness and disease result from a movement from this state of dynamic, or relative, balance. The TCM concept of ‘dynamic balance’ is similar in some ways to the biomedical concept of *homeostasis* which involves a physiological equilibrium or balance of functions and chemical composition within living beings.

⁶³ See G. Maciocia (1989) for a comprehensive account of TCM ‘patterns of disharmony’.

⁶⁴ Moxibustion is a technique used by TCA practitioners. *Moxa* is a herb (*artemisia vulgaris*) that can be burnt on or above the skin. It can be used to affect the *qi* and *xue* of the channels via the stimulation of the acupuncture points. The heat and other substances generated by the burning moxa is believed to increase the *yang qi* of a person when it is deficient.

2.3.5 No Mind-body Dualism in TCM

The avoidance of dualisms has been a constant motif in Oriental philosophy. This is exemplified in the Chinese philosophical conception of the human being which avoids dualistic notions of mind and body.⁶⁵ From the Daoist perspective, both so called psychological and physiological processes are understood as manifestations of the one *qi*. There is no need to explain *how* mind and body interact since they are *both* expressions of the one complex, which *is qi*. In TCM, the ‘mind’ is understood to be a more refined state of *qi* when compared with the denser *qi* of the ‘body’. This understanding is expressed by Hua Ching Ni (1979a, pp.156-157), “[a] human being is a model of the integration of yin and yang, with the physical energy manifesting as his body and the subtle energy manifesting as his mind and spirit.” Mind could be described as being more *yang* in nature when compared to the ‘objective’ physical body; however, it must be remembered that from the Chinese philosophical perspective, the mind and body are *not* two intrinsically different substances; rather, they are the two aspects of the one mind-body complex. It follows that a change in a person’s ‘psychological state’, ‘mind’, or *shen* can result in a *simultaneous* change in the body.

Mind-body dualism is one example of ontological dualism in which categorical distinctions are made between the human and natural worlds. Wood (1986, p. 58) claims that according to Wartofsky (1976), other distinctions that arise from ontological dualism include “the sociological dichotomy between determinism and nominalistic choice”, and, in medicine, “the contrast between physicochemical conceptions of disease and all that is associated with healing, a dichotomy often conceived of as one between facts and values.” From the perspective of TCM, these distinctions are no longer useful since they can create extreme polarisation which can result in inflexible health care practices and research orientations. The Chinese Daoist conception of *qi* would seem to offer a way forward in understanding the relationship between the mind and the body and other questions related to ontology.

Fay (1996) claims that a dualistic way of thinking tends to predominate in the philosophy of social science and the author would suggest the same could be said for contemporary

⁶⁵ For a discussion of this idea see Y. Ikemi and A. Ikemi, 1986, pp. 150-157.

Biomedicine. Fay (1996, p. 241) states that

[m]uch social thought consists of oppositional categories - self vs. other; particular vs. universal; subjectivity vs. objectivity' ... The same dualistic thinking mars metatheories in the philosophy of social science: atomism vs. holism; cause vs. meaning; interpretive social science vs. causal social science' ... Such thinking promotes an "either-or" mentality in which one category precludes its supposed opposite. But many categories are fluid and open. Often one side of a dichotomy depends on and invokes the other - in which case the dichotomy is subverted. Frequently an entity can be in both categories; or one category gradually slides over into its supposed opposite; binary alternatives rest on fallacious presuppositions which mistakenly restrict the range of possible choices.

Fay (1996, p. 241) suggests that people should beware of dichotomies and avoid pernicious dualisms. Fay's claim is congruent with the non-dualist Chinese philosophical understanding of *ying/yang*.

2.4 The Practice of Acupuncture

2.4.1 *The acupuncture needling technique.*

Acupuncturists use a technique that involves the insertion of acupuncture needles into specific loci of the body called acupuncture points, many of which are located along pathways called *channels* (or *meridians*) which are located at various depths within the body (Cheng, 1987; Shunpei & Shunyi, 1997).⁶⁶ According to TCA theory, the needling of these acupuncture points can influence the *qi* of the person. From the perspective of TCM, a person's configuration of *qi* can be related to relative states of health, illness and disease.

According to TCA theory, one aspect of *qi*, termed *zhen qi* (or true *qi*), circulates through both the superficial and deep aspects of the body via the *jing luo* channel system that covers and connects all parts of the body (Maciocia, 1989, p. 44). It is through this channel system that communication between the various organs, the mind, and other parts of the body is maintained (Maciocia, 1989). One tenet of TCA theory is that a person's state of health and wellbeing is dependent on a harmonious flow of *qi* through the channels.

⁶⁶ It could be noted that acupuncturists can 'activate' acupuncture points through a variety of methods in addition to needling: these include moxibustion, acupressure, laser, electrical stimulation and magnets.

The nature and function of *qi*, as it is understood by TCA practitioners, can only be understood in the context of other philosophical concepts that have emerged from the Chinese philosophical tradition. According to Larre and Rochat de la Vallee (1986, p. 8), the movement of *qi* in the body is only one example of “the movement of energy through the collective network of pathways that surround and penetrate all living beings.” This statement conveys the idea that *qi* flow is not conceived as occurring only within the boundaries of the individual human body, that is, within a ‘closed system’. Rather, *qi* flow needs to be understood as occurring in an ‘open system’, where there is a constant and dynamic flow of *qi* between human bodies and their surrounding physical and social environments. This idea will be developed further when the concepts of ‘systems’ theory are discussed in relation to TCM (chapter 3).

2.4.2 *The different forms of acupuncture*

TCA is one of the modalities that is utilised by TCM practitioners. A definition of what TCA therapy is, or at least an understanding of how TCA is practised by members of the TCA profession, is a necessary requirement to fully appreciate the claim that much contemporary acupuncture clinical research is seriously flawed. To begin this analysis, it will be necessary, first, to briefly describe the different types of acupuncture that are practised by traditional and medical practitioners so as to make explicit the reasons why certain research designs that have been transposed from biomedical research for acupuncture are not been appropriate for the evaluation of traditional forms of acupuncture.

There are many different forms of acupuncture practised within and outside of China (Seem, 1992; Scheid, 1993; Ernst & White, 1997; Dale, 1997a; Dale, 1997b; 1997c; Birch & Felt, 1999; Birch & Kaptchuk, 1999). This is easily comprehended if one considers the many schools of Chinese medical thought that have existed in China over acupuncture’s two thousand year history (see Unschuld, 1985). Each school of traditional acupuncture tends to emphasise one or more sets of theories and practices from among the considerable body of TCM theory and practice. In the occident, numerous forms of acupuncture can be identified (Seem, 1990). For example, many Western medical practitioners use a ‘medicalised’ form of

acupuncture.⁶⁷ Gunn (1998, p.12) has termed this type of acupuncture, *scientific acupuncture*. Scientific acupuncture is based on a biomedical understanding of neurophysiology, anatomy, diagnosis and disease. This type of acupuncture usually involves a biomedical diagnosis, which is then followed by the needling of a corresponding set of classical acupuncture points for each *specifically* diagnosed biomedical disorder or disease. This form of acupuncture is sometimes referred to as *formula acupuncture* (Vincent, 1993). Vincent (1993, p. 291) states that “[p]ractitioners of traditional acupuncture may criticize the formula approach on the grounds that it gives inferior results and is not in keeping with the spirit of traditional acupuncture.” Formula and ‘scientific’ acupuncture cannot be said to be more rational than traditional approaches since the acupuncture point combinations prescribed and used for the various biomedical disorders are derived from a traditional understanding of acupuncture point function, and *not* from an understanding of how these acupuncture points function in terms of biomedical physiological understandings. While some research has been conducted on the physiological changes that occur when specific acupuncture points are needled⁶⁸, Bensoussan and Myers (1996, p. 30) claim that

TCM cannot be practised adequately without knowledge of TCM theory. The therapeutic tools (acupuncture points and medicinal substances) currently have no functional characteristics other than those defined by their traditional attributes, although it is possible that research may subsequently define their functions in western medical terms and allow them to be used in a different fashion.

Bensoussan and Myers (1996, p. 46) claim that from their literature survey of the neurophysiological research of acupuncture that, “neurophysiological [biomedical] findings are not able to be used predictively in a clinical context.” With the current limited knowledge of the function of acupuncture points in terms of biomedical physiology, it could be argued that ‘formula’ and ‘scientific’ acupuncture are unhealthy hybrids: Eastern medical practices without a Western biomedical theoretical foundation.⁶⁹

⁶⁷ See J. Filshie and M. Cummings (1999) for an account of Western medical acupuncture.

⁶⁸ For an account of the physiology of acupuncture see Special Supplement: Research on Paradigm, Practice, and Policy. Proceedings of the 1996 International Symposium on the Physiology of Acupuncture (1997). *The Journal of Alternative and Complementary Medicine*, 3, Supplement 1.

⁶⁹ It could be noted that there are systems of acupuncture such as ear and scalp (head) acupuncture that draw on both traditional and biomedical understandings (as examples see Huang, 1974 and Shunfa, 1997).

It could be noted that some biomedical acupuncturists must restrict themselves to using ‘formula’ or ‘scientific’ acupuncture’ and tend not to use more traditional forms of acupuncture since this would require a comprehensive understanding of traditional Chinese medical theory and TCA diagnostic principles. As previously suggested (chapter 1), TCA is not merely a therapeutic technique (like some forms of ‘formula acupuncture’) but rather a medical discipline based on individual patient symptomatology calling for individualised treatment protocols and management (Guillaume, 1991, p. 54). Following the lead of Vincent and Richardson (1986, p. 2), the term *traditional acupuncture* in this dissertation will be reserved for those types of acupuncture where classical acupuncture points are needled and where diagnosis is based on traditional Chinese concepts and related understandings of health, illness and disease (see Cheng, 1987; Maciocia, 1989; Zhiya, 1995). Birch (1997a, p.148) claims that a defining characteristic of traditionally based systems of acupuncture (TBSAs) is “the employment of documented historically based explanatory models.”⁷⁰

Traditional Chinese medical texts sometimes make a distinction between enlightened physicians (*ming-i*) and common physicians (*yung-i*). Kung Hsin [A.D. 1600] in the *Ku-chin t’u-shu chi-ch’eng* (cited in Unschuld, 1979, p. 69) explains that enlightened physicians [*ming-i*]

cultivate humanness and righteousness in their attitude. Their study is extensive and embraces all of the writings in their entirety. For this reason they are well versed in theoretical medicine and its practical use. They know yin and yang, and understand the macrocosmic phases [yun] and the types of climate [ch’i]... They ponder over the best procedures, are [flexible] in their treatments and do not cling mechanically to any formulas.

The above quotation strongly suggests that best traditional acupuncture practice requires more than the mechanical application of acupuncture point formulae. Rather, best practice requires the practitioner to fully understand traditional Chinese medical theory so that TCA therapy can be tailored to the particular needs of each individual patient.

2.4.3 *Traditional Chinese acupuncture therapy*

TCA therapy is based on traditional Chinese philosophical and medical theories and the

⁷⁰ See Birch (1997c, p. 16) for examples of traditionally based explanatory models of acupuncture.

associated understandings of the human being, health and illness, diagnosis and treatment. TCA practice cannot be said to be homogeneous, since individual TCA practitioners tend to place different degrees of emphasis on the various TCM theories and practices. In addition, as TCA has spread from China to other countries, it has been observed to change and adapt to the needs, ideas, philosophies and culture of the local people. For example, many TCA practitioners in Australia have been influenced by Western psychotherapy and counselling philosophies which has translated into the introduction of psychology and counselling subjects into Australian university TCA programs.⁷¹ TCA practitioners often attempt to develop close therapeutic relationships with their clients so as to facilitate healing.⁷² Vincent and Furnham (1997, p. 11) in an examination of the complementary therapies state that “[h]ealing can mean marshalling the will-power and faith of the patient, but more commonly implies an active transmission of some kind of therapeutic energy between healer and patient.” The idea that healing involves a change or transmission of energy (or *qi*) is held by many TCA practitioners.

In the United Kingdom, Dale (1997b, p. 221) claims that many holistic acupuncture therapists practise a psychotherapeutic style that draws on the ideas of humanistic psychology.⁷³ While there are many different forms of traditional acupuncture, there are nevertheless a number of core assumptions and tenets that most TCA practitioners would accept as underpinning their practice.

2.4.4 *Traditional Chinese acupuncture therapy is dynamic and not static*

TCA practitioners, using traditional approaches, routinely modify their treatment plan (with its associated sets of acupuncture points) in response to the constant changes in a client’s health

⁷¹ As examples, see the Bachelor of Health Science - TCM (Acupuncture) course offered by the Victoria University of Technology and the Bachelor of Health Science (TCM) course offered by the University of Technology, Sydney.

⁷² See also Appendix B: ‘What respondents said Chinese medicine care does and why they liked it’.

⁷³ Chung-yuan (1975, p. 5) also notes the importance of *Dao (Tao)* in the light of Jungian psychology, “[t]he value of *Tao* lies in its power to reconcile opposites on a higher level of consciousness” and that it is the endeavour of psychotherapy “to reconcile the polarities in order to achieve a balanced way of living and a higher integration.”

status. TCA is hence a dynamic therapy in the sense that the therapy can be modified and tailored to the individual needs of the client. This can be contrasted with the practice of some practitioners who use a 'formula acupuncture' approach in which the same sets of points are used repeatedly after an initial biomedical diagnosis is made.

Kaptchuk (1983, p. 4) explains that during the clinical encounter, client information can be woven together by the acupuncture practitioner until it forms what TCM practitioners term a 'pattern of disharmony'. This pattern of disharmony describes the situation of 'imbalance' in the client. The signs and symptoms of illness and disease are therefore understood by TCA practitioners as 'patterns of disharmony', which can be indicative of a blockage, excess or deficiency of *qi*. An example of a TCM 'pattern of disharmony' is '*kidney yang xu*'. *Kidney yang xu* can manifest in a person as a pattern of signs and symptoms. These signs and symptoms could include a feeling of coldness in the back and knees, weak legs, abundant clear urine, loose stools, lassitude and edema (Maciocia, 1989, p. 253). TCA practitioners might attempt to rebalance such a pattern of disharmony by influencing the *qi* through the needling of acupuncture points (and probably by using moxibustion), with the intention of restoring the *qi* flow and/or *qi* levels to a 'balanced' state for the individual concerned.⁷⁴

2.4.5 *TCA therapy is more than the application of the acupuncture needling technique*

It is believed by many TCA practitioners that TCA therapy can enhance a person's natural defence and self-healing processes, as well as promoting balance between the biological, emotional, psychological and spiritual aspects of the person and their outer environment. An assumption held by many TCA practitioners is that the body is essentially self-healing and that it is the role of the practitioner to facilitate this healing process. Vincent and Furnham (1997, p. 21) following Fulder (1984) have noted that since complementary practitioners (including no doubt many TCA practitioners) view the patient's body "as healing itself, rather than being acted upon by drugs or surgery, the patient must do what they can to help themselves." As a consequence, "[t]he patient is encouraged to discover why they are sick and to work for their own cure, with the therapist as a partner in the enterprise. In some cases the journey to health is

⁷⁴ Traditional acupuncturists claim to treat 'patterns of disharmony' that result from a disharmony of the *whole person* rather than just physiological dysfunction of the biological body (see Maciocia, 1989; Zhen, 1995).

also seen as a journey to self-discovery” (see chapter 3).

It is an understanding of TCA practitioners that people are continually interacting with the environment in which they are embedded. There is also the understanding that there is a process of mutual interaction between systems. The physical and social environments can act upon the individual, with individuals simultaneously modifying these same systems (Kaptchuk, 1983, p. 348). The TCA practitioner therefore holds a holistic orientation and sees human health disorders as being multifactorial in nature. From the perspective of TCM, the health status of the human being is determined by the interaction of the physical/biological, emotional/psychological, social, and spiritual realms.

TCA practitioners maintain a holistic perspective which emphasises, in Western terms, the unity of spirit, mind and body. In TCA, a person’s signs and symptoms of illness are viewed as an imbalance in the person’s total state of being, and not simply as the malfunction of a particular part or organ of the body. Edlin and Golanty (1988, pp. 5-6) state that holistic conceptions of health recognise

the interrelatedness of the physical, psychological, emotional, social, spiritual, and environmental factors that contribute to the overall quality of a person’s health and life. In holistic models of medicine, the *whole* is always understood to be greater than the sum of its parts. No part of the mind, body, or environment is truly separate and independent.

Birch (1995, p. xiii), following (Needham, 1956), also notes that “[w]ith the exception of politically influenced modern Chinese works on acupuncture and East Asian medicine, both practitioners and scholars agree that these medical systems are founded on a non-reductionist paradigm.” (see Chapter 3).

2.4.6 *The TCA practitioner-client encounter*

The TCA practitioner is expected to be a teacher in addition to being a healer. As Ferrigno (1997, p. 19) notes, “[i]n Chinese medicine the physician’s task of healing could not be separated from also being a benefactor and teacher. Indeed, it was more important that physicians teach people how to stay well.” TCM practitioners emphasise the importance of

disease prevention (Patel, 1987; Zhiya, 1995, pp. 296-297). This idea is a constant theme in Chinese medical texts. For example, in the *Nei jing* (Inner Canon of the Yellow Emperor), emphasis is placed on “giving treatment before a disease arises.” In Basic Questions⁷⁵ it states that

[g]reat practitioners give treatment before diseases occur and prevent diseases before they rise ... To give treatment when a disease has occurred is late [*sic*]. This is similar to not digging a well until you are thirsty or not making weapons until the war breaks out (quoted in Zhiya, 1995, p. 296).

A common belief held by TCA practitioners is that the ‘superior’ TCA practitioner attempts to maintain the health of their clients by correcting minor *qi* imbalances by needling acupuncture points *before* the actual appearance of clinical signs and symptoms. Detection of these minor *qi* imbalances can be accomplished through one of the TCM diagnostic systems such as pulse and tongue diagnosis (see Maciocia, 1989). On the other hand, the ‘common’ TCA practitioner is said to treat people only after actual disease has manifested. Since TCA practitioners generally regard the prevention of disease to be just as important as its cure, it is not surprising that TCA practitioners often advise clients on what they need to do if they are to prevent a recurrence of a disorder. TCA practitioners would generally agree that people are at least partly responsible for their own health through their decisions, actions, and lifestyle. As a consequence of this understanding, TCA practitioners sometimes suggest dietary changes (in the form of *shi liao*), meditation, *tai ji quan* (a Chinese form of exercise), encourage a more positive attitude or lifestyle, or provide some form of Oriental health counselling in addition to acupuncture (Watson, 1995, p.13).⁷⁶

The aim of the TCA practitioner during the clinical encounter is to help the client to achieve the best possible adaption to their total environment by restoring balance within the individual’s total biopsychosociospiritual environment. To achieve this end, the client will often need to play an active role in the TCA therapy, since from the TCM perspective, the individual is responsible in part for the maintenance of their own health, and to a large extent for its

⁷⁵ *Basic* (or *Simple*) *Questions* is one part of the *Nei jing*, the other part being *The Miraculous Pivot*.

⁷⁶ See Appendix A: The Therapeutic Techniques of the Contemporary Practitioner of Traditional Chinese Acupuncture.

restoration when equilibrium or balance is lost (Kaptchuk, 1983, p. 345). As a result of this TCM philosophical orientation, the practice of TCA therapy must be seen as a therapeutic approach and not as merely a medical technique that is used by the TCA practitioner.

While TCA practitioners work in a variety of ways, there are several stages of the TCA therapeutic encounter that are common to many TCA therapeutic approaches:

(i) The TCA practitioner gathers information from the client so as to be able to determine a 'diagnosis' and management plan to assist the client to resolve their perceived health concerns. The collection of relevant information to determine a diagnosis and management plan usually proceeds through four stages termed the 'Four Examinations'. These 'examinations' are 'Looking' (*wang-zhen*), 'Listening' and 'Smelling' (*wen-zhen*), 'Touching' (*qie-zhen*), and 'Asking' (*wen-zhen*) (see Kaptchuk, 1983, pp. 138-174; Zhiya, 1995, pp. 316-386). As an example, 'asking' (*wen-zhen*) involves the gathering of information from the client through verbal means by interviewing the client, or by taking a case history. This often involves the asking of questions covering the traditional diagnostic areas.⁷⁷ Other questions are often asked to ascertain states of the *shen* and well-being.

An evaluation of a client's *shen* is critical, since the state of a person's *shen* can be correlated to one's general health and level of well being. Through this procedure the TCA practitioner may come to understand the occurrence and process of the person's disharmony or illness.

'Looking' (*wang-zhen*) is one means by which can the TCA practitioner can determine the state of the client's *shen*. Beinfield and Korngold (1991, p. 29) state that, "[s]hen refers to the organising force of the self, reflected in the mental, emotional, and expressive life of an individual"⁷⁸ An indication of a client's state of *shen* can be assessed by the client's speech,

⁷⁷ These include sensations of heat and cold; headaches and dizziness; location and type of pain; perspiration; thirst; sleep patterns; urination and stool; appetite and tastes, and in women, gynaecological concerns. See also Zhiya, 1995, pp. 349-361.

⁷⁸ Beinfield and Korngold (1991, p. 29) contrast *shen* with *jing*, with the *jing* relating to "the material substance, physical structure, and sensate life of a person." They note that "[w]hen referring to the totality of a person, the expression *Shen-Jing* is used, encompassing both the intangible and tangible realms of experience."

posture, facial expression, clarity of thought and the shine of the eyes (Kaptchuk, 1983, p. 45).⁷⁹ It should be noted that there is no Cartesian dualism to be found in the TCM concept of *qi*. The *shen* (psyche) and the *jing* (soma) are both understood as being manifestations of the one *qi*.⁸⁰

Kaptchuk (1983, pp. 142-43) states that each of the Four Examinations

focuses on a different way of recognizing signs in a patient. ...The physician completes each of the Examinations, gathering signs to weave into the final diagnosis. The signs themselves may fall neatly into place, pointing unanimously to a particular disharmony. Or they may seem to contradict each other, requiring the physician to interpret closely and carefully before making a determination.

The signs and symptoms indicating a particular TCM pattern of disharmony or syndrome may be differentiated and identified thorough a variety of TCM theoretical frameworks or conceptual templates, including the ‘eight principles’ (*ba gang bian zheng*), ‘six divisions’ (*liu jing bian zheng*) and the ‘theory of the *zang-fu* organs’ (*zang-fu bian zheng*) (Flaws, 1972; Zhen, 1995; Bensoussan & Myers, 1996, pp. 23-24). However, since from the TCM perspective human beings are understood to be unique configurations of *qi*, often they display patterns of signs and symptoms that do not coincide with any single TCM ‘pattern of disharmony’ or syndrome. This suggests the important role *interpretation* plays in the development of a diagnosis in TCA. This process of interpretation is part of the ‘art’ of traditional acupuncture practice.

(ii) The information elicited from the client during the clinical encounter is analysed and synthesised in the light of TCM philosophy and theory. This process is a creative one, since the TCA practitioner is constantly dealing with complexity and uncertainty in the clinical situation. Schon (1983, pp.18-19) notes that there *are* “artful ways in which some practitioners deal competently with the indeterminacies and value conflicts of practice”. Schon has suggested that some practitioners can be “disturbed because they have no satisfactory way of describing or accounting for the artful competence which practitioners sometimes reveal in what they do.”

⁷⁹ T. Kaptchuk (1983, p. 45) states that, “[s]hen is the awareness that shines out of our eyes when we are truly awake.”

⁸⁰ Beinfield and Korngold (1991, p. 29) claim that “[p]syche and soma comes nearest to conveying the meaning of the Chinese concepts Shen and Jing.”

TCA practitioners generally do not have this problem, since they hold the view that medicine is not a pure science and that it requires dealing creatively with the uncertainties that are found in actual practice. Experience, discrimination and wisdom are required by the TCA practitioner to determine the proper course of action in each clinical encounter with a client.

(iii) The TCA practitioner will negotiate a treatment and management plan with the client.

Since most TCA practitioners regard the prevention of disease to be just as important as its cure, TCA practitioners often advise a client as to what needs to be done, from a TCM perspective, to prevent a recurrence of a disorder. As mentioned previously, this could involve some form of Oriental health counselling or adjunctive therapy, in addition to acupuncture.

Kleinman (1980) has noted that for a consultation to be successful, there must be a consensus of understanding between the practitioner and patient regarding the aetiology, diagnosis, the processes involved in the condition, the optimal form of treatment and the prognosis. This would require the TCA practitioner to explain to the patient the reasons for their condition in terms that the patient could understand using the concepts of TCM.⁸¹

(iv) Feedback is obtained from the client after each consultation and treatment. This allows both the practitioner and client to assess the treatment and management plan, and to modify it, if necessary, until the desired objective is achieved or the health concern is resolved.

An important part of the TCA therapeutic encounter is to explain to the client the possible 'causes' of their illness in terms of TCM theory, Oriental philosophy and psychology. There is now a general consensus in health care that a practitioner's explanation of illness and disease to the client enhances the client's cooperation, autonomy, and capacity for self-care (Waitzkin & Stoeckle 1972; 1976). This finding has come from the attribution theory of social psychology which is based on the idea that human beings try to understand their perceptions and experiences by assigning 'causes' to them (Shaver, 1975, cited in Stoeckle and Barsky, 1981, p. 224). According to Stoeckle and Barsky (1981, p. 225), "*causal explanations provide control [to patients] because they give personal meaning to bodily discomfort as well as suggesting actions to take.*" Ryan (1995, 75) also notes that "[a]cupuncture therapy demands

⁸¹ Vincent and Furnham (1997) have suggested that this may not be difficult since there are parallels between patients' views and lay theories of illness and the metaphors used in TCM.

that the practitioner be intuitive and focused, an educator and catalyst who can assist in the healing process while still insuring that the responsibility for health remains the custodianship of the patient.”

All health care professionals attempt to provide care and to cater to the needs of their clients; however, practitioners of some professions do this primarily through technical means while others do it more through the interpersonal medium (Stengelhofen, 1993, p. 5). Ferrigno (1997, p.188) has correctly noted that “Chinese medicine possesses structural similarities to Western ‘talking cures’ such as psychotherapy.” It would appear that the TCA profession in Australia and some other countries is beginning to move towards the interpersonal skills end on the ‘technical-interpersonal continuum’. In Australia, this is in part due to the TCA educational philosophy of many of the lecturers teaching in Australian TCM university programs, whose essential aim is to produce primary care TCA practitioners with a high level of interpersonal skills in addition to technical competence.⁸² Many of the case studies documented by traditional acupuncturists working in Europe and America would suggest that a similar process is occurring in other parts of the world (see MacPherson & Kaptchuk, 1997).

The examination in the first section of this chapter has identified the nature of Traditional Chinese Acupuncture (TCA) and the core philosophical concepts, characteristics and recurring themes of Traditional Chinese Medicine (TCM) that underpin TCA practice. This examination has been a necessary prerequisite so as to be able to determine the types of inquiry and research methods that are congruent with the philosophy, theory and practice of TCA.

⁸² As an example, see the curriculum and educational philosophy of the Bachelor of Health Science - TCM (Acupuncture) course of the School of Health Sciences, Victoria University of Technology.

Section 2: The Domain of Traditional Chinese Acupuncture Research

2.5 Appropriate Research Methods for Traditional Chinese Acupuncture

The research strategy and design employed for any particular TCA study will be dependent upon the aim of the study, the type of research question addressed, or the problem to be solved. Researchers of TCA should recognise the legitimacy and value of a variety of investigative strategies to obtain knowledge in a systematic way. For this reason, the definition of *research* needs to be broad to encompass the various approaches that are required to explore the wide range of research questions in the field of TCA. De Poy and Gitlin (1993, p. 5) define research as

multiple systematic strategies to generate knowledge about human behaviour, human experience, and human environments in which the thought and action process of the researcher are clearly specified so that they are logical, understandable, confirmable, and useful.

De Poy and Gitlin's definition of research is one that could be adopted by researchers of TCA since multiple research strategies would seem to be required to address the broad range of TCA research questions that have been identified (see section 2.9 below). Research in the field of TCA, if done correctly, should validate and refine existing knowledge and generate new theory and knowledge.

At the beginning of each TCA study, the research design should be determined by carefully considering the specific research aim or question. Some research questions will suggest a quantitative or experimental research design (see chapters 8, 9 & 10), while others will require a qualitative approach (see chapter 12). An examination of the domain and variables that are of interest to the researcher can also suggest, or dictate, the most appropriate type of research design. For example, if the independent variable is technically impossible to control or manipulate, then a nonexperimental or qualitative research design might be considered appropriate. It is the research question that guides the selection of an appropriate research design and methodology for any specific TCA study given the theoretical foundation of the

study. This point can be illustrated by two types of research question:

- (i) Is TCA therapy more effective in the treatment of insomnia than pharmaceutical drug therapy?
- (ii) Which factors are involved in establishing a beneficial TCA practitioner/client relationship?

The first question clearly requires a comparison of health outcomes that would require measurement and hence necessitate a quantitative approach. In contrast, the second question lends itself more to a qualitative research approach such as the qualitative research interview (see Kvale, 1996). Although the second question could be approached through a quantitative research design such as a survey, an insight into the range of relevant factors would be more likely to be obtained through qualitative interviews with both TCA practitioners and their clients.

The research design selected for any TCA study should produce results and outcomes that are *meaningful*. Results and outcomes from the various research designs will have meaning only if the phenomenon under investigation is studied in context. This is especially important in regard to qualitative research where the researcher is often trying to understand the *meaning* that a particular phenomenon has for those involved in the TCA study. If the research findings are published, it is also necessary to accurately describe the context or setting of the study in addition to the methodology used. If this is not done meaningfulness will be lost (Field & Morse, 1985).

The quest to determine appropriate research methods to examine TCA might not be as simple a task as one might suspect, since it is not always possible to simply adopt the approaches used in other disciplines without adaptation. The reason for this is that the philosophic premises and tenets from which TCA has been derived are substantially different from those of many Western health care disciplines that are based on Western scientific premises. It is also a mistake to believe that other health care disciplines have fully resolved the debate as to which research approaches are the most appropriate for particular types of research question in the field of health care. Controversy still remains because different groups of researchers

emphasise the strengths of particular research designs (Bowling, 1997, pp. 18-19; Grbich, 1999, pp. 16-19). In medical research since the 1940s there has been an emphasis on quantitative data and analysis using the randomised controlled trial (RCT). However, in recent times there has been an increasing number of advocates for qualitative research approaches who often point to the limitations of the RCT and the inappropriateness of quantitative research designs for certain research questions in the field of health care (see chapters 5, 10 & 12).

Contemporary acupuncture research outside of China has focused on three main areas. Firstly, the evaluation of the clinical effectiveness of acupuncture through the utilisation of clinical trials; secondly, the translation of classic Chinese medical texts; and thirdly, the examination and analysis of classic Chinese medical texts and their commentaries.⁸³ While there are other research approaches that can be utilised to obtain knowledge and understanding of TCA and generate theory, for example, the various qualitative research methods - these approaches have not been used to any significant extent by researchers of TCA (see chapter 12).

2.6 The Purpose and Role of Basic Research, Applied Research and Evaluation

Patton (1990, p.150) claims that it is the *purpose* of any instance of research that dictates appropriate research design and methodology. Patton's typology of research includes: (i) basic research; (ii) applied research; (iii) evaluation; and (iv) action research. The purposes of TCA research can be examined using the categories of Patton's typology.

2.6.1 The role of basic research in TCA

The aim of *basic research* is to contribute to fundamental knowledge and theory. The purpose of this type of research is to understand and explain the essential nature of the phenomenon under study. According to Patton (1990, p.152), "the most prestigious contribution to knowledge takes the form of a theory that explains the phenomenon under investigation." The

⁸³ P. Ferrigno (1997, p. 2) notes that some translations of Chinese medical classics have been accompanied by commentaries and analyses for Western audiences.

purpose of basic research is often to generate theory and discover 'truth': that is, to obtain knowledge for its own sake. This is sometimes achieved through first gathering empirical data which constitutes the information from which theory can be formulated or refined. Basic research in the field of TCA should be judged by its contribution to theory, and by its ability to provide explanations as to *why* things occur as they do. For example, basic research could provide an explanation as to *how* TCA therapy ameliorates illness and disease. Some researchers might attempt to answer this question in biomedical terms while other researchers might explore this question in terms of TCM and psychological theories.⁸⁴ Basic research could also be used to explore the nature of acupuncture points and channels in terms of electrical and magnetic characteristics (see Birch & Felt, 1999, pp. 169-173 for examples of this type of research). Other types of basic research in the field of TCM include the historical studies of Paul Unschuld (1985) and Joseph Needham (1956) and the etymological studies of Claude Larre's and Elizabeth RoCHAT de la Vallee (1986, 1995).⁸⁵

2.6.1.1 *Types of basic research*

2.6.1.1.1 *Descriptive research.*

Descriptive research could increase the TCA knowledge base through the observation, description and the further classification of TCA phenomena. An example of a research question in the field of TCA that could be investigated using this approach is: How do traditional acupuncturists actually practise acupuncture in the Occident? This would require the researcher to carefully observe and describe the various actions, activities, therapeutic techniques, communication and counselling skills that are used by traditional practitioners in occidental settings. The answer to the previously posed question could be important for the development of TCA clinical trial protocols where the type of acupuncture intervention that is to be evaluated must be clearly defined. Descriptive research could therefore be used to elucidate

⁸⁴ As examples, see A. White (1999) and T. Lundeberg (1999) for accounts of the effects of acupuncture in terms of biomedical understandings. In contrast, see S.J. Birch and R.L. Felt (1999, pp. 87-146) for an account of how acupuncture is understood to effect health and disease in terms of traditional concepts (*e.g. qi*).

⁸⁵ See F. Diebschlag, 1994, pp. 52-57.

and define the various types of acupuncture practice (*e.g.* the various forms of traditional acupuncture, scalp acupuncture, auricular acupuncture) that are used by practitioners. Such research could be a first step in the identification of the features of the different types of traditional acupuncture. This would enable the different types and styles of acupuncture to be defined which would enable the determination of those therapeutic approaches that could be regarded as constituting ‘adequate acupuncture treatment’ in TCA clinical trials.⁸⁶ Lewith (1993, pp. 41-42) also notes that descriptive studies can “simply describe the response to treatment in a given group of individuals. They provide an important data base from which controlled trials can be developed, but are not in themselves proof of the efficacy of acupuncture.”

2.6.1.1.2 *Exploratory research.*

Exploratory research is another type of basic research: a form that can be more complex and multifarious than descriptive research. It can be utilised to obtain insights into TCA phenomena by exploring the many levels or dimensions of a TCA phenomenon in an attempt to understand its nature or essence. This type of research would tend to require more analysis and interpretation than descriptive research to discover the various aspects and factors that are involved in the TCA phenomenon examined. A qualitative research approach such as the ‘in-depth interview’⁸⁷ or the qualitative research interview⁸⁸ are appropriate for this type of research. An example of a research question that lends itself to exploratory research is: Which factors do clients and TCA practitioners believe aggravate and ameliorate illness? Another use of exploratory research in the field of TCA could be to explain why particular TCM ‘patterns of disharmony’ manifest as they do. Such research could be linked to TCA theory to provide an account of the ‘causes’ and factors related to particular manifestations of TCM ‘patterns of disharmony’. The generation of theory could integrate and explain how TCA phenomena are interrelated.

⁸⁶ For a discussion of this point, see S. Birch, 1997b.

⁸⁷ See V. Minichiello *et al.* (1990) for a comprehensive account of this qualitative research method.

⁸⁸ See S. Kvale, *Interviews: An introduction to Qualitative Research Interviewing*, 1996.

2.6.2 *Applied research and evaluation*

The findings of basic science can be utilised in applied research. Often the purpose of applied research is to “generate potential solutions to human and societal problems” (Patton, 1990, p. 154). In applied research, the knowledge, theory and understandings of basic research are *applied* to problems that are experienced by people. In the context of TCA research, these studies have as their primary purpose the resolution of human health problems. From a positivist⁸⁹ perspective

[t]he application of basic science yields applied science. Applied science yields diagnostic and problem solving techniques which are applied in turn to the actual delivery of services. The order of application is also an order of derivation and dependence. Applied science is said to “rest on” the foundation of basic science. And the more basic and general the knowledge, the higher the status of its producer. (Schon, 1983, p. 24)

However, Schon (1983, p. 41) notes that, “[e]ven when a problem has been constructed, it may escape the categories of applied science because it presents itself as unique or unstable.” It needs to be remembered that TCA practice is an artful process and is not merely the rigid application of techniques according to narrow theory and guidelines of practice (The relationship between TCA theory and practice is examined in chapter 8).

Patton (1990, p. 11) defines the term *evaluation* broadly to include any effort to increase human effectiveness through systematic data-based inquiry. When an examination of effectiveness is conducted systematically through careful data collection and thoughtful analysis, one is engaged in *evaluation research*. According to Argyris *et al.* (1985), evaluation is a type of applied research. Evaluation can determine program or policy effectiveness (summative evaluation) or improve program effectiveness (formative evaluation).⁹⁰ The purpose of evaluation research is often to assess the “effectiveness of specific solutions and human interventions” that have been identified by applied research (Patton, 1990, p. 155). In the context of TCA research, these studies have as their primary purpose the measurement of the

⁸⁹ Positivism is a philosophic doctrine that claims that researchers must confine themselves to what is provided to them by sense-experience as their source of knowledge. See chapter 5 for an account of the positivist paradigm.

⁹⁰ See A. Bowling (1997b) for an account of research methods to investigate health and health services.

therapeutic effectiveness of TCA therapy.

Applied research and evaluation can hence inform action, enhance decision making, and enable the application of knowledge to solve human and societal problems (Patton, 1990, p. 12).

Applied TCA research should be evaluated and judged by its *usefulness* in making TCA interventions more effective, and by its practical utility to policy makers and others who have a stake in efforts to improve the health of people by improving health care systems.

According to Patton (1990, p. 12), data-collection options and strategies for any particular applied research inquiry are dependent on answers to the following questions:

- (i) Who are the research findings for, and who will use them?;
- (ii) What kinds of data or information are needed?;
- (iii) How is the data or information to be used, and for what purposes is evaluation being conducted?;
- (iv) When is the data or information needed?;
- (v) What resources are available for the evaluation to be conducted?

Given that the above questions need to be addressed by the researcher of TCA, it must be decided before the commencement of any TCA study which research method is the most appropriate to answer the particular research question, taking into account the particular audience(s) that will be expected to utilise the findings of the research.

Evaluation research involves the creation of a research design and the gathering of information that is appropriate for a specific purpose and particular decision making context. This will require being cognizant of all stakeholders, whether they be decision makers, policy makers, funders, researchers, professional groups, research participants, TCA practitioners, or the general public who may be affected by the results of the research. The research design chosen will necessarily involve an interplay of resources, possibilities, creativity, and the personal

judgments of the researchers involved (Patton, 1990, p. 13). In research of TCA, the philosophical premises and assumptions of the selected research approach will also need to be considered to determine if they are congruent with the perspective of TCM. The challenge in evaluation research is getting the best possible information to the people who can use it, and then getting those people to actually use the research findings in appropriate ways for the purposes intended (Patton, 1990, p.13). This has relevance for the TCA profession, since if TCA is found to be efficacious, this information must be presented in such a form that it can be utilised by health departments when making decisions on how funds for health care are to be distributed.

The aim of much TCA clinical research has been to improve TCA practice. The assumption here has been that research findings will be effectively disseminated and utilised by TCA practitioners to improve client care. This however has not been a smooth process in some professions. The work of Glasser, Abelson and Garrison (1983) would suggest that the average length of time between a discovery and its utilisation is almost twenty years. One would hope that TCA practitioners would not take as long to adopt innovative ideas that are generated by research. A priority for TCA educators will be to develop ways to reduce the time lag between knowledge production through research and its utilisation by TCA practitioners.

2.6.2.1 *The evaluation of the effectiveness of TCA therapy*

TCA research could provide the evidence to support TCA practice. Research could demonstrate TCA to be effective if it could be shown that TCA therapy increases positive health outcomes for clients. If TCA research is undertaken in a systematic manner, it should be possible to determine the scope of application of TCA. Such research could provide the rationale for any particular therapeutic approach in any given clinical situation. TCA research is an ethical necessity if one of the aims of the TCA profession is to substantiate and improve TCA practice. The TCA profession is accountable to society for providing effective acupuncture therapy and for conducting research to improve it. TCA research is important for professional practice, since it can provide sound information on which to base changes in TCA methods to facilitate improved client health outcomes.

The randomised controlled trial (RCT) is the research design that is regarded by many researchers as the ‘gold standard’ or benchmark for determining clinical effectiveness (Pocock, 1993; Lewith, 1994, p. 44; Kiene, 1996a; Kiene, 1996b; Filshie & White, 1998, p. 4).⁹¹ It is easy to gain the impression from advocates of Biomedicine that all new medical procedures are evaluated by such clinical trials before they are used on the general public. However, in reality, not all biomedical procedures are evaluated by a RCT before they are used by medical practitioners in hospitals and general practice. Surgery, some non-drug biomedical procedures, and some of the natural and traditional medicine therapies do not lend themselves easily, because of their nature, to evaluation by randomised controlled trials.

The ‘double-blind’ RCT is the research design favoured by many researchers of Biomedicine and government funding authorities who see this approach as yielding the most ‘objective’ and valid results for the assessment of *any* medical intervention. This research design is used widely by biomedical researchers since it is believed to be a rigorous design which minimises researcher bias. It is claimed that this method can determine the extent of the therapeutic outcome which is attributable to the specific medical intervention as opposed to the general therapeutic ‘placebo effect’ of the therapeutic encounter (see chapters 8 & 10). The strength of this design, it is argued, lies in its ability to account for so called placebo or, more precisely, the ‘non-specific’ effects of the medicine or therapy. While some pharmaceuticals are evaluated, before their general use, by the ‘double-blind’ RCT, this is simply not the case with all pharmaceuticals (Glasziou, 1995), medical and surgical interventions (Moynihan, 1998).

2.6.3 *The improvement of TCA clinical practice and TCA teaching programs through ‘action’ research*

According to Schwandt (1997, p.1) the term ‘action research’ was coined in the 1940s by the social psychologist Kurt Lewin to “describe a particular kind of research that united the experimental approach of social science with programs of social action to address social problems.” The purpose of this type of research is usually be to solve a specific problem within a program, community or organisation (Patton, 1990, p. 157). Action research could be used

⁹¹ For a review of the history, rationale and some of the problems of the clinical trial see E. Ernst and K.L. Resch (1996).

by TCA practitioners and researchers working *within* a specific program to bring about change to solve a perceived problem in that program. This method would also seem applicable to TCA practitioner-researchers and TCA educators wanting to improve outcomes in clinical TCA practice, health promotion, teaching programs, or to influence government health policy.⁹²

Bowling (1997, p. 366) claims that a 'revival in action research stems from some disillusionment with the use of positivist methods of evaluation. Bowling (1997, pp. 366-377) states that Hart and Bond (1995) have identified seven criteria which distinguish action research from other research methods: (i) it is educative; (ii) it 'deals with individuals as members of social groups'; (iii) it 'is problem focused, context-specific and future-orientated'; (iv) it 'involves a change intervention'; (v) it 'aims at improvement and involvement'; (vi) it 'involves a cyclic process in which the research, action and evaluation are interlinked'; and (vii) it 'is founded on a research relationship in which those involved are participants in the change process.' Action research methods would appear compatible with the nature of the TCM perspective and should have a larger role in TCA research considering some of the priorities of TCA research (see Chapter 2.9 below).

2.7 The Flaws of Contemporary Acupuncture Clinical Research

Over the last two decades, much of the research effort in the field of acupuncture has been devoted to the evaluation of the effectiveness of acupuncture. This is not surprising when one considers the growing interest in acupuncture by the public and health care practitioners.

Clinical research has been seen to be the way to determine the effectiveness of acupuncture for a variety of medical conditions.

It should be noted that research questions in the field of health care tend to be formulated within the framework of a particular paradigm (see chapter 5). Most clinical acupuncture research that has endeavoured to determine the therapeutic effectiveness of acupuncture has been formulated within the theoretical framework of Biomedicine. Much clinical research been conducted by non-practitioners or by those who have been poorly trained in TCM (Bensoussan, 1993, p. 38). As a result, the value of much contemporary acupuncture clinical research, when

⁹² For one account of this approach to research, see D. Schon, 1983.

considered from the perspective of the TCA profession, is questionable. The reason that this perception is held by many TCA practitioners is that in most instances the research design that has been used in clinical trials has not permitted practitioner-researchers to use acupuncture therapy in the same way that it is used by TCA practitioners working in private practice (Kaptchuk, Edwards and Eisenberg, 1996, p. 49). Most researchers have attempted to evaluate 'formula acupuncture' rather than TCA. As a consequence, many researchers have routinely attempted to standardise, or control the therapeutic intervention as is usually done in conventional biomedical research. This controlling, or standardisation of the therapeutic intervention goes against the nature of TCA practice, which attempts to 'tailor' the therapy in each clinical encounter to the unique and changing presentation of the client. From the perspective of the TCA profession, one of the disappointing findings of the report on the practice of TCM by Bensoussan and Myers (1996, p.35) was that throughout the world where acupuncture trials have been conducted, TCM diagnostic and treatment methods have not been sufficiently realised in clinical trial designs.

Gerard Guillaume (1991) has claimed that the assessment methods that were developed for the evaluation of pharmaceutical drugs by Western medical scientists are entirely inappropriate for traditional acupuncture. While two patients in an acupuncture clinical trial might receive the same Western biomedical diagnosis, a TCM diagnosis of each patient might reveal different aetiological factors (from a traditional perspective) which would necessitate a different acupuncture treatment (see chapter 4). This again highlights the important point that TCA is not merely a therapeutic technique but is rather a medical discipline based on an *individualised* symptomatology, calling for specific treatment protocols and management (Guillaume, 1991, p. 54).

In recent years, most acupuncture clinical trials have involved 'formula acupuncture' or a medicalised form of acupuncture (so called 'scientific' acupuncture) rather than traditional approaches. There have been few controlled trials conducted that have attempted to evaluate traditionally based systems of acupuncture (Patel, 1987; Vincent, 1993; Birch, 1997b, p. 149; Birch, 1997c). This point can be illustrated by the review of controlled acupuncture trials completed by Kleijnen, ter Riet and Knipschild (1991) to determine the effectiveness of

acupuncture in the treatment of asthma. In only one of the thirteen studies was traditional acupuncture used; the other twelve studies involved a 'formula acupuncture' approach in which the *same* set of acupuncture points were used on every patient (Kleijnen, ter Riet & Knipschild, 1991, p. 800). As a result of such studies, much of the published acupuncture literature might not be truly indicative of the real value of TCA therapy when 'tailored' to the individual needs of the patient as is done by practitioners that utilise traditionally based systems of acupuncture.⁹³

Not all therapies, including TCA, lend themselves to evaluation using the 'gold standard' of biomedical research: that is, the 'double-blind' RCT. Vincent and Richardson (1986, pp. 10-11), following Lewith and Machin (1983), have argued that "double-blind trials of acupuncture, while technically possible, are inherently flawed in that by definition a truly blind procedure must be carried out by a naive and inexperienced practitioner who may not produce an adequate standard of treatment." They make the important point that the delivery of acupuncture therapy can only be administered by a skilled practitioner who is fully conscious of the therapy that they are giving. TCA is a therapy that does not lend itself to 'double-blind' RCTs, since the acupuncturist must be aware of the treatment that is being administered, whether it be real or 'sham' acupuncture⁹⁴. It is therefore not possible for the TCA practitioner-researcher to be 'blinded', which is one requirement of the 'double-blind' RCT research design.⁹⁵

It is however possible to use what is termed a *single-blind* RCT in TCA clinical trials to evaluate the efficacy of acupuncture (Vincent & Richardson, 1986; Watson, 1991). In this research design, the researcher *is* aware of the treatment that is being delivered (*i.e.* 'real' TCA or placebo) while the subjects are not (see also chapter 10). Spilker (1991) states that a clinical

⁹³ The study by M. Garvey *et al.* (1997) is an example of one of the few recent studies that has attempted to evaluate *traditional* acupuncture rather than the 'formula acupuncture'.

⁹⁴ 'Sham' acupuncture is a control that has been used to control for any 'non-specific' (placebo) effects of TCA therapy. It can involve the needling of points on the skin that are not classical acupuncture points. See C. Vincent (1993, p. 295) for a full account of this type of 'sham' acupuncture control.

⁹⁵ The 'double-blind' randomised controlled trial (RCT) research design cannot be used to evaluate the efficacy of TCA therapy using acupuncture needles; however it could be used to evaluate laser acupuncture therapy (see chapter 10).

trial does not have to be 'double-blind' to be regarded as a well-controlled clinical trial. He believes that the 'double-blind' is but one feature of a well-controlled clinical trial and that there are other important factors such as the adequacy of the groups used as controls.

It has been argued that single-blind RCTs with an independent outcome assessment are adequate for acupuncture efficacy research, provided efforts are made to monitor independently the impact of non-specific (placebo) effects to ensure that they do not vary between treatment and control groups (Vincent and Richardson, 1986; Vincent, 1993). Single-blind RCTs provide a degree of control over research validity as compared with uncontrolled trials in which no blind is used, that is, where both researchers and subjects *are* aware that TCA therapy is being given. It has been claimed that uncontrolled (or 'open-label') clinical trials should not be used to obtain therapeutic efficacy measures since they have been shown to give a greater percentage of positive outcomes than 'double-blind' RCTs (Spilker, 1991, p. 63).

In a recent comprehensive survey of clinical acupuncture by Bensoussan and Myers (1996) it was concluded that, "there is a sufficiently strong case for the clinical use of acupuncture to manage pain, nausea and vomiting" and that "[a]cupuncture also shows significant promise in other clinical areas, such as in hypertension and other cardiovascular disorders, digestive disorders, neurological problems, and drug addiction." Further research is now required to determine which other conditions, syndromes, illnesses and diseases can be ameliorated by TCA therapy. It is important that government health departments and funding bodies do not dismiss out of hand, therapies such as TCA because their efficacy cannot be evaluated by that research design that is used to evaluate the efficacy of pharmaceutical drugs. Not even the 'double-blind' RCT can guarantee conclusive or definitive results for any therapeutic intervention, since it is impossible to control for all variables, or to eliminate all alternative explanations for the outcome of a clinical trial (chapter 10). No *single* research design is suited to answering *every* clinical research question; therefore, the development of appropriate research designs becomes a matter of creative compromise that is based upon the explicit understanding of the implications of the choices made due to the practical and resource constraints of the study (Shapiro, 1989, p.164).

2.8 Priorities for Traditional Chinese Acupuncture Research

One of the major aims of many researchers in the field of TCA has been to establish the effectiveness and limitations of acupuncture therapy for a variety of health disorders that continue to torment humanity. For some TCA practitioners, such research might be believed to be unnecessary if one considers the substantial body of TCA literature that has accumulated over the last fifteen hundred years in China. However, much of this Chinese acupuncture research is not of a form that Western biomedical researchers would find acceptable; that is, it has not utilised the randomised controlled trial (RCT). This is not to say that the empirical methods that were used by TCA practitioners in the past to acquire medical knowledge are not valid, but rather that their type of research is not considered by many biomedical researchers working within the dominant Western biomedical paradigm to be sufficiently rigorous.

The aim of some contemporary clinical acupuncture research has been to account for acupuncture's mode of action and to legitimate its practice in terms of biomedical theory. Bensoussan (1991, pp. 1-2) has suggested that research to understand the mechanisms of acupuncture in physiological terms could enlarge the applications of acupuncture. This approach might be fruitful; however in a sense it undervalues the traditional theory, tenets and concepts from which acupuncture has developed, and which still inform its practice today by TCA practitioners. A 'marriage' between Biomedicine and TCA might be difficult, if not impossible, because of the fundamentally different premises and concepts of the two medical systems at the level of ontology.

2.9 TCA Research Questions and Issues

Each health care profession, including TCA, has its own set of fundamental questions that emerge from the tradition of the discipline. The research aims of academic researchers can be guided by intellectual questions and also by social and professional concerns. In the discipline of TCA, it would appear that a variety of research approaches and designs would be required to answer the broad range of research questions that the TCA profession need to address. At this point in time, priority needs to be given to research to:

- (i) better understand the phenomenon of TCA so that TCA knowledge can be appropriately placed in relation to other bodies of health care knowledge;
- (ii) further demonstrate the effectiveness and limitations of TCA therapy for various health disorders.
- (iii) determine the medium and processes by which TCA therapy improves health and wellbeing. Can it be demonstrated that a clients' improvement is due to the TCA therapy, rather than to non-specific (placebo) effects or to chance?;
- (iv) develop appropriate research instruments to measure therapeutic outcomes in TCA clinical research;
- (v) demonstrate the level of safety of TCA therapy. Is the effect of TCA therapy always positive, or does it have side-effects like many of the drug therapies of Biomedicine?;
- (vi) gain a greater understanding of the nature of TCA therapy and the factors that contribute to its effectiveness. Which conditions facilitate the beneficial effects of TCA and which retard them?;
- (vii) determine which forms of acupuncture (*e.g.* 'formula', 'scientific', TCA) are the more efficacious. Is there a 'best' way to practise acupuncture? Are acupuncture clinical guidelines and protocols appropriate or desirable?;
- (viii) assess the extent of acupuncture's therapeutic value. Is TCA potent enough to be used alone, or should it be combined with orthodox biomedical therapies. Is it possible that pharmaceuticals could interfere with the action of acupuncture?;
- (ix) determine the relationships between a TCA practitioner's beliefs, intent, consciousness, qualities and the therapeutic outcome. Is there an important synergy between the skills and qualities of the individual TCA practitioner and the successful application of TCA therapy?;

- (x) understand the reasons why people use TCA
- (xi) determine if TCA is cost-effective.

This list is not comprehensive; however, it provides some insight into the critical issues and questions currently faced by researchers of TCA and the TCA profession. Some of the TCA research questions listed above might suggest that the TCA profession is a relatively new one, since the profession outside of China still needs to fully articulate its foundational knowledge, theory, and practice. From a traditional perspective this is not so, since there is a vast body of traditional knowledge that has accumulated from the practice of TCA practitioners over the last fifteen hundred years in China. This traditional body of TCA knowledge, however, could be viewed as being insubstantial and anecdotal when measured against the research quality criteria of western biomedical researchers. The current biomedical research perspective often presumes that authentic and dependable knowledge in the field of medicine is produced through the use of the scientific method and controlled clinical trials and not through the reporting of case studies: a method that historically in China has been one of the dominant vehicles for TCM knowledge transmission.

2.10 The Need to Use a Variety of Research Approaches and Designs to Study TCA

Some of the TCA research questions listed in the previous section (2.9) can be understood to have social dimensions and implications that would require investigation using the research methods that are utilised in the social sciences. For example, critical social theory methodology (see chapters 5.4.8 & 12.6.7) might be required to construct a picture of Biomedicine that exposes its prevailing methods of domination in health care. Through such a critical assessment of the weaknesses in the prevailing health care system, change could be encouraged in order to improve it. Such research could determine the future role of TCA in an improved and integrated health care system.

Many current TCA research questions and issues cross discipline and paradigm boundaries and might not be answered solely by positivistic research methods (see chapter 5). While many

researchers have tended to utilise quantitative research methods in the pursuit of TCA knowledge, there is a plethora of other qualitative research methods that could be used for particular TCA research questions (chapter 12).

Scheid (1993, p. 23) has remarked that there is a general acceptance by various interest groups that occidental methods of research will resolve and clarify the many questions that relate to alternative medicine. He argues that

[a] congruence of interests between politicians, biomedical physicians, alternative medical practitioners and the general public is presumed as a given, and 'scientific research' is presented as the logical way to pursue these common goals. In this way, differences between varying groups and medical practices can be portrayed as essentially methodological in character and therefore resolvable within a commonly accepted research framework.

The main purposes of TCA research from a conventional research perspective would be to describe, explore, explain, and then to make predictions about TCA therapy and related phenomena. These aims could be achieved by using a variety of research designs and approaches. Again, it must be emphasised that the type of research design and methodology that is appropriate for any given TCA study will be dependent on the *purpose* of the research and the nature of the associated research question. Clearly, from a postmodernist perspective, there is not just *one* single research design and methodology that can be used to investigate and enlarge the knowledge base of TCA. It is in fact desirable to examine TCA, which is a multifarious therapy, from multiple perspectives. The examination of TCA utilising different research approaches (*i.e.* through triangulation, see chapter 12) could produce *different* types of TCA knowledge and hence provide a greater understanding of TCA as a whole.

2.11 TCA and Social Research Methods

Research strategies and designs in any discipline are always dependent upon the subject or phenomenon that is being investigated. Researchers of TCA should be cognizant of the various research methodologies used in the social sciences in addition to those of Biomedicine since most research in health care is by definition social research (Smith & Hope, 1992, p. 3).

According to Smith and Hope (1992, p. 2), research in the health professions can be regarded

as social research since the research often concerns itself with questions and problems that in many cases involve communication between health care professionals and patients. Research projects that study TCA therapy, often require researchers to *interact* with TCA practitioners and their patients which requires more than merely observing, recording, and analysing data at a distance.

Some research methods of the social sciences would seem appropriate for investigating particular TCA research questions since TCM theory views illness, disease and healing in a social context. TCM theory assumes that the origin of illness and disease involves not only localised disturbances of the biological body but also environmental and social determinants (see chapter 4). Scheid (1993, p. 30) suggests that social science research methods are, as a whole, perhaps more appropriate for Chinese medicine (*i.e.* TCM) than other research methods that are used in Biomedicine. He claims that the social sciences “produce less facts”, and that “there is more awareness of the cultural relativity of modes of thought and therefore perhaps more emphasis on understanding. They also come much closer in many ways to the forms of inquiry through which Chinese medicine has traditionally developed.”

2.11.1 *Health care research is often interactive*

The Nobel Prize winner Werner Heisenberg claims that according to the Heisenberg Uncertainty Principle, one cannot look at *any* ‘physical’ object without changing it (Heisenberg, 1978, p. 42). According to contemporary quantum mechanics it is now understood that an observer (or researcher) can affect the phenomenon that is being studied by the mere act of observation alone. This claim is in conflict with some positivist views which assume that the researcher can be separated, or distant from the phenomenon or aspect of the world that is being studied (chapter 5).

Clinical TCA research to determine the effectiveness of TCA therapy often involves practitioner-researchers interacting with their patients. This is required to determine a TCA diagnosis and formulate a treatment plan. The TCA practitioner conducting clinical trials with patients must obtain sufficient information to determine an accurate TCM diagnosis which

cannot be done adequately by observation alone. Clearly, diagnostic palpation and the asking of questions to determine a TCA diagnosis cannot be achieved without interacting with the patient. The subsequent acupuncture treatment employed by the TCA practitioner-researcher after the diagnosis is determined is also interactive since it involves the insertion of acupuncture needles into the bodies of patients. Many other types of research methods that can be used to examine TCA, including case study and qualitative research (chapter 12) can also be regarded as social research since they involve communication between practitioner-researchers and their patients.

The trust that exists between researchers and research participants (*i.e.* patients) can be related to research validity. Researchers of TCA will only obtain honest and accurate answers to their questions if research participants feel that the information that they provide to researchers, which could be of a highly personal nature, will not be used to identify them in any report that is published by the researcher. Research participants' anonymity and the confidentiality of the information obtained by the researcher must be guaranteed by the researcher to the participants, if valid data is to be generated. The relationship that exists between the researcher and the research participant is crucial, not only on ethical grounds (see chapter 11), but also because it impacts on the quality of data obtained in the research process.

2.11.2 *TCA research can be reflexive*

Smith and Hope (1992, p. 20) claim that social research is 'reflexive'. They claim that when researchers observe and question people during the research process they can actually change the people that they are studying. It follows from this line of reasoning that research participants would behave differently if the researchers had not been present. This phenomenon in the research context has been termed the 'Hawthorne effect' (Polgar and Thomas, 1995, p.78). This is relevant to the researcher of TCA, since the gathering of information from patients (or research participants) to determine a diagnosis, can at the same time be actually changing the participants in subtle ways. The changes that are brought about in participants as a direct result of the information gathering process will be dependent, in part, upon the nature of the relationship that is established between the researcher and the research participants. If trust exists between the researcher and those participating in the research, then it is more likely that

the research participants will behave in a way that is more natural and similar to their usual behaviour, that is, the behaviour that would occur if the researchers were not present.

It is important to note that TCA practitioner-researchers are not normally passive observers of their patients while they administer TCA therapy. Rather, TCA practitioners in private practice routinely endeavour to facilitate change in their clients by interacting with them through the clinical encounter. This needs to be noted for future TCA clinical trials, since if the TCA practitioner-researcher attempted to be a dispassionate observer while applying the acupuncture needling technique, this would reduce the external validity of the clinical study because this is not how TCA is normally practised in the field.

2.12 Desirable Characteristics of TCA Researchers

Drawing on Salner's (1989, pp. 66-68) insights of desirable characteristics for the researcher in human science research, the author would like to propose some characteristics for researchers wanting to conduct future research in the field of TCA:

(i) In addition to having a comprehensive understanding of TCM philosophy and the practice of TCA, the researcher of TCA should, ideally, be liberally educated and conversant with history, languages, philosophy, the arts, medicine and the sciences. The broader and deeper the vision of the researcher of TCA, the more profound will be the researcher's potential contribution to our collective understanding of TCA and human experience.

(ii) Researchers of TCA should have more than a passing acquaintance with formal epistemology and the philosophical issues underlying methodological debates. TCA research methods are not a set of procedures that can be learned and applied without attention to the world view which they presume. For this reason, philosophical analysis will need to continue to be an integral part of TCA research design.

(iii) Researchers of TCA should have a comprehensive understanding of the development of rational thought and knowledge in Western culture, as well as an awareness of the various criticisms that have been levelled against this tradition. Such an ability to critique systems of knowledge and research paradigms requires refined critical thinking skills and an understanding

of the “rules of evidence” of the various research traditions.

(iv) Researchers of TCA should interpret their research findings not in terms of a search for absolute truth or certainty, but rather as part of “an on-going scholarly debate or ‘conversation’ in which ‘reality’ is socially constructed.” (Salner, 1989, p. 66).

(v) The TCA researcher needs to “have experience with a variety of research methods ranging from experimental clinical research to philosophical inquiry. The wider the array of options that the researcher can draw on, the more likely it is that his or her research process will reflect the best route rather than the route that he or she knows best.” (Salner, 1989, p. 66).

2.13 Desirable Characteristics of TCA Research

Research in the health sciences should be logical, understandable, confirmable and useful (De Poy and Gitlin, 1993, pp. 8-9). TCA research too should be logical in the sense that it conforms to the accepted norms of quantitative and qualitative research methods. TCA research should also be intelligible to consumers of research. If the researcher clearly articulates the research design and methodology used in each particular research project, the research should be able to be confirmed and verified by other researchers following a similar path. Research findings should also be useful. Ideally, research should lead to improved TCA practice and client health outcomes. This can be accomplished if research of TCA generates or verifies TCA theory and evaluates TCA knowledge and practice.

2.14 Summary

For researchers to develop appropriate research designs and methodologies to investigate TCA they need to fully understand the philosophy, theory and practice of TCA. Many of the concepts and theories of TCA can only be comprehended in the context of the philosophical tenets of the major philosophical systems of Confucianism, Daoism and Buddhism. TCA must be seen as a system of medicine and not as merely a medical technique that is used by a health care practitioner.

Much contemporary acupuncture research that has endeavoured to evaluate the therapeutic

effectiveness of TCA has been formulated within the theoretical framework of Biomedicine. As a result, from the perspective of the TCA profession, the value of much contemporary TCA clinical research is questionable since the research design in most cases has not permitted researchers to use acupuncture therapy in clinical trials in the same way that it is used by traditionally trained acupuncture practitioners working in private practice.

In the second section of chapter two, the domain of TCA inquiry and research was outlined. Attention was given to how a researcher of TCA could determine what is an appropriate research design or method of inquiry for any given TCA research question. It was argued that the research design selected for any particular TCA study is, in part, dependent upon the nature of the research question that is to be addressed. TCA research should involve the creation of research designs that are appropriate for specific research questions and particular decision making contexts. This will require being cognizant of all stakeholders, including policy makers, research funders, professional groups, TCA practitioners, research participants, and the general public who may be affected by the results of the research.

CHAPTER 3

PHILOSOPHICAL AND SOCIOCULTURAL ASPECTS OF MEDICAL SYSTEMS

“The lower doctor heals the illness; the median doctor heals the whole person; the higher doctor heals human society.”

- Sun Sze-Mo, a Chinese physician of the eighth century A.D.,
(cited by Holbrook, 1981, p. 336)

“The concept of perfect and positive health cannot become a reality because man will never be so perfectly adapted to his environment that his life will not involve struggles, failures and sufferings.”

- Rene Dubos (1965, p.1)

3.1 Introduction

In this chapter, some philosophical and sociocultural concepts of medical systems are examined and analysed to determine their implications for TCA research. While the primary focus of this thesis is on the critical issues in the field of TCA research, it is necessary to also examine Western systems of health care (including Biomedicine) and their associated research methods to see if these can be utilised, or adapted, to meet the needs of researchers wanting to study TCA. To accomplish this task, the theoretical premises and assumptions of Biomedicine (the dominant system of health care in the developed world) and TCM need to be compared and contrasted to determine if the differences necessitate different methods of inquiry. It will be argued that the different understandings of the human being, health, illness and disease in the two medical systems can have implications for what is actually studied by researchers, and for what is considered to constitute sound and valid research. The examination reported in this

chapter will draw on the related discourses of holism⁹⁶, holistic medicine⁹⁷, and systems theory.⁹⁸

Aakster (1989) has previously outlined the differences in emphasis between the approaches of orthodox medicine and the complementary therapies, most of which hold true for TCA. TCM, like many other complementary therapies, maintains a somewhat different understanding of the essential nature of the human being and a different perspective on the 'body-mind' when compared with Biomedicine. It will become evident through the examination that follows that the concepts and assumptions of different medical systems have implications for how research with human beings should be conducted, and how medical interventions are to be evaluated. It will be argued that what constitutes health and disease in each system of medicine has a direct bearing on the domains and parameters which are thought important, considered relevant, and assessed in clinical research.

Mitchell and Cormack (1998, p.17) claim that throughout the ages there have been two complementary refrains in the practice of health care. The first is represented by Hygeia, the Greek goddess of health⁹⁹, who symbolised

the belief in health as the natural way of things, that people could remain well if they lived a sane life in a pleasant environment. In this tradition there is an expectation of health as the normal state, which is related to equilibrium and balance, and treatment is seen as a way of aiding the person's own natural, self-healing capacities. The role of the physician is to help the person achieve inner balance (between the physical, emotional and spiritual aspects of themselves) and outer balance (between themselves and their world).

⁹⁶ According to P. Pietroni (1997, p. 9), the term *holism* came into common use with the publication of *Holism and Evolution* by Jan Christian Smuts in 1926. Two fundamental ideas of holism are that there is in nature the tendency for wholes to be produced and that "the whole is greater than the sum of the parts". Koffka (cited in Pietroni, 1997, p. 9) suggests that it is more correct to say that "the whole is something else than the sum of its parts", rather than the whole is more or greater than the sum of its parts.

⁹⁷ Medicine or therapy that attempts to treat the 'whole' person: body, mind and spirit.

⁹⁸ Various forms of 'systems theory' have been developed from von Bertalanffy's (1972) original general systems theory. Stephen Francis (1995, p. 254) remarks that "[g]eneral systems theory is an approach to understanding the behaviour of systems by studying the interaction within and between different levels of a system. ... a system cannot be understood by being reduced to its constituent parts and each of the parts studied in isolation."

⁹⁹ Mitchell and Cormack (1998, p.17) note that the name Hygeia was derived from the same source as the Greek word for *health*.

The physician's task, from this perspective, is "to promote health through teaching the natural wisdom by which the person can retain harmony and balance." TCM philosophy and contemporary TCA practice clearly resonate with this understanding of health care (see chapter 2).

The second refrain is represented by Asclepius, the Greek god of medicine. Asclepius (son of Apollo) is said to

have achieved fame through his use of the knife and by knowledge of the curative power of plants. His focus was on dealing with disease, rather than on promoting health. In this tradition, there is an expectation of disorder, disharmony and disease and the role of the physician is to bring forces to bear to challenge and overcome the disorder in order to bring the individual to an ordered state of health (Mitchell and Cormack, 1998, p.17).

Again, if TCM is examined, it is evident that some aspects of TCM practice resonate with the Asclepian approach. Mitchell and Cormack (1998, p.18) claim that

[i]deally, a balanced health care system would incorporate both approaches, shifting the focus when appropriate according to the patient's needs. In practice, it seems that different traditions of health care offer greater strengths in one or the other type of approach: modern Western biomedicine is powerful and effective in the Asclepian tradition of using technical means to fight disorder, while many complementary approaches [including TCA] seem particularly adapted to the Hygeian ideal of promotion of health through balanced living.

3.2 Sociocultural Considerations of Medical Systems

From an anthropological perspective, it is apparent that the beliefs, customs, culture and philosophy of a society are involved in the genesis of both illness and healing (Hahn, 1985). Illsley and Svensson (1986, p.101) claim that "[t]he health and health-related behaviour of the individual emerge as manifestations of his or her long-term exposure to societal and environmental influences and the lifestyles of his or her group and culture."

Gaines and Hahn (1985) suggest that western anthropologists have failed to examine their own culture to the same extent as they have other cultures. Gaines (1979) claims that anthropologists

have not perceived Biomedicine to be as susceptible to the same type of cultural analysis as other systems of medicine and healing. Gaines and Hahn (1985, p. 4) explain that

[a]nthropologists exploring Biomedicine have met resistance both from fellow anthropologists, even from medical anthropologists, and from their biomedical host-subjects. This resistance may have a common source - a blindness to a domain of one's own culture whose powers and prestige make it invisible to member participant observers. Even for many anthropologists Biomedicine is *the* reality through the lens of which the rest of the world's cultural versions are seen, compared and judged.

As a result, most anthropologists have not generally regarded Biomedicine as an 'ethnomedicine' and as a consequence have not subjected it to the same type of analysis as other systems of medicine. Gaines and Hahn (1985, p. 4) have noted that most medical anthropological text books have separate sections for ethnomedicines and Biomedicine. The reason for the exclusion of Biomedicine from the classification of ethnomedicines could be the belief held by medical practitioners and other members of a dominant Western culture that Biomedicine, having been derived from the sound principles of the scientific method, is undoubtedly a superior system of medicine.

Ethnomedicines are characterised and defined by their conceptions of health and disease, their theories of disease causation and treatment, the patient 'sick role', and their moral evaluations of health status (Parsons, 1951). If this definition of an ethnomedicine is accepted, then Biomedicine could be seen to be an ethnomedicine, as can TCM (Porkert, 1978). This point is important with regard to the development of research methods for TCA, since it allows the premises and assumptions of TCM to be evaluated on an equal footing with those of Biomedicine. This has been historically difficult to do because the premises and assumptions of Biomedicine have been supported by the dominant metanarrative of science. A critical anthropological perspective allows the commencement of a critique of the premises and assumptions of Biomedicine and its associated research approaches and designs.

3.3 Models of Health, Illness and Disease

Systems of medicine such as TCM have their own distinct understandings of health, illness and disease which have implications for TCA research. Svensson *et al.* (1980, cited in Nizetic,

Pauli and Svensson, 1986, p. 96) suggest that there are three distinct perspectives from which to understand the concepts of health and disease ¹⁰⁰:

- (i) the subjective: from the point of view of the ill person;
- (ii) the objective: established through the diagnosis of disease by measuring physical changes in physiological processes (*e.g.* laboratory and pathology tests);
- (iii) a 'relative' perspective, where health and disease are measured in relation to one's fellow beings, the social system as a whole, or to an ideal state of health.

These three perspectives might necessitate different forms of inquiry. While laboratory tests could be useful to measure changes in the health status of the biological body, interpretive research approaches (see chapters 5 & 12) might be more appropriate for obtaining information on the subjective perspective of the ill person. The third, 'relative' perspective could require the collection of information on health at the population level, which might be best investigated by using sociological and epidemiological research methods.

Naidoo and Wills (1998, 21) claim that "[h]ealth is a contested concept which is the subject of many different and competing discourses [*e.g.* medical, popular, moral and legal]. ... Each of these discourses constructs health in a particular way, which is relevant in different contexts and situations". Stacey (1977, cited in Illsley & Svensson, 1986, p. 96) has summarised the ways in which the concepts of health and disease have been described in contemporary Western society:

- (i) '*Health as the absence of disease*'. This is a biomedical concept with a primary focus on individual biological processes and pathology within individuals;
- (ii) '*Health as the absence of illness*'. The focus in this case is on the personal subjective feelings of pain, discomfort, or suffering;

¹⁰⁰ P.H.N. Wood (1986, p. 62) makes some distinctions between the terms *disease*, *illness* and *sickness*. Wood states that *disease* "is a condition of the body in which its structure or function is disturbed or deranged. *Illness* is the state that is perceived by the individual when he or she is suffering from disease." While *sickness* "is the state that develops as a reaction to illness, where the individual manifests behaviours in response to the expectations others have of him or her when he or she is ill." These distinctions are important, since some authors mistakenly use these three terms as synonyms.

- (iii) '*Health as a capacity*'. Health in this context is functional, being the ability to perform certain highly valued social roles;
- (iv) '*Health as a functional prerequisite for the maintenance of the social system*'. Health in this context is something more collective than individual, in which attention is paid to the health of those who are productive, or to the health of the potential labour force;
- (v) '*Health as welfare*'. In this definition, attention is directed towards the accessibility to care as well as to the cure of disease;
- (vi) The term *health* has been used when describing the state of a social system as a whole, rather than the state of an individual.

Newman (1986) has also defined *health as expanding consciousness*. Newman (1986, p. 12) has argued that "disease and non-disease are reflections of the larger whole" and that a real "synthesis of health and disease yields a new concept: *pattern of the whole*." Newman (1986, p. 43) states that

[t]he process of the evolution of consciousness is also the process of health. The human being comes from a state of potential consciousness into a world of determinate matter and has the capacity for understanding that will enable him or her to gain insight regarding his/her pattern. This instantaneous insight represents a turning point in evolving consciousness with concomitant gains in freedom.¹⁰¹

Biomedicine and other Western forms of health care have usually attempted to measure health in a negative sense by the absence of signs and symptoms (Williams, 1992, p. 124). The biomedical model generally uses the terms *health* and *disease* as in Stacey's first three descriptions above. Laura and Heaney (1990, pp. 57-58) have also noted that Western countries have tended to utilise the expensive pharmaceutical drugs and medical interventions of Biomedicine, which do not appear to have resulted in better levels of health at the population level (chapter 1). This provides some evidence for the idea that the focus of Biomedicine is at the level of the individual (and generally on the biological level) rather than at the collective

¹⁰¹ The concept of *pattern* is also fundamental in TCM (e.g. the recognition of TCM 'patterns of disharmony' is required in order to determine a TCM diagnosis).

level of society.

While both biomedical and TCA practitioners attempt to ameliorate health problems at the level of the individual, it could be argued that TCM tends to place a greater emphasis on social determinants of health and disease when compared with Biomedicine. This is an outcome of TCM's 'holistic' orientation with its central tenet that phenomena at all levels are interdependent and constitute a single whole. This idea is encapsulated in the writings of Sun Sze-Mo, a traditional Chinese practitioner of the eighth century A.D., who wrote that the "lower doctor heals the illness; the median doctor heals the whole person; the higher doctor heals human society." (cited in Holbrook, 1981, p. 336). Sun Sze-Mo acknowledged the idea that the health of the individual is related to, and is dependent upon the health of the society in which one lives. This understanding of TCM corresponds to the 'relative' perspective of Svensson *et al.* (1980), where health and disease are measured in relation to the social system as a whole.

3.4 The Different Discourses of Traditional Chinese Medicine and Biomedicine

It is important to note that particular terms, concepts, and practices might only have meaning in the context of a particular discourse. Scheid (1993, p. 25) explains that a *discourse* is a common way of discussing a topic based on a set of ideas, concepts and theories which are often historically and culturally specific.¹⁰² TCM and Biomedicine can be understood to constitute different discourses since many of the concepts, ideas and terms used in the two systems of medicine are disparate. In many cases, equivalent concepts cannot be found in the two systems of medicine. For example, there is no equivalent term in Biomedicine for the TCM concept of *qi*.

While TCA and Biomedicine at times employ similar notions of illness and pursue related goals (Scheid, 1993, p. 27), there are differences in many of their philosophical and theoretical premises and underpinnings. So as not to be accused of simplifying complex medical systems, it is important to acknowledge that any discussion of a medical system in the abstract is

¹⁰² The term *discourse* is often associated with the French post-structuralist philosophers.

extremely difficult since medical systems are not usually homogeneous, and are often practised in different forms. For example, Payer (1990) has noted that Biomedicine is practised in a variety of ways in different countries. Similarly, traditional acupuncture has been, and is still practised in a number of different ways both within and outside of China (chapter 2).

Scheid (1993, p. 27) has made the claim that systems of medicine are difficult to separate from the institutions, beliefs and practices that have developed and sustained them over time

[c]omplex institutions and practices such as biomedicine or Chinese medicine are not homogeneous structures. They contain different and sometimes competing discourses, as well as remnants of older knowledge systems. Homogeneity is not necessary, because different discourses may fulfil different structural functions. Biomedicine, for instance, uses two diametrically opposed discourses to legitimise itself. Apart from the dominant scientific discourse, it also sees itself as an art.

While the image of the 'art of medicine' in the biomedical discourse can be helpful in certain contexts in order to emphasise the caring aspect of biomedical practice which requires personal knowledge and compassion, it nearly always remains subordinate to the scientific discourse. In contrast, TCM draws less on the scientific discourse and places greater emphasis on the 'art of medicine'. The 'art' of TCA practice requires personal knowledge, experience and flexibility in the therapeutic approach when attempting to help individuals. As a consequence of the flexibility of TCA practice, there is no demand to comply with rigid treatment protocols as is sometimes the case in Biomedicine.

3.5 Philosophical Underpinnings of Biomedicine

3.5.1 *Mind-body dualism*

In Biomedicine there can be found a mind-body dualism that is not evident in the ontology of TCM (chapter 2). It has been claimed that the dualistic interactionist ideas of the seventeenth century philosopher Rene Descartes have influenced all aspects of Western culture and science (Leder, 1992). In the sphere of medicine, the ideas of Descartes have been influential on the biomedical model (Capra, 1982, p. 118; Little, 1998). Biomedicine has been strongly influenced by Descartes' idea that phenomena can be divided into two separate and

fundamentally independent realms: the mind (*res cogitans*) and matter (*res extensa*)¹⁰³.

Descartes, in his philosophical works makes this understanding explicit, “[w]e may thus easily have two clear and distinct notions or ideas, the one of created substance which thinks, the other of corporeal substance, provided we carefully separate all the attributes of thought from those of extension” (Descartes, 1955, p. 241, cited in Cornman and Lehrer, 1974, p. 241). According to this Cartesian model, the human being consists of an isolated mind that exists *inside* a body.

For Descartes, all knowledge could be developed from a fundamental set of axiomatic ideas or principles. This belief constitutes the idea of ‘reductionism’ that is prevalent in Western science, biomedicine, and positivist research methods (see chapter 5). In the early twentieth century, many scientists understood all matter as consisting of various building blocks such as sub-atomic particles, atoms, and molecules. From this perspective, it was believed that most if not all phenomena could be understood by separating and examining these basic building blocks. This view is fundamentally the atomism of Aristotle.¹⁰⁴ Guzzetta (1989, pp. 87) has suggested that much biomedical research that utilises quantitative methods is reductionist and “cannot account for the whole person as an integrated unit.”

The Cartesian model understands the mind to be a mechanism. From this perspective, the mind can be understood by analysing its various ‘parts’. This idea forms the basis of what is sometimes termed ‘mechanistic’ thought. The mind of the human being, from the Cartesian perspective, can be seen as being somewhat separate from the body, with the body being governed by the laws of chemistry, physics and biology. As a consequence of this philosophy, it would appear that Biomedicine has created an artificial and arbitrary division between psychology and physiology. Other outcomes from the influence of Descartes’ philosophy on orthodox medicine include the following:

¹⁰³ It should be noted that Descartes himself was not a materialist. Descartes differentiated between mind (*res cogitans*), and matter (*res extensa*) but also made numerous references to God in his writings.

¹⁰⁴ According to G. Vesey and P. Foulkes (1990, p. 31), the originators of the theory of atomism were Leucippus and Democritus (5th century BC). Leucippus explained changes in the sensible world by the movements of ‘atoms’. Atomism was a reaction against Eleaticism, the idea that the universe is ‘one’ and indivisible.

- (i) all aspects of human health can be understood in physical and chemical terms. This is essentially the philosophy of materialism;
- (ii) an important aim of medical science is to analyse the structure and function of the human body in more and more detail (reductionism);
- (iii) the prerequisite basic sciences for the study of medicine are anatomy, physiology, pathophysiology, biochemistry, molecular biology, genetics, microbiology and neuroanatomy;
- (iv) the study of the mind and its pathology has become a separate medical speciality known as psychiatry. The mind is regarded as an epiphenomenon of the brain;
- (v) biomedical therapy consists of physicochemical interventions in the processes of the machine-like body.

Helman (1990, p. 86), in another analysis of Biomedicine, concluded that the basic features of Biomedicine are: (i) mind-body dualism; (ii) an emphasis on physicochemical data; (iii) an emphasis on objective, numerical or quantitative measurement; (iv) the concept of diseases as entities; and (v) scientific rationality.

According to Engel (1977), modern medicine regards the human body as a machine and disease as resulting from the malfunction of that machine. The physician's role in Western medicine, according to Engel's analysis, is simply to repair the machine when it breaks down. Leder (1992, pp. 20-21) explains that

[t]o understand an object in mechanist terms is to break it down into its constituent elements and analyze their interaction. But the knowledge so gained is precisely the sort needed if we wish to commandeer events ... Once we understand the mechanical elements and forces involved in a natural process, we can in principle alter or artificially duplicate it. This sort of knowledge thus grants us power over nature.

Leder (1992) suggests that the enormous power of modern medicine lies in its perceived power over nature. Leder (1992, p. 23) notes that it is a common view that we have now "learned to understand, remake or transform, components of the body-machine. When disease intervenes, we can intervene too. We know enough about the mechanics of bodily processes to assert over them a degree of intentional control."

The role of the medical practitioner in Biomedicine is often to remove disease entities (such as microorganisms) so that the patient can return to a state of health. Capra (1982, pp. 118-119) succinctly explains the danger of trying to understand the human being in terms of Descartes' philosophy, "by concentrating on smaller and smaller fragments of the body, modern medicine often loses sight of the patient as a human being, and by reducing health to mechanical functioning, it is no longer able to deal with the phenomenon of healing." Capra (1982, p.119) suggests that the reason for the exclusion of the phenomenon of healing from Biomedicine is that it cannot be understood in reductionist terms. This applies to the healing of physical disorders but even more to the healing of multifactorial illness which involves the interaction of the many aspects of the human condition (*i.e.* physical, psychological, environmental, social, and spiritual factors).

Leder (1992, p. 28) claims that many of the faults of modern medicine, including depersonalisation, overspecialisation and the neglect of psychosocial factors in understanding the aetiology and the treatment of illness and disease can be traced back to Biomedicine's reliance on the Cartesian model of embodiment. Leder (1992, p. 23) remarks that

it is now a cliché that modern medicine often neglects the import of psychosocial factors in the etiology and treatment of disease. Not as widely recognised are the metaphysical roots of this neglect. Insofar as the body is modelled upon a lifeless machine, the role of subjective experience in determining one's health history will tend to be overlooked. After all, a machine does not experience, does not inhabit an "existential world".

From the Chinese philosophical perspective, the Cartesian model is not complete or correct and has resulted in metaphysical confusion, creating an artificial division between the mental (including psychological and emotional aspects) and the physical realms of the human being. Scheid (1993, p. 27), in his examination of TCM and Biomedicine, has also noted an emphasis in the latter on objective rather than subjective data:

The language of objective science should exclude, as much as possible, any references to subjectivities. Diseases are described and categorised with respect to objective criteria from which the distorting influence of subjective experience, whether from the side of the researcher/physician or of the patient, has been carefully expunged. Medical practice ideally, should be reduced to the application of a technology of health, in which every aspect of decision making follows precisely worked out theoretical and therefore rational criteria.

The language of Biomedicine is often that of science, which favours data that are objective, physical and measurable. This has resulted in subjective data and psychosocial factors being somewhat neglected in the discourse of Biomedicine.

3.6 Holism and Holistic Health Care

It can be shown that there are many commonalities between TCM and the discourse of holism. While holism is often associated with the complementary therapies, holistic notions can also be found in Western medicine if one examines the history of medicine. Etymological studies of the words 'health' and 'holistic' reveal that they are derived from the same Anglo-Saxon root, *hal*, which can mean either 'whole', 'sound', 'happy' or 'to heal' (Blattner, 1981, pp. 2-3). This suggests that in the occident there was, and still, is an association between the ideas of 'health' and being 'whole'. While holistic notions may no longer be strongly associated with Biomedicine, holistic tendencies in Western medicine can be traced back to Hippocrates (Millenson, 1995, p.12). Capra (1993, p. 341) notes that "Hippocrates recognised the healing forces inherent in living organisms, forces he called 'nature's healing power'. The role of the physician was to assist these natural forces by creating the most favourable conditions for the healing process."¹⁰⁵ Mitchell and Cormack (1998, p. 5) following Cassell (1978), define healing as "a process of restoring the patient's sense of connectedness, indestructibility and control."

3.6.1 *Assumptions of holism*

Holistic health practitioners often make the claim that the analytic approach as used in the natural sciences such as physics, chemistry and biology can be found to be limited when trying to fully understand a person, a society, or 'reality' as a whole. Phillips (1976, p. 6) has identified a set of five interrelated ideas or tenets pertaining to organic wholes which could be considered to provide the core for many holistic philosophies:

¹⁰⁵ Capra (1997, p. 341) has noted some similarities between Hippocratic medicine and classical Chinese medicine: both recognise "health as a state of balance, the importance of environmental influences, the interdependence of mind and body, and nature's inherent healing power".

- (i) *'The analytic approach as typified by the physiochemical sciences proves inadequate when applied to certain cases - for example, to a biological organism, to society, or even to reality as a whole.'*
- (ii) *'The whole of the phenomenon is more than the sum of its parts.'*
- (iii) *'The whole determines the nature of its parts.'*¹⁰⁶ The part therefore reflects the whole in its totality. A consequence of such an understanding is that any 'system' (whether it be a human or a community) can be fully understood only in relation to larger systems of which it is a part.
- (iv) *'The parts cannot be understood fully if considered in isolation from the whole.'*
- (v) *'The parts are dynamically interrelated or interdependent.'*

Lyng (1990, p.16) suggests that the premises of holism might be better understood by viewing the *whole* as a hologram rather than trying to comprehend the relationships between 'parts' and a 'whole'. In Lyng's hologram analogy, the whole (*i.e.* the hologram) can be seen as consisting of many distinct but related facets. He states that

[t]he idea of facet differs from the notion of part in one important way: a facet can never be logically independent of the whole or the other units of the whole. Each facet is but one unique aspect or side of the whole; when one peers into a particular facet, the whole can be seen in its entirety, albeit a view of the whole that differs from the view seen from any other facet. Hence, the idea of removing a single facet from the whole is manifestly absurd because it is impossible to know where one facet ends and another begins.

The point to note in this analogy is that while it is possible to distinguish individual facets of a hologram, they can never be separated and understood in isolation from the whole hologram of which they are a part. If this idea is applied to the human being, it becomes apparent from the holistic philosophical perspective, why the health of the whole person cannot be *fully* understood through the examination of a *single* 'part', even if this part is the whole biological body. The reason for this understanding is that the processes of health and disease are believed to involve not only the physical body but also the psychological, emotional, social and spiritual domains of the human being.

¹⁰⁶ This is also the conclusion of contemporary quantum physics, see Capra, 1997, pp. 30-31.

3.7 A Holistic Definition of Health

One of the core elements of any health care paradigm is its definition of *health*. A health care paradigm's definition of health can be derived from the health goals of both practitioners and their patients. According to Lyng (1990, p. 64), there would seem to be two concepts that are fundamental to the formulation of a holistic definition of health. The first is that health is a process rather than a 'state of being'; the second is that health is a multidimensional process. Lyng (1990, p.65) claims that

health is not a static condition, a state of affairs in which individuals are free of the requirement of engaging in health producing action. Within the health system, health is something that can only be 'sought after' but never completely achieved. In this sense we define health as a process rather than a state of being.

Lyng considers that *health* results from three human activities: (i) effort towards maintaining existing human capabilities; (ii) effort toward developing new human capabilities; and (iii) effort towards maintaining a balance between the human 'system' and a constantly changing environment.¹⁰⁷ Maintaining such a balance could involve the process of adaption to a formerly disturbing factor. It should be noted that *adaptation* is essentially different from *restoration*. Restoration aims at a cure by countering or eliminating a disturbing factor, whereas adaptation might only allow the disturbing factor to be made tolerable (Pauli, 1986, p. 6).

The holistic view of health as a *process* is consistent with the Chinese philosophical perspective. Daoist philosophers understand all people and all things in the manifested universe as being involved in a process of constant change through the continuous transformation of *yin* into *yang* and *yang* into *yin*. All living beings are born into the world, grow, mature and eventually die. Lama Govinda, in the foreword of John Blofeld's (1976, p. 5) translation of the classic of Chinese philosophy, the *Yi Jing (I Ching)*, remarks that, "the I Ching is the only book of ancient wisdom that makes CHANGE itself the centre of observation and recognises TIME as an essential factor in the structure of the world and the development of the individual." [Govinda's capitalisation].

¹⁰⁷ Compare with Newman's (1986) concept of *health* as expanding consciousness.

Lyng (1990, p. 65) claims that holistic models of health recognise four basic kinds of change in the human *gestalt*¹⁰⁸: (i) change that is controlled or directed by the individual; (ii) change which is directed by forces that are external to the individual; (iii) change that results from the processes of growth and development; and (iv) change that results from the process of decay and decline. Lyng's analysis of *change* that occurs within the human *gestalt* is essentially in agreement with the Chinese philosophical understanding of the person. In TCM, there is the understanding that human health is a process rather than as a static state of being. A static state of being could only ever be transitory in a being who is constantly undergoing transformation. Fay (1996, p. 232) adds in a related context that

the self is not a thing but a process, and not an inner process of isolated self-creation and self direction but an interactive process in which relations with others are crucial. Selves are selves only in and through interactions with others. And just as these interactions are often conflictual, unclear, or very much of the moment, so also selves are changeable, multivocal, full of ambivalences, self-conflict, and self-alienation.

According to Lyng (1990, p. 64) the concept of 'multidimensionality' is another fundamental feature of holistic models of health. It presupposes that human biological functions are influenced by a multitude of environmental, psychological, cultural and social factors operating at several different levels concurrently. Fay (1996, pp. 50-51) also notes that

[m]ethodological holists insist that social phenomena be studied at their own autonomous macroscopic level of analysis. Moreover, they claim that theories which explain social phenomena are not reducible to theories about the individuals which perform them. The reason is straightforward: individuals are what they are because of the social whole to which they belong; the result is that the individual can only be understood by placing him or her in a social context, not the other way around. It follows that social wholes, not their individual human members, must be the bedrock of any adequate social scientific theory.

3.8 The 'Systems' Perspective of Health Care

Sally Goerner (1995, p. 22) claims that "[c]ollectively, western civilization is shaking off Newtonian clockwork-machine images and beliefs and replacing them with evolutionary and ecological images and beliefs." The increasing acceptance of TCM in Western societies is an

¹⁰⁸ According to N. Burns and S.K. Grove (1993, p. 61) the "concept of *gestalt* is closely related to holism and proposes that knowledge about a particular phenomenon is organised into a cluster of linked ideas".

example of a shift to ecological and 'systems' thinking. The 'systems' perspective is based on the pioneering work and concepts developed from 'general systems theory' during the 1940s by the biologist Ludwig von Bertalanffy (Capra, 1997). Audi (1995, pp. 784-785) explains that

[v]on Bertalanffy was both reacting against reductionism and attempting to revive the unity of science. He emphasised that real systems are open to, and interact with, their environments, and that they can acquire qualitatively new properties through emergence, resulting in continual evolution. Rather than reduce an entity (e.g. the human body) to the properties of its parts or elements (e.g. organs or cells), systems theory focuses on the arrangement of the relations among the parts that connect them into a whole (cf. holism). This particular organization determines a system, which is independent of the concrete substance of the elements (e.g. particles, cells, transistors, people).

Dalenoort (1986, p.17) remarks of systems theory that it

is not a theory of the sort generally encountered within specific disciplines, since it does not directly refer to specific phenomena. It refers rather to aspects of phenomena that are to some extent universal and similar in different disciplines. It therefore aims at formulating principles, mechanisms and scientific laws that can be used for explanation in more than one discipline.

Systems theory is therefore a "transdisciplinary study of the abstract organization of phenomena, independent of their substance, type, or spatial or temporal scale of existence." (Audi, 1995, p. 784). Laura and Heaney (1990, p.110) argue that in recent years there has been a transition from a bioreductionist model of disease to a 'systems' orientation. While Biomedicine, a product of a bioreductionist paradigm is still the dominant form of health care in the Western world, it is slowly becoming aware of its limitations and deficiencies (see chapter 1) which has allowed the ideas of the 'systems' view to take hold and to begin to permeate medical thought and theory.

Systems theory sees human beings, the world and all of its phenomena in terms of interrelatedness and interdependence. Within such a framework, an integrated whole cannot be reduced to its component parts and still be considered a system. As Capra (1982, p. 27) states, "[l]iving systems are organised in such a way that they form multilevelled structures, each level consisting of subsystems which are wholes in regard to their parts, and parts with respect to larger wholes." From the 'systems' perspective, human beings, societies, and the environment

can all be regarded as systems. All of these systems can be seen to be wholes in the sense of being integrated structures. Stephen Francis (1995, p. 254) remarks that, “[g]eneral systems theory is an approach to understanding the behaviour of systems by studying the interaction within and between different levels of a system. Furthermore, a system cannot be understood by being reduced to its constituent parts and each of the parts studied in isolation.” It is clear that parallels can be drawn between ‘systems’ theory and the ideas of holism.

3.8.1 *Characteristics of ‘systems’ theory*

There are a number of features of the ‘systems’ model of health and disease that resonate strongly with TCM philosophy and theory. For a comparison to be made, it is first necessary to outline some of the key concepts and features of the ‘systems’ view that has been derived from the ‘general systems theory’ of von Bertalanffy (Laura and Heaney, 1990, pp. 110-116):

- (i) The term ‘system’ refers to an organised set of units whose configuration of integration contributes to an indivisible whole or complex unit.
- (ii) Within the system, all units are all interconnected and contribute to the the nature of the whole system of which they are parts. In this model, every living organism, whether it be an amoeba or a human being, can be regarded as an integrated whole, and hence can be termed *systemic*.
- (iii) There is the idea of a ‘hierarchy of systems’ that are interconnected and which can be organised in an order of increasing complexity. For example, a human heart cell could be seen as a *whole* unit in itself, or as a *part* of the heart organ at a higher level of complexity. It follows from this line of reasoning that the heart organ itself can again be seen and studied as a *whole*, or seen as a *part* of a human being. In a similar way, a human being can be seen as a whole, or as a member (or part) of a society at a higher level of hierarchical complexity. Capra (1997, p. 36) notes that a “key criterion of systems thinking is the ability to shift one’s attention back and forth between systems levels.”

- (iv) According to the systems view, there is a constant exchange of energy, matter and information between each of the levels of the system. The regulation, or homeostasis and stability of biological and social systems as a whole is maintained by a system of multiple positive and negative feedback loops (Capra, 1982 p. 289). In this model, the flow of energy, matter and information is not *unidirectional* as in other health care models.¹⁰⁹
- (v) Systems theory emphasises the idea that health and disease are not discrete or mutually exclusive states but are points on a health-disease continuum. It also emphasises the idea that health is not a static state but is dynamic and changing because of the organism having to maintain internal equilibrium due its the constant interaction with the environment.

Capra (1982, p. 344) has noted that *balance*, or the maintenance of internal equilibrium, is also a key concept in the Chinese view of health:

The [Chinese] classics state that diseases become manifest when the body gets out of balance and the *qi* does not circulate properly. The causes for such imbalances are multiple. Through poor diet, lack of sleep, lack of exercise, or by being in a state of disharmony with one's family or society, the body can lose its balance, and it is at times like this that illness occur. Among the external, seasonal changes are given special attention and their influences are described in great detail. Internal causes are attributed to an imbalance of one's emotional states, which are classified and associated with specific internal organs according to the correspondence system.

Related to the concepts of the systems perspective is the Confucian understanding of embodiment. Tu Wei-Ming (1992, p. 91) explains that

[t]he Confucian conception of the body as a modality of *qi* is congruent with the lived experience that the body, far from being a static structure, may be visualized as a flowing stream constantly responsive to the vicissitudes of the changing environment. ... A distinctive feature of *qi*, as a vital energy rather than dead matter or ephemeral spirit, is its susceptibility to external force and its self-generated internal dynamism. Like a moving stream, the body made of *qi* is an open system, encountering, discovering, collecting, and enduring.

¹⁰⁹ According to Dalenoort (1986, p. 26), in systems theory there is the awareness that all living systems need to be 'open' systems in order to survive. Von Bertalanfy noted that biological systems can maintain low levels of entropy by feeding on plants and animals of relatively low entropy and then excreting digested waste of relatively high entropy. All biological systems form a hierarchy of systems in which the more complex forms of life maintain their existence by feeding on systems that are lower in the biological hierarchy.

The TCM concept of *qi* could therefore be useful in understanding the flow of energy and *information* between levels or subsystems of a system. The concepts and features of systems theory are compatible with TCM philosophical and theoretical understandings.

One problem with the model of Biomedicine, from the 'systems' perspective, is that often the 'causes' of human illness and disease are not linear and unidirectional but rather multifactorial, with aetiological factors originating from several different levels or subsystems within a 'hierarchy of systems'. Systems theorists claim that human beings live, exchange matter, energy and information with their environment in what they term 'open systems' (Blattner, 1981). It is claimed that human beings endeavour to maintain health within this open system through complex 'feedback' or homeostatic systems that attempt to maintain an internal state of equilibrium. Similarly in TCM, health is associated with 'dynamic balance', while illness and disease are believed to result from a movement away from this state of dynamic state.

Von Bertalanffy (1968, p.150 cited in Stephen Francis, 1995, p. 255) has made several distinctions between 'open systems' and 'steady-state' models. One of these differences is important in the current examination since it supports the notion of the emergence of properties from less complex systems and the transformation of consciousness to higher order states. Von Bertalanffy associated steady states with essentially closed systems, while an 'open system' may actively move toward a state of higher organization, that is, the system may pass from a lower to a higher state of order due to the conditions of the system.

In systems theory, there is the recognition that system boundaries are determined not only by the lines of demarcation of 'objective' reality but also by the questions the researcher asks and attempts to answer. As a result of systems thinking, there is a flexibility in shifting boundaries between aspects of phenomena. For example, there is no requirement to determine sharp boundaries between the biological, mental and social spheres. The systems view that the author supports is not one that is restricted to physical phenomena, rather it is one that is more extensive and which includes phenomena from the physical, mental, social and spiritual realms.

A 'systems' view of health care requires the concept of health to be redefined so that factors in

addition to the signs and symptoms of physical disease can be considered. Laura and Heaney (1990, pp. 114-115) suggest that 'health' should be construed as

a positive and dynamic process in which a living organism, reckoned as an integrated system, is able to respond adaptively to the various environmental states which confront it. These environmental states may range from stress episodes on the one hand to physical, chemical, and even social challenges to the organisational integrity of the system as a whole on the other.

From a systems conception of 'health', *disease* must also be redefined. The systems perspective would see disease as resulting from the living organism's failure to maintain internal homeostasis by not adapting sufficiently to changes in the environment. In accord with systems theory thinking is TCA therapy, with its focus on the promotion and maintenance of balance with ones' environment, and not simply the treatment of illness and disease.

The 'biopsychosocial' model of Engel (1977) is an example of a 'systems' view of health and disease. This model has, however, been criticised for not explaining how the biological, psychological and social levels interact (van der Steen & Thung, 1988). An insight into, and a possible solution as to how the interaction between levels of a system can occur could be found within the heuristic model of the stress process of Cohen, Kessler and Gordon (1995, pp.10-11). This model has potential for understanding and integrating the environmental, psychological and biological levels of illness and disease. While the model of Cohen *et al.* was developed for the syndrome of 'stress', its general principles are relevant for other syndromes (see Figure 3.1). The model of Cohen *et al.* (1995) also gives a credible account of how psychological states 'cause' physical disease. Cohen *et al.* (1995, p. 10) state that

[w]hen confronting environmental demands, people evaluate whether the demands pose a potential threat and whether sufficient adaptive capacities are available to cope with them. If they find the environment demands taxing or threatening, and at the same time view their coping resources as inadequate, they perceive themselves as under stress. The appraisal of stress is presumed to result in negative emotional states. If extreme, these emotional states may directly contribute to the onset of affective psychiatric disorders. They may also trigger behavioral or physiological responses that put a person under risk for psychiatric and physical illness.

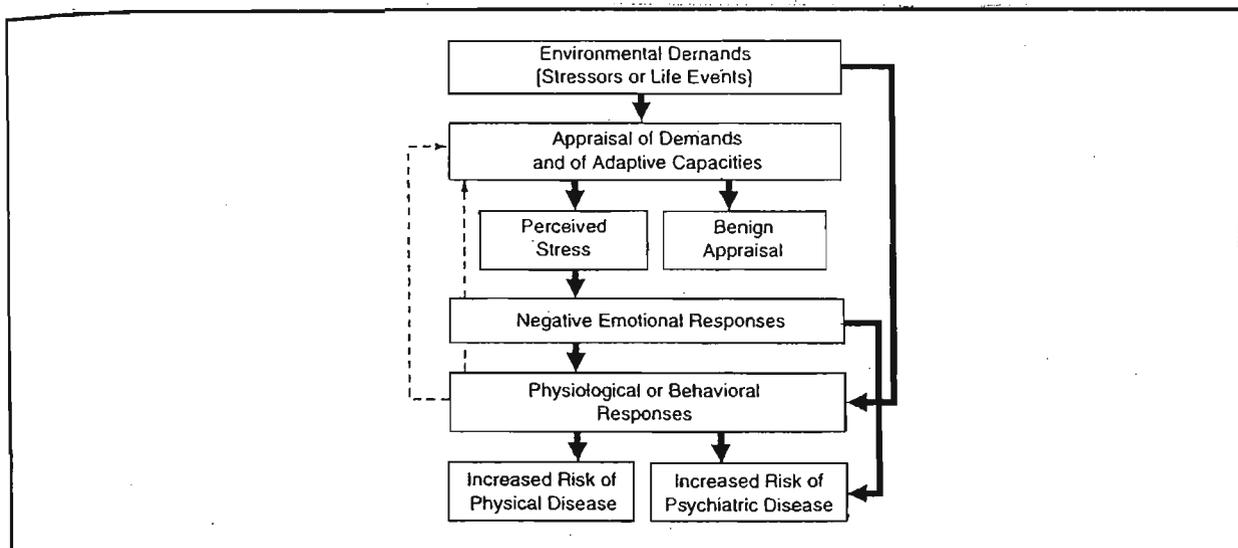


Figure 3.1 The heuristic model of the stress process that integrates the environmental, psychological and biological levels (Cohen, Kessler & Gordon, 1995, p.11)

Cohen *et al.* (1995, p.12) suggest that stressors could “influence the pathogenesis of physical disease by causing negative affective states (such as anxiety and depression) which in turn exert direct effects on biological processes or behaviour patterns that influence disease risk”.¹¹⁰ The primary biological pathway linking the emotions to disease is thought to be hormonal (Baum, Grunberg & Singer, 1982 cited in Cohen *et al.*, 1995). The relationship between mental states and physiological processes is now progressing rapidly through the work of researchers in the developing field of psychoneuroimmunology (PNI).¹¹¹ A review of 81 studies by Uchino *et al.* (1996) also claims that there is a relationship between social support and physiological processes. The review indicated that social support could be reliably related to beneficial effects on aspects of the cardiovascular, endocrine, and immune systems.

To understand the ‘systems’ perspective as it is applied to human health care, consider the following hypothetical clinical case using the Cohen, Kessler and Gordon (1995, p. 11) model:

A man presents at a community health centre with insomnia, reduced energy levels, lower back pain, headaches and depression (case from Brody, 1973).

¹¹⁰ See S. Cohen *et al.*, 1986.

¹¹¹ The science of psychoneuroimmunology (PNI) studies the links between the mind, brain, consciousness, the central nervous system and the immune system (Hafen *et al.*, 1996, pp. 21-22). See also P. Martin, *The Sickening Mind: brain, behaviour, immunity and disease*, 1997 and Cohen and Herbert, 1996, pp. 113-142 and Ader, R., Felten, D. and Cohen, N. (eds.) (1991). *Psychoneuroimmunology*. (2nd. ed.). San Diego: Academic Press, Inc.

A practitioner of Biomedicine might determine the cause of the pattern of signs and symptoms to be the result of dysfunction of various internal organs, with the possible involvement of some psychological factors. The treatment could involve some form of drug therapy to reduce the signs and symptoms and possibly some counselling. A 'systems' analysis of this case could be expected to be more comprehensive and might take the following form: The man was a timber worker who had lost his job six months ago as a result of a government decision to reduce wood-chipping in a forest which was regarded by the government to be an environmentally sensitive' area. This government decision was influenced by the lobbying of groups from the environmental movement. It was found by the practitioner on questioning the client that because of the loss of his job and income, his lifestyle was altered which led to stressed relationships between family members. This situation led to a loss of self-esteem and a fear of the future. The 'stress' that the man experienced could have contributed to the feeling that he could no longer cope (see figure 3.2 below).

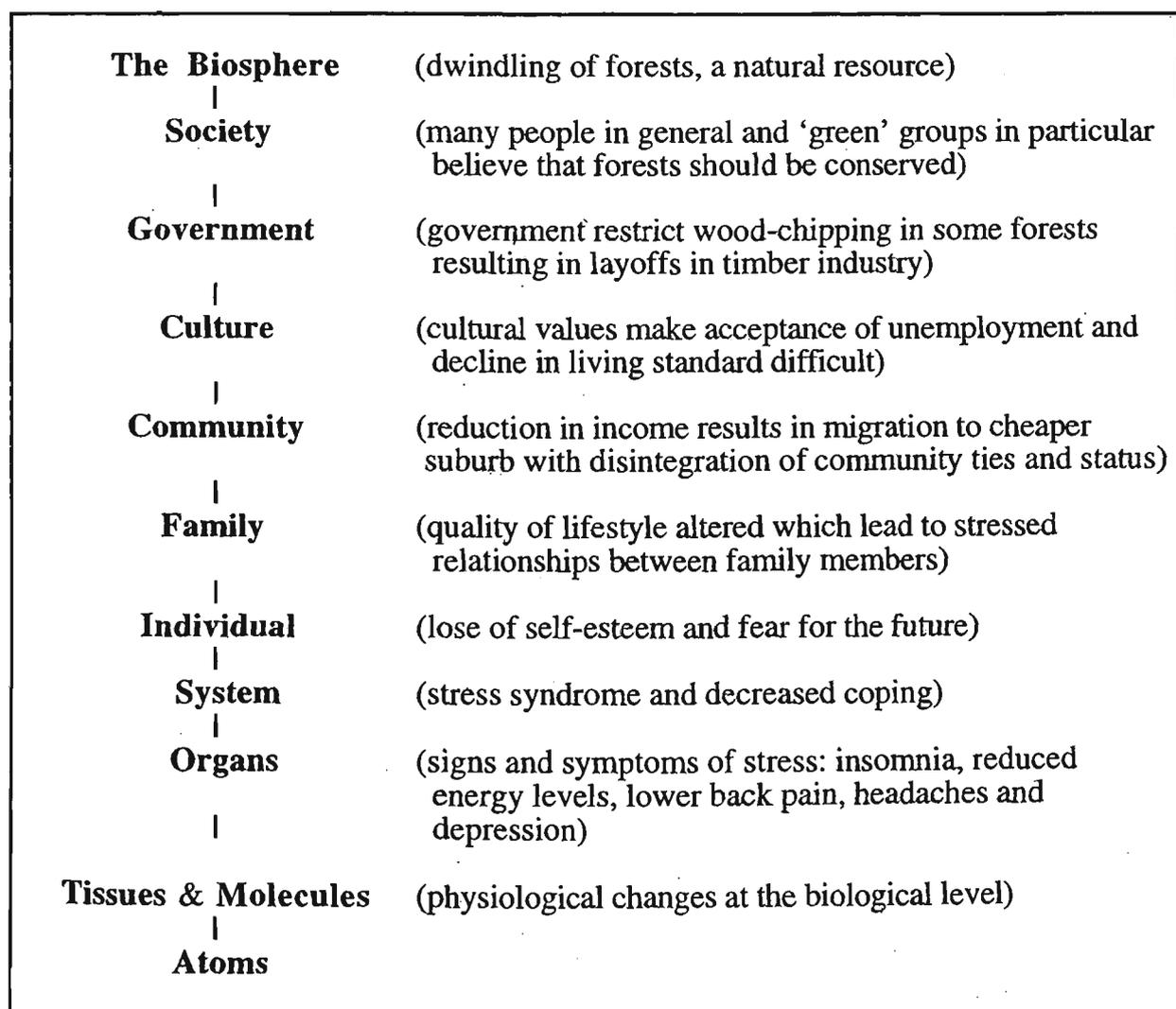


Figure 3.2 The effects on the individual by changes in the various units of a systems hierarchy (adapted from Brody, 1973)

For the TCA health practitioner with a holistic systems orientation, the man's signs and symptoms in the example above would not be seen solely in terms of physical dysfunction and personal stress but as a response by the person to multiple changes in the various levels of a systems hierarchy. As a result, the causes of illness at the individual level can be seen to be multifactorial in nature, originating from different levels of the systems hierarchy. The TCA practitioner would accept the system theorist's understanding of health and disease in so far as there is the common view that all phenomena in the world are interrelated and ultimately interdependent. The health of the human being is hence not solely an individual matter - it can also be a global matter, being dependent on both a healthy environment and healthy social structures and processes. Leder (1992, p. 32) has also noted that:

The lethal diseases of the modern industrial age, most predominantly cardiovascular disease and cancer, have been shown to be intimately bound up with sociological and personal intentionalities; that is, lifestyle, emotions, environmental agents, habits of diet, drug use and exercise. It is becoming increasingly clear that our diseases are not just mechanical affairs, but a matter of how we live our lives and inhabit our world.

3.9 The Nature of the Human Being: Levels of being

In the next section of this chapter the nature of the human being and some of the implications for TCA research will be examined. It will be argued that one's conception of the essential nature of the human being can have profound implications for what researchers of health care actually decide to study and what constitutes sound and valid research. Schumacher's (1978) topology of 'levels of being' will be first considered since it can help to clarify and elucidate the idea of 'emergent properties', which is an important feature of holistic thought.¹¹²

According to Schumacher (1978), the phenomena of the world can be divided into four 'levels' or 'kingdoms', these being the mineral, plant, animal and the human. Schumacher claims that there can be found 'ontological discontinuity' between each of these 'levels'. As one passes from the mineral kingdom to the human kingdom, new properties can be perceived at each higher evolutionary level. The lowest 'level of being' in Schumacher's topology is the mineral

¹¹² According to F. Capra (1997, p. 28), the philosopher C.D. Broad coined the term 'emergent properties' in the 1920s for "those properties that emerge at a certain level of complexity but do not exist at lower levels."

kingdom (*i.e.* inanimate matter). The next level is the plant kingdom, which can be differentiated from the simpler mineral kingdom by the additional property of *life*.¹¹³ In Schumacher's model there is no need to define what *life is*, but only to acknowledge that it exists in things that are living.

While both animals and plants have life, in the animal kingdom another property can be perceived which is not present in the two lower levels of the mineral and plant kingdoms. This additional property is consciousness. Again, it is not necessary to define what consciousness is, rather, it is only necessary to recognise its absence when it is not present.

The next 'level of being' is that of the human being. The human being has form (physical body), life, consciousness and another property that is not found to any significant extent in the other kingdoms. This emergent property of the human being is *self-awareness*. According to Schumacher (1978), self-awareness allows the person to be *aware* of consciousness. Schumacher (1978, p. 26) states that within the human being "there is a something able to say 'I' and to direct consciousness in accordance with its own purposes; a master or controller, a power at a higher level than consciousness itself" (see Table 3.1). This property of self-awareness or 'inner self' is acknowledged every time the human being begins a statement with the pronoun 'I'. Fay (1996, p. 35), in a similarly vein, suggests that a "self-conscious creature is one which is itself the object of its own reflections and assessments. It knows that it forms certain beliefs or desires certain things, and scrutinizes its own perceptions, wants, and opinions and the bases on which these are formed." At each higher level of being there is the emergence of new properties which enables new activities, capacities or achievements.

¹¹³ H. Beinfield and E. Korngold (1991, p. 5) note that in the ancient Chinese world view *qi* is understood as "life's animating force and substance."

Table 3.1 Levels of Being (rewritten from Schumacher, 1978, p. 27)

Schumacher's Levels of Being	Substances & Properties
mineral kingdom (inanimate substance)	m
plant kingdom (inanimate substance + life)	m + l
animal kingdom (inanimate substance + life + consciousness)	m + l + c
human beings (inanimate substance + life + consciousness + self-awareness)	m + l + c + s
[where m = inanimate substance, l = life, c = consciousness, s = self-awareness]	

The significance of Schumacher's topology for research of TCA is that it allows one to understand why the methods used to obtain knowledge at a particular 'level of being' might not be sufficient in themselves to understand a higher level. For example, the living plant cannot be *fully* understood by examining only its inanimate substance (the mineral kingdom) because of the *additional* property of 'life' that is present in the living plant. *Living* plants cannot be fully understood solely through the sciences of chemistry and physics since these sciences consider only the processes of inanimate substance and not those of living matter. While the sciences of physics and chemistry might yield partial knowledge of a plant's structure and function, they would not be sufficient to explain *all* of the processes of the *living* plant. Through similar reasoning, the human being cannot be fully understood by the sciences of physics, chemistry and biology alone because the human being possesses additional properties not found in the 'lower' kingdoms. Schumacher's exposition argues for 'ontological discontinuity' between the four different kingdoms of his topology. This allows for a phenomenological distinction to be made between the different 'levels of being'.¹¹⁴

From a Daoist perspective, Schumacher's use of the term 'ontological discontinuity' might not be appropriate since it might suggest that there is a fundamental difference between the 'substances' of the four different 'kingdoms', which would lead to the same philosophical difficulties as faced by dualist philosophies. From a Chinese philosophical perspective, the

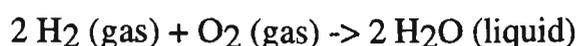
¹¹⁴ R. Singleton *et al.* (1988) note that phenomenologists' claim that *phenomena* as they are perceived are the *only* objects of knowledge.

different 'levels of being' or 'kingdoms' of Schumacher's topology could be understood as increasingly more complex configurations of *qi*, with the phenomenological *appearance* of 'ontological discontinuity' between each level being the result of 'emergent' properties that result from the increasingly more complex configurations of *qi*.

3.9.1 *Emergent properties*

The previous examination of Schumacher's topology suggests that each 'level of being', from the mineral to the human being, is progressively more complex because of the *emergence* of new properties and qualities. Such a conception helps to explain why some philosophers, including Schumacher (1978), claim that human beings cannot be *fully* understood by the research methods of the natural sciences and the study of the biological body alone, since more complex properties and qualities emerge between the mineral and the human levels. To use only the research methods of the physical sciences to understand the nature of the human mind and spirit would result in what Ken Wilber (1990, pp. 7-9) has termed *category error* (see chapter 1). To understand the mind, consciousness, wellbeing and other subjective internal states from the patient's perspective will require qualitative research methods such as the in-depth interview that can access subjective information from individuals through communication (see chapter 12.1).

It could be noted that even *within* 'kingdoms' emergent properties can emanate which could not be predicted from the study of the constituent units in isolation. An example in the 'mineral kingdom' is the formation of water molecules (H₂O) from the gases oxygen (O₂) and hydrogen (H₂). In chemical terminology this can be represented by the equation:



Phillips (1976, p.14) has noted that the emergence of the properties of an odourless, colourless and tasteless liquid (*i.e.* water) could not be deduced from a study of the component gases oxygen and hydrogen in isolation. Even at the 'physical' (mineral kingdom) level, the maxim

of holism that ‘the whole of a phenomenon is *more* than the sum of its parts’ would appear to hold. From the simple example above, it is evident that the ‘nature’ and qualities of water could only be ascertained by examining water (a more complex configuration of atoms/*qi*) and not by merely studying the simpler gases of oxygen and hydrogen. Similarly, the nature and activities of human beings can be fully revealed only by the study of human beings in the context of their total environment and not solely through a study of biological processes that are but one aspect of the human being. It also follows that animal studies in laboratories will never be sufficient in themselves to fully understand human health since humans possess emergent properties and qualities that are not present in the animal kingdom.

Schumacher’s topology could help researchers to decide which are the more appropriate research methods for different research questions involving the different ‘kingdoms’ or ‘levels of being’. The model also helps to explain why certain research approaches will not be suitable for answering particular questions involving entities at particular levels of being. Schumacher (1978, p.119) remarks that, “[w]ith inanimate matter we can indeed experiment as we like; no amount of interference can destroy its life - for it has no life - or distort its inner experience - for there is no inner experience.” Experimental research is indeed a valid and legitimate method of study when it can do no harm or destroy the subject under investigation. Experimentation is appropriate for the study of inanimate substances since these substances are only transformed rather than destroyed. This however, is not the case when human beings are involved in research. Schumacher (1978, p.119) makes several important points that are relevant in regard to research that involves human experimentation:

Life, consciousness and self-awareness are damaged very easily and are almost invariably destroyed when the element of freedom inherent in these powers is assumed to be non-existent.

It is not simply the complexity at the higher Levels of Being that militates against the experimental method, but, much more importantly, the fact that causality, which rules at the Level of inanimate matter, is at the higher Levels put into a subservient position; it ceases to rule and is being *employed* by higher powers, for purposes unknown at the levels of physics and chemistry.

Schumacher’s first point in the quotation above emphasises the need to respect human beings in the research process. This necessitates the use of ethical research designs that are appropriate

for human beings (see chapter 11). Schumacher's second point states succinctly one of the weaknesses of positivist/behaviourist accounts of research that involves human beings (see chapter 5). Human beings have minds, self awareness, desires and wills, and their actions cannot always be predicted with the certainty that behaviourists claim according to their simple notions of stimulus/response mechanisms and their associated understandings of determinism and linear causality.

3.10 Perspectives of the Body

Sociological analyses of the 'body' can provide further insights into the conception of the nature of the human being in different medical systems. This too has implications for how research that involves human beings should be conducted. The analysis of the sociologist Shilling (1993 cited in Nettleton, 1995, p.104) identified the naturalistic (or natural science) and the *social constructionist* perspectives of the body. These two perspectives appear to be polarised. Nettleton (1995, p.104), in an explanation of the naturalistic perspective, states that the body is assumed to be "a real biology entity which exists as a universal phenomenon, irrespective of the social context in which it resides." This perspective maintains that "all human behaviours and social relations can be explained in terms of their biological basis." In contrast, the social constructivist perspective claims that "the body is socially created, or invented and as such is contingent on its social and historical context."

Turner (1992, cited in Nettleton, 1995, p.104) suggests that *phenomenology* (see chapter 5) is a third perspective which can be seen as a bridge between the two extreme forms of the naturalistic and social constructionist positions. From this third perspective, phenomenologists see human beings as possessing varying degrees of free will and self-consciousness, with a volition to direct their own lives. Many phenomenologists believe that human beings have the ability to transform themselves and develop their latent potential (Wagner, 1983). From the perspective of phenomenology, it is claimed that, "the key to understanding the human body is the mind, and more especially, the notion of 'lived experience', which suggests that people interpret and thereby create their worlds in meaningful ways." (Nettleton, 1995, p. 104). The essential characteristic of the 'lived body', from the phenomenological perspective, is

intentionality (Nettleton, 1995, p.108) (see also chapter 5).

Turner (1984) and Shilling (1993) have endeavoured to develop a sociology of the body by combining insights from the naturalistic, social constructionist and phenomenological perspectives (Nettleton, 1995, p.109). Shilling (1993) argues that the body can be conceptualised as an “*unfinished* biological and social phenomenon, which is transformed, within changing limits, as a result of its participation in society.” (Nettleton, 1995, p.109). In Shilling’s model of the *body as a project*, “the body is seen as an entity which is in the process of becoming; a project which should be worked at and accomplished as part of an individual’s self-identity” (Nettleton, 1995, p.109). Shilling’s notion of the ‘body as a project’ can be seen to be similar in some respects to Maslow’s (1954) humanist idea of human transformation toward *self-actualisation* and the Chinese Daoist idea of self-cultivation (that is the development of awareness and consciousness) through meditation and reflection.

3.10.1 *The Nature of the Human Being in TCM and Biomedicine*

A central feature of any system of medicine is its conception of what a human being is. It is evident that the constitution and nature of the human being is understood differently in TCM and Biomedicine. These conceptual differences can have profound ramifications for how the health care practitioner interacts with their clients (patients) in the therapeutic encounter and how research is to be conducted on the different systems of medicine.

One central feature of TCM is its understanding of the nature of the ‘living’ human being. In TCM there is the idea that the human being is in a continuous process of change and transformation from one state to another. This idea is consistent with the teachings of both Daoism and Buddhism. For example, Capra (1975, p. 95) explains that in Buddhism’s *Four Noble Truths* it is believed that

suffering results from resisting the natural ebb and flow of nature. ... humans suffer when they cling or grasp onto a fixed view of life. This quality of separating and trying to confine the fluid forms of reality was considered ignorance by Buddha. As mankind clings to its firm reality, it becomes trapped in a vicious circle called “samsara” in which every action generates further actions and each question poses new questions.

Linked to the Oriental idea that life is a process is the belief that one can evolve in consciousness and gain wisdom and understanding from life's experiences and challenges. Change and transformation is a recurring theme in the Oriental discourse. Tu Wei-Ming (1992, p. 89) claims that in Chinese thought there is the Confucian idea that a person can grow and evolve to become an adult (a matured person) and possibly a realised person. This implies the authentic possibility for continuous growth in both consciousness and understanding. Lyng (1990, p. 56) notes that "a principle preoccupation of almost all of the different 'modalities' that make up the holistic health paradigm is a concern for the development of techniques that will allow one to control the direction of change in one's Gestalt."¹¹⁵ This understanding is also a fundamental premise of TCM. For example, TCA practitioners who draw on Daoist philosophical concepts advocate that human health, longevity, wisdom and ever increasing levels of understanding can be achieved through the cultivation of one's *qi*. It is claimed that transformation of consciousness can be attained through the practice of techniques such as meditation and *tai ji quan* (*tai qi chuan*). It is said that such practices can progressively refine ones *qi*, leading to higher levels of awareness and consciousness. Self cultivation using these practices can affect simultaneously both the 'mind' and 'body' as a whole. From the perspective of TCM, living human beings are not static entities; rather, they can be understood as beings that have centres or 'inner selves' which can direct change in their configurations of *qi* through their own efforts.

To understand the differences between the perspectives of TCM and Biomedicine in relation to the 'body' and embodiment, one needs to examine the philosophical origins of these different perspectives. Leder (1992, p. 17) argues convincingly in *A Tale of Two Bodies: The Cartesian Corpse and the Lived Body* that modern Biomedicine is based "not upon the lived body, but upon the dead, or inanimate, body." He claims (1992, p. 19) that one's methodology of investigation is inevitably tied to one's conception of what is believed to be real. Leder suggests that Descartes' extensive use of dissection implied that the dead body played a key role in Cartesian metaphysics of embodiment and subsequently Biomedicine's metaphysics of

¹¹⁵ See also A. Mitchell and M. Cormack (1998, pp. 77-90) for an account of the change process that can occur during the therapeutic encounter in complementary health care.

embodiment. Leder (1992, p. 22) notes that medical knowledge coming from the study of dead bodies is constantly reinforced during orthodox medical training:

The epistemological primacy of the corpse has shaped not only medical technology, but diverse aspects of training and practice. Medical education still begins with the dissection of a cadaver, just as the clinical case ends in the pathologist's lab. In between, the living patient is often treated in a cadaverous or machine-like fashion. ... Given the vision of embodiment which underlies our disease categories and diagnostic methods, it is not surprising that the process often culminates in mechanistic forms of treatment.

Biomedicine's use of mechanistic forms of treatment and intervention could be understood as coming from its metaphor of the person as a machine. Leder (1992, p. 23) suggests that at the centre of contemporary medical practice is the Cartesian revelation that, "*the living body can be treated as essentially no different from a machine.*" Leder makes the important observation that while the 'good' medical practitioner inevitably utilises interpersonal skills in practice and engages the 'patient-as-person', the emphasis of modern medical therapeutics is usually placed on mechanistic interventions such as pharmaceutical drugs and surgery rather than the therapeutic relationship *per se*.

3.10.2 *The 'lived body'*

In contrast to the Cartesian understanding of the body and mind is the phenomenologists' concept of the 'lived body'.¹¹⁶ Leder (1992, p. 24) explains that

[t]he term 'lived-body' derives from the German Leib. In German, the term Leib is employed when one is referring to living bodies, while the term Körper (a) [*sic*] is used to designate inanimate or dead bodies: the body of a rock, for example, or of a human corpse. The Cartesian paradigm can be said to eradicate the essential difference between the Leib and the Körper. The former becomes but a special case of the latter, one instance of the general class of physical things. The notion of "lived body" rejects this conflation. It holds that the body of a living being has an essential structure of its own which cannot be captured by the language and concepts used to explain inanimate nature.

¹¹⁶ D. Leder (1992) has noted that the concept of the 'lived body' has developed from the writings of twentieth-century philosophers and physicians including Merleau-Ponty (1962, 1968), G. Marcel (1952; 1956), and R. Zanner (1964; 1981; 1988).

Leder claims that the fundamental idea of the 'lived-body' is predicated on an understanding of the essential nature of the human being as an 'intending' entity. Leder (1992, p. 25) argues that the 'lived body' is an intending entity in the sense that "it is bound up with, and directed toward, an experienced world. It is a being in relationship to that which is other: other people, other things, an environment".

There are obvious similarities between phenomenological and Chinese philosophical ideas. For example, both have a similar understanding of the 'lived body'. The human being in the Chinese philosophical worldview is understood as a constantly transforming configuration of *qi*, with no clear distinction being made between the mind and body. The focus of TCM has always been on obtaining medical knowledge from the study of *living* people while experiencing health and illness, rather than from the study of the inanimate and the dissection of cadavers.¹¹⁷ Tu Wei-Ming (1992, p.87) claims that in Chinese thought, the body is never thought to be "merely material and mechanical, but an open and flowing system of vital energy." This conception has similarities to Merleau-Ponty's (1968) notion of the 'intertwining' of the 'lived body'. Leder (1992, p. 27) explains that the 'lived body' is an 'intertwining' of the perceiver and the perceived, the intentional and the material. Leder suggests that the concept of the 'lived body' is "a concept designed to carry us beyond ontological dualism, while acknowledging the divergence of perspectives and languages through which the self can be approached."

The concept of the 'lived body' has important ramifications for health care practice and research. It might enable health care practitioners to better integrate their objective medical interventions with the interpersonal dimension of therapy. This could result in a better understanding of the *person* and a more useful model of health care. Leder (1992, p. 28) suggests that because "the lived body is an intertwining of intentionality and materiality, subject and object", a medicine of the *intertwining* could be developed. Leder argues that in such a model of medicine, "our notions of disease and treatment would always involve a chiasmatic blending of biological and existential terms, wherein these terms are not seen as ultimately

¹¹⁷ Dissection and surgery did not feature to any significant extent throughout the history of TCM. This is no doubt a consequence of traditional Chinese medicine's focus on function rather than structure and the holistic Chinese medical philosophy of systemic correspondence (see also P. Unschuld, 1985, pp. 78-79).

opposed, but mutually implicative and involved in intricate ‘logics’ of exchange.” It would seem that the notion of the ‘intertwining’ of the ‘lived body’ is compatible with the TCM perspective.

It should be noted that the dilemma created by Cartesian understandings of the person for biomedical practitioners, does not exist for TCM practitioners because there is not the same emphasis placed on objective techniques and interventions. In TCM, the needling of acupuncture points, the prescribing of herbs and Oriental health counselling are *all* understood to be able to influence the configuration of a person’s *qi*, which can result in changes in a person’s health status and well-being. TCM would therefore seem to be a likely candidate for Leder’s ‘medicine of the intertwining’. Leder (1992, p. 29) also notes that

[t]he existential account does not replace the biological account, but rather places it within a broader perspective. The anatomy and physiology of the lived body are always intertwined with the body’s intentionality in ways that undermine facile claims of priority. Just as our physical structure lays the groundwork for our mode of being-in-the-world, so our interactions with this world fold back to reshape our body in ways conducive to health or illness. A medicine of the lived body dwells in this intertwining.

It is important to realise that TCA practitioners do not have to choose an existential account of the human being and reject the biological understandings of the body. Instead, TCA practitioners can accommodate the different perspectives within a larger context. It follows that TCA therapy can take on a fuller meaning when it is understood as not merely ‘fixing the machine’ but as engaging the patient as a *person* through the ‘lived body’.

An important idea that emerges from Leder’s (1992) study is that a particular perspective taken up by a researcher does not necessarily exclude other perspectives in certain contexts. Leder (1992, p. 31) claims that to “*attend to the lived body is not to forsake the tools and learning that Cartesian medicine has provided. It is merely to refuse to grant this mechanical wisdom the status of ruling paradigm.*” What seems to be required for Biomedicine to be revitalised is for its perspective to be subsumed within a broader framework. At this point in time, biomedical practitioners might employ appropriate medicines and interventions based on their understandings of their system of medicine; however, this does not negate the existential

preconditions of disease. (Leder, 1992, p. 29).

3.11 Health can be Something more Collective than Individual

The foci of TCM are somewhat different from those of Biomedicine. TCM therapy claims to address disturbances of the psyche in addition to dysfunction of the biological body. It also fully acknowledges many sociocultural determinants of health. Helman (1990, p. 92) has noted that “[i]n many non-industrialized societies health is conceived of as a balanced *relationship* between man and man, man and nature, and man and the supernatural world. A disturbance of any of these may manifest itself by physical or emotional symptoms”. A similar understanding can be found in the ancient Chinese philosophical model of Heaven, Earth and Man¹¹⁸ (Figure 3.3). In this model, Man (a symbol for humanity) is understood to be dependent on Earth (which includes the state of the environment) and the ideas and inspiration of ‘Heaven’.¹¹⁹

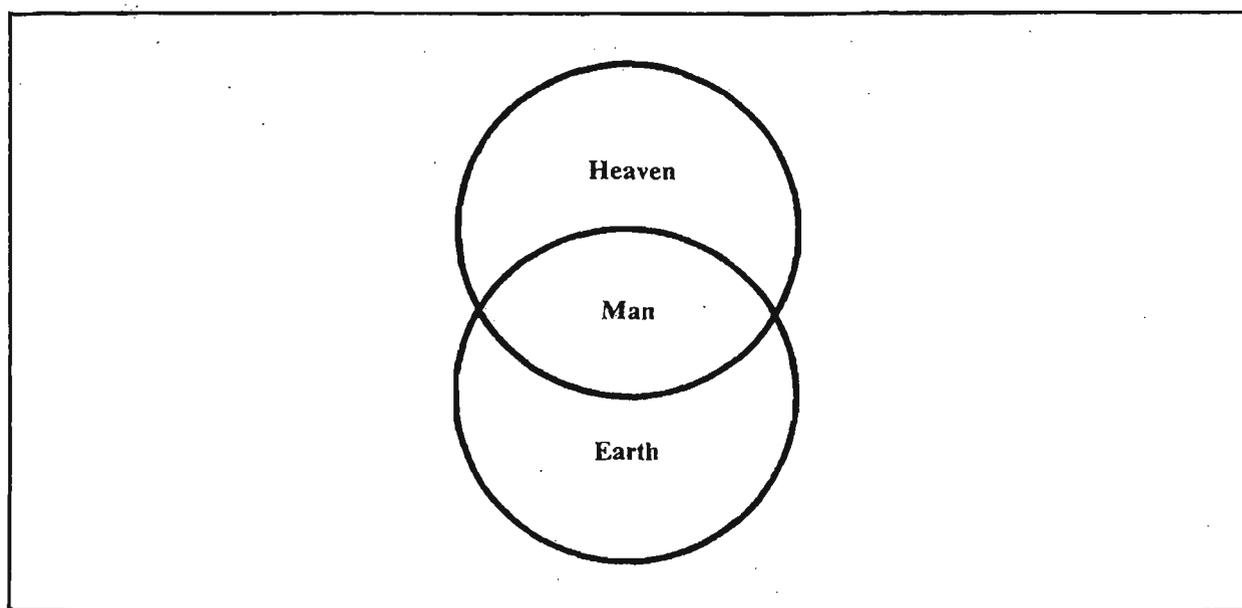


Figure 3.3 The Chinese concept of ‘Heaven, Earth and Man (Humanity)’

¹¹⁸ The original Chinese concept has been translated as ‘Heaven, Earth and Man’; however many contemporary authors now prefer to use the gender neutral phrase of ‘Heaven, Earth and Humanity’. Birch (1995, p. xiii) uses the term *person* rather than *Man* or *Humanity*. It should be noted that the term ‘Heaven’ is not used in the same way as in Judaeo-Christian religions. Beinfield and Korngold (1991, p. 406) state that ‘Heaven’ refers to “[t]he immaterial realm, belonging to *Yang*, including the sun, moon, sky, and atmosphere that surround us, as well as the invisible forces that influence us.”

¹¹⁹ Birch (1995, p. xiii) notes that the schema or image of ‘Heaven, Earth and Man (Humanity)’ is prevalent in many early Chinese philosophical, scientific and medical texts, including that classic of Chinese philosophy the *Yi Jing (I Ching)*.

Birch (1995, p. xiii) explains that in this model

Human existence (and in fact all forms of life) are the result of the interaction of heaven and earth, relative symbols referring to general cosmic organizing principles or forces. Inherent in this world view is the idea that one cannot really describe separate objects. Everything exists in a web of relations.

The idea that all phenomena exist in a web of relations is a central feature of TCM. In TCM there is what is called *shang-i* or *kao-i*, the upper or high medicine (Holbrook, 1981, preface p. 10). For the Chinese philosopher, there is the understanding that each specific practice or science in traditional Chinese culture is related to all others and is guided by the central tenet that it should promote human health and welfare. This perspective is suggestive of Stacey's (1977) concept of health as, "a functional prerequisite to the maintenance of the social system." (see section 3.3). Health in this context is something beyond the individual: it is something more collective than individual.

3.12 Holistic Models of Health Care

Scheid (1993, p. 26) claims that TCM philosophy has drawn support from the discourse of holism. Health care practitioners who claim to have a 'holistic' orientation often understand *health* as a process where one attempts to maintain optimum well-being or 'positive wellness'.¹²⁰ Positive wellness involves three conditions: (i) being free of pain and the signs and symptoms of disease as much as possible; (ii) being able to function and carry out tasks and act as desired; and (iii) being in good spirits for most of the time. This is in contrast to Biomedicine where health is often defined in terms of the absence of pathology, or the absence of signs and symptoms. Health, the goal of many 'holistic' health care practitioners, can be achieved, it is claimed, by living in harmony with oneself and the environment, and having a lifestyle which aims at reducing one's exposure to health risks (McCamy & Presley, 1975, p. 3; Edlin & Golanty, 1988, p. 3). This holistic definition of *health* could be seen as being broader than that of Biomedicine since it has both an individual and ecological context.

Rijke (1993, cited in Fulder, 1998, p. 153) has determined a number of characteristics of

¹²⁰ See L. Breslow, 1972.

'health' from surveys of 'healthy' people and those overcoming health problems. These include: (i) "[e]xperience of meaning and purpose in life"; (ii) "[i]ndividuality: the experience of being a unique part of a greater whole"; (iii) "[c]onsciousness of inner development"; (iv) autonomy; (v) creative expression; (vi) a will to live; (vii) quality relationships; (viii) body awareness; and (ix) vitality/energy. Fulder (1998) states that these "qualities reveal what in Jungian terms might be described as individuation - becoming a full person." In a similar vein, Dossey and Guzzetta (1989, p. 69) claim that 'wellness' can be understood as, "one's philosophy of living where there is awareness of purpose, meaning, and unique striving toward reaching human potentials." In such models, according to Edlin and Golanty (1988, p. 6), health is seen as an ongoing process and a way of life through which a person can develop and encourage every aspect of their body, mind and feelings to "interrelate harmoniously as much of the time as possible."

The World Health Organisation (WHO) as early as 1948 defined *health* as "a state of complete physical, mental, and social well-being, and not merely the absence of disease and infirmity" (World Health Organisation, 1948). This definition is in accord with the TCM view of health in so far as it recognises the interrelatedness of the physical, psychological, emotional, social and environmental domains that can contribute to the quality of a person's life, health and wellbeing. Many holistic health perspectives build on this definition of health. For example, in Daoism there is the belief that a person's spiritual outlook, feelings, thoughts and experiences can affect the person's state of health and well-being. Spiritual experiences, it is claimed, can engender feelings of contentment, compassion, tranquillity of mind, and harmony with one's environment: such experiences, according to Oriental philosophy, are important precursors of health.

It has also been suggested that the spiritual dimension of health can act "as a *unifying force*" that can integrate the other dimensions of health, that is, the physical, mental, emotional, and social. This spiritual dimension of health has been thought to be able able to create, or bring into focus a *meaning in life* (see Hafen, 1996, p. 380).¹²¹ This explains why TCA practitioners would wish to add the additional domain of the 'spiritual' (or *shen*) to the WHO

¹²¹ For an insightful exploration of the relation between spirituality and health, see B.Q. Hafen *et al.*, *Mind/Body Health: The effects of attitudes, emotions, and relationships*, 1996, chapter 17.

definition of health. The essential message of holistic health care philosophy is the recognition that health involves the unity of body, mind and spirit.

In TCM, there is the idea that there is no part of the mind, body or environment that is truly independent or separate: all are interrelated and constitute a whole. Cohen (1996, p. 9) states that:

Chinese medicine is a system of preserving health and curing disease that treats the mind/body/spirit as a whole. Its goal is to maintain or restore harmony and balance in all parts of the human being and also between the whole human being and the surrounding environment. ¹²²

Davis and George (1983, p. 370) claim that one factor that accounts for the demand for 'alternative' therapies (of which TCA is one) is that patients' psychological and spiritual needs are met by alternative health practitioners. In TCA therapy, the practitioner often attempts to gain an insight into the client's psychological, emotional and spiritual state through evaluation of the person's *shen*. Often TCA therapy involves some form of Oriental health counselling to address the psychological and spiritual concerns of clients (chapter 2).

There can also be found in TCM the idea that health and disease are two extremes of a continuum. Health and disease are not understood as discrete states. One cannot simply say that a person is either healthy *or* has disease; there are in fact many intermediate states on the continuum. Holistic models of health allow for degrees of health and illness that can accommodate the TCM idea of pre-pathological 'energetic' disharmonies existing within a person before 'physical' pathology manifests (Zhiya, 1995, pp. 296-298). TCA practitioners claim to be able to detect these pre-pathological 'energetic' disharmonies through their diagnostic system (*e.g.* pulse diagnosis).

Guzzetta (1989, 86) claims that "[t]he framework guiding client/patient care research is shifting from an illness model to a wellness model of health care." She states that, "[t]he wellness model views individuals holistically as biopsychosocial units who assume responsibility for

¹²² C. M. Cassidy (1998) has found that the patients of TCM practitioners often perceive TCM practitioners as addressing their spiritual needs, that is, Chinese medicine attempt to treat the "whole" person: body, mind and spirit.

their own health. It emphasises the enormous potential possessed by each individual to use the healing potential of his or her own bodymind.” This holistic understanding is congruent with TCM philosophy and practice.

3.12.1 *The tenets of holistic forms of medicine*

Wolpe (1990, p. 915) has defined holistic medicine as

a philosophy of practice that generally emphasises the primacy of the doctor-patient relationship, the importance of psychological, social, and spiritual factors in health and illness, the acceptability of nonconventional modalities of treatment, and the responsibility of the patient for participation in the health process.

Kopelman and Moskop (1981, cited in van der Steen & Thung, 1988, p. 196) outline five tenets which are characteristic of holistic forms of medicine: (i) health is defined positively in terms of well-being rather than in the usual negative way; (ii) individuals are encouraged to take responsibility for their own health and illness; (iii) health care providers have an important role in client education; (iv) holistic forms of medicine need to acknowledge environmental, behavioural and social causes of illness; and (v) well-being is to be promoted primarily with natural or non-invasive techniques and therapies. Against Kopelman and Moskop’s (1981) criteria, TCA can be said to meet most of the requirements of a holistic form of medicine.¹²³

No doubt medical practitioners can also practise in a holistic manner, however, Vincent and Furnham (1997, p. 23) suggest that “the daily pressures and the increasingly specialized and technical nature of modern medicine may conspire to prevent the doctor providing the kind of care that he or she would wish.”

3.13 Traditional Chinese Acupuncture Therapy: An example of holistic and humanistic health care

The TCM perspective can be likened to some Western schools of Humanism. For example, there is a similarity between the Oriental concept of spiritual enlightenment and the final stage of

¹²³ The only caveat is that TCA might be seen to be somewhat invasive by some people since acupuncture needles are inserted into the body.

Maslow's (1954) humanistic theory of human development which he termed 'self-actualization'. According to Maslow, self-actualization results from the desire to become everything that one is capable of and becoming what one truly is (Maslow, 1954, p. 92). Self-actualized people are said to experience subjective feelings that include euphoria, happiness, joy, calmness and serenity, in addition to having the ability to successfully deal with the stresses and problems that confront them (Maslow, 1968). This understanding has implications for a holistic model of health since the self-actualised person is believed to have exceeded the basic human requirements of 'belongingness' and 'ego' needs that are found at the lower level of Maslow's hierarchy of needs (see Figure 3.4). TCM and the humanist philosophy of Maslow (1968) would appear to be kindred paradigms in regard to the related concepts and understandings of change, transformation, self-actualisation and enlightenment. Humanism is also similar to the perspective of TCM in its recognition that there are aspects of person that go beyond the purely biological (see also chapter 5).

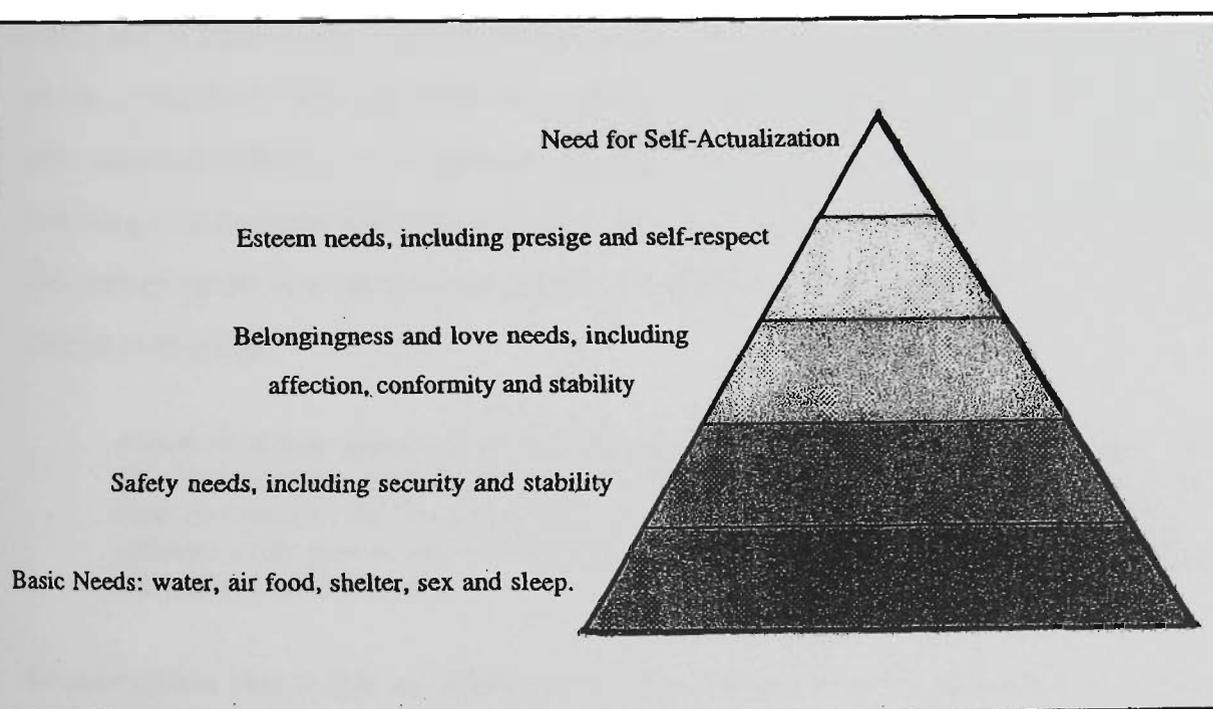


Figure 3.4 Abraham Maslow's Hierarchy of Needs
(Figure adapted from Edlin and Golanty, 1982, p. 229)

According to Fink (1976, p. 27), the concepts that are characteristic of the holistic health care

perspective include those of humanistic medicine, alternative health care, pre-primary care¹²⁴, and altered provider-patient relationships. Humanistic medicine is based, in part, on the ideas of humanistic psychology. Within this framework the client is seen as a *person* rather than as a body that has a disease. The aim of holistic systems of health care such as TCM is to attend to the needs of the *whole* person and not just the *disease*. In contrast, the emphasis or focus of many practitioners of Biomedicine is on *disease states* rather than the *person*. This is a consequence of a medicine that focuses on the processes of the biological body.

A humanistic health practitioner could practice any system of medicine; however, the focus in each case would be on the person who happens to be ill, rather than on specific disease states (Blattner, 1981, p.13). In this model, the role of the holistic health care professional is more than merely that of a technician who uses a particular type of medical intervention; rather, the focus of therapy is on the interaction that occurs between the health care practitioner and the client. The aim of the clinical encounter can be to facilitate change and transformation in the client, and in some cases to help the client to see the significance and meaning of health and illness in their life. TCA practitioners view illness as an inevitable part of life. Daoists do not view pain and suffering as intrinsically good in themselves; however, they could be perceived as having a meaningful role for a person if they force a person to stop, to reflect on their lives and perhaps grow in awareness as a result of their illness. Newman (1986, p. 18) in a related context claims that

events that may appear to be undesirable, such as disease or disability, are part of a much larger, meaningful process. By interacting with the event, no matter how destructive the force might seem to be, its energy augments our own and enhances our power in the situation. In order to see this, it is necessary to grasp the pattern of the whole.

An assumption here is that an individual has the potential to develop in consciousness, self-awareness, understanding and wisdom through the processes of illness, healing and transformation.

¹²⁴ The third concept of holistic health care put forth by D. Fink (1976) is 'pre-primary care'. This involves health problems being managed by the people who have them, without having to consult medical professionals. Examples include 'self help' groups, that are organised by those who are directly affected by a particular health problem. The participants of such groups help each other by the sharing of knowledge and experiences within the group. There are also numerous books of the 'How to have a healthier lifestyle' type which is another manifestation of the self-care dimension of holistic health care.

The reason that some TCA practitioners refer to the people they try to help as *clients* rather than *patients* stems from an altered health care provider relationship. The term 'patient' can connote a passive receiving of a therapy by a dependent person. The term 'client', in contrast, suggests a person who is essentially independent and capable of making judgments based on the advice given to them by their health care practitioner. The use of the term *client* by some TCA practitioners acknowledges the idea that a person is partly responsible for their own health through their decisions, actions, and lifestyle. Szasz and Hollender (1956) have termed this altered health care provider relationship, in which the health care practitioner helps the client to help him or herself, 'mutual participation'. This is the type of relationship that many TCA practitioners encourage and adopt. It is more of a collegial relationship in which the 'medical' knowledge of the health care practitioner is shared with the client.

3.14 Holons ('wholes' that are simultaneously 'parts')

Koestler (1975), in *The Ghost in the Machine*, examined the concept of 'hierarchic order', which can be related to 'systems theory' and the concepts of holism. Koestler's ideas provide the beginnings of a possible resolution to the debate between the value of 'holistic' health care and 'reductionist' biomedical perspectives.

Koestler (1975, pp. 45-47) begins his examination with a parable. The parable involves two watchmakers named Bios and Mekhos who build their watches in two different ways. This parable is used as a metaphor for the role of sub-systems within a 'whole', or larger system. Mekhos, one of the two watchmakers, assembles each watch one piece at a time, whereas Bios develops a superior method of first building sub-assemblies, each of which is held together as an independent unit which could then be fitted together to form a whole and complete watch. Without going into the finer details of the parable, it is suffice to say that the method of Bios is far more efficient in terms of assembly time when compared with that method used by Mekhos. Koestler uses this analogy to support his claim that complex systems will tend to evolve from simpler systems much more rapidly if there are stable intermediate forms.

Later in his exposition, Koestler likens the mechanical pieces of the watchmakers to amino

acids and organic molecules of biological systems, and then argues that ‘nature’ must have used a method like that of Bios so as to have been able to develop the array of complex life forms in the time calculated by biologists. Dalenoort (1986, p. 30), in his discussion of systems theory, adds something to this concept:

properties correspond to levels of stability, as introduced in relation to processes of self-organisation. The existence of a class of systems is based on that of levels of stability, and the properties of that class emerge from the interactions leading to stable configurations or processes.

Koestler (1975, pp. 47-48) claims that “*wherever there is life, it must be hierarchically organised*” and that “[t]he first universal characteristic of hierarchies is the relativity, and indeed ambiguity, of the terms ‘part’ and ‘whole’ when applied to any of the sub-assemblies.” Koestler has noted that there are problems associated with adopting a purely ‘holistic’ or a purely ‘atomistic/reductionist’ perspective. Each of the two perspectives has its respective strengths and weaknesses. To deny the merits of each of these two perspectives would not be in keeping with the Buddhist maxim of ‘taking the middle path’, and would amount to only looking at one side of the debate. Koestler (1975, p. 49) remarks that

[t]he Gestalt school has considerably enriched our knowledge of visual perception, and succeeded in softening up the rigid attitude of its opponents to some extent. But in spite of its lasting merits, ‘holism’ as a general attitude to psychology turned out to be as one-sided as atomism was, because both treated ‘whole’ and ‘part’ as absolutes, both failed to take account of the hierarchic scaffolding of intermediate structures of sub-wholes.

Koestler (1975) suggests that the ‘part-whole’ paradigm is deeply engrained in our psyche and in our unconscious habits of thought but that it is no longer useful since often phenomena do not lend themselves to these labels:

A part, as we generally use the word, means something fragmentary and incomplete, which by itself would have no legitimate existence. On the other hand, a ‘whole’ is considered as something complete in itself which needs no further explanation. But ‘wholes’ and ‘parts’ in the *absolute sense just do not exist anywhere*, either in the domain of living organisms or of social organisations.

Koestler (1975) puts forward the idea that a ‘subunit’ can act as a ‘whole’ *and* a ‘part’

simultaneously. In the following passage, Koestler (1975, p. 48) discusses the functions of these subunits, (or what he also termed sub-wholes) in a hierarchical system:

The members of a hierarchy, like the Roman god Janus, all have two faces looking in opposite directions: the face turned towards the subordinate levels is that of a self-contained whole; the face turned upward towards the apex, that of a dependent part. This '*Janus effect*' is a fundamental characteristic of sub-wholes in all types of hierarchies.

Koestler's Janus like entities can therefore be seen to be located on hierarchic trees which can behave partly as wholes and as parts, according to the way that one looks at them. This is reminiscent of how physicists describe the nature of light. Light can be thought of as particles or as waves, the conception dependent on what aspect of the light phenomenon is being observed and measured. To overcome the problem of 'part/whole' terminology, Koestler (1975, p.48) coined a new word, the 'holon'.¹²⁵ The term 'holon' can be defined as a 'subunit' that can act as *both* a 'whole' *and* as a 'part' *simultaneously*.

Koestler's notion that holons can behave as both 'wholes' and 'parts' has a strong Daoist flavour. From the Chinese philosophical perspective there is the recognition that phenomena of the world of experience have a certain 'greyness', that is, the borders that separate one phenomenon from another are usually 'fuzzy' and not clearly defined. In mathematics and logic discrete units and boundaries exist; this though is the exception rather than the rule.¹²⁶

Fay (1996, p. 241) claims in a related context that

[m]uch social thought consists of oppositional categories - self vs. other; particular vs. universal; subjectivity vs. objectivity' ... The same dualistic thinking mars metatheories in the philosophy of social science: atomism vs. holism; cause vs. meaning; interpretive social science vs. causal social science' ... Such thinking promotes an "either-or" mentality in which one category precludes its supposed opposite. But many categories are fluid and open. Often one side of a dichotomy depends on and invokes the other - in which case the dichotomy is subverted. Frequently an entity can be in both categories; or one category gradually slides over into its supposed opposite; binary alternatives rest on fallacious presuppositions which mistakenly restrict the range of possible choices.

¹²⁵ *Holon* comes from the Greek *holos* = whole, with the suffix *on*, as in *proton* to suggest a particle or part.

¹²⁶ See B. Kosko, *Fuzzy Thinking*, 1993.

TCA practitioner-researchers could be expected to support Fay's analysis that dualism needs to be avoided (see Table 3.2). Fay (1996, p. 241) claims that dualistic thinking can be avoided by thinking dialectically (see chapter 6).

Table 3.2 Dualisms to Avoid
(Based on Fay, 1996, pp. 223-224, with additions)

part	vs.	whole
atomism	vs.	holism
Western Culture	vs.	Oriental Culture
science	vs.	tradition
sameness	vs.	difference
agency	vs.	culture/society
autonomy	vs.	tradition
cause	vs.	meaning
objective	vs.	subjective
matter	vs.	energy
objectivism	vs.	relativism
quantitative	vs.	qualitative
particular	vs.	universal
body	vs.	mind
self-knowledge	vs.	knowledge of others
sensation	vs.	intuition
thinking	vs.	feeling

'Systems' theory when combined with the concept of the holon, allows the researcher to combine holistic thinking with the scientific analytical approach. Dysfunction within a 'systems' framework can then be defined as a loss of stability at one or more of the subunit levels (Dalenoot, 1986, p. 30). For example, dysfunction at the social level might result from a country's poor economy, while dysfunction of the individual could result from a psychological factor such as stress.

The previous discussion of the 'systems' perspective has implications for any analysis of health care models and research of them. As an example, a 'frozen' shoulder could be seen by a biomedical practitioner as only a local disturbance of the muscles in one localised part of the body. In contrast, from a 'systems' analysis, the 'causes' of the shoulder might be understood as being partly the result of heavy repetitive manual work that is an outcome of the way work in capitalist societies is structured and distributed. From the perspective of the biomedical model,

the treatment of a person with a 'frozen' shoulder would be at the biological level. The focus of the medical intervention would be to restore the function of the muscles and surrounding tissues. In contrast, from a 'systems' perspective, this analysis would be inadequate since one of the aetiological factors lies within the social subunit at a higher level of the systems hierarchy. To treat only at the biological level (the shoulder) would amount to treating only the 'symptom' and neglecting the 'cause', that is, the other aetiological factors originating in another system at the societal level.

A similar line of reasoning could be used to understand some psychological conditions. For example, depression could result in part from long term unemployment. In such a case psychological counselling at the individual level could help the person to adapt to their situation and regain self esteem; however, this may not be sufficient in the long term if one of the major factors is a deficiency of jobs which could be an outcome of social structures and environmental resources. In summary, from the perspective of 'systems theory' and TCM, illness and disease are understood as disorders of an 'open' system and not as a result of processes in a closed or isolated system.

3.15 Implications of the TCM Model of Health Care

The TCM model of health, illness and disease would appear to be more comprehensive than the biomedical model in the sense that it recognises and fully acknowledges an extensive range of psychological and social aetiological determinants (see also chapter 4). As a result, the TCM model has the potential to meet many of the expectations of the holistic health movement and could provide some philosophical insights for an improved and integrated model of health care.

One objective of both TCM and biomedical practitioners is to attempt to reduce illness and disease for their patients through various therapeutic interventions that are offered in the context of the clinical encounter. However, this chapter has shown that a key difference between the two medical approaches is the relative degree of control the practitioner and the patient have in the healing process during the clinical encounter. In biomedical practice, control is usually held by the practitioner. The reason for this, in part, is due to the philosophical assumptions of the

biomedical model - a model that at times views the human being as essentially a biological organism that can be restored to health by restoring physiological processes, or by replacing defective 'parts'. It is argued by proponents of Biomedicine that this can only be done by the practitioner who has specialist knowledge of anatomy, physiology and pathology, drug therapy or surgery. In Biomedicine, illness and disease is understood to be the result of essentially physical processes. This could account for some patients' perceived belief that there is a lack of care given to patients by some biomedical practitioners. From the perspective of Biomedicine, a good bedside manner is desirable, although it is not always seen to have an important effect on physiological disease processes. This view is partly an outcome of Biomedicine's focus on the science of medicine.

In contrast, the TCA practitioner usually allows the client to take greater control of all of the domains relevant to their health. This transfer of control to the client results from one of the roles of the TCA practitioner. The word 'doctor' is derived from the Latin word *docere* meaning 'teacher'. The TCA practitioner sees himself or herself as a 'doctor' in the literal sense of the word, that is, as an 'educator' in addition to being a technician of the body. This claim is only comprehensible if it can be demonstrated that people's choices and lifestyle can be contributing factors in the production of illness and disease. Theoretically and in practice, it is possible for people to correct some disease processes themselves by a change in psychological state or lifestyle. The point to note here is that by fully acknowledging psychological, environmental, and lifestyle illness and disease determinants, the responsibility of health restoration and a degree of control can be placed back into the hands of the patient.

TCM posits that the origin and cure of many health problems lies with the decisions made by both individuals and society, and not only with the interventions of the health care practitioner, who often targets only physiological processes of the biological body. Ideally, from the perspective of holistic medicine, a system of client self-healing through education would be preferable to the situation where the passive patient is completely dependent on a health care practitioner for the cure of their illness or disease. However, only an idealist could believe that this is possible when one considers the amount of medical knowledge that individuals would have to internalise to be able to treat the numerous health problems that one could encounter

during a lifetime (Lyng, 1990, p. 60). It is simply not possible for every member of society to acquire large amounts of medical knowledge, and, as a result, the existing health care practitioner/client relationship seems both necessary and inevitable in future health care systems. Therefore, from a holistic TCM perspective, perhaps a more realistic goal is that of self-care or self-healing, where clients are given as much information concerning their health concerns as possible by their health care practitioners. With this information, clients then have the freedom and power to make an informed decision as to which type of therapy or course of action they wish to take to reestablish health if that is possible. It must also be acknowledged that what is regarded as 'relevant' medical information and therapy options to be provided to clients would be dependent upon the practitioner's own philosophical and theoretical understandings of what constitutes health and disease and valid therapy.

3.16 Summary

In this chapter, TCM and its associated conceptions of health, illness and disease have been compared and contrasted with Biomedicine. It has been argued that a central feature of any system of medicine is its conception of what a human being is. It is clear that the 'nature' and constitution of the human being is understood differently in the biomedical and TCM models of health care. While both biomedical practitioners and TCA practitioners attempt to ameliorate health problems at the level of the individual, TCM tends to place a greater emphasis on psychological, social and spiritual determinants of health and disease as compared with Biomedicine. This is an outcome of TCM's 'holistic' orientation with its central tenet that phenomena at all levels are interdependent and constitute a single whole. These differences in medical models can have profound ramifications for how health care practitioners interact with their patients during the therapeutic encounter and how health care research is to be conducted and evaluated.

CHAPTER 4

AETIOLOGICAL MODELS OF HEALTH, ILLNESS AND DISEASE

“The medical profession have concentrated on the biological aspects of disease, whereas we now increasingly realise the importance of the psychological and social aspects.”

- Dalenoort (1986, p. 31)

All societies have developed aetiological models to explain the presence of illness and disease (Foster, 1986). In the first part of this chapter, the ‘causes’ of illness and disease are examined from the perspective of TCM and the implications for TCA research are explored. The concepts of causality and determinism¹²⁷ are also considered in relation to TCA research. Much contemporary biomedical research has relied upon the randomised controlled trial (RCT), which assumes a determinist understanding of cause and effect. In contrast, it has been argued in the previous chapter that the TCM model of health, illness and disease is more holistic and maintains a ‘systems’ orientation that does not assume the same linear causal links. These differences need to be considered when designing TCA studies. In addition, the roles that psychological and sociocultural factors play in the processes of illness and healing in the system of TCM and the implications of these for TCA research will be examined.

¹²⁷ G. Vesey and P. Foulkes (1990, p. 84) state that *determinism* is the “view that events, including people’s actions, do not occur by chance, but are caused to occur, usually with the implication that they could not be otherwise than they are. ...The implication is absent in the case of self-determinism (meaning that an agent is the cause of his own actions) since he could have decided to act otherwise than he did.”

4.1 Oriental and Western Understandings of the Causes of Illness and Disease

A major distinction between TCM and Biomedicine are the different understandings of the processes of illness, disease and healing. Often biomedical practice endeavours to neutralise, overcome or control disease, whereas practitioners of TCM generally attempt to maintain and restore health by strengthening the body's natural healing processes and adaptive powers by influencing *qi*. As Zhiya (1995, p. 296) explains:

Diseases involve both pathogenic and antipathogenic *qi*. The former constitutes an important condition for the occurrence of diseases, whereas the insufficiency of the latter provides the internal factor for it. Pathogenic factors become operative through the internal factor. Thus, giving treatment prior to the occurrence of diseases must proceed two aspects: building up the health and strengthening its resistance to diseases; and distancing oneself from pathogenic factors.

Tu Wei-Ming (1992, p. 91) notes that Chinese medical texts constantly refer to what is termed the *yuan qi* ('original vital energy') of individuals, which is the life source that maintains and sustains wellness.

From the TCM perspective, 'diseases' are not recognised in the same way as they are in Biomedicine. For example, before a Western medical practitioner attempts to treat a person who is ill, the practitioner usually endeavours to first determine a *specific* diagnosis for a defined disease or pathology. To fully understand this point, consider as an example the autoimmune deficiency syndrome (AIDS). Biomedical practitioners did not attempt to treat this syndrome until it had first been identified and named. The attempt to find a cure from the biomedical perspective did not begin until there was some understanding of the 'cause' of the syndrome in terms of pathophysiology. In contrast, a TCM practitioner might attempt to treat or manage such a syndrome (assuming it was legal to do so) by understanding the 'pattern of disharmony' through an examination of the signs and symptoms of the AIDS syndrome in terms of TCM theory. For the practitioner of TCA, it would be possible to begin TCA therapy with a person with 'AIDS' without first having to understand it in biomedical (*i.e.*

physiological) terms.¹²⁸ This is only possible because the TCM model does not require the identification of *all* aetiological determinants of a particular illness or disease *before* treatment begins. TCM assumes that the ‘causes’ of illness and disease are multidimensional and that in many cases all of the aetiological determinants will never be known. This is not necessarily a limiting factor for the TCA practitioner, since treatment requires only the identification of a TCM ‘pattern of disharmony’ and not necessarily all of the ‘causes’ of the disorder.

It should also be noted, that from the perspective of TCM, there is sometimes no clear boundary between a ‘cause’ and the TCM ‘pattern of disharmony’ itself (Kaptchuk, 1983, p. 116). For example, the TCM sign of ‘dampness’ can be both a ‘cause’ of a condition and an aspect of a TCM ‘pattern of disharmony’. Kaptchuk (1983, p.116) states that in Chinese pattern-thinking, “what might at first seem to be a cause becomes part of a pattern, indistinguishable and inseparable from the effect. Pattern-thinking subsumes the cause, defining it in terms of the effect and making it part of the total pattern.”

4.2 Disease Entities

A disease entity in Biomedicine is often seen as existing independently of the person. As Laura and Heaney (1990, p. 109) note, “by conceptualising disease as a micro-organism, or germ external to the body which somehow gets into it, we implicitly relinquish responsibility for the infirmity with which we are afflicted.” This quotation encapsulates one important distinction between Biomedicine and holistic systems of medicine such as TCM. In Biomedicine, disease is often understood as originating outside of the person, whereas from the TCM perspective, disease is understood to be the result of the individual not being able to successfully adapt to changes in their inner and outer environments. The prevailing metaphor of Biomedicine is that of the doctor as soldier, who sees disease as a physical and alien object that has to be removed

¹²⁸ J. Resnick (1990, p. 10) notes that, “[t]he great strength and beauty of Chinese diagnosis is its openness to what is happening in the present without recourse necessarily to other people’s past (as in Western medicine). Theoretically and practically we need only begin with what we find before us as it unfolds. If the past is significant it will become present to us.”

with force (Spiro, 1986, p. 64).¹²⁹ As an example of this biomedical understanding, consider the following scenario: two members of a family develop the signs and symptoms of a 'sore throat' at the same time. A biomedical practitioner, after examining the two family members, might conclude that the two family members had the *same* disease and that one member of the family had passed it on to the other. From the biomedical perspective, this conclusion would seem reasonable since the disease could be understood to be caused by one type of microorganism. It follows that the disease entity in both family members is seen to be essentially the *same* and independent of the person. A consequence of this line of reasoning is that the treatment will remain constant across circumstances: that is, drug 'x' (the appropriate antibiotic or pharmaceutical drug) will always be given for disease 'x' regardless of other factors. This approach focuses on the biological level of the person, a focus that might undervalue the patient's perception of their loss of wellbeing.

A consequence of the biomedical approach to treatment, from the patient's perspective, is that it can be felt as being impersonal and lacking care. The biomedical practitioner may be perceived as not treating the person as a whole but rather focussing on the treatment of a localised disease entity. In contrast, TCA practitioners when addressing the same scenario would usually attempt to consider other factors including the patient's psychological and emotional state. From the perspective of TCA, some syndromes can be treated by first identifying a 'pattern of disharmony' and then correcting the imbalance through appropriate TCA therapy. While in TCA practice various combinations of acupuncture points are used in the treatment of different 'patterns of disharmony', many diverse syndromes and diseases can be treated in essentially the same way - by stimulating the person's adaptive and healing powers (*via the qi*) to restore internal balance. Crowley (1973, p. 39) has noted in a related context that

[I]luckily for all of us, most of the acts essential to continued life are involuntary; the 'unconscious' has become so used to doing its 'True Will' that there is no need of interference; when such need arises, we call it disease, and seek to restore the machine to free spontaneous fulfilment of its function.

It should be noted that when a TCA practitioner attempts to treat a syndrome or disease, the

¹²⁹ This metaphor can be also found in TCM (*e.g.* dispelling *xie qi*); however, it is not the dominant metaphor. For *xie qi* (pathogenic *qi*) to be present in the human being there must be first a deficiency in the person's *zheng qi* (antipathogenic *qi*).

treatment prescription will not be the same in all cases. Different TCM 'patterns of disharmony' will require different acupuncture point combinations as a result of the individual's unique presentation of signs and symptoms. This is an example of the TCM dictum of *tong bing yi zhi*, meaning 'different treatment for the same disease'. It should be noted there is not a one-to-one correspondence between biomedical diseases and TCM 'patterns of disharmony'. For example, 'arthritis', a biomedical syndrome, cannot be equated with a *single* TCM 'pattern of disharmony' (see also chapter 10.8).

Whilst TCA therapy is tailored to the needs of the individual, the general aim will be the same in all cases, that is, to maintain, or restore, health by strengthening the body's own natural healing processes and rebalancing the equilibrium of the person at all levels. For this reason, TCA practitioners do not have to name a disease to be able to treat it since any manifestation of signs and symptoms is treated in the same way - by encouraging the body's natural healing processes to reestablish internal homeostasis. The goal of TCA therapy is therefore to help the client restore balance to all levels of their being and to help them to better adapt to their current situation and environment.

4.3 The Concepts of Determinism and Causality in Health Care Research

One of the aims of biomedical research has been to establish the efficacy of various pharmaceutical drug treatments for specific diseases. In such medical research there is often the prerequisite that the researcher identify the cause or causes of the specific human disease. It is generally believed that if the cause of disease is known, the clinician is then in a position to begin to formulate and justify their diagnosis, treatment plan and therapeutic intervention. Proponents of Biomedicine often attempt to justify their medical interventions by demonstrating through controlled clinical trials that it is the *specific* medical intervention being evaluated that has 'caused' any beneficial changes in subjects (patients) rather than some other factor.

The determination of whether a particular medical intervention is efficacious for a particular medical disorder assumes a causal relationship between the therapy and the medical condition that is treated. It is evident that in biomedical research that utilises the RCT that researchers are

endeavouring to establish lawful relationships between ‘causes’ and their ‘effects’. There are two aspects to consider here. First, there is the assumption that specific diseases have specific causes. Secondly, there is the assumption that medical interventions can reestablish health by changing, or correcting, disease processes in human beings. Causality is not established by merely demonstrating that a relationship exists between a medical intervention (the cause) and a change in health status (the effect). Such an observation only indicates that there is a correlation between them and does not guarantee that one has caused the other (see chapter 8.10.1). Experimental research designs such as the RCT are an attempt to detect causal relationships between specific medical interventions and patterns of signs and symptoms in research subjects. In this type of research, the researcher attempts to monitor the outcome of a medical intervention by the controlled and active manipulation of variables (see chapter 8.10.2).

Positivist notions of causality can be traced back to Aristotle (Slife & Williams, 1995). In modern times, the notions of determinism and causality feature prominently in the philosophy and theory of David Hume (Vesey & Foulkes, 1990). The doctrine of *determinism* claims that, “events, including people’s ACTIONS [Vesey & Foulkes’ capitalisation], do not occur by chance, but are caused to occur, usually with the implication that they could not be otherwise than they are.” This is in contrast with *indeterminism*, or *self-determinism* where people are thought to be the cause of their own actions, such that they could have *decided* to act otherwise than they did. (Vesey & Foulkes, 1990, p. 84). According to Hume’s doctrine, “the only empirical content of a causal law is the set of actual concomitances of events that have been and will be observed” (Harré, 1981). Harré (1981, p. 14) explains that

[a]n event is identified as a cause by its temporal priority to a later event and by the statistical fact that events of that type regularly precede events of the type identified as effects. ... Neither the activity and productive power of the agent, nor reference to the workings of a generative mechanism are admitted as part of the meaning of a causal law. To say that something caused something else, is only to say that an event of a certain sort regularly precedes an event of the kind to be explained.

Heron (1981) claims that most conventional research takes absolute determinism as its general model of explanation. This, he argues, cannot be correct since research behaviour is an original and creative activity which cannot in principle be contained within an explanatory model of absolute determinism. Heron (1981, p.21) claims that

[t]o say that the researcher is an intelligent agent is to say that his behaviour is not fully subsumable under the causal laws of the natural order. There are two fundamental statements here: (1) there is a causal law in nature; (2) there are creative acts of self directing agents occurring in nature. But if the second statement cannot be included within, or reduced to, the first, how then can they be reconciled and made consistent while retaining their relative independence? One answer is provided by the thesis of relative determinism... .

Heron's model of relative determinism contends that

antecedent conditions delimit and determine a range of possible outcomes, and ... the width of this range is a function of the position of an entity in the hierarchy of chemical and biological types from the atom to the human being: the human being, if not seriously damaged, has a significant degree of freedom and can bring intelligent, rational principles to bear on the direction of his or her activity within nature (Heron, 1981, p. 21).

This suggests that the outcomes of events that involve human beings may not always be able to be predicted with certainty. It is the view of some members of the TCA profession that the beliefs and wills of both the TCA practitioner and their patient can influence the outcome of any TCA therapeutic intervention.

4.3.1 *In TCM it is not always possible to identify the 'causes' of illness and disease*

It could be argued that the practice of TCM emphasises the perception of 'patterns of disharmony' rather than the identification of causal factors of illness and disease. According to Ted Kaptchuk (1983, p.15), the Chinese philosophy of Daoism lacks the idea of a creator, and focuses on the the web of phenomena and not its weaver:

For the Chinese, that web has no weaver, no creator; in the West the final concern is always the creator or cause and the phenomenon is merely its reflection. The Western mind seeks to discover and encounter what is beyond, behind, or the cause of phenomena. In the Chinese view, the truth of things is immanent; in the Western, truth is transcendent. Knowledge, within the Chinese framework, consists in the accurate perception of the inner movement of the web of phenomena. The desire for knowledge is the desire to understand the interrelationships or patterns within the web, and to become attuned to the unseen dynamic.

This idea is in contrast with Western notions of medical knowledge where the emphasis is on trying to understand the cause and mechanism of disease. The aim of Western biomedical diagnosis is usually to determine the specific causative agent of a particular disease state, with

the aim of subsequent treatment to isolate, change, or eliminate *the* 'cause' of the disease.

A disease, as defined by Biomedicine, might affect many parts of a human body and yet clinically it is often treated as a self-contained phenomenon. Kaptchuk (1983, p. 4) remarks that the Western physician uses an analytic logic to determine a diagnosis and treatment protocol by "cutting through the accumulation of bodily phenomena like a surgeon's scalpel to isolate one single entity or cause." Kaptchuk admits that this is a simplification of the situation; however, it is certainly true that some signs and symptoms of the client are disregarded when formulating a diagnosis because the disease is seen as a relatively self-contained phenomenon, which, in most cases does not affect the *whole* organism.

Dubos (1979, p. 28 quoted in Laura and Heaney, 1990, p.110) points out that even in Biomedicine, client presentations of signs and symptoms cannot be easily classified as the result of specific micro-organisms or biological entities:

What the patient experiences and what the physician observes constitute generally a confusing variety of symptoms and lesions rather than a well defined entity. In most cases, a syndrome such as anaemia, cardiac insufficiency, gastric disturbance, and depression is more in evidence than the unique pathological manifestations of a specific aetiological agent. Furthermore, each noxious agent can express itself by a great variety of pathological states.

TCA practitioners, reasoning in a holistic manner, consider the client's sociocultural environment in addition to their physical signs and psychological symptoms before trying to understand their illness or disease. Kaptchuk (1983) claims that client information can be woven together by the TCM practitioner until it forms what TCM terms a 'pattern of disharmony'. This pattern of disharmony describes the situation of 'imbalance' in the client. Kaptchuk states that for the TCM physician

[t]he question of cause and effect is always secondary to the overall pattern. One does not ask, 'What X is causing Y?' but rather, 'What is the relationship between X and Y?' The Chinese practitioner therefore, is more interested in discerning the relationships among bodily events occurring at the same time. The logic of Chinese medicine is organismic or synthetic, attempting to organise symptoms and signs into understandable configurations ...The therapy then attempts to bring the configuration into balance, to restore harmony to the individual (Kaptchuk, 1983, p. 4).

From a TCM perspective, a person who is well will be in harmony with themselves and with

their environment. Such a person will not experience any distressing signs and symptoms; whereas a person who is ill will experience various signs and symptoms which will be reflective of the imbalances in their life as well as their body (Kaptchuk, 1983, p. 7).

TCM can be understood as being holistic in the sense that no single sign or symptom can be understood except in its relation to the whole person. Within the TCM framework it is seldom possible to trace the 'cause' of a 'pattern of disharmony' to a single aetiological factor because of the constant interaction of a multitude of interrelated aetiological factors originating from the various spheres or subsystems (*i.e.* the environmental, psychological, biological, social and spiritual) in which the individual is embedded.

4.4 Aetiological Models Used to Explain the Presence of Illness and Disease

Foster (1986, p. 49) claims that all societies have developed aetiological models to explain the presence of illness and disease in human beings. These aetiological models can be classified broadly into two types: (i) supernatural/magical and (ii) naturalistic/systemic.

4.4.1 Supernatural/magical aetiological models

In supernatural/magical aetiological models, illness and disease are explained as the acts of angry deities, ancestral spirits, ghosts, or malevolent enemies who might be witches or sorcerers. Foster (1986, pp. 49-50) claims that supernatural/magical aetiological models can be called 'personalistic' since the illness is believed, by the person who is ill, to be caused by the deliberate and purposeful intervention of an external agent in the form of a supernatural entity. If one looks at the long history of TCM, one can indeed find periods of time when sections of Chinese society believed that illness resulted from supernatural entities such as demons (Unschuld, 1998, p. 9).¹³⁰ Unschuld (1985, p. 7) claims that there have been various periods in China where illness and disease have been believed to be caused through the intervention of supernatural phenomena such as spirits, demons, god(s), ancestors and 'Transcendental Law'.

¹³⁰ According to P. Unschuld (1985, p. 37), it has been well documented in Chinese historical literature of the Chou period and the Ch'in and Han dynasties that there was the belief that demons could cause illness.

In contemporary university TCA programs in Australia, supernatural and magical phenomena are usually only discussed as historical illness concepts of TCM. Causation is generally explained through the influence of 'natural' phenomena through a naturalistic model. For example, Ferrigno (1997, p. 47) in his examination of TCM, suggests that *possession* "is now more a metaphor describing the manifestation of *qi* as an 'evil energy' circulating through the body's functional systems and conduits rather than referring to an actual presence of spiritual beings."

4.4.2 *Naturalistic/systemic aetiological models*

Foster (1986) claims that in naturalistic aetiological models there is not the need to postulate that illness results from supernatural intervention; rather, illness and disease are believed to occur "as the consequence of natural or predictable events". Foster (1986, p. 50) makes the point that naturalistic aetiological models conform to an 'equilibrium' model of health and disease, where illness and disease result from an imbalance of 'elements', humours, or energies within a person. Such models have existed, and continue to exist, in many parts of the world. Examples of such models include the Greek Hippocratic, Indian Ayurvedic, and the traditional Chinese medical systems. Hippocratic medicine for example, understood health in terms of a balance of the four humoral factors. The 'four humour theory' was abandoned by Biomedicine and taken up later by practitioners of homeopathy: a system of medicine based on the healing laws of Hahnemann.¹³¹ In TCM, health is also understood to be dependent on a balance of energies: that is, a dynamic balance of *yin* and *yang*.

4.5 **Aetiological Factors Involved in Health and Disease According to TCM**

In TCM, human illness and disease are believed to manifest (or, in deterministic language, to be 'caused') as a result of 'natural' processes and phenomena. These aetiological determinants include the following:

¹³¹ Hahnemann's healing laws are outlined in his *Organon* which was published in 1810.

4.5.1 *Imbalances of yin/yang*

Imbalances of *yin/yang* can manifest as an excess, deficiency or a stagnation of the 'fundamental substances' (*qi*, *xue* [blood], *jing*, *jin-ye* [fluids], and *shen*) of TCM theory which can result in various patterns of signs and symptoms.¹³²

4.5.2 *Disturbances of shen*

In Chinese medicine, illness can result from a disturbance of a person's *shen*. *Shen* is regarded as a *yang* 'substance' that is unique to human life (Kaptchuk, 1983, pp. 45-46). *Shen* has sometimes been translated as *spirit* (Larre & de la Vallee, 1991) and mind (Maciocia, 1989, p.41; 1993); however, scholars generally agree that the term is not captured adequately by any one English word. Kaptchuk (1983, pp. 45-46), in his examination of the concept of *shen*, states that

human consciousness indicates the presence of *Shen*. *Shen* is associated with the force of human personality, the ability to think, discriminate, and choose appropriately. ... In the healthy person, *Shen* is the capacity of the mind to form ideas and is the desire of the personality to live life. When *Shen* loses its harmony, the individual's eyes may lack lustre and his or her thinking may be muddled. A person so affected may be slow and forgetful, or perhaps suffer from insomnia. Certain *Shen* disharmonies are marked by unreasonable responses to the environment, such as incoherent speech.

Shen is understood to have a 'material' aspect (Kaptchuk, 1983, p. 45), which is one further example of how Descartes' dichotomy of mind-body is not relevant to Chinese thought. According to TCM practitioners, a disturbance of *shen* can result in a multitude of diseases, manifesting in 'patterns of disharmony' with both psychological/emotional symptoms *and* 'physical' signs (see Maciocia, 1989).

¹³² See Maciocia, 1989 or Zhiya, 1995 for detailed accounts of these imbalances.

4.5.3 *The quality of a person's zheng qi ('right' or antipathogenic qi) and resistance to pathogenic qi*

In TCM, the quality of a person's *zheng qi* ('right' or antipathogenic *qi*) can determine one's predisposition to aetiological factors. TCM practitioners believe that no single 'pathogenic' factor is usually sufficient in itself to cause disease. There must be first a deficiency in the person's *zheng qi*. If the *zheng qi* of a person is weak or deficient then it is believed that the person will be more susceptible to *xie qi* ('pathogenic' factors) (Maciocia, 1989; Zhiya, 1995).¹³³

4.5.4 *The bu nei wai yin*

There are other factors, termed the *bu nei wai yin*, that are regarded by TCM practitioners as being neither 'internal' nor 'external' and which can be involved in the loss of health and the manifestation of illness and disease. These include lifestyle, the amount of physical activity one partakes of, the amount of sexual activity, diet, the quality and quantity of *jing* (constitutional *qi*), and other miscellaneous factors including parasites, trauma, burns, bites, and incorrect treatment. (Cheng, 1987; Maciocia, 1989; Zhiya, 1995).

4.6 Sociocultural Factors of Health and Disease

Foster (1986, p. 50) notes that in societies with 'personalistic' aetiological models, the explanatory role is more comprehensive in the sense that it attempts to explain *all* misfortune, whether it be personal relationships, economic ruin, or loss from 'natural' disasters such as floods and earthquakes. In contrast, 'naturalistic' aetiological models are generally restricted to illness and disease at the level of the individual. This point is significant, since it prescribes the

¹³³ According to Maciocia (1989, pp.132-134), the *xie qi* include: (i) the external external causes of disease (*wai yin*): 'wind' (*feng*), 'cold' (*han*), summer-heat (*shu*), 'dampness' (*shi*), 'heat' (*huo*), 'dryness' (*zao*) and 'fire' (*huo*). In the TCM model there is the recognition that environmental climatic factors can be involved in producing 'patterns of disharmony', illness and disease; (ii) The internal pathogenic factors (*nei yin*) including the 'seven emotions' (*qi qing*) of joy, worry, pensiveness, sadness, anger, fear and fright. In TCM, there is the recognition that psychological states and the emotions can be aetiological factors in the manifestation of 'patterns of disharmony', illness and disease.

role of the therapist and the patient in that society. In societies with personalistic aetiological models, patients are more likely to ask questions such as, 'Why has this illness and misfortune happened to me?' or, 'Who has caused this illness and misfortune?' As a consequence the therapist would be expected to be an 'all-purpose source of help' rather than purely a medical specialist. In contrast, in societies with naturalistic aetiological models of health and illness, patients tend to ask questions such as, 'What can I do to become well?' Such questions would suggest that some individuals do believe that they themselves can be at least partly responsible for their condition, and that they can contribute in some way to regaining their health. The believed cause(s) of illness and disease can therefore have a bearing on the expected roles of both the therapist and the patient.

Hahn (1985, pp.167-169) has claimed that the biomedical paradigm cannot account for many sociocultural factors involved in the processes of both illness and healing. Hahn argues that health and illness are defined by society. This is done by members of a society informing each other as to the name, effect, the believed cause, and the appropriate responses to each of the various disorders and diseases. Hahn (1985, p. 169) makes the claim that medical realities are partly constructed by society:

Medical realities are not social fictions, as some social observers have argued (Sedwick, 1981). But neither are they simply facts of nature, as the ideology of Biomedicine assumes. Pathology and its relief accord with the interests and values of sufferers (Hahn, 1984); they are at once physiological and cultural (and psychological, biochemical, etc.) in origin, course, and consequence. Medical realities are constructed from nature by cultural plan.

Hahn (1985, p.169) explains that one way sociocultural events can affect health and disease is through what he calls *mediation*:

The concepts, ideas, and values of an ethnomedicine and its broader culture, along with a society's rules of social interaction, guide the acts of societal members, distributing them in time, space, and activity. There is thus an economy of activity in which persons as well as impersonal things are literally moved around. By such socioculturally guided movement, societal members may be brought into greater or lesser contact with both pathogenic and therapeutic sources; thus disease may be fostered or prevented, and cured (or palliated) or not. Mediation may be regarded as a form of transportation of persons, pathogens, and therapeutic agents.

Both public health officials and occupational health officials have long recognised that the organisation of society can either prevent or cause disease by providing or withholding various health services. Therefore, the production of illness has a social element and is not merely the result of individual choice. This understanding is in accord with sociological models of health and illness and explains the process by which human biological functions are influenced by cultural and social aetiological factors operating in different systems within a hierarchy of systems.

4.6.1 *The role of beliefs in the production of health, illness and disease*

Many proponents of ethnomedicines claim that *beliefs* can act as both pathogens and medicines. This position takes a view of pathogenesis and therapy that is very different from that of Biomedicine, which is based on different philosophical premises. Hahn (1985, p. 170) contends that

[b]eliefs are not simply propositional attitudes about the world; as humans maintain and profess them, they are a part of, and inseparable from, human physiology. Conversely, the human body is not only a natural entity; it is at the same time a mindful entity (in conscious, functioning persons), socially and culturally imbued.

If this is true, it has important ramifications for Western understandings of aetiological factors involved in the production of illness and disease. Hahn is suggesting the possibility that psychosocial factors can directly affect human physiological processes. This view is congruent with the understandings of TCM (chapters 2 & 3). Such a position, however, would appear to be in conflict with the idea of simple linear causality as it is often expressed in biomedical literature, where physical entities such as micro-organisms are believed to cause disease independently of other factors.

4.6.2 *Research that supports a sociocultural model of health and disease.*

Hahn (1985) has reviewed many sociocultural factors involved in the production of illness, disease and health. It is clear from this review that there exists an immense body of research that supports the idea that social influences, including social networks, the family, workplaces,

national and international relations and social class, can affect the health status of a person at the individual level.¹³⁴ Berkman (1981, pp. 63-64) has suggested that there are a number of possible pathways leading from the social environment to physical disease:

(1) behavioural processes whereby people living in certain social and cultural circumstances maintain health practices which are either beneficial (e.g. physical activity) or harmful (e.g. cigarette smoking) to their health; (2) psychological processes whereby people respond to circumstances by becoming depressed or changing their coping and appraisal processes; (3) direct physiological changes in both known risk factors (e.g. blood pressure, serum cholesterol) and unidentified processes which are directly altered by exposure to certain environmental circumstances.

Berkman (1981, p. 64) has claimed that psychological factors such as depression and coping processes seemed to be “likely candidates as mediators between environmental conditions and illness responses.” Kiecolt-Glaser and Glaser (1995) also claim that there is evidence linking psychosocially mediated immunological alterations with infectious illness, cancer and HIV progression. Kiecolt-Glaser and Glaser (1995, p. 269) state that the research literature indicates that “the impact of chronic stressors and psychosocial factors on sympathetic nervous system and endocrine function influences the immune system, thereby providing shared mechanisms that may impact on disease susceptibility and progression across a broad spectrum of disorders.”

4.7 Psychological Determinants in Health and Disease

It has been previously suggested that Biomedicine has had a tendency to play down play the importance of psychological determinants involved in health and disease, just it has done with sociocultural factors. This position is in keeping with Biomedicine’s primary focus at the level of the biological body. Some TCA practitioners believe the biomedical model of health and disease to be somewhat inadequate because it cannot satisfactorily account for what are termed psychosomatic diseases. Psychosomatic diseases are a class of disorders which usually involve both the ‘mind’ and the ‘body’ and which appear to have an aetiological factor that is psychological in nature. Pelletier (1977, p. 7), cites several examples of illnesses that are classified as being psychosomatic: these include asthma, essential hypertension, arthritis, and

¹³⁴ See also B.Q. Hafen, 1996.

peptic ulcer.¹³⁵ Gannon (1981) suggests that psychosomatic disorders have two common features: (i) psychological factors are implicated in their origin; and (ii) there is no explanation or understanding of their aetiology in biomedical terms.

The claim that is often made by TCM practitioners is that the biomedical model does not really include mental states in its theories of aetiology. The study of the mind and its pathology is regarded as a separate medical speciality known as psychiatry (chapter 3). According to Hahn (1985, p.187)

mental and social phenomena are troublesome to the theory and practice of medicine [biomedicine], for they threaten either causative interference from a different realm and/ or the engagement of phenomena not well understood. Mental and sociocultural phenomena are most often regarded as peripheral, if not obstructive to the core of medical work - that is, the maintenance or restoration of physiological integrity.

Many TCA practitioners hold the view that holistic health care approaches are now needed that treat the totality of the person (body, mind and spirit) and which fully acknowledge the psychological and social factors involved in the development of illness and disease.

Some proponents of Biomedicine have defended their system of medicine with a *materialist* account of psychosomatic disease. Materialists are people who believe in “the existence of material things over and above the sensory IDEAS [Vesey & Foulkes’ capitalisation] we have of them” (Vesey and Foulkes, 1990, p. 182). Materialists argue that psychological processes, even if they do contribute to disease, can be accounted for by claiming that every psychological event is identical to some physical event that occurs in the brain. It follows from this line of reasoning that psychological causation will be consistent with physiological causation since they will be *identical* in nature. This philosophical doctrine is sometimes referred to as *central state materialism* (Audi, 1995 p. 600).

Clark (1985, p. 91) remarks that, for the materialist, “psychological terms are not labels for a different kind of stuff; they are different kinds of terms for describing the same stuff. To call a term ‘psychological’ is to make a comment about our vocabulary, not about the things that

¹³⁵ Recent evidence has suggested that ulcers and some other conditions are caused in part by bacteria. As an example see D. J. Kelly, 1998.

vocabulary describes.” By taking such a position, the materialist will always be able to account for changes in psychological health in material (*i.e.* physical/physiological) terms.

Some biomedical researchers who believe themselves to hold a materialist account of the mind appear really to be ‘epiphenomenalists’ because they do not seem to actually believe that psychological states have the same causal influence as physiological processes in the production of illness and disease. Epiphenomenalists hold the position that mental or psychological states are epiphenomena of brain states (Clark, 1985, p. 80; Audi, 1995, p. 598). In this account, psychological states are like ‘shadows’ of brain states with no reality in causal terms in the sense that they cannot cause physical effects. Such a view goes against common sense and denies that psychological states have an effect on the activities of people. The weakness of the epiphenomenalist position is stated concisely by the philosopher Campbell (1970, p. 112):

This doctrine [epiphenomenalism] makes the mind an impotent side show to the serious business of real events in the physical world. It denies that mental events can be causes of behaviour. It robs us of any satisfactory way of specifying different mental states, for this must be done through the links with behaviour which the theory denies.

Norman Cousins (1979, p. 56), in his examination of the subject of ‘mind-body’, remarked that, “[t]he placebo is proof that there is no real separation between mind and body. Illness is always an interaction between both. It can begin in the mind and affect the body, or it can begin in the body and affect the mind”. The TCM model goes a step further by claiming that both ‘mind’ and ‘body’ are aspects of the one *qi* complex and are not two intrinsically different substances that interact.

A key psychological factor believed to be implicated in the origin of many psychosomatic disorders is ‘stress’. Clark (1985, p. 69) cites the studies of Rahe¹³⁶ and others as evidence that stress, and not the presence or absence of pathogenic micro-organisms, might be the critical factor in the genesis of many diseases. In one of these ‘life change’ studies, the relationship between stress levels and illness among naval personnel on one particular navy ship was examined (Rahe, 1974). It was found on one ship that some naval personnel became

¹³⁶ See E.K.E. Gunderson and R.H. Rahe, *Life Stress and Illness*, 1974.

sick and others did not. Such a discovery is not surprising; however, from a biomedical perspective this is not so easily explained in terms of its model of disease. One could presume that all of the navel personnel were exposed to the same potentially infectious agents: therefore the critical factor that was involved in the genesis of the disorder was something other than a pathogenic factor (*e.g.* bacterium or virus). Rahe concluded that the critical variable in the disease process was the psychological factor of 'stress'. A conclusion that can be drawn from the studies of Rahe and others is that certain life events and psychological factors such as stress can contribute to the development of observable and 'physical' disorders of the body. Proponents of Biomedicine might argue that the studies of Rahe show that life events and psychological factors can weaken the immune system to such a point that infectious agents can initiate a disease process.¹³⁷

The findings of Gunderson and Rahe (1974) can easily be accommodated by the model of TCM which views human illness as having multifactorial aetiological factors that can be involved simultaneously. The TCM model acknowledges that psychological and social factors can be involved in the disease process and that disease cannot always be attributed solely to a single aetiological agent such as a micro-organism or virus.

Prospective studies such as the study of Schaefer (1979, cited by Pauli, 1986a, p.10) indicate that psychosocial conditions can result in long-term overactivity of physiological functions. Schaefer suggests that such overactivity of physiological functions can be the result of many contemporary life experiences that exceed the range of long-term physiological adaptation.

From the perspective of TCM, the concept of *qi* is fundamental to understanding pre-pathological states of the human organism and can fully account for Rahe's findings in the studies previously cited. The TCA model could explain the illness of *some* of the naval personnel in terms of a decrease in their internal *zheng* (or 'antipathogenic') *qi* levels, which could allow pathogenic agents to initiate pathological processes in the body. From the perspective of TCA, it could be argued that some naval personnel were not affected by the pathogenic agents because their internal *zheng qi* levels were adequate to defend them from the 'pathogenic' attack. The *wei qi* (protective *qi*), of TCM theory is said to circulate in the outer

¹³⁷ See also B.Q. Hafen *et al.*, 1996.

layer of the body and represents the first line of defence of the body against 'pathogenic' factors (*xie qi*). In TCM terms, exogenous pathogenic factors (*xie qi*) can only enter and harm a person when their *wei qi* is deficient (Maciocia, 1989).

From the TCA perspective, a blockage or deficiency of *qi* can precede the actual manifestation of signs and symptoms that would generally be regarded as an expression of disease in the biomedical model. It is worth noting that the TCA practitioner claims to be able to detect such *qi* blockages and deficiencies through subtle TCM diagnostic procedures. For example, a deficiency of *qi* (*qi xu*) could be ascertained by TCM pulse diagnosis by feeling an 'empty' pulse (*xu mai*) on palpation (Kaptchuk, 1983, p.163). Other traditional signs and symptoms that are indicative of a deficiency of *qi* (*qi xu*) include lethargy, pale bright face, shallow respiration, little desire to speak, dislike of movement, general weakness, soft voice and pale tongue (Kaptchuk, 1983, p. 202). What is interesting, when one considers the signs and symptoms of the TCM pattern of disharmony known as '*qi* deficiency' is that they might not be regarded by the biomedical model as being outside the 'normal' range of signs and symptoms of a 'healthy' human being, and would not constitute disease or pathology in themselves. Again, this highlights one of the claimed strengths of TCA - if an energetic imbalance can be detected at an early stage and the imbalance treated, disease and serious pathology can be prevented.

An understanding of the constitution of the individual is also important for determining in which way psychological factors such as stress will affect a person. For example, in the diathesis-stress model of holistic health, stress is understood to manifest in different ways, the specific pattern of signs and symptoms being dependent on the constitution of the individual (Gannon, 1981). The concept of the diathesis is common to many systems of holistic medicine, including TCM. In TCM *wu xing* ('five phase') theory for example, a preponderance of *gan* (liver) *qi* could manifest as a migraine in one person (the *gan qi* ascending to the head) or as indigestion in another (the *gan qi* invading the *pi* [spleen] and *wei* [stomach] via the *ke* cycle) (see Maciocia, 1989, pp. 15-34), the particular manifestation in each case being dependent in part on the constitutional strengths and weaknesses of the individual.

According to TCM theory, essence (*jing*) is inherited from one's parents, with the constitution of the person being determined at conception as a result of the configuration of the person's 'congenital essence' (*xian tian zhi jing* or pre-natal *qi*).¹³⁸ According to TCM theory, the 'energetic blueprint' of the individual is determined at conception and will influence the way in which external environmental factors will affect the person when they interact with that individual. One type of stressor may be detrimental to a particular person's health because of a constitutional weakness that can make that individual susceptible to that particular stressor. From this perspective, it can be understood why TCA practitioners hold the position that environmental 'stressors' do not have the same effect on all individuals. The TCM model also provides an account of why some people develop the diseases that they do. For example, some people might react to 'stress' by developing respiratory signs and symptoms, while others might develop a digestive disorder: the signs and symptoms of each disorder being the result of the interaction between aetiological factors and the constitutional configuration of the *qi* of the individual.

If it is provisionally accepted that psychological factors (*e.g.* stress) can be aetiological in the disease process, it can be understood in the context of psychosomatic disease what holistic TCM health care practitioners mean when they say that the 'whole' person should be treated and not just their disease. Putting it simply, it means that in the treatment of illness and disease the 'mind' must be considered in addition to the pathology of the body. What follows from this line of reasoning is that in the case of illness that involves psychological factors, pharmaceutical drug therapy by itself might be an insufficient treatment since many drugs are only designed to correct physiological processes of the biological body. What might be required is a therapy with a psychotherapeutic component to address the psychological factors that could have contributed to, or initiated, the illness.

TCM practitioners claim that psychological processes (*e.g.* the emotions) can be both aetiological and therapeutic in the formation and treatment of illness in the same way as a drug

¹³⁸ Both G. Maciocia (1981, pp. 1-2) and Z. Zhiya (1995) note that the congenital essence is believed to be involved in the nourishment and growth of the embryo, and later the fetus. Essence (*jing*) is understood to play a role in growth and development from conception to death. According to Kaptchuk (1983, p. 44), "[d]isharmonies of *Jing* might involve improper maturation, sexual dysfunction, inability to reproduce, and pre-mature aging. What the West calls congenital defects often are considered *Jing* irregularities."

or surgery. Clark (1985, p. 70), in his analysis of holistic medicine, states that

if the holistic view were merely that treatment has psychological effects and some aspects of treatment are intended to secure some of those effects, then it would trivially apply to current [biomedical] practices, and no change at all would be needed. The claim, however, is much stronger than that; it is that psychological processes are aetiological (and not ancillary) in whatever malady the physician is treating; and that those psychological aspects of treatment are therapeutic in just the same way as an antibiotic or a surgical intervention. They have a direct causal impact on the pathogenic factors leading to symptoms.

Clark (1985, p.70) contends that, if this were acknowledged to be the case, medical students would be faced with the daunting prospect of having to become psychotherapists as well as physicians.¹³⁹ This is in fact the whole thrust of the holistic TCA practitioner's argument, that the healing of illness is not merely the result of the therapeutic technique used by the practitioner, but also relies on effective communication between the practitioner and the client during the clinical encounter. In relation to the holistic health care practitioner's maxim of 'treating the whole person and not just the disease', this means to at least acknowledge that psychological factors as well as pathophysiological processes of the biological body can contribute to illness and disease.

Willis (1994, p. 55), in his analysis of health care, suggests that the clinical success of the complementary therapies (of which TCA is one) could be due the psychosocial aspects of the therapies. Willis asks the question: how can the clinical success of the complementary modalities as indicated by high levels of patient satisfaction be explained? He concludes by suggesting that perhaps complementary therapists have better interpersonal skills:

Apart from the obvious answers that they [the complementary therapies] may actually work or may be substantially due to the placebo effect, a number of different explanations have been advanced. A major one is to stress the psychosocial aspects of treatment, that the complementary practitioner may be more interpersonally skilled in the sense of being more attuned to the total needs of the patient than doctors are.

In TCA therapy, as the author understands it, the practitioner-client relationship is seen as being

¹³⁹ It could be noted that J. Bowman and R. Sanson-Fisher (1997, p. 47) make the claim that "[m]edical practitioners do not currently display the interactional skills necessary to facilitate optimal patient outcomes" and that "communication problems are common in clinical practice."

just as important as the acupuncture needling technique, with the *total* therapeutic effect of TCA therapy being the result of the synergistic combination of a good practitioner- client relationship and the proficient application of acupuncture therapeutic techniques.

4.7.1 *Implications for TCA Research.*

Defenders of the biomedical model such as Clark (1985, p. 77) claim that holistic health care practitioners must demonstrate that psychological states such as stress or anxiety can actually *cause* physical disease states (*e.g.* a stomach ulcer) in psychosomatic disorders. Clark declares his position on this subject with the following questions: “How can a state of mind cause a lesion? Doesn’t this suggestion fly in the face of orthodox physiology by requiring occult energies dabbling in the digestive tract?” Clark’s rhetorical questions suggest a reductionist understanding of the processes that occur within human beings and a conception of the mind that is both epiphenomenal and dualistic. On the other hand, Dossey (1993, p. 42) claims that research in biofeedback laboratories has demonstrated that

mind can move matter. It is possible to make meters move dramatically merely by willing, and to trigger bells and whistles on sophisticated electronic gadgetry *merely by taking thought*, changing one’s mental images and feeling states. Moreover these feats can be duplicated *on command*.¹⁴⁰

Considerable empirical evidence has demonstrated that the ‘mind’, through psychological states, can result in physiological changes in the body (see Kiecolt-Glaser and Glaser, 1995; Cohen, Kessler, & Gordon, 1995). In fact, as early as the 1950s, Klopfer (1957) claimed that the placebo (an essentially psychological phenomenon) could shrink tumours in patients with malignant lymphosarcoma. Placebos, through psychological processes, do appear to affect not only subjective symptoms but also physiological processes in ways that are objective and measurable (see chapter 10 for an examination of the placebo phenomenon).

The biomedical model could be seen to be limited in the sense that it cannot claim that psychological factors do not have an important aetiological role in the cause of ‘physical’ disease and pathology and at the same time advocate research designs with placebo controls that aim to account for, or control the therapeutic effect that is inherent within the practitioner/ client

¹⁴⁰ See P. B. Amar, 1992.

relationship. The studies of Gelbman (1967) and Slesinger (1958) would suggest that some so called placebo effects can be due to the practitioner-patient relationship. If this is so, the therapeutic effects of the practitioner-patient relationship must be essentially psychological or energetic in nature.

4.8 'Mind-Body' and TCM Research

To break the impasse on the subject of psychosomatic disease and the mind-body problem as it is posed in Western philosophical and biomedical terms, one should seriously consider the traditional Chinese philosophical perspective. It is the author's belief that an important inroad into the so called 'mind-body problem' of Western philosophy could be achieved by adopting the Chinese philosophical perspective which redefines the problem. In the Chinese philosophical model, both psychological and physiological processes are seen as energetic manifestations of the one *qi*. Therefore, there is no need to explain *how* the 'mind' and 'body' interact, since they are both expressions of the same complex which is *qi*. The 'mind' can be understood to be a more subtle or refined state of *qi* when compared with the more physical [or denser] *qi* of the 'body' (Ni Hua Ching, 1979a, pp. 156-157). In the TCM model, changes in 'psychological state' could be expected to result in a change in the configuration of *qi* of the whole person. In TCM, emotional (psychological) states can be correlated with both subjective symptoms and objective signs through changes in the *zang-fu* and *jing-luo* systems (Maciocia, 1989). For example, the emotion of 'anger' in TCM theory is believed to affect the normal function of the *gan* (liver) *qi*. Anger could make the *gan* (liver) *qi* ascend along the *dan* (gall bladder) channel, resulting in a migraine (the effect). Another example from TCM is the emotion of 'fear' depleting the *shen* (kidney) *qi*, the depletion possibly manifesting as lower back pain, or perhaps loss of bladder control. There are numerous other examples in TCM literature that provide support for the notion of the 'mind' (through psychological and emotional states) bringing about 'physical' changes in the body (see Maciocia, 1989; Zhiya, 1995).¹⁴¹

¹⁴¹ For example, when the acupuncture point *neiguan* (pericardium 6) is needled it is said to relax the 'mind and spirit' (Lade, 1989). It has also been claimed that this same acupuncture point can influence the physiological processes of the heart organ by reducing the heart rate (Shanghai College of Traditional Medicine, p. 531), that is, the needling of the point can bring about *both* psychological and physiological changes.

The Chinese concept of *qi* could be likened to Einstein's understanding of the relationship between energy and matter. Einstein's famous equation, $E = mc^2$, claims essentially that energy and matter are interconvertible and that they can be understood as two poles of one energy-matter continuum. If one accepts Einstein's conception of energy-matter, then it would not be too difficult to provisionally accept, as a working hypothesis, the Chinese concept of *qi*. Both concepts (*i.e.* *qi* and 'energy-matter') stipulate that there is but one 'substance' that can take many forms. An acceptance of the concept of *qi* resolves the 'mind-body' problem since one does not need to account for how energy affects matter or how the 'mind' interacts with the body. As a result of this Chinese philosophical orientation, TCA practitioners will often not see a division between what could be called the psychotherapeutic aspect of TCA therapy and the acupuncture needling procedure. For the TCA practitioner, the idea of separating these two aspects of TCA therapy is purely for the purposes of communication with other disciplines. To suggest that there is a fundamental difference between the two would amount to an admission that there is an ontological difference between psychological and physiological processes, and therefore an intrinsic or ontological difference between the *qi* of the 'mind' and the *qi* of the 'body'.

As there could be a synergistic relationship between the TCA practitioner-client relationship and acupuncture therapeutic techniques, it might be more fruitful for researchers to attempt to evaluate TCA therapy as a whole therapy, rather than to attempt to account for the effects of its components. Such an approach has been termed a 'pragmatic' randomised controlled trial and has been outlined by Pocock (1993) for the complementary therapies (see chapter 10.18). This is an approach that could be utilised for the determination of the effectiveness of TCA which is not particularly concerned with the theory and mechanism of therapy (see Kaptchuk, Edwards and Eisenberg, 1996, p. 44).

4.9 Summary

All societies have developed aetiological models to explain the presence of illness and disease. These aetiological models can be classified broadly into two categories types:

(i) supernatural/magical and (ii) naturalistic/systemic. Health and illness are defined by society.

This is done by members of society informing each other as to the name, effect, the believed cause, and the appropriate response to each of the various illnesses and diseases.

Biomedicine has been seen to minimise the importance of psychological determinants in health and disease, just it has done with sociocultural factors. This stance is in keeping with Biomedicine's primary focus at the level of the biological body. In contrast, TCA practitioners claim that psychological processes can be aetiological and therapeutic in the formation and treatment of illness and disease in the same way as a drug or surgery.

TCA therapy can be seen as being holistic in the sense that no single sign or symptom can be understood except in relation to the whole person and the sociocultural environment in which the person is embedded. According to TCM theory, there are numerous factors that can contribute to a client's pattern of signs and symptoms; therefore, it is seldom possible to trace the 'cause' of a person's 'pattern of disharmony' to a single factor because biological functions can be influenced by mental and social aetiological factors operating in different subsystems within a hierarchy of systems.

The possible synergistic relationship between the TCA practitioner-client relationship and acupuncture therapeutic techniques would also suggest that TCA therapy might be best evaluated as a whole, rather than attempting to account separately for the effects of its components.

CHAPTER 5

PARADIGMS OF RESEARCH

“When we allow those who are powerful to hold all the definitions of what is good and what is useful, we can never get beyond the dominant world views”

- Noblit (1984 cited in Marshall, 1990, p.196)

This chapter will examine several paradigms of research and their interface with knowledge production in the field of TCA. While some health care professions might have an affinity with particular research methods, it will be argued that it is the *type* of research question that should direct the selection of an appropriate research approach for any particular TCA study. The methods of inquiry derived from the various research paradigms can produce different types of knowledge, most of which can be of value and useful for particular TCA research goals.

5.1 Paradigms of Research

Thomas Kuhn (1962) brought the concept of the *paradigm* to the attention of academics in his classic work *The Structure of Scientific Revolutions* where he examined the concept of the *paradigm* in relation to the philosophy of science. The term *paradigm* has been defined in various ways by numerous academics working in diverse fields. Masterson (1970) claims that Kuhn himself used the term *paradigm* in twenty-one different ways. Smith and Hope (1992, p. 4) describe a *paradigm* as, “[t]he assumptions concerning the nature of ‘reality’, ‘knowledge’ and ‘truth’ and their associated epistemologies and ontologies characteristic of each way-of-knowing”. They define a paradigm as, “a set of criteria and principles by which scientific problems are selected and defined and procedures by which scientific investigation, in a particular discipline or area of knowledge, is undertaken.” (Smith and Hope, 1992, p. 59).

Guba and Lincoln (1994, p.107) suggest that

[a] paradigm may be viewed as a set of *basic beliefs* (or metaphysics) that deals with ultimates or first principles. It represents a *worldview* that defines, for its holder, the nature of the 'world,' the individual's place in it, and the range of possible relationships to the world and its parts, as, for example, cosmologies and theologies do. The beliefs are basic in the sense that they must be accepted simply on faith (however well argued); there is no way to establish their ultimate truthfulness.

The paradigm is a sociological concept and does not have to be thought of as a description of 'reality'. For example, Capra (1986 cited in Capra, 1997, pp. 5-6) defines a social paradigm as "a constellation of concepts, values, perceptions, and practices shared by a community, which forms a particular vision that is the basis of the way the community organizes itself." A paradigm can be understood as a basic set of beliefs that guide action (Guba, 1990, p.17). The TCM paradigm could therefore be understood as consisting of a constellation of traditional ideas, theories and philosophy that can guide clinical practice.

From the various accounts of what a paradigm is, it is evident that TCM and Biomedicine can be understood as constituting different paradigms since their ontologies and world views, with their associated conceptions of what 'reality' *is*, are different. TCM can be understood to constitute a distinct health care paradigm in the sense of having its own cluster of philosophical, ontological, and theoretical understandings which are shared by members of the TCA profession (chapter 2).

The theoretical framework of the paradigm in which a health care researcher works can influence all aspects of the research process. It begins with the formulation of the research question and the selection of the research design and proceeds through to the methods of collecting, analysing and interpreting information and data. A researcher's beliefs cannot be avoided. They should be acknowledged and recognised as something that can have a strong bearing on the research design thought to be appropriate, the design that is eventually selected, and the subsequent outcomes of the research. It should also be noted that paradigms can sometimes place limitations on the growth of knowledge since they can "define for inquirers

what falls within and outside the limits of legitimate inquiry.” (Guba and Lincoln, 1994, p.108).

Research questions often originate out of the ontology and epistemological orientation of the discipline. In addition, every health care discipline would seem to have its own language and its own set of metaphors. As Joris (1980, p. 750) notes, “[e]very scientific discourse is based on a set of culture-and ideology-bound *metaphors*, and has therefore to be read as metaphor, and not as an ‘objective’ transparent language that would stand in a one-to-one relationship with an immutable, absolute reality.” It might be expected that health care practitioner-researchers would tend to gravitate toward particular research approaches that ‘resonate’ with the profession’s philosophical and theoretical understandings. A consequence of this could be that particular health care professions would tend to adopt particular research methods that would have an affinity with, and be congruent with the profession’s world view. However, it should be remembered that the appropriateness of the research design selected for any particular TCA study will be dependent upon the nature of the research question that is to be addressed.

Whilst it could be argued that TCA practitioners of the past have utilised their own traditional methods to produce knowledge (*e.g.* through the study of classical Chinese texts and reflection on clinical practice), these may not be adequate to address some of the research questions of the contemporary TCA profession (see chapter 2.9). At this point in time, an examination and analysis of several research paradigms would seem necessary to determine appropriate forms of inquiry and research methods for a comprehensive study of TCA.

5.2 Paradigms and the Postmodern Context

Thomas Kuhn (1962, p. 33) claimed that science has failed to live up to Karl Popper’s ideal of a rational pursuit of knowledge because the paradigm in which one works filters the ways in which we access, interpret, and test data. Skinner (1985, p.10 cited by Higgs & Titchen 1995, p.133) has interpreted Kuhn’s claim as meaning that there are no ‘facts’ that can be independent of one’s theories about them, and as a result no *one* way of viewing, understanding and explaining the world that all rational persons are obliged to accept. This is one of the essential

messages of postmodern thought: that no method of inquiry has a privileged status. Laural Richardson (1994, pp. 517-518) explains that

[t]he core of postmodernism is the *doubt* that any method or theory, discourse or genre, tradition or novelty, has a universal and general claim as a “right” or the privileged form of authoritative knowledge. Postmodernism *suspects* all truth claims of masking and serving particular interests in local, cultural, and political struggles. ... postmodernism does not automatically eject conventional methods of knowing and telling as false or archaic. Rather, it opens those standard methods to inquiry and introduces new methods, which are also subject to critique.

Guba and Lincoln (1994, p.108) claim that paradigms “are not open to proof in any conventional sense; there is no way to elevate one over another on the basis of ultimate, foundational criteria. ... All paradigms are ‘human constructions’ and are therefore subject to human error.” They make the further claim that “[n]o construction [or paradigm] is or can be incontrovertibly right; advocates of any particular construction must rely on *persuasiveness* and *utility* rather than *proof* in arguing their position.”

Denzin and Lincoln (1994, p. 99) claim that a paradigm encompasses three elements: epistemology, ontology, and methodology. Guba and Lincoln (1994) suggest that issues of ontology, epistemology and research methods in any paradigm are interconnected and that one’s belief as to what constitutes the nature of ‘reality’ determines the nature of the relationship between the knower and what can be known. They note (1994, p.112) that, “[d]ifferences in paradigm assumptions cannot be dismissed as mere ‘philosophical’ differences; implicitly or explicitly” and that “these positions have important consequences for the practical conduct of inquiry, as well as for the interpretation of findings and policy choices.”

Grbich (1999, p. 7) notes that there are both advantages and disadvantages of paradigmatic approaches, “[t]he advantages of paradigm-based approaches lie in the systematisation of knowledge. Placing different orientations into separate boxes achieves a sense of order and control, and provides a way of managing, highlighting and contrasting varying approaches.” On the other hand, a disadvantage of paradigm-based approaches is oversimplification. For example, Grbich claims that this is evident when the quantitative and qualitative paradigms are examined.

5.3 The Languages of Paradigms

Benjamin Whorf (1956, cited by Porkert, 1982, p. 23), a linguist, was one of the first to suggest that the use of a technical language could eventually lead to an impasse in scientific progress. He argued that the language a people speak not only influences the way in which they communicate, but it can also predetermine the way in which they reason, analyse nature, and see relationships between phenomena. As Hanson (1958) has noted, what we 'see' is in part determined by our 'conceptual baggage', that is, the concepts and theories that we bring with us to a phenomenon when we wish to study it. Whorf claims that the concepts and theories we use are themselves an outcome of the language we speak. Foucault (1980) argued that what we are allowed to see is limited by our language and its culturally associated discourse. If this is true, Western researchers should take note of the possible limitations that ethnocentric language based concepts pose for a fair evaluation of TCM.

TCA practitioners wanting to conduct research to increase their understanding of TCA should be mindful of the limitations imposed by language. Even TCA practitioners themselves are sometimes found using the reductionist and dualistic language of Biomedicine. Leder (1992, p. 24) notes that it is far from easy for the occidental to challenge the Cartesian model since this position is "now so firmly entrenched in our culture that it is difficult to think outside its parameters. Even those who seek 'holistic' alternatives often find themselves caught in dualistic terms, asserting the importance of mind, soul, or spirit vis-a-vis bodily events." Porkert (1982, p. 23) argues that "language creates for a community of scientists a finite reservoir of potential solutions to problems, and when these are exhausted, scientific progress is no longer possible." The same argument can be applied to medical research. Many of the health problems of humanity have not been adequately addressed by Biomedicine even though large sums of money have been channelled into biomedical research (see chapter 1). The therapeutic 'solution' for some currently 'untreatable' disorders might not be achieved by spending increasingly more money on biomedical research, or by developing ever more sophisticated high-technology diagnostic techniques. What might be required in order for health care to progress is a change from the current biomedical paradigm.

In the physical sciences, Cartesian and Newtonian concepts have decreased somewhat in stature through the development of the concepts of the relatively new sciences of quantum mechanics and the theories of 'chaos' and 'complexity' (Capra, 1997): yet Biomedicine still operates on the premises and tenets of nineteenth century Newtonian science. Perhaps insights into a more comprehensive medical paradigm can be found within the paradigm of TCM which has an affinity with these new scientific concepts of physics. However, if researchers are to uncover any valuable insights from TCM, they will need to fully immerse themselves in the ideas of the TCM paradigm. Even those TCM concepts that have been translated into English are difficult to understand outside the context of the Chinese philosophical paradigm. cursory explorations of TCM can be expected to result in either its rejection as a rational form of health care, or its reconstruction in accord with the biomedical model.

The way in which research is conducted in TCA cannot be simply modelled on that of the natural sciences and Biomedicine, since the methods of obtaining knowledge in a discipline are often dependent upon the basic assumptions, premises, theories and ontology of the discipline itself. Sensory data, while being essentially neutral, can be perceived in different ways by researchers working in different disciplines. Researchers tend to develop different ways of obtaining knowledge based on their prior learning and the paradigm of the discipline in which they were trained. As a result, it is not surprising that researchers often conduct research within different paradigms based on their own ontological and epistemological understandings of the world.

Wittgenstein (1922), in the *Tractatus Logico-Philosophicus*, suggested that the world could be explained by simple facts and that a scientific language could be developed to mirror those facts. His assumption was that scientific language could be structurally isomorphic with those 'simple' facts that are obtained through the senses. Wittgenstein later rejected his earlier position, as Bhasker (1994, p. 197) explains:

Language is tied to differentiated social practices, oriented to human purposes. The transcendental solipsism of the *Tractatus* is rejected: no purely private language is possible. Moreover, languages are governed by rules which are specific to particular language games, between which only relations of family resemblance at best holds.

This has relevance for the examination of the paradigm of TCM. TCA practice takes place in the 'empirical world' where immediate tangible outcomes of therapy are often desired by clients. TCA therapy begins with the formulation of a diagnosis, which involves empiricism, that is, the gathering of data through the senses. However, in obtaining diagnostic information during the clinical encounter, TCA practitioners do not simply observe and collate a number of 'facts' or a collection of signs and symptoms in order to formulate the diagnosis. As Midley (1979, p. 5) notes in a related context:

What counts as a fact depends on the concepts you use, on the questions you ask. ... There is no neutral terminology. So there are no wholly neutral facts. All describing is classifying according to some conceptual scheme or other. We need concepts in order to pick out what matters for our present purpose from the jungle of experience, and to relate it to the other things that matter in the world. There is no single set of all-purpose 'scientific' concepts which can be used for every job. Different enquiries make different selections from the world.

Therefore what TCA practitioners 'see', and the information that they select to use when determining a diagnosis, will be dependent upon the abstract TCM philosophy and theory that provides the context for that which the TCA practitioner is actually *able* to see.

5.4 Research Paradigms and TCA

In ancient China, TCA knowledge developed through a variety of means. Avenues to knowledge included the study of classical Chinese texts and reflection on clinical practice, trial and error, personal experience, authority and tradition, and apprenticeship (see chapter 6). In contemporary times, researchers of TCA have also borrowed from other disciplines. An example is the appropriation by TCA practitioner-researchers of the randomised controlled trial (RCT) from biomedical research methodology to evaluate the effectiveness of TCA.

Several research paradigms and perspectives of research will now be considered to determine if they can be drawn upon, or appropriated, to further understand the nature of TCA and to develop TCA knowledge. The paradigms and perspectives that will be examined are:

(i) realism; (ii) positivism; (iii) postpositivism (and neopositivism)¹⁴²; (iv) the naturalistic

¹⁴² N. Denzin and Y. Lincoln (1994) claim that *postpositivism* developed in response to the criticisms leveled at the positivism paradigm. The *Neopositivism* of Mosey (1992) can be understood as a postpositivist orientation of practice that addresses some of the problems of positivist accounts and understandings.

paradigm; (v) the humanistic perspective; (vi) the interpretive paradigm; (vii) constructivism; (viii) critical social theory; and (ix) phenomenology. Other issues related to the use of the methods of science to produce TCA knowledge will be examined in more detail in chapter eight.

Ideally, research approaches for TCA should be congruent with the TCM paradigm if they are to be acceptable to not only researchers but also to TCA practitioners. Guba and Lincoln (1994, p.105) note that “[q]uestions of method are secondary to questions of paradigm”. With this in mind, the next objective will be to examine the tenets and assumptions of the various research paradigms and their associated research methods to determine their possible utilisation for the examination of TCA. It is clear that appropriate research methods for TCA can only be determined after due consideration of the Chinese philosophical paradigm from which TCA is derived (chapter 2). If this is not done, dissonance could be expected to be found between the TCM paradigm and the research methods used to investigate TCA. The author has already suggested that some dissonance has been found to exist between TCA practice and conventional biomedical research methodologies (*i.e.* randomised controlled trial) (chapters 1 & 2).

Throughout the second half of the twentieth century there has been an emphasis on quantification, measurement and statistical analysis in biomedical research. This could be seen as an attempt by medicine to achieve the same level of attainment as has occurred in the physical sciences (*e.g.* chemistry and physics) by using similar research methods. There has been the belief by some academics that the ‘scientific maturity’ of a field is related to the degree of quantification found in that field. It is therefore not surprising that positivist and postpositivist research orientations have been dominant in many fields including medicine, psychology and the social sciences.

5.4.1 *Realism*

Proponents of *realism* take the position that researchers using the methods of science can have “direct access to the reality of the world” (Slife & Williams, 1995, p. 176). From this

perspective, scientific descriptions of phenomena are not merely theories or models about the world, but rather statements about the world as it really is. *Realists* often assume that only one 'reality' exists independently of the observer, and that facts and valid data can be collected by researchers which can be 'objective' and free of researcher bias. The doctrine of *realism* has been challenged by many philosophers. Sometimes the doctrine of realism is confused with that of *positivism*.

5.4.2 *Positivism*

Positivism is a movement which began in the 1920s and was inspired by both empiricism and verification (Audi, 1995, p. 445). Positivism is a philosophic doctrine which claims that inquirers must confine themselves to sources of knowledge provided to them by sense-experience, that is, sense-data. When positivism was combined with an emphasis on the logical analysis of scientific language, it gave rise to the philosophy known as *logical positivism* (Vesey and Foulkes, 1990, p. 229).¹⁴³ Higgs and Titchen (1995, p. 132) contend that the scientific method as it is used in the natural sciences is part of what they term the empirico-analytical paradigm which is based on logical positivism. The major ideas of logical positivism originated from a group of philosophers, mathematicians and scientists that came to be known as the Vienna Circle (Edgerton, 1988, p.174).¹⁴⁴ The logical positivist paradigm has been perhaps the most influential philosophy of science in the twentieth century and has been thought to have facilitated immense technological developments in the physical sciences. It is based on the idea that knowledge can be gained by recording observations and then understanding these through analysis using mathematical, deductive and statistical means. Schon (1983, p. 33), in his analysis of the positivist perspective, remarks that for the positivist, "[p]ropositions which were neither analytically nor empirically testable were held to have no meaning at all. They were dismissed as emotive utterance, poetry, or mere nonsense."

¹⁴³ G. Vesey and P. Foulkes (1990, p. 229) note that *logical positivism* was an influential philosophy until after the mid-20th century.

¹⁴⁴ See R. Audi (1995, pp. 445-446, 836-839) for accounts of both the philosophical movement known as *logical positivism* and the Vienna Circle. Audi (p. 445) notes that *logical positivism* is sometimes referred to as simply *positivism*.

It is not an easy task to summarise the assumptions and premises of positivism since positivists have diverse understandings of what the core tenets of the philosophy are. Hammersley (1995, p. 2) claims that the assumptions of positivism vary but typically include some, or all of the following six assumptions:

- (i) The methods utilised in the natural sciences are the only rational means to obtain knowledge;
- (ii) Ideal features of scientific research include quantitative measurement, the manipulation of variables and statistical analysis;
- (iii) Research should and can produce findings that “correspond to an independent reality”;
- (iv) Scientific knowledge “consists of universal laws”;
- (v) Subjective bias should be avoided or minimised. Research should be objective “through commitment to the principle of value neutrality.”;
- (vi) The methods used in the natural sciences should be utilised in social research “irrespective of any supposedly distinctive features of social reality”.

One should be careful when treating positivism as a paradigm, since the premises and assumptions listed above, or subsets of them, do not necessarily belong together either philosophically or empirically. A potential danger of simplistic notions of paradigms is that they can disguise real research options. Hammersley (1995, p. 3) notes that thinking in terms of paradigms can obscure “both potential and actual diversity in orientation, and can lead us into making simplistic methodological decisions”.

Many forms of positivism do not claim, as in the doctrine of realism, that scientists through the methods of science can describe ‘reality’ as it *is*, but rather that the purpose of science is to form a coherent model of the world (Slife & Williams, 1995, p. 176). From this understanding, scientists formulate constructs, theories, and finally laws to account for

regularities found in the world that are discovered through experimentation using the methods of science. The distinction between realism and positivism is an important one, since some researchers when discussing their research findings suggest that their research conclusions are a true and accurate description of the 'way things are' rather than a plausible explanation or model.

It is apparent from reports in the media that many people do not have an understanding of the distinction between the two positions of *realism* and *positivism*. As a consequence, the status of science and technology is often elevated to a position above other areas of knowledge. According to Slife and Williams (1995), the production of useful technology from science has created the myth for the public that the scientific method produces a more certain and objective type of knowledge than other forms of inquiry. Slife and Williams (1995, p. 177) remark that

when scientific advance leads to real technological advance, it is difficult to keep reminding ourselves, 'This is only a construct.' We are tempted instead to think, 'If it works, it must be real.' What this means is that positivist positions often shade into realist positions, especially among scientists who care more about their work than about philosophical questions.

One important outcome from the blurring of the two positions of realism and positivism is that science in the twentieth century has become the metanarrative that dictates what is thought to be real and true.

In the positivist paradigm, according to Higgs and Titchen (1995, p. 132), there is the idea that, "[k]nowledge is discovered (*i.e.* universal and external truths are grasped) and justified on the basis of empirical processes which are reductionist, value neutral, quantifiable, objective and operationalizable. Only statements publicly verifiable by sense data are valid." It has been argued by many philosophers of science that observations and so called 'facts' cannot be neutral or completely objective; that is, they cannot be independent of the researcher's interpretation (see Hansen, 1958; Kuhn, 1962; Popper, 1972; Feyerabend, 1975). In fact, observations are often highly subjective and are influenced by the beliefs, theories and perceptions of the observer.

One of the aims of both positivism and postpositivism (see below) is *explanation* (von Wright, 1971) enabling the *prediction and control* of phenomena (Denzin and Lincoln, 1994 p. 113). Positivists believe that if hypotheses can be stated and operationalised, they can then be tested and analysed to determine functional relationships. One of the claimed strengths of the positivist empirico-analytical paradigm is that it can produce generalisations about phenomena and events of the world which can be used to predict future phenomena and events (Moore, 1982).

A criticism of some experimental and clinical research based on the philosophy of positivism is that it can be alienating for those involved, and can allow people to be treated with less respect than they deserve. Rowan (1981a, p. 93) states that this can be done by

putting a person into the role of 'research subject' and then only permitting a very restricted range of behaviour to be counted. This is alienating because it is using the person for someone else's ends - the person's actions do not belong to that individual, but to the researcher and to the research plan. In the fully alienated paradigm, a person's actions are not even called actions or conduct, but are called rather 'emitted behaviours', or 'variables'.

5.4.2.1 *Objectivity and the avoidance of subjectivity*

Some versions of positivism seem to assume the existence of one objective 'reality' as in the doctrine of realism. If an objective external reality exists, then it would follow that research and inquiry could converge upon it (Guba and Lincoln, 1994, p. 111). The positivist position can be contrasted with the understandings of many social scientists where the conception of "knowledge as a mirror of reality" has been replaced by the conception of "the social construction of reality"¹⁴⁵, where the emphasis is on the "interpretation and negotiation of the meaning of the social world." (Kvale, 1996, p. 41).

In the positivist paradigm, there is to be found a dualistic relationship between the researcher and the phenomenon being studied. It is assumed that the researcher and the 'object' of investigation can be separate and independent entities, and that it is possible for the researcher to study the 'object' without substantially influencing it. The epistemology of positivism

¹⁴⁵ See P.L. Berger and T. Luckmann, *The Social Construction of Reality*, 1966.

follows logically from the ontology of the paradigm. Guba and Lincoln (1994, p.108) note that if an objective 'reality' is assumed, the posture of the knower must be one of objective detachment in order to be able to discover "‘how things really are’ and ‘how things really work.’"

Research methodologies follow from the ontology and epistemology of the research paradigm. Positivism often uses an experimental methodology that focuses on the verification of hypotheses. In positivism, an appropriate methodology would be one that controls for possible confounding factors. From the perspective of positivism, it is believed that knowledge "accumulates by the process of accretion, with each fact (or probable fact) serving as a kind of building block that, when placed into its proper niche, adds to the growing 'edifice of knowledge.'" (Guba and Lincoln, 1994, pp.113-114).

The ideological power of the scientific narrative that generally accepts the assumptions and methods of positivism must be acknowledged. Scheid (1993, p. 25) claims that

[s]cience is believed to be the most effective method by which we can influence the world because of its privileged access to reality. Research is the single most important vehicle through which this reality of seeming objective facts is created. Research lifts issues out of the realm of common sense knowledge where they are easily contestable and transforms them into objective facts. Once this transformation has occurred, it becomes increasingly difficult to challenge and reverse.

Scheid (1993, p. 30) adds that, "[t]he more closely knit and professionalised, the more bureaucratic and rigidly organised a scientific community is, the more value it seems to place on consensus, integrated knowledge systems, the settling of controversies and supposedly objective knowledge."

At this point in time, TCA is still a relatively new profession in the Occident and has not made the decision to restrict its development by using only the methodologies of positivism, postpositivism and science. In the next section, a brief critique of positivism will be completed so as to identify the weaknesses of the positivist paradigm from which many quantitative research methods have been derived. This critique will provide the reasons for why researchers

of TCA will need to use naturalistic inquiry and qualitative research methods to answer particular TCA research questions (see chapter 12).

5.5.2.2 *Criticisms of positivism*

Positivism began in the 1920s, flourished for approximately twenty to thirty years, and has come under considerable attack in the second half of the twentieth century (Audi, 1995, p. 445). Positivism has been an influential philosophy in the sciences but has been criticised in recent times for its metaphysical assumptions. Guba and Lincoln (1994, pp. 106-107) have noted several intraparadigm weaknesses of the conventional positivist paradigm:

- (i) There is context stripping. Quantitative research designs that have been derived from positivist concepts, such as the randomised controlled trial, select and monitor a limited number of variables. There are always variables that are excluded through the use of 'appropriate controls', which, if assessed could, theoretically change the interpretation of a study's findings. Guba and Lincoln (1994, p. 106) contend that "such exclusionary designs, while increasing the theoretical rigor of a study, detract from its relevance, that is, its applicability or generalizability, because their outcomes can be properly applied only in other similarly truncated or contextually stripped situations".
- (ii) There can be the exclusion of meaning and purpose. Guba and Lincoln (1994, p. 106) claim that "[h]uman behaviour, unlike that of physical objects, cannot be understood without reference to the meanings and purposes attached by human actors to their activities."
- (iii) There is often a disjunction between grand theories and local contexts. It is now accepted by many researchers that qualitative research approaches are more appropriate for uncovering emic (insider) views. The etic (outsider) theory brought to bear on a study by a researcher (or the hypothesis proposed to be tested) "may have little or no meaning within the emic (insider) view of studied individuals, groups, societies or cultures." (Guba and Lincoln, 1994, p. 106).
- (iv) General theory can be inapplicable to individual cases. The inapplicability of general theory to individual cases has sometimes been referred to as the nomothetic/idiographic disjunction. It

has been argued that “[g]eneralizations, although perhaps statistically meaningful, have no applicability in the individual case” (Guba and Lincoln, 1994, p. 106). For example, a number of clients might present at a TCA clinic with similar sets of signs and symptoms that might suggest a particular TCM ‘pattern of disharmony’. Following TCA therapy, the majority of these people might show substantial improvement; however, even if 95% of those treated were significantly helped by TCA therapy, there is no way of predicting beforehand if TCA would be able to help any *one* particular individual since not *all* factors and characteristics of the person can ever be accounted for.

(v) In positivistic research there can be the exclusion of the ‘discovery dimension’. For example, in quantitative research often specific hypotheses are tested and it has been claimed that the source of many of these hypotheses comes from what is sometimes termed the ‘discovery process’: this process is an intuitive and creative one that is often downplayed and not fully acknowledged in positivist research (Guba and Lincoln, 1994, p. 106).

Guba and Lincoln (1994, p. 107) also note other external ‘extraparadigm’ weaknesses of the conventional positivist paradigm:

(i) There is the theory-ladenness of facts. As early as the 1950s, Hanson (1958) noted that the images that fall on the retina of an observer can be interpreted in more than one way. Sensory data, while being essentially neutral, can be perceived in many ways by different observers. Therefore, the interpretation and meaning researchers give to their data and results will be partly dependent upon their own belief systems with their various assumptions, theories and possible biases. Therefore, the answers obtained by researchers will be dependent on the framework or paradigm within which the researcher *perceives* phenomena. Guba and Lincoln (1994, p. 107) remark that

it now seems established beyond objection that theories and facts are quite *interdependent* - that is, that facts are facts only within some theoretical framework. Thus a fundamental assumption of the received view is exposed as dubious. If hypotheses and observations are not independent, “facts” can be viewed only through a theoretical “window” and objectivity is undermined.

(ii) There is the underdetermination of theory, that is, it is now generally accepted that “it is never possible, given a coherent set of facts, to arrive by *induction* at a single, ineluctable theory.” It was this realisation that led philosophers, including Karl Popper (1968) to reject the idea of theory *verification* in favour of the notion of theory *falsification* (Guba and Lincoln, 1994, p. 107).

(iii) Facts are value laden. There would appear to be a relationship between one’s theories and values. Guba and Lincoln (1994, p. 107) claim that, “it can be argued that theories are themselves value statements. Thus putative ‘facts’ are viewed not only through a theory window but through a value window as well.”

(iv) There is the inevitable interaction between the inquirer and that which is studied (Guba and Lincoln, 1994, p. 107). Even in the ‘hard sciences’ (*i.e.* chemistry and physics), the ‘Heisenberg uncertainty principle’¹⁴⁶ and the ‘Bohr complementarity principle’¹⁴⁷ have shattered the idea that the inquirer (or researcher) can merely observe phenomena without influencing that which is observed (Capra, 1983). With this point acknowledged, Guba and Lincoln (1994, p. 107) conclude that “even greater skepticism must exist for the social sciences”. A similar skepticism could be applied to the health sciences as for the social sciences. Many TCA practitioners could be expected to support Guba and Lincoln’s (1994) analysis and critique of positivism because of TCM’s ‘holistic’ philosophical orientation, which would seem at odds with some of the premises and assumptions of positivism.

¹⁴⁶ Capra (1983, pp. 67-68) in a discussion Heisenberg’s *uncertainty principle* explains that “neither the electron nor any other atomic ‘object’ has any intrinsic properties independent of its environment.” As a result of the uncertainty principle, Grbich (1999, p. 20) states that “the act of measurement disturbs the object that is being measured, causing a different action to that which existed prior to measurement.” According to Heisenberg one cannot even look at a physical object without changing it. Heisenberg’s perspective does not appear to be congruent with the positivist view that a researcher can study an ‘object’ or phenomenon at a distance without influencing that which is studied.

¹⁴⁷ According to Capra (1983, pp. 68-69), Neils Bohr considered the particle picture and the wave picture as two complementary descriptions of the one ‘reality’ (or atomic phenomenon). “Both pictures are needed to give a full account of the atomic reality ... The resolution of the particle/wave paradox forced physicists to accept an aspect of reality that called into question the very foundation of the mechanistic world view - the concept of the reality of matter.” Complementarity is also a feature of Chinese thought as exemplified by *yin/yang* theory.

5.4.3 *Postpositivism and neopositivism*

Denzin and Lincoln (1994) claim that the philosophy of *postpositivism* developed in response to the criticisms leveled at the positivism paradigm. In regard to ontology, postpositivism moved from the naive realism of positivism to a position where an objective reality is assumed to exist but where it can only be apprehended imperfectly and probabilistically (Guba and Lincoln, 1994, p. 111). Postpositivist knowledge is an outcome of Popper's (1968) theory of falsification where nonfalsified hypotheses could be regarded as probable facts or laws (Guba and Lincoln, 1994, p. 111).

The *Neopositivism* of Mosey (1992) can be understood as a postpositivist orientation of practice that addresses some of the problems of positivist accounts and understandings (see chapter 7). Although postpositivism (and neopositivism) have weaknesses, they might still provide the best epistemological orientation to adopt when attempting to answer some research questions that relate to the evaluation of a therapy's efficacy at the population level (see chapters 8, 9 & 10).

5.4.4 *The naturalistic paradigm*

In contrast to positivism is the broad *naturalistic paradigm* of Lincoln and Guba (1985). This paradigm assumes that: (i) the knower and known are interactive and inseparable; (ii) only time and context-bound working hypotheses are possible; (iii) causes and their effects are difficult, if not impossible to discern since all entities are in a state of mutual simultaneous development and transformation; and (iv) inquiry is value bound (Lincoln & Guba, 1985). The contrasting axioms of positivism and the naturalistic paradigm are outlined in Table 5.1.

Table 5.1 The Contrasting Axioms of Positivism and the Naturalistic Paradigm (Lincoln & Guba, 1985, p. 37).

<i>Axioms About</i>	<i>Positivist Paradigm</i>	<i>Naturalistic Paradigm</i>
The nature of reality	Reality is single, tangible, and fragmentable.	Realities are multiple, constructed, and holistic
The relationship of knower to the known	Knower and known are independent, a dualism.	Knower and known are interactive, inseparable.
The possibility of generalization	Time- and context-free generalizations (nomothetic statements) are possible.	Only time- and context-bound working hypotheses (idiographic statements) are possible.
The possibility of causal linkages	There are real causes, temporally precedent to or simultaneous with their effects.	All entities are in a state of mutual simultaneous shaping, so that it is impossible to distinguish causes from effects.
The role of values	Inquiry is value-free	Inquiry is value-bound.

Some perspectives and paradigms, including phenomenology, the humanistic and interpretive paradigms and constructivism share many of the assumptions of the naturalistic paradigm. Often naturalistic inquiry involves the use of qualitative research methods which generally assume the axioms of the naturalistic paradigm (chapter 12). Given the many common features and themes of TCA and naturalistic inquiry, it is likely that qualitative research methods will have a more important role in the future development of TCA knowledge (see chapter 12).

5.4.5 *The humanistic paradigms*

The Humanistic paradigms can also be contrasted with positivist orientations. Higgs and Titchen (1995, pp. 132-33) state that

[a] criticism of the empirico-analytical [positivist] paradigm has come from the humanistic paradigms where it is believed that knowledge is 'generated through a search for meaning, belief and values, and through looking for wholes and relationships with other wholes. This way of knowing is different to that in the medical model where facts are described and phenomena are reduced to component parts to describe, explain and predict how these parts work

Many of the humanistic paradigms share with TCM the tenets of holism and the idea that understanding and knowledge can be gained through establishing relationships between phenomena based on experience.

Habermas (1974) has claimed that the model of positivism that has been used successfully in the natural sciences is not appropriate for the social sciences because it fails to recognise significant human qualities. Habermas (1974, quoted by Higgs & Titchen 1995, p. 133) states that, “‘positivism’ fails to recognise one of the significant features which makes us human, *i.e.* the capacity for ‘self-reflection’ or ‘reflexivity’ and the consequent ability to change our future.” The argument of Habermas holds for Biomedicine and TCM as it does for the social sciences, since both deal with human beings who demonstrate reflexivity.

The humanist health care movement has developed from several sources, including Maslow’s (1954) humanistic approach to psychology. This approach could be seen as a reaction to the mechanistic tendency of behaviourism and the medical orientation of psychoanalysis (Capra, 1983, p. 402). The humanistic perspective would appear to form the basis for an increasing number of researchers in the area of health care who believe that the model of positivism is not always appropriate for particular research goals in the area of the social and health sciences.

Maslow (1954), a major contributor to humanist theory, claimed that human beings should be studied as integral organisms, and concentrated his own research on healthy people and positive human behaviour. Maslow formulated the concept of *self-actualization*, a process in which he claimed the person can develop and go beyond, or exceed, the basic safety, security, belongingness and ego needs of the behaviourist and medical psychoanalytic models (see chapter 3.13). According to Maslow (1954), self-actualization results from the desire to become everything that one is capable of, and what one truly is.

Carl Rogers (1967), another important figure in humanism, developed a ‘client-centered’ psychotherapy that aimed to help clients grow as human beings. The humanistic notions of Maslow and Rogers are similar to TCM philosophical understandings in the sense that there is the recognition that there are aspects of the person that extend beyond a purely biological

understanding. TCM and humanism are also similar in regard to their concepts and understandings of change, transformation, and self-actualisation.

The humanist paradigm, according to Smith and Hope (1992, p. 5), is based on the assumption that 'reality' and 'truth' are not objective and independent of the observer. This position holds that perceptions of 'reality' are "highly subjective and even unique to each individual" since each individual is continuously being influenced by changing sociopolitical, economic and cultural factors. One of the aims of researchers working from a humanist perspective is to *understand* the unique individual in his or her particular environmental setting and cultural context. This is in contrast to research based on the ideas of positivism and postpositivism, where often the focus is on making generalisations, determining laws and predicting causal relationships between phenomena.

5.4.6 *The interpretive paradigm*

Higgs and Titchen (1995, p.132) in their typology of paradigms, contrast the empirico-analytical paradigm (which is based on positivism) with that which they term the *interpretive* paradigm. The purpose of the various research methodologies of the interpretive tradition is not to look for cause-effect relationships as in experimental research, but rather to examine the phenomenon of the study as a whole, in the context of the situation with its particular subjective meanings (Higgs & Titchen, 1995, p.134). Naidoo and Wills (1998, p. 30) state that the interpretive tradition "aims to explore and describe the meaning of phenomena as experienced and perceived by the individual. The tradition derives from the social sciences' concern to understand the subjective meaning of human experience." Higgs and Titchen (1995) claim that there are several qualitative research approaches that are rooted in the interpretive paradigm which some researchers consider more appropriate for generating knowledge in the human sciences. These research approaches include grounded theory, hermeneutics¹⁴⁸, ethnography and phenomenology (see chapter 12).

¹⁴⁸ According to Audi (1995, p. 323), hermeneutics is "the art or theory of interpretation, as well as a philosophy that starts with questions of interpretation." Originally, hermeneutics was concerned more narrowly with the interpretation of sacred texts.

Scheid (1993, p. 30) has noted that scientific communities that are loosely organised and are still developing “seem to generate interpretative types of understanding, as well as an awareness of or even some degree of tolerance for different traditions of knowledge and practice.” At this point in time, the TCA profession in the occident would appear to be in this position. Consequently, the TCA profession might be expected to embrace interpretative types of research since the profession appears to have some degree of tolerance for different traditions of knowledge and ways of knowing (see chapters 6 & 7).

The researcher of TCA should avoid the extreme forms of both positivism and humanism. Extreme forms of positivism wish to produce laws of human behaviour that can be generalised universally, while extreme forms of humanism insist that each situation that involves a human being is truly unique. This tension has been resolved in the postmodernist perspective, as Kvale (1996, p. 232) explains:

[i]n the postmodern approach the quest for universal knowledge, as well as the cult of the individually unique, is replaced by an emphasis on the heterogeneity and contextuality of knowledge, with a shift from generalization to contextualization.

5.4.7 *Constructivism*

A *constructionist* view of science holds that “the subject matter of research depends on the theoretical assumptions of the scientific community and therefore does not exist as something real and independent of the beliefs and theoretical commitments of scientists.” (Little, 1995, p. 180). Researchers who hold a constructionist position attempt to remain open to new and more sophisticated interpretations as they evolve, with the aim of eventual consensus. The aim and process of inquiry from the constructivist perspective is to understand and reconstruct the constructions that people (including the inquirer) hold. According to Guba and Lincoln (1994, p.113), “[t]he criterion for progress is that over time, everyone formulates more informed and sophisticated constructions and becomes more aware of the content and meaning of competing constructions.” Activism and advocacy are key concepts of this perspective.

Guba and Lincoln (1994, p.111) note that constructivism could be said to have a relativist ontology

[r]ealities are apprehended in the form of multiple, intangible mental constructions, socially and experientially based, local and specific in nature (although elements are often shared among many individuals and even across cultures), and dependent for their form and content on the individual persons or groups holding the constructions. Constructions are not more or less 'true', in any absolute sense, but simply more or less informed and/or sophisticated.

The important point to note here is that the conventional distinction between ontology and epistemology disappears in the paradigm of constructivism. This is because knowledge is understood to be created during the interaction between the researcher and the informant. The methodology utilised by constructivism is often hermeneutics and dialectics (see chapters 6 & 12), which attempt to reconstruct previously held constructions (Guba and Lincoln, 1994, p. 111). From the constructionist perspective, "knowledge accumulates only in a relative sense through the formation of ever more informed and sophisticated constructions via the hermeneutical/dialectical process, as varying constructions are brought into juxtaposition." (Guba and Lincoln, 1994, p.114).

5.4.8 *Critical social theory*

Critical social theory began in the 1920s and has been influenced by the writings of the philosopher Karl Marx during the 1920s and 1930s, and later by the writings of Habermas (1971). The thrust of this theory is that any social phenomenon can only be understood when examined within an historical context. Some philosophers of this school contend that most societies operate based on 'closed systems' of thought that can lead to constraints that impede the free and uncoerced participation in, and the personal growth of individuals in that society (Burns and Grove, 1993, p. 83).

It has been previously suggested that the current 'crisis' in Western health care has arisen, in part, from the dominance of Biomedicine with its flawed philosophical premises and practices (see chapter 1). Some researchers, through the use of critical social theory, have deconstructed Biomedicine to expose its prevailing methods of domination of health care (see Foucault, 1973;

Willis, 1989). As yet, no health care paradigm is so comprehensive that it can account for and explain the origin and nature of all illness and disease. All health care paradigms have anomalies and unsolved problems; however, these do not necessarily lead to a crisis for that paradigm. In Biomedicine for example, many pharmaceutical drugs have been found to have adverse side effects (Illich, 1975; Lazarou *et al*, 1998) and yet they continue to be the most commonly used form of therapy by practitioners of Biomedicine. A crisis for a paradigm only results when practitioners and their patients lose confidence in the paradigm itself.

It could be argued that beneficial changes in government health care policy can be expected only if the tacit philosophical assumptions of the dominant biomedical paradigm are challenged. If a critical assessment of the weaknesses in the prevailing health care system were undertaken, changes could be instigated to improve it. Such critical analyses could possibly allow for a fairer evaluation of 'holistic' systems of health care such as TCM. Higgs and Titchen (1995) have advocated that in order to challenge learned restrictions, compulsions or dictates of habit, one must become aware of how a person's thinking is socially and historically constructed and how this can place limits on one's actions (Freire, 1970; Kemmis, 1985; Mezirow, 1990 cited in Higgs and Titchen, 1995, p.134).

Rowan (1981a, p. 96) has outlined a continuum of research designs from pure basic research to 'participatory' research. He suggests that research designs at the 'participatory' end of the continuum such as critical social theory can result in substantial social change as compared with basic research, which tends to be experimental and descriptive.

5.4.9 *Phenomenological approaches to obtaining knowledge*

Phenomenological approaches to research can be found in many diverse disciplines including philosophy, psychology and health care. Wagner (1983, p.10) claims that phenomenological thought can be traced back to the early centuries of the modern age.¹⁴⁹ Phenomenology is a

¹⁴⁹ The German philosopher Edmund Husserl (1859-1938), one of the major figures in phenomenology, believed that phenomenology began in the philosophy of Rene Descartes (1596-1650 AD). Other major contributors to phenomenological literature have been Henri Bergson (1859-1938), Max Weber (1864-1920), Martin Heidegger (1889-1976), John Dewey (1859-1952), Alfred Schutz (1899-1959), George Mead (1863-1931), Merleau-Ponty (1908-1961) and Jean-Paul Satre (1905-1980) (See H. Wagner, 1983, pp. 10-11, 213-15; S. Kvale, 1996, pp. 52-55 and T.A. Schwandt, 1997, pp. 114-115).

system of interpretation that allows the researcher to perceive and conceive of their own self and others through their own internal or subjective conscious experiences. Wagner (1983, p. 9) states that phenomenologists “concern themselves with what is experienced inside consciousness. They deal with human awareness, specifically awareness of human experience. They want to understand how we experience ourselves and how we experience things outside ourselves, that is, all that is non-self.”¹⁵⁰

The phenomenologist’s rationale for their position is that *phenomena* are considered to be the only objects of knowledge, or the only forms of reality (Singleton *et al.*, 1988). Cheek *et al.* (1996, p. 137) state that

[f]or phenomenology the central concern is the meaning and understanding given to everyday actions, events and institutions by the individual actor in a world already present. Phenomenology asks how the individual interprets this world and how is it that these interpretations are shared by others.

The approach of phenomenology can be contrasted with positivist orientations, where what is studied is believed to be *outside* of individual consciousness in the natural world. Wilber (1990, p. 55) has remarked that

the moment one starts investigating intersubjective phenomena, one is immediately ushered into the realm of discourse, dialogue, communication, introspection, hermeneutics, phenomenology, and so on. And trying to handle these mental-phenomenological *data* with empiric-analytic methods - by, for instance, calling them “verbal behaviour”- is about as effective as trying to discover the meaning of *War and Peace* by analysing the objective paper and ink by which it is expressed.

5.4.9.1 *Phenomenology and the language of consciousness*

In Descartes’s (1955) *Meditations on First Philosophy*, which was published in 1641, a phenomenological orientation can be identified. This is exemplified by his most often cited *cogito* argument ‘*Cogito ergo sum*’ (I am thinking, therefore I exist), where Descartes’ uses the pronoun ‘I’. Wagner (1983, p. 45) claims that the use of the ‘I’- form is a necessary

¹⁵⁰ Buddhism would seem to have an affinity with phenomenology; both regard actual perception and direct experiential awareness as central to understanding.

characteristic of phenomenological accounts:

When you read phenomenological expositions, you will find that their authors related their findings to themselves; they use the first-person singular pronoun, 'I'. This is not a sign of vanity and self-importance. Rather, it indicates modesty in the sense of asserting no more than what can be truthfully asserted: the experiences reported are *my* experiences. Any presentation of introspective observations and insights that does not underline the I-experiences that they represent may be read as a claim to universal validity for observations that, strictly speaking, are of a particular case.

Therefore, when a phenomenologist uses the first-person singular pronoun, 'I', he or she is acknowledging that the raw data that they are accessing is their *own* and is located in their *own* consciousness.

One should be cognizant of the difficulties associated with describing experiences of consciousness with the language that we use to describe things and events in the 'outer world' that appear to be external to the phenomena of our minds. Bergson (1910) in *Time and Free Will* claimed that the phenomena of consciousness occur not as isolated objects but rather as a continuous flow of consciousness¹⁵¹, with the perception of 'inner' time having no resemblance to the clock time of the 'outer' world. Bergman suggests that language is 'laid out in space' just as objects are located in three dimensional space. The consequence of this is that language is more suited to describing the phenomena of the natural world than events that occur in the 'stream of consciousness' of our minds. Wagner (1983, p. 27) states that, "not only do we face the task of moving from the outside to the inside, but we have to do it with a language ill-suited to the task." Laozi (Lao Tzu) said something similar in the Daoist classic the *Dao De Jing*: "The Tao [dao] that can be told of [i]s not the Absolute Tao [dao]" (Yutang, 1958, p. 51). One interpretation of this quotation in the context of the current examination of phenomenology is that verbal descriptions of some internal states of consciousness will not capture the essence of the experience as it is experienced subjectively. Phenomenological understandings have implications for the assessment and measurement of states of consciousness, wellbeing and emotional states in TCA research. It suggests the potential difficulties of assessing subjective knowledge and 'psychological' states of patients using the language that is used to describe things and events in the 'outer world'.

¹⁵¹ Cf. William James' (1980) concept of the 'stream of consciousness'.

5.5 Research Paradigms and their Different Conceptions of the Human Being

The essential nature of the human being is understood differently within the various research paradigms. This point needs to be addressed, since it impacts on which research approaches will be deemed appropriate for the study of human beings and subsequently used in research of TCA. Positivist orientations sometimes adopt behaviouristic¹⁵² understandings of the person. From the perspective of Behaviourism, knowledge is often obtained by studying phenomena from the 'outside' through experimentation on 'subjects' that are external to the researcher. Behaviourists tend to focus on 'objective' empirical data (*i.e.* behaviours). From the perspective of TCM, the accounts of the essential nature of the human given by behaviourists and positivists often ignore the many defining qualities and characteristics of human beings (see chapters 2 & 3). Often behaviourists see human beings as no more than stimulus/response animals, like Pavlov's dogs, since they concentrate on observable behaviour rather than exploring the states of consciousness that precede behaviour.

In contrast to the behaviourists, phenomenologists tend to understand humans as possessing varying degrees of free will and self-consciousness, with a volition to direct their own lives. Human beings would appear to have the ability to transform themselves and develop their latent potential. Wagner (1983) claims that human beings are able to go beyond their original endowment and to transcend themselves. Wagner remarks (1983, pp. 16-17) that human beings "not only assert themselves in the world in which they find themselves, and in which they forge considerable changes, they also sometimes abandon this world and create new worlds like those of the arts, sciences, philosophy, and religion." From a phenomenological perspective, behaviourists, when investigating phenomena that involves humans action and endeavour can understate or ignore the potentiality of human beings and metaphysical ideas concerning the will, psyche and the mind.

¹⁵² According to G. Vesey and P. Foulkes (1990, pp. 40-42), the school of psychology that came to be known as *Behaviourism* developed out of the 'classical conditioning' idea of the physiologist Ivan Pavlov. Behaviourists essentially see human action in terms of 'conditioning' involving a stimulus and response mechanism. Behaviourism is an example of a type of psychology that tends to adopt a positivistic orientation and that often utilises quantitative research methods.

5.6 The Relative Value of a Paradigm's Approach to Knowledge

Chinese philosophers advise that one should avoid taking up any extreme position. It is believed by Confucians, Daoists and Buddhists that it is better to keep to the 'middle path'. This should be kept in mind when debating the relative values of the various paradigms' paths to knowledge. Wagner (1983, p.18) emphasises the danger of extremes when he discusses behaviourism and phenomenology

[i]f we pursue the implications of these two approaches to their extreme consequences, we discover a mutual exclusiveness. The consistently behaviourist approach reveals external behaviour and its external conditions, but no consciousness. A consistent inner approach reveals inner consciousness but not outside aspects and conditions. The one completely eliminates from consideration all qualities that make human beings human; the other completely neglects the realities of the outside world. For the one, only a world of causal-mechanistic properties exists; for the other, only inner consciousness.

The positivist paradigms (including postpositivism/neopositivism) and phenomenology should not be seen as incommensurable approaches to knowledge; rather each orientation should be understood as complementing the other. Phenomenology places an emphasis on the certitude of personal 'subjective' phenomena, whereas positivistic approaches (as exemplified by behaviourism), place a greater value on 'objective' data that are more accessible to external modes of measurement. The methods of positivism and phenomenology could be understood as complementary ways of obtaining knowledge in the field of TCA: positivism being the 'outer' (*yang*) method which complements phenomenology, the 'inner' (*yin*) approach.

5.6.1 *The 'voices' of the various paradigms*

Guba and Lincoln (1994, p.115), in their cross-paradigm analysis, claim that the 'voice' of a paradigm is mirrored in the inquirer's activities. They claim that the 'voice' of positivism and postpositivism is often that of the 'disinterested scientist', whose activities are directed at decision and policy makers. In contrast, the 'voice' of the inquirer from the constructionist paradigm is often that of the 'passionate participant' acting as the facilitator of multi-voice reconstruction (Lincoln, 1991 cited in Guba and Lincoln, 1994, p. 115). From the constructionist perspective, "[c]hange is facilitated as reconstructions are formed and

individuals are stimulated to act on them.” (Guba and Lincoln, 1994, p. 115). The ‘voice’ of the phenomenologist reminds us of the importance of subjective experience.

Researchers of TCA should remain open to the diverse voices of the various research paradigms, since the different research approaches have the potential to reveal different facets of any given TCA phenomenon. Higgs and Titchen (1995, p.136) claim that “[r]estricting oneself to any single paradigm or way of knowing can result in a limitation to the range of knowledge and the depth of understanding which can be applied to a given problem situation.” Vickers (1996, p.16), in his examination of research paradigms in mainstream and complementary medicine, believes that it is now “time to foster discourse and incorporate different points of view and to abandon the forced choice between different, global systems. In short, we need to stop talking about paradigms and to start embracing pluralism.” When one considers the diversity of research questions that need to be addressed by the TCA profession (chapter 2.9), it is clear that researchers of TCA need to embrace pluralism and utilise a variety of research approaches.

5.7 Summary

Researchers of TCA need to remain open to the many varying research perspectives since the various approaches have the potential to reveal different aspects of any given TCA phenomenon studied. Researchers of TCA who restrict themselves to any *single* way of knowing or research paradigm could place limitations on the domains of knowledge and the depth of understanding that could be obtained. TCA practitioner-researchers need to continue to foster discourse and to consider different points of view from beyond the boundary of their own world view. While individual researchers might have an affinity with particular research methods, it has been argued that it is the *type* of research question that should direct the selection of an appropriate research approach for any particular TCA study. Researchers of TCA need to embrace research plurality and continue to utilise the methods of the various paradigms of research to explore the many facets of TCA.

CHAPTER 6

KNOWLEDGE AND THE WAYS-OF-KNOWING IN TRADITIONAL CHINESE ACUPUNCTURE

“In the ideal case, the structure of a man’s knowledge would match the structure of reality. At the highest level, there would be ‘knowledge for understanding’ in its purest form; at the lowest, there would be ‘knowledge for manipulation’. Understanding is required to decide what to do; the help of ‘knowledge for manipulation’ is needed to act effectively in the material world.”

- Schumacher (1978, p. 69)

In this chapter, the nature of TCA knowledge and the ways by which it has been and can be obtained are to be examined. The forms of knowledge that are held by members of the TCA profession and those that can be found in TCM literature will be identified. Consideration will be given to Chinese philosophical concepts of knowledge and how TCA practitioners transform their clinical experiences into knowledge. It will be argued that the contemporary TCA practitioner now utilises several types of knowledge including propositional knowledge, professional craft knowledge, practical knowledge and personal knowledge.

Knowledge in the discipline of TCA has been gained through a variety of traditional and contemporary methods, the most important of which are:

(i) The study of and reflection on classical Chinese texts by practitioners. The classic texts of TCM such as the *Nei Jing* (circa 200 B.C.) and *Nan Jing* (circa 100 A.D.) which were written and compiled by renowned TCM practitioners and philosophers have provided a source of traditional philosophical ideas, medical theories, and practices.

- (ii) Clinical knowledge has developed through continued practice and in some instances *via* the process of trial and error, where clinical procedures have been tested in the clinic after reflection on both the ideas from classical texts and clinical experience.¹⁵³ TCM knowledge can be understood as the “accumulation of subjective experience refined through a process of continuous reflection.” (Scheid, 1993, p. 27);
- (iii) Reflection on clinical experiences by TCA practitioners can result in *personal* knowledge that can be used in subsequent clinical encounters with clients;
- (iv) Apprenticeship. In China, until the 1950s, students of TCA obtained clinical knowledge through apprenticeships with experienced practitioners;
- (v) Through the appropriation and use of research methods from other disciplines (*e.g.* the randomised controlled trial and qualitative research methods).

6.1 Chinese Philosophical Concepts of Knowledge

According to Scheid (1993, p. 26), it is now generally accepted that Biomedicine and its knowledge claims have been “legitimised by a discourse which claims affinity to scientific rationality.” In contrast, until recent times TCM has generally engaged in a discourse emphasising tradition for this purpose. It is often claimed that TCA knowledge relies on an understanding of Chinese philosophy; hence an examination of the classic texts of Confucianism, Daoism and Buddhism could be expected to provide some insight into Oriental concepts of knowledge.

In the Daoist classic, the *Dao De Jing*, Laozi (Lao-tzu) (trans. 1972, chapter 71) states that: “Knowing ignorance is strength. Ignoring knowledge is sickness.” This quotation suggests that in Daoist thought a distinction can be drawn between knowledge and belief, and between the known and the unknown. It is often said in Chinese philosophical texts that the arrogant

¹⁵³ J. Resnick (1990, p. 10) notes that, “the spirit of the Nei Jing, is not about constructing clever concepts which then tell us what to do. Rather the richness lies in the contact we make, the quality of our involvement with patients. The essence of the diagnosis resides in the freedom it allows to reach people in a human, personal way as opposed to the purely technical.”

already believe that they have knowledge when in fact they are ignorant. In Daoism, it is believed that for one to gain knowledge and wisdom one usually has to first acquire humility, and that real knowledge can only be differentiated from belief after this has been achieved. In the Chinese language there is a term *chih*, which roughly corresponds to 'knowledge'. A concise explanation of the term *chih* is found in the *Hsun Tzu*: "[t]hat in man by which he knows is called *chih*; the *chih* that accords with actuality is called wisdom" (Audi, 1995, p. 116). Audi (1995) notes that in Chinese philosophy a distinction can be made between intelligence, or the ability to know, and its achievement, which is wisdom.

One finding that can be drawn from an analysis of the various classical source books of Chinese philosophy is that 'knowledge' was understood somewhat differently in ancient China than in the modern Western world. For example, when Fan Ch'ih asked Confucius about knowledge in that Confucian classic the *Analects*, Confucius replied that "[i]t is to know man". Wing-Tsit Chan (1963, p. 40), commenting on this passage of the *Analects*, claims that throughout the many periods of Chinese history that have been influenced by Confucian thought, there has been the idea that *knowledge* is the knowledge of the human being, and that power results from having this knowledge. In early Chinese thought, knowledge was not something abstract but rather something that could be utilised to benefit oneself and others. According to Chan (1963), China's humanistic philosophy could have prevented China from developing a tradition of knowledge for its own sake as has occurred in the occident. It would appear that many TCM concepts of knowledge have been formulated in the light of Chinese humanistic ideas. According to Morgan (1983, p. 373), an important evaluation criterion for 'knowledge' is whether it "serves to guide and shape ourselves as human beings". For the Chinese people, knowledge was often sought to understand the world in which they lived, to improve their quality of life, and to find some certainty in a world that at times might have seemed chaotic.

Joseph Dietzgen (1928, p. 96 quoted in Lyng 1990) has noted the importance of context when considering ideas and concepts. He claims that "any thing [*sic*] that is torn out of its contextual relations ceases to exist". The author would argue that TCM knowledge also needs to be considered in context, in terms of its holistic premises. TCM concepts can only be understood

through establishing their relationships with other concepts of the TCM discourse. The significance of this is that TCA ideas, theories, and practices might only be able to be comprehended in the context of the TCM paradigm. It needs to be remembered that what is regarded as knowledge is judged in terms of the epistemology of those who are evaluating particular knowledge claims: that is, what constitutes knowledge is dependent on the philosophical and epistemological orientation that one adopts (Higgs & Tichen, 1995, p. 130). Farquhar (1987, p. 1015), in her examination of the concept of knowledge in the Chinese medical discourse notes that 'knowing' is understood "as personal and historical experience formed in scholarly, didactic, and therapeutic practice." She adds that, "knowledge of this kind is not as radically cognitive as it is in our usual western use of the term."

A starting point in the examination of knowledge production in TCA is to analyse the ways in which TCA practitioners actually transform their clinical experiences into knowledge. The reason for this approach is predicated on the idea that much TCA knowledge has developed through the accumulated clinical experiences of TCA practitioners.

6.2 Modes of Thought Used by Practitioners of Traditional Chinese Medicine

That which constitutes knowledge in a medical system is determined, in part, by the mode of thinking used by the practitioners who work within that particular system. Manfred Porkert (1978, p.1), in *The Theoretical Foundations of Chinese Medicine*, states that

Chinese medicine, like other Chinese sciences, defines data on the basis of the inductive and synthetic mode of cognition. ... Inductivity corresponds to a logical link between two effective positions existing at the same time in different places in space. (Conversely, causality is the logical link between two effective positions given at different times at the same place in space.)

Porkert claims that if the mode of thought used by TCM practitioners is analysed, it would appear that an inductive and synthetic mode of thinking is more often used than the more causal and analytic forms that are used in Western science and medicine. A consequence of this orientation for TCA practitioners is that they will tend to make inductive links between phenomena first, and look for causal connections later. This is in contrast to Western thinking

that is found in science and medicine, which tends to make causal connections first and then only occasionally consider 'inductive links' between phenomena. Porkert's (1978) statements cannot be fully comprehended without an understanding of what is termed 'correlative thinking'. Correlative thinking is used by both Chinese philosophers and TCM practitioners and involves the idea that relationships can be established intuitively between phenomena because of a 'resonance' between them.¹⁵⁴ TCM diagnosis is based, in part, on such a system of correspondences (Kaptchuk, 1983, pp. 343-347). This can only be comprehended by understanding the Chinese view of causation in which things can

influence one another not by acts of mechanical causation, but by a kind of 'inductance'. ... Things behave in particular ways not necessarily because of prior actions or impulses of things, but because their position in the ever-moving cyclical universe was such that they were endowed with intrinsic natures which made that behaviour inevitable for them. (Needham, 1956 cited in Kaptchuk, 1983, p.15)

For example, the TCM concept of *xin* (heart) does not refer only to the heart organ, but rather to an entire system which includes other related phenomena such as the tongue, the colour red, joy, the complexion, the blood vessels and the *shen*. For the TCA practitioner, all of the above mentioned phenomena are related because they all 'resonate' with the 'fire' phase of TCM *wu xing* theory.¹⁵⁵ Clearly, practitioners of Biomedicine would not normally be able to see the relations between the above mentioned phenomena because the Chinese system of correspondence is not a feature of Biomedicine. Researchers of Biomedicine usually attempt to find *causal* connections between phenomena rather than seeking relations between phenomena based on resonance or correspondence.

6.3 Thought Processes and Reasoning in TCA

An initial insight into the forms of TCA knowledge used by practitioners can be gained by examining the modes of thought utilised by TCA practitioners to obtain clinical knowledge during clinical practice. Thought processes are necessary in both TCA practice and research,

¹⁵⁴ See Lu Gwei-djen and Needham, 1980, p. 216.

¹⁵⁵ For a full discussion of *wu xing* (five element/five phase) theory see G. Maciocia, 1989, pp. 15-34 or Z. Zhiya, 1995, pp. 173-177.

for without them practitioners and researchers could only observe and participate in phenomena without understanding them.

Reasoning is a type of mental process that allows people to make sense of, organise, and understand their thoughts, ideas and experiences. Reasoning is a thought process that allows empirical observations and clinical findings to be developed into ideas and theories within a philosophical and theoretical framework. These ideas and theories can then be applied and evaluated in clinical practice. For example, in TCA practice thought processes of TCA theory allow TCA practitioners to identify TCM 'patterns of disharmony' from clients' signs and symptoms (chapter 2). Without abstract thought, coherent bodies of medical knowledge could not be formed and transmitted from the TCA practitioner to the acupuncture student.

It should be noted that not all effective TCA procedures can be explained in terms of theory. For example, the needling of some acupuncture points have been found through clinical experience to be effective for particular health disorders and yet the reasons for their effectiveness is not clear in terms of either TCM or biomedical theory.¹⁵⁶ From the TCM perspective, a full understanding of the process or 'mechanism' by which an acupuncture point works is often of secondary importance when compared with the knowledge that an acupuncture point is clinically effective for a particular condition or 'pattern of disharmony'. This is one example that supports the notion that TCM places a greater emphasis in determining that which is *useful* to people rather than on 'theory' or 'knowledge' for its own sake, which is a characteristic of the Western scientific tradition.

6.3.1 *Logistic Reasoning in TCA.*

Reasoning is one means by which the ideas and thoughts of TCA practitioners and researchers can be organised and processed to reach conclusions about experiences of phenomena.

Logistic reasoning involves the mental dissection of a phenomenon into 'parts' so that the relationships between the 'parts' or aspects can be examined. In logistic reasoning it is assumed that the 'whole' is the sum of its parts and that the parts organise, or determine the whole

¹⁵⁶ See X. Cheng (1987, p. 506) for some examples: the ear acupuncture points 'Ear Apex' can be used for pain, redness and swelling of the eyes, and 'Helix 2,4, and 6 for swelling and pain of the throat.

(Burns & Grove, 1993, p. 9). Logistic reasoning often involves the process of reduction so that theories about phenomena can be developed. These theories can then be evaluated through further research. TCA practitioners no doubt use logistic reasoning in both practice and research. For example, logistic reasoning is required by researchers of TCA to select the most appropriate research design for any particular TCA study given the nature of the question to be addressed.

6.3.2 *Inductive and deductive reasoning*

When conducting experimental-type clinical research (see chapters 8, 9 & 10) deductive reasoning is utilised. This can involve testing a general principle or theory by examining specific cases of the phenomenon under investigation. Deductive reasoning is valued in biomedical research for its ability to explain cause and effect relationships between phenomena. In contrast, researchers who prefer to use ‘naturalistic inquiry’¹⁵⁷ and qualitative research methods (see chapter 12) tend to use inductive reasoning. Through inductive reasoning, theory or generalisations can be developed by examining a finite number of instances of the phenomenon being investigated (*e.g.* as in the qualitative research method of ‘grounded theory’¹⁵⁸). The two research approaches of naturalistic inquiry and experimental research can be seen to produce different types of knowledge by using two complementary reasoning processes. Table 6.1 below (p. 192) outlines some of the major differences between naturalistic inquiry and experimental-type research.

There can be marked differences between the purposes of naturalistic inquiry and experimental-type research. Naturalistic inquiry is often used to generate theory, to gain understanding, and to uncover the meaning of human experience, while quantitative research designs often test or evaluate theory. Over many centuries, TCA practitioners in China have both developed TCA concepts *and* evaluated TCA therapy through continued practice. This suggests that both

¹⁵⁷ Egon Guba (1978) describes ‘naturalistic’ inquiry as a discovery-oriented approach that minimises researcher manipulation of the study setting and which places no prior constraints on what the outcomes of the research will be. Often naturalistic inquiry involves the use of qualitative research methods.

¹⁵⁸ This is a method developed by B. Glasser and A. Strauss (1967) that primarily uses the inductive process of constant comparison to generate theory (see also chapter 12).

inductive and deductive reasoning is utilised by TCA practitioners.

Table 6.1 Major differences between naturalistic inquiry and experimental-type research (adapted from De Poy & Gitlin, 1993, p. 6)

Domain	Naturalistic Inquiry	Experimental-type
ontology/epistemology	multiple perceived realities	single objective reality
primary thinking process	inductive	deductive
purpose	reveal complexity, uncover the meaning of human experience	prediction, explanation of phenomena
theory	generates theory	tests theory
context	natural setting	controlled setting

6.3.3 *Dialectical reasoning*

Dialectical reasoning can be found in ancient Chinese philosophical and medical literature and is a natural outcome of the fundamental Chinese philosophical concept of *yin/yang* (see chapter 2).¹⁵⁹ In dialectical reasoning, a point of view is provisionally accepted and then analysed for its contradictory consequences. The process involves passing from one position to its opposite or antithesis, and from this to a 'higher' position through a synthesis.¹⁶⁰

In the modern world, the German philosopher Georg Hegel [1770 - 1831] is perhaps the best known philosopher to have utilised and promoted dialectics (Rowan, 1981b, p.129). Hegel claimed that the process of dialectic generates change and that this change can reveal new

¹⁵⁹ Vesey & Foulkes (p. 85) note that the word *dialectic* comes from the Greek term meaning the 'art of discussion'.

¹⁶⁰ G. Vesey and P. Foulkes (p. 85) note that Socrates, in Plato's writings, used this cyclic question and answer method of dialectic to attempt to apprehend the form of the 'Good'. Dialectical reasoning in the occident has been attributed in the first instance to the Eleatic philosopher Zeno and was used by him in Plato's *Parmenides*.

features that can appear to contradict previous understandings. There are two important characteristics of dialectical reasoning: (i) there is an emphasis on process and change rather than on static structures; and (ii) change comes about through opposition and conflict: hence the dialectic can be described as movement through contradiction. Dialectical reasoning and the development of dialectical theories involves looking for contradictions within people, situations and phenomena (Rowan, 1981b, p.130). Rowan (1981b, p. 131) remarks that the lessons of dialectic are not easy to comprehend. He claims that

any value we have, if held to in a one-sided way, will be an illusion.
 ...The only values, the only ideas, the only concepts, the only form of existence which will be truly stable and coherent will be one in which opposition is included rather than kept out; all such notions, from the standpoint of traditional logic, will appear paradoxical and absurd.

Fay (1996, p. 224) adds that in a dialectical approach

differences are not conceived as absolute, and consequently the relation between them is not one of utter antagonism. Indeed, on a dialectical view, alternatives, while genuinely competing, only appear to be completely "other" to each other. They are in fact deeply interconnected, and the confrontation between them reveals how these differences can be comprehended and transcended (transcended not in the sense of being obliterated but in the sense of being held in tension within a larger framework). Competing alternatives originally thought to have exhausted the possibilities can then be placed with a wider viewpoint which recognizes the worth in the original positions but which goes beyond them.

It could be expected that TCA practitioners conducting research would use dialectic reasoning since a central feature of *yin/yang* theory is that within any phenomenon 'polar opposites' can be found: that is *yin* can be found within the *yang*, and *yang* within the *yin*. Dialectical thinking can be used to make sense of data of a phenomenon that might on an initial examination seem contradictory to other data or studies obtained on that same phenomenon. For example, it might not always be possible to account for the signs and symptoms of clients in terms of a single TCM 'patterns of disharmony'. While the signs and symptoms might appear conflicting at the level of a *single* 'pattern of disharmony', the difficulty might be resolved at a higher level of organisation by merging ideas from other parts of TCM theory and creating a larger unit of analysis.

By looking for contradictions using the dialectic, the researcher has a greater chance of understanding the subtle nuances in data or the TCA phenomenon under investigation. The use of dialectics allows the researcher to appreciate the richness and ‘fuzziness’ of phenomena and prevents the all too frequent simplification of complex phenomena to simple categories or processes through the formulation of simple bivalent¹⁶¹ or black and white hypotheses of the experimental type. A type of dialectic reasoning is employed in Glasser and Strauss’ (1967) qualitative research methodology called *grounded theory* (see chapter 12). In *grounded theory*, the *constant comparative* method is used in which each datum is compared with others to discover differences and similarities within the data or the phenomenon being studied. This comparative method allows categories to be made and enables the exploration of differences within categories. In Chinese philosophical terms, this amounts to finding the *yin* within the *yang*, and the *yang* within the *yin*.

Dialectical reasoning can also be used in meta-analyses of TCA clinical trials where the various studies yield seemingly conflicting findings. By using dialectical reasoning, a resolution between conflicting findings could be achieved by generating a more comprehensive theory. For example, the evaluation of the efficacy of TCA for particular medical conditions using ‘single-blind’ randomised controlled trials has at times yielded conflicting findings (chapter 2). Dialectical reasoning might enable the identification of study design factors that could explain the differences in findings of such clinical trials.

6.4 Thought Processes used in TCA Diagnostic Reasoning

Further insights into how TCA knowledge is generated could be obtained by examining the thought processes used by practitioners when determining a TCA diagnosis. Zaslowski (1995, p.14) claims that while TCM is unique in that it has its own philosophy, theories and practices, it requires the same cognitive processes that are essential for problem solving and effective therapy in other knowledge domains.

¹⁶¹ According to B. Kosko (1993, p. 288) bivalent logic is the “logic most people mean when they say *logic*. Every statement or sentence is true or false or has the truth value of 1 or 0.” Kosko (1993) demonstrates some striking parallels between the contemporary theory of *fuzzy logic* and Oriental philosophical concepts *e.g.* Kosko’s *yin-yang* equation: $A = \text{not } A$.

Cox and Ewan (1988) have identified three cognitive strategies in clinical reasoning: (i) Pattern Recognition; (ii) Hypothetico-deductive Reasoning (HDR) and; (iii) Systematic Scanning.

Zaslowski (1995; 1997), a teacher and practitioner of TCA, claims that these three models of clinical reasoning could be used to explain the cognitive processes that occur when a TCA practitioner formulates a clinical diagnosis. He suggests that TCA practitioners utilise all three methods, with the 'expert' practitioner tending to use 'pattern recognition' or 'systematic scanning', while the novice is more likely to use 'hypothetico-deductive reasoning' (HDR).

Zaslowski (1995; 1997) claims that effective acupuncture therapy requires not only adequate interpersonal skills but also the ability to reason so as to determine a diagnosis by identifying the client's TCM 'pattern of disharmony'. In the *Bian Zheng Lun Zhi* (discrimination of patterns/differentiation of syndromes) school of TCM, effective therapy is believed to be dependent upon an accurate diagnosis that enables an appropriate treatment principle, therapy plan, and associated acupuncture points to be selected. This can only be achieved by the TCA practitioner reflecting on their theoretical knowledge and prior clinical experiences.

6.4.1 *Pattern recognition in clinical practice*

Cox and Ewan (1988, p.103 cited in Zaslowski 1995) argue that 'pattern recognition' can be used by practitioners and involves the recognition of a pattern stored in 'clinical memory'. Cox and Ewan claim that this pattern recognition can be so immediate as to be called *intuitive*. It would be expected that this form of 'intuitive knowledge' could only be utilised if the practitioner had substantial clinical experience upon which to draw. Zaslowski (1995, p.18; 1997) suggests that this type of clinical reasoning is often used by 'expert' TCA practitioners. From the perspective of *gestalt* psychology, it could be argued that each new client's 'pattern of disharmony' perceived by a TCA practitioner is spontaneously checked against the patterns of images that have been stored away in the practitioner's memory. Wagner (1983, pp. 52-53), a phenomenologist, in a related context claims that

[t]he perceived *Gestalt* instantly activates the traces of past memory. Thus, a perceived object, which is unique, and which has never been seen before, is directly identified, for instance, as an object like certain other objects encountered (some time, or many) times before. The newly experienced object is familiar; it is known from past experiences with similar objects.

The process of pattern recognition could involve seeing the *gestalt* of the client's 'pattern of disharmony'; however, this could not be done without a prior knowledge of the theory of TCM 'patterns of disharmony'.¹⁶² Wagner (1983, p. 53) also notes that it is the 'self' of the person that recognises the similarities between various patterns. It is people who have memories, not sensory impulses:

Such familiarity does not dwell in the sensory impulses; these are not endowed with memory. Such familiarity occurs to, and is in the person who perceives the object in question. This person is not a bunch of disconnected sense organs, but a human being who experiences each sensory impression as part of being alive, having a self with a life story.

Wagner's remarks give support to the importance of the concept of 'person'. This understanding can be contrasted with those more materialist and behaviourist conceptions which view the human being as only a biological entity.

6.4.2 *Hypothetico-deductive reasoning (HDR)*

Hypothetico-deductive reasoning (HDR) can be used by the novice and the 'intermediate' practitioner to solve clinical problems (Barrows & Tamblyn, 1980). This type of reasoning involves formulating diagnostic hypotheses early during the clinical encounter which are then compared with the client's pattern of signs and symptoms. In TCM practice, practitioners using HDR could consider the various TCM 'patterns of disharmony' and related diagnoses in relation to the client and progressively eliminate them until the most probable diagnosis is determined. This could be achieved by using the four methods of diagnosis (*si zhen*) and *bian zheng lun zhi* (discrimination of patterns/differentiation of syndromes) theory.¹⁶³

6.4.3 *Systematic scanning*

According to Zaslowski (1995; 1997), *systematic scanning* is inductive in nature and can yield

¹⁶² See G. Maciocia (1989) for a comprehensive account of TCM 'patterns of disharmony'.

¹⁶³ See B. Flaws, 1972.

a provisional holistic diagnosis by combining various types of client data, including such information as the signs and symptoms of TCM 'patterns of disharmony' and perceptions of psychological 'inner states'. The Worsleyian 'five element school' of acupuncture is an example of an acupuncture approach that utilises systematic scanning (Zaslowski, 1995, p. 17). Zaslowski (1995, p. 16) states that

This approach [systematic scanning] is well suited to non specific complaints such as tiredness, emotional disharmonies and the myriad of complaints that often have no organic cause from the biomedical point of view but represent a TCM pattern of disharmony. In a sense, it could be deemed more holistic in nature in that many different aspects and functions of the body are examined and assessed in order to offer an explanation of the condition in terms of TCM. It refuses to focus on the sign/symptom but prefers to view the body from a wider perspective.

Hicks (1987, p. 5 cited in Zaslowski, 1995, p.17) believes that the effectiveness of systematic scanning rests upon the clinician's ability to discern clients' 'inner states' from their behaviour, in addition to interpreting patterns of signs and symptoms. Therefore, the quality of client diagnostic information is dependent on what the clinician chooses to read and what is used in the formulation of a client diagnosis. The ability of a TCA practitioner to discern a client's 'inner states' from their behaviour would be dependent on the practitioner's clinical experiences and personal knowledge.¹⁶⁴

Students of TCA and novice TCA practitioners, because of their limited clinical experiences, are more likely to use hypothetico-deductive reasoning when trying to solve clinical problems. Students would be confined to using HDR since pattern recognition or systematic scanning requires a substantial 'clinical memory', which can only be obtained from extensive clinical experience. 'Expert' diagnosticians would tend to use either pattern recognition or systematic scanning and revert to the HDR mode only when faced with a novel or atypical case (Zaslowski, 1995, p.18).

¹⁶⁴ *Personal knowledge* has been defined by R. Butt and L. Yamaguishi (1982 cited in J. Higgs and A. Titchen, 1995, p. 139) as, "the unique frame of reference and knowledge of self which is central to the individual's sense of self." It is therefore the result of the individual's personal experiences and reflections on their experiences.

6.4.4 *The role of introspection and intuition in clinical reasoning*

The psychologist William James (1890, vii) once described introspection as, “the looking into our own minds and reporting what we there discover”. What we discover there are states of consciousness. Introspection is a process by which one can focus on one’s own internal mental states, thoughts and experiences. During this process, ‘internal states’ can be examined and patterns can be discerned among ideas, thoughts and mental phenomena. The relationships that one sees among the various ideas that make up these patterns might be real or imagined. It is sometimes claimed that intuitive insights can be achieved through introspection.

Rew and Barrow (1987) claim that *intuition* is an insight into the comprehension of a phenomenon, event or situation as a whole which cannot be logically explained. Intuitive insights must be derived from something, and it has been claimed that such insights are the result of ‘deep’ personal knowledge or ‘tacit’ knowing (Polanyi, 1966). This is the conception that knowledge can be stored deep in memory below the usual level of consciousness, and that an insight can result when a thought or idea reenters consciousness, with the insight often not being able to be explained in a logical way (Kaplan, 1964).

Researchers who work within positivistic paradigms are not always comfortable with intuition. Intuitions can be seen as ‘unscientific’, the result of unexplainable processes of consciousness. Insights that result from intuition might not be able to be accounted for in terms of logistic reasoning; however, sometimes they can be validated by further research, or through confirmation by others who have also experienced the same insight or experience. The philosopher, Bertrand Russell (1935, p.178) has also noted that

[w]hen a man of science tells us the result of an experiment, he also tells us how the experiment was performed; others can repeat it, and if the result is not confirmed it is not accepted as true... . The mystic himself may be certain that he *knows*, and has no need of scientific tests but those who are asked to accept his testimony will subject it to the same kind of scientific tests as those applied to men who say they have been to the North pole... . The chief argument in favour of the mystics is their agreement with each other... . I cannot admit any method of arriving at truth except that of science, but in the realm of the emotions I do not deny the value of the experiences which have given rise to religion.

Russell’s reflections are relevant to TCM, since it is often claimed that much of TCM

knowledge was uncovered in the distant past from the meditations and insights of enlightened sage physicians, rather than through logistic reasoning. Not all TCM knowledge is 'objective' and susceptible to validation through quantitative research designs. Some extremely valuable knowledge can be subjective in nature and can only be validated or confirmed by others who have experienced the same 'truth' or understanding through introspective means (see also phenomenological research in chapter 12). Schon (1987, cited by Higgs & Titchen, 1995, p. 138) has suggested that

in order to deal with the crisis of professional knowledge and education we need to recognize that outstanding practitioners do not have more professional knowledge but more 'wisdom', talent, 'intuition' or 'artistry'. And, we need to assimilate such knowledge into the dominant model of (propositional) professional knowledge and to give this artistic knowledge recognition in an environment which supports the hegemony of scientific knowledge.

Schon's comments are relevant to TCA practice and research. It would appear that much of the practical knowledge used by *experienced* TCA practitioners when making clinical judgments is tacit and individual, and it is this personal knowledge and wisdom that makes TCA practice just as much an art as it is a science.

6.5 Ways of Acquiring TCA Knowledge

Knowledge development in many health care professions has accumulated through a variety of ways. For example, nursing knowledge has grown through trial and error, personal experience, authority and tradition, mentorship and through using research methods appropriated from other disciplines (Burns and Groves, 1993, pp. 12-15). Similarly, when TCA practice and TCA literature are analysed, it can be seen that TCA knowledge has accumulated through a variety of ways. In the next section, the ways in which TCA knowledge has, and can be, acquired will be examined in more detail.

6.5.1 Authority and tradition

If the history of TCM is examined, it can be found that the concepts and theories taught by renowned traditional Chinese practitioners were rarely dismissed out of hand, or discarded

easily by other TCM practitioners. The reason for this attitude is in part cultural, and can be explained by the strong influence of Confucian thought which encouraged respect towards elders and their ideas. Authorities with special knowledge were also respected. An *authority* is a person who is believed to have considerable personal experience and knowledge in a particular area. Such authorities, throughout the history of TCM, have strongly influenced TCA practice and that information which is now regarded as TCA theory and knowledge.

University based TCA education is a recent development that began in China in the 1950s (Flaws, 1986). Prior to this time, the apprenticeship system was used almost exclusively to train TCA practitioners in China over the past 2000 years. Through the apprenticeship system, TCA knowledge has been transferred both orally and through role modelling. Much contemporary TCA practice is based on customs, beliefs and traditional theories of the past which have not been extensively evaluated by contemporary research methods. This does not mean however that TCA theory and practice is without value, since it is often claimed that TCA knowledge has been generated from the many positive patient outcomes that have occurred during TCA practitioner-patient encounters.

A concern for some commentators on TCA is that some TCA theories and practices espoused by some 'authorities' may have little clinical value from a Western biomedical research perspective (see Bensoussan, 1993). While the 'knowledge' derived from TCA 'authorities' has in the main *not* been validated by controlled clinical trials, it might still constitute valuable knowledge. It could also be noted that traditional practices are often difficult to change since they are frequently supported by people who have authority, prestige and power.

6.5.2 *The study of classical Chinese texts*

Linked to tradition is the veneration and respect for classic Chinese medical texts such as the *Nei Jing* and *Nan Jing*, which were written and compiled by learned sage physicians. The study of such texts has allowed TCA practitioners to access traditional Chinese knowledge (Ferrigno, 1997). It could be noted that the *Nei Jing*, one of the classic texts of TCM, essentially involves a dialogue between the Yellow Emperor and his physician Qi Bo (Chi Bo)

on topics of mutual interest including medicine. The *Nei Jing* could be seen as a precursor of postmodern knowledge production through 'conversation', since according to Kvale (1996, p. 42), 'conversation' is one feature of postmodern knowledge construction.

According to Farquhar (1994), knowledge can be gained through experience and reflection. This process involves the continuous reflection on practice, which she terms 'knowing practice'. Farquhar claims that the relationship between theory and practice is understood differently in Chinese medical texts when compared with Western science and medicine. In TCM, theory and practice are seen as dialectically linked, rather than practice being the application of theory. Scheid (1993, p. 27) explains:

Traditional Chinese medicine cannot be said to be the practical application of knowledge contained in abstract form in classical or modern texts. Texts merely serve as a guide from which individual practice originates and which it returns. ... practice should evolve dialectically in a conversation between the texts of the tradition and the experience of the clinic. Whatever the statement of a given author, each clinician is able to test and evaluate it within the boundaries of her [or his] own surgery. No other investment is needed than the ability to read, to reflect and to practice.

The testing of traditional theory from classic Chinese texts by individual TCA practitioners would seem a valid type of research, although researchers with strong positivist convictions who champion the strengths of quantitative research methods might not agree.

6.5.3 *Role-modelling*

Role-modelling through association with an exemplar is another way for the student of TCA or novice acupuncturist to gain clinical knowledge. This exemplar could be a TCA lecturer or TCA practitioner, who is seen by the TCA student or novice, as having an exceptional understanding of the knowledge and practice of TCA. This type of student learning is acknowledged by many TCM teaching institutions which require students to spend considerable hours observing and assisting experienced TCA practitioners.¹⁶⁵ One of the educational aims of clinical placement with experienced TCA practitioners is to help the student to integrate TCA philosophy, theory

¹⁶⁵ For example, students of TCA at the Victoria University of Technology in Australia have to complete in excess of 600 hours in approved clinical settings over the four years of the Bachelor of Health Science - TCM (Acupuncture) program.

and practice, and to learn the necessary interpersonal and clinical skills required for professional practice. Some TCA practitioners also take on the role of mentor. The mentor-mentee relationship is a more intense form of role-modelling. This relationship sometimes develops during a clinical placement from the respect a student has towards a particularly charismatic TCA practitioner who inspires the student through their example of successful practice.

6.6 Types of Knowledge

Higgs and Titchen (1995, p.136) claim that in Western philosophy, knowledge has been classified into two broad categories: (i) *propositional* and (ii) *non-propositional*. They claim that a hierarchical relationship has developed between propositional and non-propositional knowledge, with propositional knowledge now having a higher status. This parallels the hierarchical relationship between theory and practice that is often found in Western scientific and medical discourses.

6.6.1 *Propositional knowledge*

Propositional knowledge encompasses that knowledge that is found in text books and academic journals. It can be expressed in the form of “abstract, logical and formal relationships between concepts or constructs, and formal statements concerning interactional and causal relationships between events” (Benner 1984, cited in Higgs & Titchen, 1995, p. 137). Heron (1981 cited by Higgs & Titchen, 1995, pp. 137-138) states that “the outcome of research is stated in propositions, which claim to be assertions of facts or truths” that can be added to the body of knowledge statements. Higgs and Titchen (1995, p. 138) note that, “propositional knowledge can be generated in any research paradigm”. Propositional knowledge is the ‘objective’ knowledge of a profession in the sense that it constitutes the public knowledge of the profession. Classic Chinese philosophical and medical texts (*e.g. Nei Jing*) and the various commentaries and interpretations of them constitute much of the propositional knowledge of the TCA profession.

6.6.2 *Non-propositional knowledge*

Non-propositional knowledge can be contrasted with propositional and declarative forms of knowledge. Non-propositional knowledge “is derived primarily through practice, without an attempt to generalize.” (Higgs & Titchen, 1995, p. 136). According to Higgs and Titchen (1995, p. 138), non-propositional knowledge includes *professional craft knowledge*, *practical knowledge* (Benner, 1984; Reason and Heron, 1986), *experiential knowledge* (Reason and Heron, 1986; Kolb, 1984), *intuitive knowledge* (Agan, 1987; Rew and Barrow, 1987; Benner, 1984; McCormack, 1992), *aesthetic, personal and ethical knowledge* (Carper, 1978).

6.6.2.1 *Professional craft knowledge.*

Professional craft knowledge is a term used by Higgs and Titchen (1995, pp. 138-39) for that practical expertise, skill and intuitive clinical knowledge “which guides everyday activities of caring for patients and underpins the practitioner’s rapid and fluent response to a situation”. Higgs and Titchen (1995, p. 139) claim that the “ability of health practitioners to interpret incomplete and ambiguous data and to identify implications which are not directly deducible from explicit data depends upon clinical knowledge or judgment which can be likened to intuitive knowledge”. They claim that professional craft knowledge is a rhetorically useful term because it gives a sense of the aesthetic and of knowing the *what*, *when*, and *how* in real clinical situations.

Professional craft knowledge involves tacit, intuitive and practical expertise. Salner (1989, p. 57) suggests that, “[t]he explication of pretheoretical (tacit) knowledge is a way of epistemologically describing and incorporating human intuition and the fact of human consciousness into the process of inquiry.” From Higgs and Titchen’s (1995) description of professional craft knowledge, it would appear that TCA practitioners utilise this type of knowledge as demonstrated by their judgments and actions during clinical practice (see chapter 2).

Brenner (1984) has noted that practical knowledge has remained tacit in some professions. For example, in the nursing profession, many nurses see professional craft knowledge as so obvious and ordinary that until recent times it was rarely articulated in nursing literature. The same conclusion could be drawn for professional craft knowledge in the TCA profession. It is important for the TCA profession that an effort is made to further transform professional craft knowledge into propositional knowledge. This could allow the development of guidelines for best TCA practice (see chapter 7.4.3.2) or provide detailed descriptions of TCA interventions that could enable clinical trials to be replicated.¹⁶⁶

6.6.3 *Personal knowledge*

Personal knowledge has been defined by Butt and Yamaguishi (1982 cited in Higgs & Titchen, 1995, p. 139) as “the unique frame of reference and knowledge of self which is central to the individual’s sense of self.” Personal knowledge is the result of the individual’s personal experiences and reflections on their experiences. Scheid (1993, p. 27) suggests that “the ongoing exegesis and interpretation of the classical [Chinese] literature” provides the “conceptual frameworks for the development and transmission of highly personalised medical knowledge.” Higgs and Titchen (1995, p. 139) claim that “knowledge of self is the core of personal knowledge and wisdom”. This same idea is also found in the classic Daoist text the *Dao De Jing*, where Laozi writes that “knowing self is called wisdom” (cited in Higgs & Titchen 1995, p. 139). Higgs and Titchen (1995, p.139) claim that

an individual’s knowledge base has a personal foundation, since it is constructed and tested within the individual’s frame of reference which comprises the individual’s value systems, prior learning and current convictions. We also suggest that the individual has a store of personal knowledge into which other knowledge becomes incorporated, or which becomes revised as a result of the individual’s developments in knowing.

Wylde (1989, p.115 cited in Higgs & Titchen, 1995, p. 140) adds that it is only possible to use something that is read or heard if that ‘something’ connects with one’s own experience.

Hundert (1987 cited by Higgs & Titchen, 1995, p.140) believes that personal knowledge needs to incorporate feelings and spiritual elements of self, and to look beyond the limits of cognition.

¹⁶⁶ A therapeutic intervention needs to be first defined before it can be evaluated in clinical trials. If the therapeutic intervention is not clearly defined it will be difficult to generalise the findings to other settings.

A related understanding is found within TCM, where the state of the TCA practitioner's *shen* is regarded as being an important factor in determining an accurate diagnosis and providing appropriate therapy.

Many researchers in the health professions believe that it is important to challenge the conventional idea that knowledge is only generated through research, and to cultivate the equally valuable idea that practitioners produce knowledge through their practice and through their personal quest for meaning (see Schon, 1983; Eraut, 1985; Elliott, 1991; Higgs, 1992; Titchen & Binnie, 1993 cited in Higgs & Titchen, 1995, p. 143). Scheid (1993, pp. 27-28) has made the important observation that for the TCM practitioner, clinical skill develops progressively throughout one's lifetime, with knowledge growing through continued practice. This is in contrast to Biomedicine, "where the college graduate is usually closer to the frontier of current knowledge than the retiring G.P."¹⁶⁷

6.6.4 *Knowledge from personal experience though 'trial and error'*

From the TCM perspective, people are understood to be unique individuals (see chapter 2). From this understanding, it follows that there will be no *standard* treatment plan that could be devised by a TCA practitioner that will be appropriate for other clients with a similar 'pattern of disharmony'. TCA management plans, even with the *same* client, will change with the client's changing circumstances, health status and disposition. As a consequence, there will always be an element of uncertainty in TCA clinical practice, which can only be dealt with through clinical experience. Even when there is insufficient knowledge to make a definitive TCA diagnosis, sometimes therapy is begun, with the TCA practitioner drawing on tacit knowledge gained from his or her prior experiences in similar situations. Health outcomes for clients are often maximised by changing treatment plans and drawing on different TCM theories and approaches when one particular approach is not working. In this way, a type of knowledge can be gained through the process of 'trial and error'. Salner (1989, p. 55) has noted that, "the ability to learn from trial and error - a universal human ability - is the foundation of our capacity to create hypotheses and theories, test them in practice, and amend or abandon them according to the demands of communal existence."

¹⁶⁷ 'G.P.' is an abbreviation for a general practitioner (of biomedicine).

Personal TCA knowledge that is developed in clinical practice by individual practitioners is often tacit and not documented formally and communicated to other practitioners. Most TCM practitioners claim that TCM is based on experience (*jingyan*) (Scheid, 1994, p.16). It is evident that over time, through personal experience, it becomes easier for TCA practitioners to intuitively grasp the 'whole' of a clinical situation by linking or clustering ideas, theories and observations into a *gestalt* that has meaning for the practitioner. It is this ability that provides the foundation from which therapy begins. It should be noted that this process is not specific to TCA but can also be found in biomedical practice. Heron (1981), in his typology of knowledge, discusses what he terms *experiential* knowledge. This is knowledge gained through direct face-to-face encounters with persons, places, or things. TCA practitioners gain this type of knowledge through client encounters. A substantial proportion of TCA knowledge has come from clinical experience, that is, through practice. This experience guides TCA clinical practice as does theory.

Western biomedical researchers often undervalue clinical experience when compared with that knowledge which is generated by controlled clinical studies. Perhaps one reason for this is that experience is often based on correlations between phenomena and does not necessarily provide an account of the *mechanism* behind the various factors involved in the phenomenon studied. Some Western biomedical researchers speak of empirical knowledge gained through experience in derogatory terms because sometimes no explanation or theory is given for the observed phenomenon. It should be remembered though that a theory, or an explanation that provides an account of the reasons for the correlation between a therapy and its associated health outcomes, is not essential in research that endeavours to determine a therapy's effectiveness. This is because the purpose of therapy evaluation is to determine if, and to what degree, a therapy works, rather than determining *how* it works. Clearly, explaining *how* a therapy works is not what makes a therapy useful. Some Western medical practitioners dismiss out of hand some of the 'esoteric' theories of TCM but admit that the acupuncture technique can be efficacious. Perhaps the more important question in health care in societal terms is not *how* a therapy works, but rather *does it work*. Black (1988) relates a story that is relevant to this point. In 1983, the *Los Angeles Times* reported on a study conducted in Texas on the therapeutic effect

of Chinese herbs for cancer. The article quoted the project manager as saying, “we have something that works, or at least seems to. Our problem, however, is that we do not know *why* or *how* it works [my italics], and until we do, we cannot develop this as a modern medicine.” (Black, 1988, p. 71). This example supports the notion that Western biomedical science assigns a much higher value to knowing *how* a therapy works than to knowing that a therapy is efficacious. As a result, therapies such as TCA can be regarded as unscientific or unproven because medical researchers do not understand *how* the therapy works, even though there is evidence that it has therapeutic value.

6.6.4.1 *Practical knowledge*

Heron (1981) has described what he terms *practical knowledge*. Practical knowledge is that which is “concerned with how to do something - it is knowledge demonstrated in a skill or competence”. It could be noted that it is often *experience* that is the final arbitrator when decisions have to be made as to whether a particular medical intervention is safe and can be continued to be used. For example, there have been many instances where a new pharmaceutical drug has been approved for use on the general public after being found to be ‘safe’ and effective through a double-blind randomised clinical trial, and which has been later withdrawn by the manufacturer based only on a few reports of doctors that have reported side effects of the drug. This would suggest that the information gained from clinical *experience* can be superior to that obtained by randomised clinical trials. In the scenario just described, medical researchers would lose their credibility if they insisted that the double-blind randomised clinical trial was the superior test of truth. Despite some exceptions, Western medical researchers would now seem to rely more on controlled clinical trials and less on observation and clinical experience. Knowledge gained through clinical experience might not be regarded as scientific in the strictest sense; however, it has been the foundation on which TCA practitioners have developed an apparently effective system of therapy.

Empirical information collected by practitioners during clinical practice should not be undervalued. Correlations between a therapy and its effects can persist across time, and it is possible that these correlations have been noted by TCA practitioners in China over the last two

thousand years. If medical practitioners can notice the *adverse* side-effects of a prescribed pharmaceutical drug after only a few months of experience with it, it is also quite reasonable to believe that TCA practitioners could have determined patterns of *beneficial* effects from the use of TCA with their patients.

It should also not be forgotten that a single clinical trial often tests only the skill of the practitioner rather than the effectiveness of the therapy. The remarks of Kuhn (1970, p. 5) for the research scientist apply similarly to the medical researcher:

the practitioner of such an enterprise [science] must often test the conjectural puzzle solution that his ingenuity suggests. If it fails the test, only his own ability not the corpus of current science is impugned. In short, though tests occur frequently in normal science, these tests are a peculiar sort, for in the final analysis it is the individual scientist rather than current theory which is tested.

This same argument holds for the individual practitioner-researcher who conducts clinical trials. It is for this reason that when conducting clinical research to establish the effectiveness of TCA therapy, several researchers should administer the therapy that is to be evaluated, or else the study could be criticised as having only tested the skill of an individual practitioner-researcher and not the therapy *per se*.

6.7 Appropriation of Research Methods from other Disciplines

The TCA profession is now in the process of appropriating the methods of obtaining knowledge from other disciplines. This is a result, in part, of the changes in professional TCM education in universities. For example, the aim of Australian university TCA programs is to train undergraduate students to become primary health care practitioners. This has resulted in the introduction of psychology, counselling and research methods subjects into university TCA degree programs. While health counselling has been an important part of TCA practice for some TCA practitioners, it is one example of an area that has been developed to a high level in other disciplines and which can be adapted where necessary to meet the specific needs of TCA practice.

6.7.1 *Clinical Trials, Naturalistic inquiry and Qualitative Research*

In recent years, knowledge regarding the effectiveness of TCA has been obtained through controlled clinical trials using research designs that have been adapted from biomedical research methods (Bensoussan & Myers, 1996). The benefits and limitations of this approach to obtaining TCA knowledge will be examined in detail in chapters eight, nine and ten. The uses and future roles of naturalistic inquiry and qualitative research methods to investigate TCA will be examined in detail in chapter twelve.

6.8 **Summary**

This chapter has examined the nature of TCA knowledge and the methods by which it has been and can be obtained. An insight into the forms of knowledge used by TCA practitioners was gained through an exploration of the modes of thought utilised by practitioners to transform their clinical experiences into clinical knowledge. The contemporary TCA practitioner now utilises at least four kinds of knowledge: (i) propositional knowledge; (ii) professional craft knowledge; (iii) practical knowledge; and (iv) personal knowledge. Knowledge in the discipline of TCA has developed through a variety of traditional and contemporary methods including the study of classical Chinese texts, authority and tradition, mentorship, reflection on clinical practice and personal experience, trial and error, and through the use of research methods appropriated from other disciplines. Considering the types of knowledge that are utilised in TCA suggests that a variety of research methods will need to be employed to both produce and understand TCA knowledge.

CHAPTER 7

THE EPISTEMOLOGICAL ORIENTATIONS OF TRADITIONAL CHINESE ACUPUNCTURE PRACTICE: IMPLICATIONS FOR RESEARCH

The previous chapter examined the various ways that TCA practitioners and researchers have obtained knowledge of TCA in both China and in the Occident. This chapter will develop the findings of the last chapter and make explicit the epistemological orientations of these various approaches to obtaining TCA knowledge. This analysis will draw upon Mosey's (1992) topology of 'epistemological orientations of practice' that have been found in the health care professions. This will enable the determination of the epistemological orientations to TCA practice that have been, and are currently being used by TCA practitioners. This analysis will allow for the detection of any dissonance between TCA practice, its purported philosophy, and the methods of contemporary TCA inquiry.

7.1 Research and the Health Professions

One factor that has influenced the types of research method that have been utilised by the TCA profession in recent times has been the models of professional education that have been drawn upon by academics involved in TCM education. Della Fish (1995) claims that there are two distinct models of professional education. The first is the *technical-rational view of professional practice* that has given rise to the competency-based approach to professional education. The second is the *professional artistry model of professionalism* which is derived from reflective practitioner philosophy.¹⁶⁸ If one examines the TCA profession in Australia,

¹⁶⁸ See D. Schon, *The reflective practitioner: How professionals think in action*, 1983.

the United States and the United Kingdom, it is clear that both models have been drawn upon by TCA practitioners, educators, and researchers of TCA. Table 7.1 compares the characteristics and features of the *technical-rational view of professional practice* with those of the *professional artistry model of professionalism*.

Table 7.1 Comparison of the characteristics and features of the Technical-rational View of Professional Practice and the Professional Artistry Model of Professionalism (adapted from Della Fish, 1995)

<i>The technical-rational view of professional practice</i>	<i>The professional artistry model of professionalism</i>
* sees knowledge as graspable, permanent	* sees knowledge as temporary, dynamic
* theory is applied to practice	* theory emerges from practice
* technical expertise is all	* professional judgment counts
* sees professional activities as masterable	* embraces uncertainty
* standards are measurable	* sees mystery at the heart of professional activities
* emphasises assessment, appraisal, and accreditation	* emphasises investigation, reflection, deliberation
* quality is really about quantity of that which is easily measurable	* quality comes from deepening insight into one's values, priorities, actions
* technical accountability	* professional answerability
* uses routine prescriptions	* sees patterns and utilises frameworks
* uses diagnosis analysis	* utilises interpretation analysis

According to Schon (1983, p. 21), the dominant 'epistemology of practice' in many professions is that of the model of 'technical rationality'. Schon claims that it is this view of professional knowledge that has most powerfully configured both our thinking about the professions and the institutional relations with education, research and practice. In this model, problem solving is made rigorous by the application of scientific theory and technique.

Since the 1950s, the technical-rational view of professional practice has influenced much TCA

research in both China and the West. For example, the randomised controlled trial (RCT), which is strongly associated with the technical-rational view of professionalism, has been used extensively to evaluate the efficacy of TCA (see chapters 8, 9 & 10). One reason for the TCA profession embracing the RCT has been political. Some members of the TCA profession have held the belief that acupuncture practitioners and researchers in the West must *prove* that TCA is an efficacious treatment for illness and disease by using research methods (*e.g.* the RCT) that are considered sound by government health departments, research bodies and mainstream medical researchers. In the last few years, however, there has been a greater appreciation of the professional artistry model of professionalism (Fish, 1995). This would suggest a greater role in the future for qualitative and interpretive research approaches (see chapter 12) that are flexible enough to acknowledge the artistry and uncertainty of TCA clinical practice.

7.2 Epistemological Orientations of Practice

According to Anne Mosey (1992), that which constitutes knowledge for a profession is dependent on the profession's assumptions and tenets, and in part on the profession's orientation to practice. The term 'epistemology of practice' was coined by Schon (1983) and defined by Mosey (1992, pp. 4-5) as the "investigation of the origin, nature, forms of inquiry, and organisation of knowledge in the science based professions and the use of such knowledge in practice." Mosey adds that it "includes the study of how professions describe their ideology and its relationship to scientific knowledge."¹⁶⁹

Health care professionals claim expertise in assisting people when experiencing illness and disease, and it could be argued on ethical grounds that it is the responsibility of such professionals to develop the body of applied professional knowledge upon which their practice is based. Philosophers have tended not to investigate the ways in which theoretical knowledge and the methods of science are employed to meet practical needs. According to Bunge (1983, p. 62 cited in Mosey, 1992, p. 3), "the application of theory to practical goals poses considerable and largely neglected philosophical problems".

¹⁶⁹ According to Mosey (1992, p. 5), there is a deficiency of knowledge within the subject field of 'epistemology of practice'. The reasons for this include: (i) a preoccupation of health practitioners with assisting patients; (ii) no pressing feeling of urgency felt by health practitioners to examine the subject; and (iii) a hesitancy by health practitioners to enter a new area of study.

7.3 Reasons for the neglect of the epistemologies of practice

Schon (1983, p. 24) has claimed that, “[t]he concept of ‘application’ leads to a view of professional knowledge as a hierarchy, in which ‘general principles’ occupy the highest level and ‘concrete problem solving’ the lowest.” According to Grove (1989), praxis served the needs of humankind up to the time of the Greeks. The role of praxis in old cultures was to solve the common and *real* problems that were experienced by people living in society. Similarly, in ancient China, TCM practitioners developed their own pragmatic system of traditional medicine to treat disease and reduce suffering.

The formulation of general principles or theories to explain the nature and structure of the universe was initiated by the Ionians around 600 B.C. (Mosey, 1992, p. 6). It was at this time that inquiry and investigation began to be motivated more by the desire to understand the world for its own sake rather than for any practical purpose. As Mosey (1992, p. 6) states

[t]he praxis of craftsmen, physicians, and artisans was quite different than the *theoria* of philosophers. Praxis was concerned with the solution of practical problems, *theoria* with the universe. Greek philosophers recognised the necessity of praxis but viewed it as far inferior to *theoria*.

It could be argued that in contemporary biomedical research there is still an emphasis on determining the mechanisms of pathological processes (*theoria*) rather than finding solutions to the more important societal problems such as determining the best available therapy for particular human health problems (*praxis*).

7.4 Epistemological Orientations to Health Care Practice

Mosey (1992, p.14) suggests that the ‘epistemological orientations to practice’ found in the health care professions can be reduced to four general types: (i) the *traditional*; (ii) the *disciplinal*; (iii) *neopositivism*; and (iv) the *phenomenological* orientation. It would appear that some health care professions have a distinct epistemological orientation, while others have features of more than one type. During the process of a profession’s development there can even be a change in epistemological orientation (Mosey, 1992). An analysis of TCA, using

Mosey's (1992) topology, will allow for the determination of the epistemological orientations to TCA practice used by TCA practitioners. This examination will reveal how TCA practitioners have produced, and continue to produce, different types of TCA knowledge through the various epistemological orientations.

7.4.1 *The traditional epistemological orientation to practice*

In Mosey's (1992) *traditional epistemological orientation to practice*, it is acknowledged that the origin of knowledge that is regarded as fundamental to practice is embedded in the past. Within this orientation, knowledge consists mainly of particular practices and solutions for specific problems. In this orientation, the tradition of practice can be accepted as 'truth'. In professions that are based in this epistemological orientation, knowledge is often transferred from one generation of practitioners to the next with only small modifications and additions being made to it. The acquisition of knowledge is usually gained through apprenticeship, which is considered to be one of the ways to ensure mastery of the body of knowledge. It should be noted that the apprenticeship system was used almost exclusively to train TCA practitioners in China over acupuncture's 2000 year history. Formal university based TCA education in China only began during the early 1950s and is therefore a relatively recent phenomenon (Flaws, 1986). The clinical placement of TCA students with experienced practitioners is still regarded by TCM academics of both Chinese and Australian universities as being very important for enabling TCA students to integrate TCM theory and practice, and to gain clinical experience and knowledge.

The traditional epistemological orientation to practice still remains operant in the TCA profession since many members of the profession continue to rely on traditional knowledge, information, and practices from the past which have not been substantiated by contemporary research methods. It should be noted that many contemporary TCA practitioners in the West still have the utmost respect for the classical writings (*e.g. Nei Jing and Nan Jing*) of China's learned TCM practitioners of the past.

One possible disadvantage for professions that utilise only a traditional epistemological

orientation to practice is that knowledge can be slow to advance, since professions based on the authority of the past might not easily embrace innovative ideas. One reason that science in the occident is believed to have progressed so rapidly from the 16th century is due to the skepticism of great thinkers who thought that any proposition or statement, even if made by great authorities, was open to doubt and analysis (Polgar and Thomas, 1995, p. 5). In contrast, if the history of TCM is examined, it can be found that many of the concepts and theories of the various schools of TCM taught by renowned practitioners were rarely dismissed out of hand by other TCM practitioners. One possible reason for this attitude could have been the belief that the value of a theory is context dependent. A theory's level of acceptance could increase or decrease in response to a change in social-political or environmental (*i.e.* climatic) factors (Unschuld, 1985; Bensoussan, 1993, p. 39). A second explanation as to why theories were not discarded easily can be found in cultural terms, through the strong influence of Confucian thought which encouraged respect towards elders. The denigration of any theory, idea or practice could have resulted in a 'loss of face' for the person whose theory was found to be deficient, an outcome that the Chinese people would attempt to avoid.

Paul Unschuld (1985, p. 57) has noted that if one examines the history of Chinese medicine there can be found a syncretism¹⁷⁰ of ideas. In TCM, there have always been many opposing schools of thought, and yet somehow a way was always found to reconcile opposing views. This has permitted TCM practitioners to draw liberally from all of the concepts and practices available from the various schools of thought, as long as they were not regarded as being harmful or destructive to individuals or society. The complex mosaic of Chinese medical ideas and theory might be seen to support Paul Feyerabend's 'anarchistic' theory of knowledge.

Feyerabend (1975, p. 47) states in *Against Method* that, "[t]here is no idea, however ancient and absurd, that is not capable of improving our knowledge. The whole history of thought is absorbed into science and is used for improving every single theory". Feyerabend suggests that this "may be needed to overcome the chauvinism of science that resists alternatives to the status

¹⁷⁰ According to D. Polkinghorne (1983, p. 252) *syncretism* "denotes the uniting or combining of differences, a meaning which *synthesis* does not carry. This approach proposes something more than the use of multiple systems of inquiry: it proposes the additional step of syncretizing the results of the multiple inquiries into a unified and integral result."

quo.” Feyerabend (1975, p.35) claimed that the “[p]roliferation of theories is beneficial for science, while uniformity impairs its critical power.” Similarly, the plethora of TCM theories could be beneficial for TCA and medicine in general. No TCM theory should be dismissed without due consideration and a fair assessment.

The traditional epistemological orientation to practice of most health professions is usually described in retrospect as professions change and develop a coherent ‘scientific’ foundation. It is at this time that terms such as *science*, *theory* and *research* begin to appear in a profession’s literature (Mosey, 1992, p. 19). Some academics claim that the TCA profession is in just this position in the 1990s. TCA might be seen as a profession in transition, looking for an epistemological orientation for its future growth. As an example of this movement, Bensoussan (1993), in a journal article titled, “Where to now?” questioned the future directions of acupuncture research. In this article it was suggested that acupuncturists should scrutinise more closely its ‘sacred cow-TCM theory’ and begin to evaluate which parts of TCM theory are important and to what degree. Pronouncements similar to Bensoussan’s are becoming more common in Western TCA academic circles. This suggests that TCM knowledge and theory from the past may no longer be accepted without question, and that it is becoming more likely to be scrutinised by the process of analytic critique and scientific inquiry. If the fundamental theories of TCA are to be further examined and assessed, it is possible that there will be a shift from a ‘traditional’ epistemological orientation to one that is more positivistic in nature (see chapter 7.4.3 below).

7.4.2 *The disciplinal epistemological orientation to practice*

In health care professions in which practitioners utilise Mosey’s (1992) *disciplinal epistemological orientation to practice*, there is the belief that it is the responsibility of the profession to develop, refine, and test the validity of the profession’s theoretical body of knowledge. According to some authors, professions with a disciplinal epistemological orientation to practice try not to draw upon the bodies of knowledge of other disciplines (Beckstrand, 1986; Christiansen, 1990). According to Mosey (1992, pp.21-22), the theoretical

body of knowledge of professions that adopt a disciplinal orientation to practice tend to take one of two forms:

- (i) a 'comprehensive' theory that constitutes a paradigm.¹⁷¹ This comprehensive theory tends to have loose boundaries and addresses a spectrum of phenomena through the use of global or open-ended concepts (Merton, 1982 cited in Mosey, 1992). The comprehensive theory of a profession with a disciplinal orientation is believed to contain all of the theoretical information required to address all of the phenomena that will be encountered by practitioners of the profession¹⁷²;
- (ii) a set of 'multiple theories', each of which addresses a circumscribed set of phenomena encountered by practitioners of the profession. These multiple theories are less global than a 'comprehensive' theory and describe only limited phenomena within the broader category of phenomena that are of concern to the profession.

In the disciplinal epistemological orientation to practice, a profession's body of theoretical knowledge is understood by members of the profession as being unique, and not shared by other professions or disciplines. Theoretical information that is not found within the 'comprehensive' or 'multiple theories' is often considered by members of the profession to be highly suspect. This, to some degree, is the position held by some members of the TCA profession who see a knowledge of Western medicine as being of minimal use in their TCA practice. From personal communications with TCA practitioners, it appears that some practitioners only draw upon Western medical knowledge to determine if referral to another modality or medical system is required, rather than to help them determine a diagnosis and treatment plan.

¹⁷¹ The comprehensive theory tends to be holistic. Holism maintains that all entities should be studied as wholes, and that aspects or parts of the entity can only be understood with due consideration of their relationship to the 'whole' (chapter 3). This position is in contrast to the philosophy of reductionism which attempts to understand entities by investigation and analysis of their parts.

¹⁷² Comprehensive theories tend to be based on a fundamental first principle that is identified as the essence of reality. Such a monistic account views all structures and processes as being derived from one governing principle. If the 'disciplinal epistemological orientation' were to be applied to TCA, the one fundamental theory or principle would be the Daoist concept of *dao* and its manifestation, *qi*.

In professions with a disciplinal epistemological orientation, the comprehensive theory or the set of multiple theories tend to dominate all aspects of the profession and often act as a filter to determine which new concepts, ideas and methods will be considered legitimate for the profession. Basic scientific inquiry is usually regarded as an acceptable form of investigation for a profession with a disciplinal orientation, since it is believed that theoretical knowledge can be used directly to guide practice. Therefore, in this orientation, the knowledge base of the discipline can be expanded by either refining or testing the validity of aspects of the 'comprehensive' or 'multiple' theories.

In a disciplinal epistemological orientation there might or might not be specific guidelines about how the comprehensive theory is to be applied in practice. Judith Larsen (1981) suggests that the comprehensive theory sometimes provides only a context for the application of the theory rather than giving specific methods for practice. This aspect of the disciplinal orientation can be found to an extent in the TCA. For example, in the classic TCM text, the *Nei Jing*, many of the theoretical tenets of TCA are outlined; however, specific guidelines as to how some of these concepts are to be applied clinically is absent, or open to interpretation.

Transmission of clinical knowledge in professions with a disciplinal epistemological orientation to practice is often achieved through the presentation of case studies (Mosey, 1992, p. 27). In contemporary TCA education, the case study is regarded as being an important means by which clinical reasoning to arrive at a TCA diagnosis and treatment principle can be learned. The examination of cases studies has certainly been one of the favoured teaching methods used in many TCA colleges and university TCM programs for integrating TCA theory and clinical practice. The need for case studies in the teaching of TCA suggests that the 'theory' of the TCA profession does not contain sufficient information in a form that can be used as the *sole* basis for clinical practice.

One advantage of a disciplinal orientation to practice, with a comprehensive theory, is the sense of identity and direction it gives to a profession (Mosey, 1992, p. 27). This, however, can also be a disadvantage in that the comprehensive theory can be so central to the profession that independent thinking that questions any aspect of the comprehensive theory is not encouraged.

A reluctance to question fundamental beliefs could lead to a stagnant profession. It has also been observed that professions with a comprehensive theory do not tend to distinguish strongly between the beliefs of the profession and the comprehensive theory of the profession: that is, it is not always easy to separate ideology, or philosophical doctrine from theoretical tenets (Mosey, 1992, p. 25).

There are two factors that can lead to difficulties in evaluating a comprehensive theory of a 'disciplinal' orientated profession. The first factor is the global and often open-ended nature of the comprehensive theory, which makes it difficult to test. Possible examples from TCA theory would be the concepts of *qi* and *yin/yang*, both of which pervade theory and practice and are difficult to deduce to usable operational variables as required by positivistic experimental orientations. Secondly, the disciplinal orientation, with its comprehensive theory tends not to draw on the knowledge of other scientific disciplines because of the difficulty of 'marrying' the concepts from other paradigms or disciplines. As a result, the growth of knowledge in a profession that adopts a disciplinal epistemological orientation to practice could be slow since it does not access the ideas and methods of other disciplines.

7.4.3 *Neopositivism*

Mosey (1992) suggests that professions with multiple theories tend to move towards what she has termed *neopositivism*. Neopositivism could be understood as a postpositivist epistemological orientation to practice that addresses some of the problems of positivist accounts and understandings. According to Wulff *et al.* (1986), neopositivism holds the position that basic scientific inquiry is important for the growth of knowledge. The neopositivist epistemological orientation embodies the idea of solving problems by applying theoretical information. With respect to the health professions, this orientation acknowledges that practice is much more than the application of theoretical data. There is also the recognition that clinical practice is to a degree an art as well as a science. Earlier, biomedical practitioners of a positivist orientation might have been dismissive of, or understated the artistic and intuitive side of clinical practice. It is, however, naive and simplistic to think that neopositivists (and postpositivists) hold the same extreme position as earlier positivists (see chapter 5.4.2). In the

neopositivist epistemological orientation to practice, the knowledge base can be discussed at three levels: (1) the fundamental body of knowledge; (2) the applied body of knowledge; and (3) the actual practice of members of the profession (Mosey, 1992, pp. 29-30).

7.4.3.1 *The fundamental body of knowledge of the neopositivistic orientation to practice*

Mosey (1992) has observed that the theoretical basis of a profession's fundamental body of knowledge can be the last thing to be clearly stated. The process can begin with the identification of theoretical information that appears essential to practice; then, later, the fundamental theories and concepts of the profession are determined and refined as 'sets of guidelines' for clinical practice. The process of articulating the essential theoretical foundation of TCA has accelerated since TCA programs have begun at universities in both China and Australia. With the entry of TCA programs into Australian universities, academics have been required to write detailed curriculum and approval documents for university academic boards which have required clear statements of the essential theory and practice of the discipline. Through this process, the acupuncture profession's philosophical assumptions, its domain of concern, and its legitimate therapeutic techniques and methods have been to some extent articulated and documented.¹⁷³

The 'fundamental body of knowledge' of neopositivism can be seen to be drawn from five categories of information. According to Mosey (1992), the five domains that are believed to influence the practice of neopositivists are:

(i) *The philosophical assumptions of the profession.*

This domain consists of the profession's basic philosophical assumptions. This includes the profession's beliefs about the nature of the individual, the causes of health and disease,

¹⁷³ As an example, see the Bachelor of Health Science - TCM (Acupuncture) approval document, School of Health Sciences, Victoria University of Technology.

and the goals of the profession.

(ii) *The ethics of the profession.*

This is the ethical code that outlines the principles of human conduct that guide the profession's clinical practice and research activities.

(iii) *The theoretical bases of the profession.*

This includes the theories, ideas and other information, selected from appropriate disciplines, that provides the bases for practice.

(iv) *The profession's domain of concern.*

The profession's domain of concern refers to the areas of human experience that members of the profession believe they have the expertise to address.

(v) *The legitimate tools (methods and techniques) of the profession.*

These are the methods and techniques in which members of the profession have expertise that can be used to assist clients to collaboratively identify and resolve health concerns and disorders (see Appendix A: The Therapeutic Techniques of the Contemporary Practitioner of Traditional Chinese Acupuncture).

7.4.3.2 *The applied body of knowledge of neopositivism*

The applied body of knowledge of neopositivism comprises the sets of guidelines for practice that have been extrapolated from the theory of the discipline. These sets of guidelines for clinical practice are derived from theory but are not regarded as part of the theoretical knowledge base. Neopositivists believe that sets of guidelines for practice can be assessed and refined through scientific inquiry. From the perspective of neopositivism, guidelines for TCA practice could be further refined and evaluated.

7.4.3.3 *Professional practice of neopositivism*

The *professional practice of neopositivism* includes information regarding the ethical use of a

profession's 'applied body of knowledge' for the purpose of collaborative problem identification and resolution with clients. Factors such as the practitioner-client relationship, which is part of the 'art of practice', are included in this category.

In neopositivism, it is likely that not all of the theoretical ideas drawn from other disciplines will be directly applicable to practice. As a consequence, there is no attempt to form a 'comprehensive theory' as in the disciplinal orientation. The neopositivist orientation is therefore pluralistic in the sense that all information in the 'fundamental body of knowledge' is considered to be of equal importance. The relationship among the five domains of knowledge is a dynamic one, since a change in one or more of the knowledge domains can lead to changes in the others (Mosey, 1992, p. 30).

7.4.6.4 *Advantages of the neopositivist epistemological orientation to practice*

According to Mosey (1992) there are three advantages of a neopositivist epistemological orientation to practice:

- (i) it defines the link between theoretical knowledge and its application;
- (ii) it gives specific information about the assessment and intervention relative to the various elements of a profession's domain of concern; and
- (iii) it utilises the research methods of science to transform theoretical knowledge into information that can be used to resolve the health concerns of patients.

7.4.3.5 *Possible disadvantages of neopositivism*

Argyris and Schon (1983) argue that there can be an inappropriate use of sets of guidelines in the neopositivist orientation. They maintain that complacency is fostered by this orientation because often sets of guidelines are not evaluated for their efficacy either formally or informally. It is their opinion that sets of guidelines can be used out of habit, to maintain a profession's ideology or world view. In regard to TCA practice, sets of guidelines for practice have not become formalised to the same extent as in other health care disciplines. This is due in

part to the different schools of thought within the TCA profession, with their different associated theoretical emphases.

Mosey (1992, p.35) claims that some individuals both inside and outside of the health professions believe that professions must become scientific disciplines if they are to remain viable in society. Some TCA practitioners of a traditional or disciplinal orientation would be opposed to such a position. These practitioners might argue that the TCA profession should concentrate on the refinement of its own traditional theoretical ideas and theories that are unique to the profession and which should form the legitimate basis for practice.

Some TCA practitioners whose professional training has not been in the neopositivist mode might feel uneasy with using sets of guidelines for practice. They might believe that guidelines would restrict their style of therapy rather than enhancing it. TCA practitioners who use a client-centered approach and see clients as unique individuals might feel that a more intuitive and flexible approach to diagnosis and therapy is necessary to resolve client health concerns.

Schein (1972) suggests that in the neopositivist orientation to practice there is conflict between the convergence of theoretical information and the divergence of practice.¹⁷⁴ In developing theory, common factors are identified, while often idiosyncratic or unique characteristics are regarded as less important, or are ignored. Human beings are superficially similar to each other in some respects (*e.g.* anatomically); however, they vary immensely with respect to other more subtle traits and characteristics (*i.e.* personality, likes, ideas, values, emotions and beliefs).

Theory generation often involves looking for similarities within data, while actual clinical practice tends to emphasis divergence between individuals in a population. Neopositivists argue that sets of guidelines can overcome the convergence/divergence issue in practice since sets of guidelines provide a direction for problem identification and resolution but are not rigid and inflexible rules. They claim that sets of guidelines can be adapted to meet the specific health needs of each unique client. However, it certainly has never been easy for researchers to evaluate sets of guidelines for practice due to individual client differences and the difficulty in controlling variables. Evaluative findings of studies that involve 'sets of guidelines' for practice

¹⁷⁴ This relates to the criticisms of positivism as examined in chapter 5.5.3.2.

are usually stated in terms of probabilities for populations of clients and therefore there is no way to determine if the guidelines will be of value in assisting any *particular* client in a research program (Wulff, Pedersen and Rosenberg, 1986).

7.4.4 *The phenomenological epistemological orientation to practice*

In the *phenomenological orientation to practice*, the development of general principles, universals, or theories is not considered to be an appropriate goal of scientific inquiry (Mosey, 1992, p. 38). From a phenomenological perspective, a person can only be understood in terms of their own particular configuration of emotions, feelings, values, motives, beliefs and current life situation. The *understanding* of phenomena, from a phenomenological perspective, is achieved through reflection on the phenomenon studied. The phenomenologist believes that for a phenomenon to be fully understood, it is first necessary for the observer to temporarily suspend their own beliefs in order to fully comprehend the situation of which they are a part. This step in the research process has been termed 'bracketing' or 'phenomenological reduction' by phenomenologists (Toombs, 1992, p. xii).¹⁷⁵

TCA practitioners also acknowledge that people who seek them out for help have unique histories that will require therapy to be tailored to their unique needs. In response to this view, Brooks (cited in Schon, 1983 p. 16) remarks that, "[t]he unique case calls for an art of practice which 'might be taught, if it were constant and known, but it is not constant'." This response has a phenomenologist flavour and is relevant to the TCA therapeutic approach. TCA therapy is dynamic and is continually tailored by the practitioner to the needs of the individual client. It is not confined to rigid protocols and is never simply the systematic application of techniques (chapter 2). In this sense, TCA practice resonates with the phenomenological orientation.

The phenomenological orientation to practice emphasises the importance of understanding phenomena through subjective knowledge. This orientation is in stark contrast to neopositivism, which stresses the need for 'objective' knowledge and which attempts to

¹⁷⁵ *Bracketing or phenomenological reduction* is a phenomenological research technique of Edmund Husserl which requires the suspension or laying aside of what is known about an experience being studied.

explain and make predictions about phenomena. The phenomenological orientation can be seen as a reaction to positivistic positions. The phenomenological orientation posits that there can be no sets of guidelines for actual practice and no 'theoretical knowledge' as it is known in the positivist sense. The phenomenological orientation could be seen as an attempt to address the unpredictable and fluid nature of real clinical practice. Chuang Tsu, considered by many scholars as the greatest exponent of Daoism, would be sympathetic to this orientation since he taught that all individuals and phenomena are constantly involved in a process of change and transformation. Therefore, to unravel the mysteries of TCA clinical phenomena, the TCA practitioner-researcher must reflect carefully on their clients with whom they are interacting or the phenomenon that is being studied.

Some TCA practitioners are known to combine acupuncture with various forms of Oriental health counselling or psychotherapy (see Watson, 1995; Dale, 1997b, p. 221). The psychotherapist Carl Jung maintained that psychic health can only be achieved by harmonising the conscious and unconscious contents of the mind. This process, according to Radmila Moacanin (1986, p. 44), is a non-rational life process. Jung, in his psychotherapy, used the techniques of dream analysis and active imagination, yet stressed that there are *no* fixed methods of treatment. The methods used by the therapist are determined on the basis of the perceived needs of the individual client, which become evident through interaction with the client. Jung (1966, pp. 7-8) went as far as suggesting that psychotherapists should rid themselves of all theoretical assumptions and preconceptions and abandon all techniques and methods. Some therapists working from a phenomenological orientation use theoretical knowledge only as a backdrop for understanding the individual. They believe that physiological, psychological, and sociological theories can be used to describe the objective situation of the individual but not the inner feelings, thoughts and motives of the person. This is to say that knowledge derived from theory is considered inadequate to fully understand the *whole* person because it is only partial. For the phenomenologist, knowledge of the human being is uncovered in action, during the clinical encounter, as opposed to being articulated *via* theory before the encounter. According to Mosey (1992, p. 39), the phenomenologist believes that knowledge can result from the immediate apprehension of a fact or truth which can be intuitive and independent of any linear reasoning process.

The phenomenological orientation to practice acknowledges the uncertainty and uniqueness of the practitioner-client relationship in actual TCA clinical practice. From this realisation comes the idea that healing is more than a science and has aspects of an art. This 'art' of practice requires practitioner experience, understanding, and wisdom to decide on the best course of action in each individual encounter with a client in both clinical practice and research settings.

A fundamental difference between neopositivism and the phenomenological orientation to practice can be found in the use of theory. In neopositivism, theories are used to understand phenomena that are believed to be common to groups of people. In contrast, the 'theory' of the phenomenologist is often a description of a single individual. The information obtained from a unique case study is particular to that one individual and from a phenomenological perspective cannot be used to make predications or generalisations about another individual, or a group of people.

7.7.1 *Advantages and disadvantages of the phenomenological orientation to practice*

It could be asked, what exactly is the body of knowledge in the phenomenological epistemological orientation to practice? From the phenomenological perspective, it would seem that there is only one level of knowledge: the unique and individual case study. This 'knowledge' is short-lived, since it cannot be applied again in the *same* way with another client. The information that is obtained from one client cannot be used with another because it is a requirement for the practitioner to begin therapy with each new client with a certain degree of naivete, without fixed or preconceived ideas and theories. Such an extreme account of the phenomenological orientation would, however, have to be regarded as naive. As Wilbert Moore (1970, p. 56 cited in Schon, 1983, p. 24) remarks

[i]f every professional problem were in all respects unique, solutions would be at best accidental, and therefore have nothing to do with expert knowledge. What we are suggesting, on the contrary, is that there are sufficient uniformities in problems and in devices for solving them to qualify the solvers as professionals. ... professionals apply very general principles, *standardized* knowledge, to concrete problems... .

From the perspective of neopositivism, one disadvantage of the phenomenological orientation is that there is not an enduring body of knowledge as it is understood in neopositivism. Mosey (1992, p. 41), in summarising the phenomenologist account of knowledge, states that

there is no substantial body of knowledge. Knowledge is ephemeral, short-lived, and transitory. In the context of a unique-case theory, when intervention with a client is ended the knowledge dissipates. A unique-case theory is never applied again because it is specific to a client in a given situation.

While it is acknowledged that it is desirable in a therapeutic encounter to attempt to resolve a client's health problems in the context of the client's unique situation, the question could be asked that if the practitioner brings no general preconceived ideas and theories to the therapeutic interaction then how is the practitioner to help the client? A practitioner who adopted a phenomenological orientation would be free to observe and question the client, and then engage in reflective thinking; however, the practitioner must surely derive his therapeutic strategy from some body of knowledge even if it is tacit and not clearly articulated.

While phenomenological research might not be the method of choice when attempting to determine the efficacy of a therapy, it could be the most appropriate approach for addressing other research questions in the discipline of TCA. For example, phenomenological research could be used to gain a better understanding of the human subjective experiences of pain, illness, health and wellbeing (see Morse and Field, 1995).

7.5 Summary: The Epistemological Orientations of Traditional Chinese Acupuncture Practice and the Implications for Future Research

The four epistemological orientations of practice identified by Mosey (1992) have implications for TCA research. While both the traditional and disciplinal orientations to practice provide the TCA profession with a sense of identity and direction, a disadvantage of these orientations is that the comprehensive theory can be so central to the profession that independent thinking beyond its paradigm boundry might not be encouraged. This could result in a reluctance to accept the ideas, methods and research findings from other disciplines which could possibly lead to a stagnant profession.

Neopositivism can be understood as a postpositivist orientation of practice that addresses some of the problems of positivism. A strength of neopositivism is that sets of guidelines for TCA practice could be assessed, refined and evaluated through systematic inquiry. While neopositivism has its weaknesses, it might still be the preferred epistemological orientation to adopt when attempting to answer some research questions that relate to the evaluation of a therapy's efficacy for groups of patients.

The phenomenological orientation to practice, with its emphasis on a client-centred approach, does not produce a body of knowledge that can be utilised easily with other clients. Clearly, a phenomenological approach to research would not generate the type of knowledge that would be seen as valuable from a neopositivist perspective since it cannot be easily drawn upon when treating other clients. It should be noted, however, that an understanding of the *meaning* of a phenomenon obtained in one setting could give insights into a similar phenomenon in a similar setting (Burns and Grove, 1993, p. 29). While the phenomenological orientation might not be appropriate to determine the efficacy of TCA therapy, it certainly is of value in answering other types of research question in the field of TCA.

If one examines the health professions, it would appear that members of professions do not always adopt only one orientation to practice exclusively (Mosey, 1992). Many health care practitioners in actuality appear to be able to combine two or more epistemological orientations. This is extremely interesting considering the apparent incompatibility that exists between some of the epistemological orientations of practice, in particular the phenomenological orientation and neopositivism. To accommodate the reality of this situation, the notion of epistemological purity needs to be replaced with the postmodern idea that acknowledges the value of a plurality of perspectives.

One explanation for the TCA profession's hesitancy to extend the knowledge base of the discipline through contemporary research methods could stem from the different epistemological orientations of practice used *within* the TCA profession. It has been noted by Mosey (1992) that when a profession uses more than one epistemological orientation to practice

it can have difficulty identifying and developing its body of knowledge. However, TCA practitioners do not need to choose a *single* epistemological orientation: rather they can choose to acknowledge the various strengths and weaknesses of each of the epistemological orientations to practice. Dualistic notions of epistemology need to be abandoned. Researchers of TCA who restrict themselves to only one way of knowing can expect to limit the types of knowledge and understanding that can be obtained by research.

CHAPTER 8

SCIENTIFIC INQUIRY AND TRADITIONAL CHINESE ACUPUNCTURE

“Science is believed to be the most effective method by which we can influence the world because of its privileged access to reality. Research is the single most important vehicle through which this reality of seeming objective facts is created. Research lifts issues out of the realm of common sense knowledge where they are easily contestable and transforms them into objective facts. Once this transformation has occurred, it becomes increasingly difficult to challenge and reverse”

- Scheid (1993, p. 25)

In this chapter issues related to the utilisation of the methods of science to study TCA and to evaluate its therapeutic effectiveness will be explored. Since there are different ways in which social scientists understand science, the nature of science is examined first in order to determine if TCA *is*, or *can be*, scientific. It is argued that the methods of science can be utilised to investigate particular TCA research questions, as long as a broad definition of science is adopted. The task of the second part of this chapter is to outline the roles that the various quantitative research designs can play in the production of TCA knowledge.

Over the last two decades, researchers have tended to adopt positivistic orientations in relation to the determination of the therapeutic efficacy of acupuncture. Postpositivism and neopositivism (see chapters 5 & 7) maintain the position that basic scientific inquiry is important for the growth of knowledge and embodies the idea of solving problems by applying theoretical information. If researchers intend to utilise postpositivist research methods, then they should consider carefully the relationship between TCA and the methods of science. This examination is important since some incongruence has already been identified in some published TCA research that has attempted to utilise postpositivist research methodologies (chapter 2.6). For example, several researchers have already noted a number of problems in

adapting the randomised controlled trial (in its usual form) to evaluate the efficacy of TCA (Vincent & Richardson, 1986; Guillaume, 1991; Vincent, 1993; Nester, 1997).¹⁷⁶

8.1 TCA and Scientific Inquiry

Some researchers and members of the TCA profession (*e.g.* Bensoussan, 1993) argue from what would appear to be a postpositivist perspective that the methods of scientific inquiry should be utilised to further develop the TCA knowledge base. The TCA profession could profit from reflecting on the experiences of other health care practitioners who have already confronted the question of what constitutes appropriate research methods for their profession. For example, Slife and Williams (1995) claim that the history of the behavioural sciences has been marked by that profession's struggle to separate the behavioural sciences from philosophy, and to establish them as a distinct set of scholarly disciplines. This struggle in the behavioural sciences has led to continuing concern about their scientific status. TCA, in the West, appears to be entering a similar phase in its development, with TCA practitioners and researchers having to decide how the knowledge base of the TCA profession can be best developed using the methods of science, in addition to those more traditional methods that have been used by TCM practitioners (chapter 6).

The desire to adopt the methods of science is understandable, since the utilisation of the scientific method by natural scientists has resulted in the production of various useful technologies and solutions to many practical problems. It would therefore seem reasonable to think that the same level of success might be realised by the TCA profession by utilising the methods of science. The analysis of Slife and Williams (1995) for the behavioural sciences is relevant for TCA for the reason that both TCA and the behavioural science therapies have an interpersonal component and a therapeutic method or technique.

8.2 Science and the Scientific Method

To begin this analysis, it is useful to attempt to define the term 'science'. The word *science*

¹⁷⁶ Anthony (1993a) has also outlined a number of methodological problems in the assessment of the complementary therapies in general that are relevant for the evaluation of the efficacy of TCA therapy.

comes from the Latin word for *knowledge* (Slife & Williams, 1995, p.168). Bertrand Russell (1935, p.8), in *Religion and Science*, defined *science* in the following way:

Science is the attempt to discover by means of observation, and reasoning based upon it, first, particular facts about the world and then laws connecting facts with one another and (in fortunate cases) making it possible to predict future occurrences

If one provisionally accepts Russell's definition of science, TCA practitioner-researchers should embrace science as a method for developing and evaluating TCA knowledge since it could be argued that a large proportion of TCA knowledge has accumulated using the general principles of Russell's definition of scientific inquiry. For example, some of the theories of the 'naturalist' TCM schools of the Han period (*e.g.* *wu xing* [five phases]) were probably derived through the process of induction after careful observation of the processes that occurred in both human beings and the natural world. Slife and Williams (1995, p.168) claim that the term *science* has come to be used in at least two ways. Science can refer to "a type of knowledge that is trustworthy", and secondly, to a *method* by which knowledge that is trustworthy can be obtained (Slife & Williams, 1995, p. 169).

Many Western notions of knowledge can be traced back to Greek philosophy, where knowledge was linked to the notion of 'truth'. Slife and Williams (1995) note that in Greek philosophical thought, knowledge was always contrasted with opinion. Opinion related to belief, whereas knowledge related to that which was real or true. In contemporary times, science has been strongly linked to that which is 'true', and this belief remains deeply embedded in the psyche of most people living in the Western world. Slife and Williams (1995, p.168) claim that, "[i]n the minds of many, science encompasses what we *know* to be true, in contrast with what we only think to be true."

Science has become for many people the metanarrative for that which is real. This is why science has such public credibility and the reason that it is trusted. This also partly explains why professions desire to become scientific, since there is the belief that the methods of science can lead to a more dependable or reliable type of knowledge. In contrast to science, philosophy appears to deal with opinion and ideas which might, or might not be true. Since the discipline

of philosophy consists of numerous and often conflicting theories and ideas, it might be easy to draw the conclusion that the ideas of philosophy are less dependable and certain when compared with the 'objective' knowledge of scientists (Slife & Williams, 1995, p.168).

Science has always had a close association with mathematics. To a certain extent, "*science has mathematics as its language*", with the 'truths' of mathematics often appearing more certain when compared with the ideas and methods of other disciplines. The language of mathematics has been perceived as being "more precise and less open to error and interpretation" than those languages which people normally use to communicate with each other (Slife & Williams, 1995, p.172). This is reflected in the value ascribed to quantitative methods and statistical analysis in medical research.

Slife and Williams (1995) argue that the defining features of science have changed over time. For the early Greek scientists, knowledge was obtained through the process of careful observation and the application of rational thought. However, since the Enlightenment, the emphasis has changed, now observation and empiricism are thought to be more reliable ways of attaining 'real' knowledge. Slife and Williams (1995, p.170) claim that in our post-Enlightenment culture, "[s]cience [has] emerged as a trusted source of knowledge, in part, because *it relies on observation and not just rationality.*"

Before attempting to determine whether the scientific method can and should be utilised in TCA research, it would be first useful to have a clear understanding of what the scientific method is. This is not an easy task, since various analyses would seem to suggest that there is not *one* scientific method: rather there are methods that share common features (Slife & Williams, 1995, p.169). Just as it was found difficult to define the essential features of positivism (chapter 5.4.2), it is not easy to define all of the features of scientific method. It should also be noted that some important 'scientific discoveries' have been made through means other than what could be called the scientific method (Gjertsen, 1989).¹⁷⁷

¹⁷⁷ D. Gjertsen (1989, p. 21) cites the scientific discoveries of people such as Archimedes, Kekule, Darwin and Maxwell which required no more than thinking. He states that these "ideas once conceived have to be worked out tested, analysed, and examined in numerous ways. ... The point remains that, in part, science is as sedentary and cerebral an activity as academic philosophy."

It is sometimes claimed that what differentiates the methods of science from what people routinely do is the way in which observations in science are made. Slife and Williams (1995, p.171) state that

[o]ne of the hallmarks of scientific observation is that it is made under *objective* conditions. This is usually understood to mean that what scientists observe is not influenced by 'outside' factors such as values, expectations, and desires of the scientist, or by Bacon's idols such as traditions, authority, or habitual ways of thinking.¹⁷⁸

A second important characteristic of scientific observations is that they can result in predictions if made under controlled conditions:

[g]ood science practice entails the scientist's *predicting* what he or she will observe under specified conditions. If the prediction is found to hold true, the theory or hypothesis that led the scientist to make the prediction is validated. Knowing what conditions to control and how to control them is often seen to be the crucial test of scientific knowledge. (Slife & Williams, 1995, p.171)

Another feature of scientific work that contributes to its credibility is that it is conducted in public: hence the results are open to public scrutiny. Scientific knowledge can enhance its credibility if the results of scientific research are repeatable. (Slife & Williams, 1995, p.172).

The characteristics and features of science outlined above have all contributed to the legitimization of science by scientists, and by the public at large.

8.3 Implications of Quantum Physics and Chaos Theory

8.3.1 *Quantum physics*

In the 1920s, quantum physics changed once and for all how scientists conceptualise the physical world.¹⁷⁹ De Berry (1993) has noted several important features of what he terms quantum psychology that are implied by quantum physics. These features of quantum

¹⁷⁸ See R. Audi (1995, pp. 60-61) for a brief account of the philosophy of Francis Bacon [1561-1626].

¹⁷⁹ See Capra (1983; 1997) for a comprehensive account of the implications of the ideas and concepts of quantum physics.

psychology are relevant to TCA, since it is evident that they share the common themes of non-linearity, holism, normal dynamic states, non-local factors and synergy. This is in contrast to classical psychological understandings which emphasise linearity, reductionism, abnormal states, fixed factors, local factors, and mechanistic notions. Whereas Biomedicine is still practised in the shadow of the ideas of Newtonian physics, the features of quantum physics are essentially compatible with many Chinese philosophical ideas and TCM. Systems of health care need to be mindful of the theories and implications of contemporary quantum physics, since the ideas of quantum physics will eventually transform our current understanding of what science is.

A consequence of this new understanding is that physical phenomena are no longer understood to be composed of material particles. Capra (1997, pp. 30-31) explains that

quantum physics shows that we cannot decompose the world into independently existing elementary units. As we shift our attention from macro objects to atoms and subatomic particles, nature does not show us any isolated building-blocks, but rather appears as a complex web of relationships between the various parts of a unified whole. ... In the formalism of quantum theory, these relationships are expressed in terms of probabilities, and the probabilities are determined by the dynamics of the whole system. Whereas in classical mechanics the properties and behaviour of the parts determine those of the whole, the situation is reversed in quantum mechanics: it is the whole that determines the behaviour of the parts.

Capra (1983, p. 76) also notes that in the light of the findings of quantum physicists that the assumptions of an absolute determinism might no longer hold

[i]n quantum theory individual events do not always have a well-defined cause. For example, the jump of an electron from one atomic orbit to another, or the disintegration of a subatomic particle, may occur spontaneously without any single event causing it. We can never predict when and how such a phenomenon is going to happen; we can only predict its probability. This does not mean that atomic events occur in completely arbitrary fashion; it means only that they are not brought about by local causes. The behaviour of any part is determined by its nonlocal connections to the whole, and since we do not know these connections precisely, we have to replace the narrow classical notion of cause and effect by the wider concept of statistical causality.

Capra (1983, p. 83) explains that *nonlocal connections* are

instantaneous and cannot be predicted, at present, in a precise mathematical way. These nonlocal connections are the essence of quantum reality. Each event is influenced by the whole universe, and although we cannot describe this influence in detail, we recognize some order that can be expressed in terms of statistical laws.

While Capra (1983, p.71) claims that 'nonlocal connections' are believed to be relatively unimportant at the macroscopic level of experience where people perceive separate objects, this might, however, eventuate not to be the case. Dossey (1989; 1993) has suggested that the mind and consciousness might be nonlocal. Dossey (1993, p. 84) states that "[t]he nonlocal view suggests that the mind cannot be limited to specific points in space (brains or bodies) or in time (the present moment)".¹⁸⁰ If Dossey is right, then one might anticipate limitations to one's ability to predict outcomes that involve the minds of human beings (*e.g.* TCA clinical research).

8.3.2 *Chaos theory*

Another of the emerging 'new' sciences is *chaos*, which is now well known through the concepts of *chaos theory*. Helms (1995, p. 58) explains that chaos theory

is based on the premise that systems that seem random are in fact describable by complex mathematical formulae that reveal a deeper dynamical order, albeit nonlinear and lacking predictability. The relevance to biological systems is that the human body can be considered as a complex but ordered system, rather than a collection of random or independent reactions and responses.

Sardar and Abrams (1998, p.137) state that "[b]iologists, physiologists and medical experts are now beginning to portray human physiology as a holistic system full of fractals¹⁸¹ and chaos."

Chaos theory maintains that human beings contain both order and chaos. This is in accord with Chinese thought that holds that there is a relationship between order and chaos. Moreover,

Sardar and Abrams (1998, p.138) note that

not all chaos in the body is bad. There is natural background chaos in the body - for example, in the brain activity - which performs useful functions. Loss of this chaos can lead to abnormal functions. The seizure in epilepsy, for example, may appear as an attack of chaos, but it is in fact due to a *loss* of chaos. It is the product of an *abnormally periodic order* in the brain.

¹⁸⁰ See Dossey (1993) for examples and research that lends some support for this view.

¹⁸¹ Fractal structures have been identified in the human body. Sardar and Abrams (1998, p.138) state that fractals "make the body more flexible and robust. Because they are self-similar, parts of the body's fractal structure can be injured or lost without serious consequences. Fractal structures also increase the surface area for the collection, distribution, absorption and excretion of a host of important vital fluids, as well as toxins, that regularly pass through the body."

Human beings can be regarded as complex systems which have the ability for spontaneous *self-organization*.¹⁸² Sardar and Abrams (1998, p.75) describe the property of self-organization as “the phenomenon by which a system self-organizes its internal structure independent of external causes. Such self-organising systems also exhibit other properties of chaos - non-linearity, feedback, fractal structures and sensitive dependence.”¹⁸³

Moreover, it appears that the concepts of *chaos* have possible implications for acupuncture clinical research:

Chaotic systems are very sensitive to initial conditions, so much so that tiny changes can lead to major differences in later behaviour. ... Efforts to utilize chaos and other nonlinear dynamics in clinical medicine suggest that inputs to the patient in the form of therapeutic interventions that seem negligible from the biomedical perspective may induce far-reaching responses in the chaotic system of the human body. Furthermore, chaos theory predicts that a multiplicity of small inputs may lead to a surprisingly large response. ... In this context, acupuncture therapy may be considered as a series of small inputs that can influence the disease process and the body's innate healing mechanisms on a level more subtle than those which are modified by conventional treatments (Helms, 1995, p. 58).

Clearly, the ideas of chaos theory have implications for TCA clinical research. First, acupuncture treatments from even one practitioner can be expected to produce a range of responses in clients: the therapeutic outcome will not be linear. Secondly, if the initial conditions of clients are critical to therapeutic outcome, it becomes evident that predications for the outcomes of TCA therapy will be somewhat difficult for groups of people. The concepts of chaos theory again call into question some of the assumptions of the postpositivists and their mechanistic notions of linearity. Chaos theory lends support to the idea that it is extremely difficult to generalise research findings to other settings because of differences in initial patient conditions.¹⁸⁴

Science cannot be defined satisfactorily without consideration of the discoveries and theories of

¹⁸² For an account of the concept of self-organisation, see I. Prigogine, *Order Out of Chaos: Man's new dialogue with nature*, 1984.

¹⁸³ For an engaging account of the concepts of Chaos, see J. Gleick, 1988.

¹⁸⁴ See Patton (1990, pp. 82-84) for some of the implications of chaos theory for qualitative inquiry on human systems.

quantum physics and other new emerging sciences. More consideration needs to be given by researchers to the interface between TCM and the contemporary scientific concepts of quantum physics and chaos theory, both of which resonate strongly with the ideas found in Chinese philosophical thought.

8.4 Is TCA Scientific?

The question of whether TCA can be regarded as scientific is dependent upon one's definition or understanding of what science *is*. Slife and Williams (1995, p.173) claim that there are two conceptualisations of science that are relevant when considering the status of the behavioural sciences and which the author considers are just as relevant for TCA. According to their first conceptualisation of science, the nature of the world can be explained by a scientific body of knowledge that is recognisable by two main characteristics

scientific explanations for the most part involve rejecting supernatural explanations of phenomena in favor of naturalistic explanations. Scientific explanations are usually given in terms of matter or other naturalistic constructs. Second, scientific knowledge is generally framed in terms of laws and principles that are assumed to determine the events of the world. These laws are taken to be the real causes of the events, and because of their lawful regularity, it is possible, at least in theory, to control and predict the events.

Based on this understanding of science, TCA might be regarded as scientific. TCM has in large rejected supernatural explanations of disease. Nevertheless, it should be noted that TCM does not explain human behaviour in strictly materialistic terms. There is a 'spiritual' dimension of TCM theory that does not lend itself to simple reduction to the laws of physics and the other natural sciences. Secondly, TCM has not developed 'universal laws' to account fully for human behaviour. The reason for this can be found in the perceived complexity and uniqueness of human beings. What we do know is that mind and consciousness cannot be easily controlled and its flow predicted. There is also the idea in TCM, derived from Chinese philosophy, that there is a level at which reality is unknowable, ambiguous, and contradictory (Ryan, 1995, p.74) (see chapter 2). At this point in time, the laws of biology are simply insufficient to account for the emergence of mind and consciousness. Because TCA practitioners deal with unique people with unpredictable desires, motives and behaviours rather than with biological bodies, TCA, like psychotherapy, will probably continue to be regarded as a 'soft science'.

The second conceptualisation of *science* suggested by Slife and Williams (1995, p.174) is that it is primarily a *method* of investigating phenomena. The scientific method usually involves careful empirical observation, control, prediction and often measurement of some kind. Therefore, any discipline that uses this method, including TCA, could be regarded as being scientific. As with the behavioural sciences, there is some debate as to whether the scientific method can be applied to TCA in the same way as in the natural sciences. Human beings are extremely complex and it is difficult, if not impossible, to control for all of the numerous variables involved when they interact with their environment. In addition, many of the important domains and parameters a researcher of TCA would wish to measure (*e.g. wellness or the state of shen*) are difficult to measure owing to a deficiency of validated instruments. Scales and instruments to assess human states such as pain and depression are fraught with problems. The assessment of emotional states, or the measurement of wellbeing in a meaningful way, is far more difficult than measuring simple variables such as velocity, weight, or hardness as in the natural sciences. Even if the scientific method can be used in TCA research, it should be remembered that human beings have emergent properties (*e.g. self-awareness*) that are not found in the non-human realm and which might not be able to be studied solely by the research methods of the natural sciences.

8.5 Typologies of Science

There are different ways in which social scientists think about science (Maslow, 1966; Hudson 1968; Mitroff, 1974; Mitroff & Kilman, 1978). While many people believe that science is the most effective method by which we can examine and understand the world and its phenomena, it is Mitroff and Kimann's (1978) view that science is in serious need of methodological and epistemological reform.¹⁸⁵ They make the claim that science has been created and is practised in one particular psychological style, that is, it is the projection of only one particular aspect of the human psyche. Mitroff and Kimann contend that researchers tend to have a preference for a particular type of research design because of their psychological constitution. The standard experimental method (*e.g. the RCT*) could be seen to be associated with one particular

¹⁸⁵ See P. Reason, 1981, pp. 43-51.

psychological type. While this method should not be abandoned with regard to particular TCA research goals, it is possible that some TCA research questions might be better examined by other approaches based on other psychologically preferred types of research.

Consideration of the typologies of the ways social scientists think about science could be important for researchers of TCA who are trying to develop research designs, since it can be shown that the way in which they can be related to their psychological type. Peter Reason (1981), in an analysis of the work of Mitroff and Kilman (1978), explains that Mitroff and Kilman's typologies were based on those of Carl Jung (1971). The original typology of Jung (1971) was based on two dimensions. The first concerns the type of input data that the researcher characteristically prefers. The second relates to the preferred way this information is dealt with, that is, the way the information is used in making decisions. Carl Jung (1971) suggested that individuals can take in information from the internal mind and the external worlds by either 'sensation' or 'intuition'. These faculties, according to Jung, are antithetical psychological processes that cannot occur simultaneously. As a result, the individual must develop a preference for either 'sensation' or 'intuition'. Researchers who have a preference for information that is obtained through the senses are often more interested in the detail of 'objective' facts. In contrast, there are those researchers who prefer to use intuition and their imagination to obtain information and who are more interested in the 'whole' or the *gestalt*, to use a psychological term (Reason, 1981, p. 44).

With respect to the decision-making dimension, Jung (1971) saw another two antithetical possibilities, these being 'thinking' and 'feeling'. It was his belief that individuals prefer to make decisions using either reasoning or feeling. The reasoning process is concerned with seeking the 'truth', which can be impersonal and couched in abstract generalisations. In contrast to this, there are other individuals who prefer the 'feeling' mode when making decisions that involve human beings. People who make decisions in the 'feeling mode' are more likely to acknowledge the uniqueness of the individual and the need to make judgments in human terms.

Research funding is often influenced by the rigour and type of research design employed by the

researcher. In many instances, funding bodies have preferred research designs that are of a type that is often used by the ‘analytical scientist’ of the Mitroff & Kilman typology, whose basic drive is towards certainty. This research style places emphasis on precision, accuracy and reliability above other considerations (see Appendix D: The ‘analytical scientist’ of the Mitroff and Kilman typology). Barnett (1990) argues that contemporary society is unreasonably dominated by the framework of science to the extent that forms of knowledge obtained by other means are down-graded and not even regarded as real knowledge.¹⁸⁶

It is Guba and Lincoln’s (1994, p. 16) view that “proponents of positivism gained hegemony over the past several centuries as Aristotelian and theological paradigms were abandoned”, with “the mantle of hegemony” in recent decades being passed to the postpositivists, the natural heirs of positivism. Guba and Lincoln (1994, p.116) have noted that people with a preference for postpositivist research methods have tended to control the sources of power and have influenced funding, promotion and tenure mechanisms, dissertation committees, and publication outlets. As a consequence, researchers who prefer to work within paradigms other than postpositivism (see chapter 5) are still seeking the same recognition for their approaches to research.¹⁸⁷

8.6 ‘Truth’ and the Methods of Science

Science is often portrayed as being unique, having the ability to produce a more certain and incontestable type of knowledge than philosophy and other disciplines. However, studies in the philosophy of science would suggest that science itself is based on assumptions and theories. Slife and Williams, 1995, p. 202) claim that, “[a]lternative views of science have emerged that suggest that science is a social practice based on paradigms that govern the legitimacy of questions, methods, and explanations.” If this is correct, it supports the postmodern perspective that science might be just another way of viewing the world rather than the exclusive means by which knowledge is ordered.

¹⁸⁶ Until recent times, some types of qualitative inquiry have not been regarded as producing ‘real’ or substantial knowledge.

¹⁸⁷ See C. Grbich, 1999, p. 19.

It should also be noted that the validity of the scientific method cannot be tested by its own method. In fact, its acceptance requires a *belief* in its core tenets and assumptions. Slife and Williams (1995, p. 202) explain:

There are lines of argument that suggest that science cannot, as has often been assumed, verify or falsify its own theories and hypotheses. Neither can it support cause-and-effect statements with certainty. Rather, it is argued, science can be understood as a logical argument, resting on language games, and thus a form of rational analysis. Given this view, many in the postmodern tradition have suggested that as science does not uncover truth, but rather requires a preexisting view of truth to proceed... .

Lakatos (1970, p. 96) notes that all theories are conjectural: science cannot *prove* any theory, although science can attempt to disprove theories on the basis of factual evidence.

8.7 Philosophical Bases of Experimental and Clinical Research

Experimental scientific research encompasses a range of research designs (including the randomised controlled trial) derived from positivist ideas in which the processes of deduction and prediction are valued and emphasised. It is argued from the perspective of postpositivism that if phenomena occur in accordance with natural laws, other phenomena can be predicted based on that knowledge which has already been attained (chapter 5). Experimental research designs follow from this philosophical view. A theory can be evaluated, and specific aspects of it can be investigated through the testing of hypotheses. According to this account, a researcher can examine phenomena objectively, by eliminating or at least reducing bias when measuring data with the senses (De Poy and Gitlin, 1993, pp.17-18).

8.8 The Role of Theory in TCM

To examine the role *theory* has, and can play, in TCA practice and research, it is first necessary to define or explain what is meant by the term *theory*. Kerlinger provides one useful definition of *theory* that could be employed by researchers of TCA. Kerlinger (1973, p. 9) defines theory as, “a set of interrelated constructs, definitions and propositions that present a systematic view of phenomena by specifying relations among variables, with the purpose of explaining or

predicting phenomena”. Researchers of TCA using this definition of *theory* could use theory like a map to make sense of their observations and experiences of TCA and associated phenomena. *Theory*, as defined by Kerlinger, could give *meaning* to both TCA practitioner and researcher observations and experiences of TCA phenomena by providing a context.

Grbich (1999, p. 27) claims that *theory* “is derived from the exploration of phenomena, the identification of, and interrelationships between, concepts surrounding phenomena and the subsequent development of a framework within which some comments can be made.” TCM theory can be understood to consist of a number of interrelated concepts derived from Chinese philosophy and medicine that are used to describe, explain, and predict phenomena in TCM and associated areas of health and disease. Huang Jitang (n.d. quoted in Farquhar, 1987, p.1016), in an essay for undergraduate students, states that

[t]he origin of Chinese medicine [TCM] is in the practice of preventing and treating disease. The experience accumulated from practice is supplemented and generalized to become medical theory. Theory in turn guides practice, so practice under the guidance of theory continuously develops and necessarily elevates the level of theory

The development of TCM knowledge can therefore be understood as a process in which practice informs theory, which in turn informs practice. From the TCM perspective, ‘knowledge’ is not something that is fixed, but is rather more fluid and changeable. Scheid (1993, p. 25) notes that “[k]nowledge, like language, continuously develops and changes. It is never closed or exhausted.”

Judith Farquhar (1987, p. 1015) warns researchers of TCM of the danger of deconstructing *theory* and *practice* and of creating a false dichotomy between them as has been the case in Western culture: “[o]nce theory and practice are drawn apart for epistemological purposes, Chinese medicine [TCM] is left with a body of theory that is elegant but lacking any connection with what we think as the ‘real world’ ”. Farquhar (1987; 1994) claims that the ‘theory - practice’ distinction that exists in the West (that is, in science and biomedicine) does not exist in the same form in TCM. Scheid (1993, p. 27) explains:

In the Chinese tradition truth has always been evaluated according to performance rather than universalist criteria. Knowledge is the accumulation of subjective experience refined through a process of continuous reflection which Farquhar terms 'knowing practice'. Theory, or the 'textual', and practice, or the 'clinical', are seen as dialectically linked with and inseparable from each other. Traditional Chinese Medicine cannot be said to be the practical application of knowledge contained in abstract form in classical or modern texts. Texts merely serve as a guide from which individual practice originates and to which it returns.

While it is acknowledged that the relationship between theory and practice might not be the same in TCA as in Western science and medicine, it cannot be denied that there are still abstract ideas that guide TCA practice. Many of these ideas could be termed theories. TCA theory is important because it informs action in clinical practice. In health care delivery, decisions have to be made by practitioners regarding which treatment or intervention is the most appropriate in any given situation. These decisions are usually based on theory and personal experience. It should be remembered, though, that the application of TCA theory is an artful process and is not merely the rigid application of techniques according to narrow guidelines of practice (chapter 2).

8.9 Theory in TCA Practice and Research

In China's past, one of the main objectives of inquiry for TCA practitioners was to improve the effectiveness of clinical practice so as to be able to reduce pain and suffering. Many of the ideas and 'theories' of TCA would appear to have developed from the personal clinical experiences and reflections on those experiences by TCA practitioners (chapter 6). The practice of TCA in China's past generated ideas and theory which in turn influenced clinical practice. Bensoussan (1991b, p.15) claims that, if one studies carefully the history of Chinese medicine, the theories of TCM can be seen to have changed as a result of using a methodology that could be regarded as 'scientific'. Bensoussan argues that traditional Chinese practitioners made clinical observations and systematised those observations into theory. These theories were verified by further observations, tested clinically, and modified in the light of any new information obtained.

In ancient China there was no formal and controlled research that would be regarded as rigorous if judged against today's biomedical research criteria. In ancient China there was in

fact no request by the Chinese public to prove the effectiveness of TCA since it was self evident to the Chinese people that TCA therapy was part of an efficacious form of health care. As a consequence, there was no demand by the State to verify that which was already common knowledge. Only in the Western world has there been the demand for acupuncturists and researchers to prove the effectiveness of TCA. There are several possible reasons for this:

- (i) TCA therapy is a foreign form of medicine (from the Western perspective), and its effectiveness and benefits might not be known by the majority of people living in Western society.¹⁸⁸;
- (ii) Government bodies, including the Australian NHMRC (1988, p. 62) have, in the past, questioned the efficacy of TCA and have suggested that it is of value only for a limited number of medical conditions;
- (iii) Practitioners of other systems of medicine have been threatened from yet another system of health care, and as a result have questioned its legitimacy.¹⁸⁹

Most contemporary studies of TCA have attempted to evaluate the efficacy of TCA therapy and not the traditional theories from which it has been derived. There has been little research on comparing therapeutic outcomes using different TCA theoretical frameworks (*e.g.* five phase theory, eight channels theory, six channel theory). Again, there has been little research that compares the therapeutic effectiveness of the different forms of acupuncture practice (*e.g.* 'scientific' acupuncture, TCA, auricular acupuncture). It would be useful to know the relative efficacies of the various types of acupuncture practice.

The growth of the TCA knowledge base will only proceed if the findings of individual TCA studies are linked back to TCA theory. This could result in new theory, or the refinement of an old theory, which could then be evaluated to improve clinical practice. Much TCA theory has been accepted as true by many TCA practitioners because it has come from so called

¹⁸⁸ This situation is rapidly changing in some Western countries, for example, see the study of C. Cassidy, 1996.

¹⁸⁹ M. Saks (1995) presents acupuncture in Britain as a case study to suggest how professional groups might pursue strategies that serve their own interests at the expense of the public interest.

'authorities' (chapter 6). While such an approach might have once been acceptable in China, it is not the view held by many academics and researchers in the occident. It is therefore desirable, at this stage in the development of the acupuncture profession in the West, that TCA ideas and theories be assessed and verified where possible through research.

Burton (1974, cited in Morse and Field, 1995, pp. 5-6) has noted several important functions of theory in the development of knowledge:

- (i) Theory can create tensions within a discipline. This can be beneficial for a profession since it can initiate dialogue between proponents of competing theories and stimulate debate.
- (ii) Theory can counter nihilism - it can fill in gaps in the existing knowledge base. Theory can provide a means to reveal or disclose aspects of phenomena by drawing the researcher's attention to a particular aspect of a phenomenon simply because a theory exists.
- (iii) Theory places phenomena in time. This anchors observations to nature and history.
- (iv) Theory can clarify, or provide an explanation, for what might otherwise appear as seemingly unrelated facts. Theory can result in selectively including, excluding, or ignoring facts and data. Theory enables one to see patterns in phenomena (e.g. theory allows TCM 'patterns of disharmony' to be identified and TCA diagnoses to be made by practitioners).
- (v) Theory allows the researcher to make predictions.

All of the above functions of theory are relevant to TCA research. These functions clearly highlight the power of theory and why it cannot be ignored by both TCA practitioners and researchers of TCA.

TCM theory can be drawn upon in research of TCA to describe, explain, understand, or predict TCA phenomena. Theory can also guide investigation in both qualitative and quantitative research; however, generally it has different roles in the two types of research (De Poy and

Gitlin, 1993, p.35). Researchers using quantitative research methods such as the randomised controlled trial (RCT) tend to work deductively by testing developed theory (see figure 8. 1). In contrast, in many types of qualitative research the method used is more inductive, with the researcher examining data for patterns and relationships and generating theory (see chapter 12).¹⁹⁰

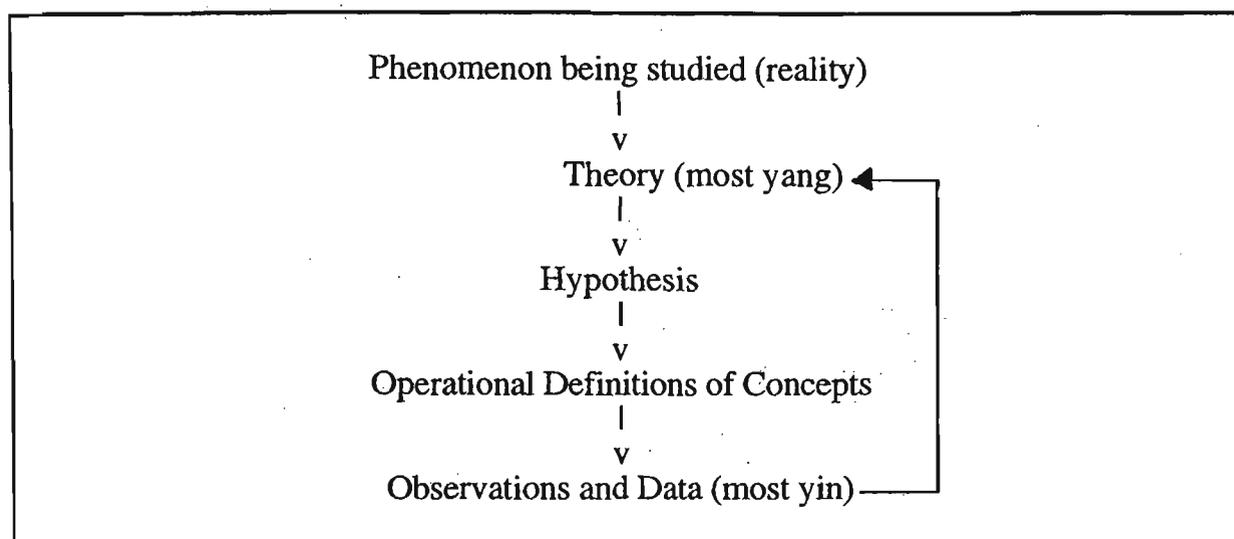


Figure 8.1 The Role of Theory in Quantitative/Experimental-type Research (based on De Poy and Gitlin, 1993, p. 35)

One of the main purposes of experimental-type research is to test or evaluate theory. This approach is appropriate for a study involving TCA when the theory appears to correspond closely to the phenomenon being investigated. Experimental-type research (*e.g.* clinical trials) test theory through a deductive process by focusing on the 'parts' of the phenomenon that is being investigated. This involves moving from the abstract to the concrete, that is, from theory to the observable and measurable parts of the phenomenon. This type of research assumes that knowledge can be developed through existing concepts and ideas. It also assumes that it is possible to understand the *whole* of a phenomenon through the study of, and the measurement of its parts or aspects.

¹⁹⁰ The role of theory in naturalistic inquiry and qualitative research is examined in chapter 12.5.

8.10 Types of Quantitative Research Designs that can be used to study TCA

Many of the science based health care professions utilise quantitative research methods. These quantitative research methods can be understood as an outcome of postpositivist understandings of the world. Quantitative research methods often require the use of standardised measures. In many types of quantitative research, parameters and variables that are regarded as important and relevant to the phenomenon being studied are measured and categorised to a limited number of predetermined response categories to which numbers are assigned (see chapter 9). This allows for statistical analysis to be used to interpret health care data. Quantitative research designs can be used to assess TCA theory and evaluate the efficacy of TCA practice.

There are a number of quantitative research methods that can be utilised to examine TCA and to increase TCA knowledge. These include correlational research, experimental-type research, quasi-experimental research, single subject experimental design ($n=1$), surveys, epidemiology, and meta-analysis.

8.10.1 *Correlational research*

Using the methods of correlational research, the researcher of TCA could establish the strength of relationships between two or more phenomena, or variables within a phenomenon.

Correlations between variables may be determined to be either positive or negative. While this type of research does not aim to prove cause-and-effect relationships between variables, it can often generate hypotheses that can be tested by experimental-type research designs.

In TCM, the ‘theory of correspondence’ is a core theory of TCM diagnosis that is based on associations between phenomena (Porkert, 1978). In the field of TCA, correlational research could be used to further categorise diagnostic phenomena to one of the ‘five phases’ of TCM *wu xing* theory. Such research could extend the scope of TCA diagnosis by adding further signs and symptoms to established TCM ‘patterns of disharmony’.

There is also the idea in TCM of pre-pathological ‘energetic’ disharmonies existing within a

person before 'physical' pathology manifests (Zhiya, 1995, pp. 296-298). TCM practitioners claim to be able to detect these pre-pathological 'energetic' disharmonies through their diagnostic system (*e.g.* pulse diagnosis). Correlational research could be used to determine if there are relationships between pre-pathological 'energetic' disharmonies and pathology.

8.10.2 *Experimental-type research.*

Many biomedical researchers regard experimental-type research that utilises quantitative research designs to be the most powerful method of obtaining knowledge because of its rigorous control of variables. One of the major purposes of experimental research is to test causality (Kerlinger, 1986). In Biomedicine, the randomised controlled trial (RCT), a quantitative research design, has become the 'gold standard' in medical research to determine a medical intervention's effectiveness (Kiene, 1996a; Filshie & White, 1998, p. 4).¹⁹¹ In this type of experimental research, the researcher attempts to control or manipulate the *independent variable(s)* and then measure the outcome on the *dependent variable(s)*. In medical research, the independent variable will usually be the therapeutic intervention or technique that is being evaluated, while the dependent variable will be the impact on, or change in the health status of the patients (*i.e.* the research subjects) involved in the study.

Campbell and Stanley (1966) define a true experimental design as one that has the following three characteristics:

(i) there is *control* in the sense that the researcher attempts to eliminate the effects of other variables beyond the independent variable being evaluated. This is often achieved through the use of *control groups*. In controlled clinical research (*e.g.* the RCT), the control group does not receive the medical intervention being assessed, and this provides the basis for a comparison that is thought necessary to evaluate the effect of the medical intervention on the outcome (dependent) variable. It is generally accepted by biomedical researchers that through the use of control groups, the researcher can claim that any changes in the outcome (dependent) variables will be due to the experimental medical intervention being evaluated.

¹⁹¹ For an account of the controlled randomised controlled trial see K. Resch and E. Ernst (1996). See also chapter 10 of this dissertation.

(ii) The independent variable is *manipulated* by the researcher. In the case of biomedical research the independent variable that is manipulated is the therapy or medical intervention being evaluated.

(iii) There is *randomisation* of research subjects. The aim of randomisation is to eliminate, or at least reduce the effect of *extraneous variables* on the outcome (dependent) variables. This requires the researcher to randomly assign research subjects from the relevant population to either an experimental treatment or control group. The assumption of randomisation is that all subjects in the relevant population have an equal probability of being selected for one of the two groups (*i.e.* treatment and control groups) and that a homogeneous composition in both groups can be achieved. From the perspective of TCM, the aim of randomisation to produce homogeneous groups is extremely difficult owing to the complexity and uniqueness of human beings (chapters 2 & 3).

A common form of the clinical experimental design is the 'pretest - posttest control group design' (Campbell and Stanley, 1966, pp. 8 & 13, see figure 8.2).

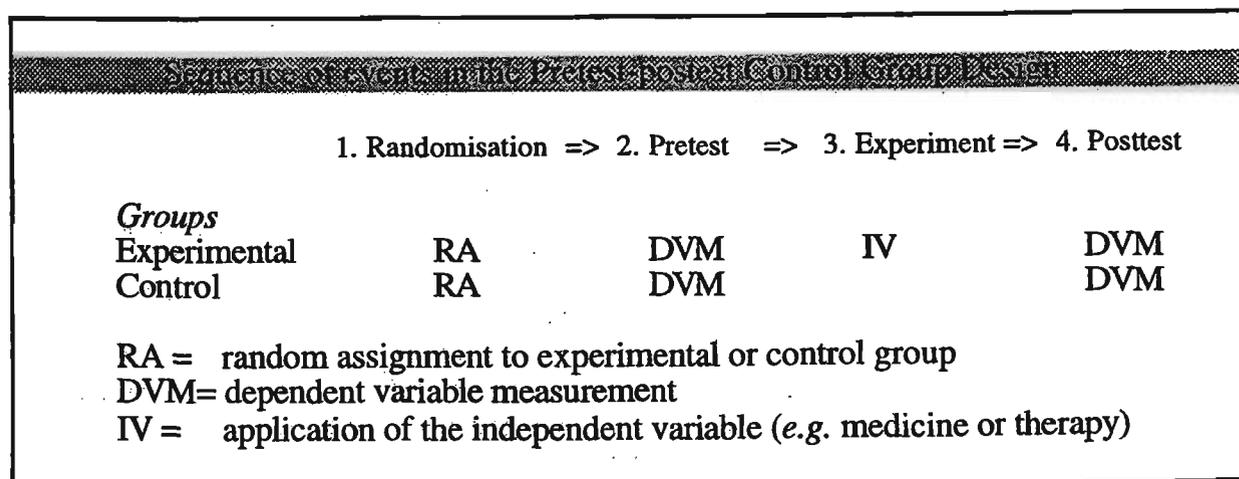


Figure 8.2 The Pretest-posttest Control Group Design (Based on D.T. Campbell and C. J. Stanley (1966). *Experimental and quasi-experimental designs for research*. Chicago: Rand McNally)

In this design, subjects are randomly assigned to either an experimental a control group. Both groups are pretested on previously selected domains and parameters. The experimental group is then given the experimental medical intervention which is withheld from the control group.

Both groups are then posttested. Analysis involves a comparison between the experimental and control groups.

It has been the desire by researchers to achieve *internal validity* that has led to the inclusion of control groups in experimental biomedical research designs. A clinical trial can be said to have internal validity if the researcher can attribute changes in health status of patients in a trial to the *independent variable*, that is, the medical intervention being evaluated. Clinical researchers in the health sciences want to be able to claim that it is indeed the treatment administered to research subjects that has caused any observed differences between treatment and control groups. According to Cook and Campbell (1979), there are several ways that the internal validity of experiments can be threatened. If these factors cannot be accounted for then the researcher cannot conclude that the experimental outcome is attributable *solely* to the medical intervention (see Appendix E: Threats to Internal Validity). If however all extraneous variables can be accounted for (which is impossible in the real world), then it can be claimed from a postpositivist perspective that the clinical experiment has internal validity. Polgar and Thomas (1995, p. 59) claim that in relation to health research, “[c]ontrol is a matter of degree, rather than an absolute. Even some tightly designed investigations allow for plausible alternative explanations arising from unexpected extraneous variables”.

Seligman (1995, p. 965), a psychologist, suggests that many researchers would claim that the ideal controlled trial to determine the efficacy of a therapy should have the following features:

- (i) Patients are randomly assigned to either a treatment or a control group;
- (ii) The control should be rigorous so that influences such as rapport, sympathetic attention, expectation of gain (*i.e.* ‘non specifics’) can be accounted for. The control selected to account for ‘nonspecific’ effects should be credible to both the patient and the therapist when used;
- (iii) The treatments are operationalised, with details of the therapy made explicit. By videotaping sessions, the validity of the procedure can be monitored and assessed;
- (iv) Patients are treated for a fixed number of sessions;

- (v) The variables and outcomes are operationalised and targeted;
- (vi) In 'single-blind' RCTs (see chapter 10), raters and diagnosticians are blind to which group (*i.e.* control or treatment) the patient comes from;
- (vii) Patients who are accepted into a clinical trial need to meet the criteria for a single diagnosed disorder. Patients with multiple disorders are usually excluded; and
- (viii) At the end of treatment, patients are followed for a specified and fixed period of time. During this period they are assessed through a thorough assessment battery.

8.10.2.1 *Prospective and retrospective research designs*

The factor of time should be given due consideration when evaluating the merit of TCA research designs. In *prospective* clinical trials, both the treatment and control groups are treated at the *same* time; whereas in *retrospective* studies the control group that is selected and compared with the treatment group and is measured at a *different* time. Most biomedical research literature suggests that prospective clinical trials are less likely to introduce bias than retrospective trials. Spilker (1991, p. 23) claims that clinical trials of the retrospective type can be best used to generate ideas and hypotheses rather than testing them, since bias is easily introduced in this type of trial because of the time variable. It is therefore desirable that in research to determine the effectiveness of TCA that the treatment and control groups run at the same time. If this is done, it cannot be claimed that there were different factors present in the two groups at the different times that could have contributed to the health outcomes of the people in the two groups.

The time at which TCA clinical research is conducted should be considered when designing clinical trials. According to TCA theory, specific acupuncture points can have different therapeutic effects when used at particular times of the day, month and year depending on the phases of the *qi* cycle (Liu Bing Quan, 1988, pp. 5-9).¹⁹² In the TCA system of acupuncture known as *Zi Wu Liu Zhu*, it is understood that certain acupuncture points are 'opened' or

¹⁹² See also P. Unschuld, 1998, pp. 39-59.

become more active within particular two hour periods of the day as a result of the cycles of *qi* (see Low, 1985; Liu Bing Quan, 1988). TCA practitioners also understand that some conditions can improve and deteriorate with changes in the prevalent *qi* of the season. For example, the TCM syndrome of ‘painful *bi*’ (which has similar signs and symptoms to the biomedical syndrome of osteoarthritis) has been observed by TCA practitioners to sometimes improve in summer and become worse in winter.¹⁹³ These TCA theories should be tested and if verified would have implications for TCA randomised controlled trials in that treatment and control groups would ideally need to be conducted during the *same* season and at the *same* time.

8.10.2.2 *Pragmatic randomised controlled trial (PRCT)*

In the pragmatic randomised controlled trial (PRCT)¹⁹⁴, two or more ‘active’ treatments are compared (often without the use of a placebo control) so as to determine the more effective and efficient therapeutic approaches for various types of human illness and disease. This research design could be utilised to compare the therapeutic efficacy of standard care (which is often orthodox biomedical treatment) with other complementary therapies such as TCA. This research design and other issues related to the evaluation of the efficacy of TCA by experimental designs will be examined in detail in chapter ten.

8.10.3 *Quasi-experimental research*

Campbell and Stanley (1966) have outlined sixteen varieties of quasi-experimental research design. Quasi-experimental research designs are similar to true experimental designs except that they do not have the same degree of control. In quasi-experimental research designs there can be the omission of randomisation in sampling or of a control group. This type of research design is sometimes used in natural settings where it is difficult to use a control group and

¹⁹³ The TCM syndrome known as *painful bi* can manifest as a result of the penetration of cold (a pathogenic *qi* associated with winter) into the body.

¹⁹⁴ The *pragmatic randomised controlled trial* approach is also known as the ‘active control equivalence study’ (Makuch and Johnson, 1989) or the *pragmatic trial* (Pocock, 1993).

randomisation, or where it would be unethical to use a control group (see chapter 11). Quasi-experimental research designs are not regarded as being as rigorous as true experimental designs (*i.e.* randomised controlled trials) because of the reduced control over variables.

8.10.4 Single subject experimental design (n=1 trial or n of 1 trial)

Single-case studies would seem to have a role in complementary medicine research (Ernst, 1998). The single subject experimental design (n=1) is quantitative in nature and could be used to address some TCA research questions.¹⁹⁵ In this design, the individual studied is used as their own control. An early example of this approach in the discipline of acupuncture is the study of tension headache by Vincent (1990).

In the simplest single subject experimental design a reverse 'AB' method is used (Polgar and Thomas, 1995, pp. 99-101). In this method, baseline data on the individual is obtained before treatment. After the treatment, the same domains and variables are measured. Treatments are made at various times and correlated to the periods where no treatment is given. A more sophisticated variation on this design is the ABAB design (Polgar and Thomas, 1995, pp. 101-103) (Figure. 8.3).

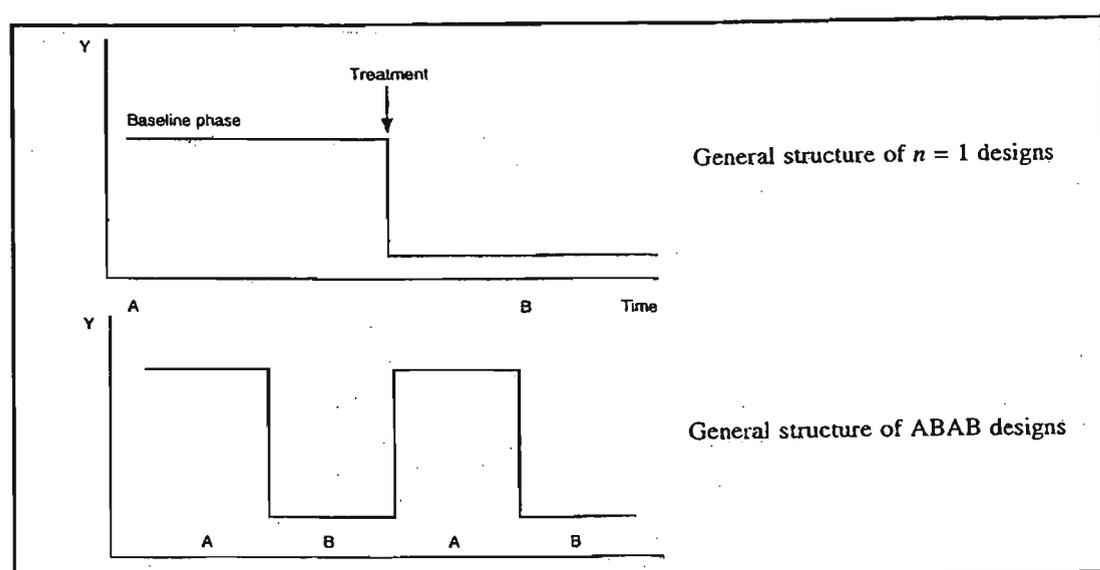


Figure 8.3 Single Subject (ABAB) experimental design (n=1)
(Adapted from Polgar and Thomas, 1995, pp. 100-101)

¹⁹⁵ This type of research design is sometimes referred to as single case design, see C. Vincent and A. Furnham, 1997, p. 153.

The ABAB design involves the measurement of a baseline (A), the introduction of the treatment, and then its withdrawal and reintroduction. This method can be used to demonstrate causal factors in a single individual. The World Health Organisation (1994, p. 33) states that, “[s]ingle case designs can evaluate the effectiveness of various specialized acupuncture methods in patients with a variety of individual differences. They are easy to adopt as an exploratory study and their cost is relatively low.” An example of an acupuncture study that has utilised this design is that of Kieth Chell (1997) for the treatment of Meniere’s disease. The graph of Chell’s results suggests that the patient’s symptoms improved after each time the acupuncture treatment was reintroduced, with the symptoms completely disappearing in the final phase (Figure 8. 4).¹⁹⁶

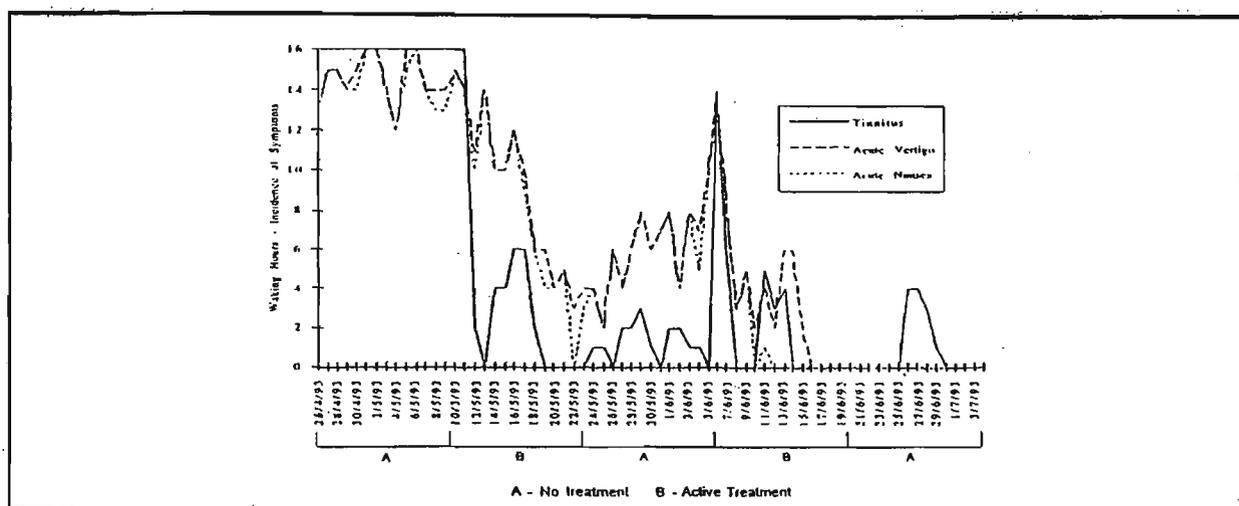


Figure. 8.4 Treatment of Meniere’s Disease by Acupuncture (Chell, 1997)

Chell’s (1997) study would suggest that the ABAB (n=1) design can demonstrate that acupuncture therapy interventions can have a measurable effect on symptom reduction of some syndromes. However, some researchers claim that the ABAB (n=1) design might not be appropriate for investigating medical interventions where it is believed that the disease or syndrome (with their associated its signs and symptoms) is irreversible after the treatment is first administered. For example, after the initial administration of antibiotics in an ABAB (n=1) study, the signs and symptoms of the original condition will probably not re-emerge if the underlying problem is cured (Polgar and Thomas, 1995, p.102). Diebschag (1994, p. 55)

¹⁹⁶ The graph in figure 8.4 was kindly provided by the author Kieth Chell. This data was originally published in the form of a table in K. Chell, *The Treatment of Meniere’s Disease by Acupuncture*, *Journal of Chinese Medicine*, (55), September, 1997, 5-9.

makes the point that AB and ABAB (n=1) designs might not be appropriate for acupuncture evaluation because the effect of therapy is not always transitory, that is, the individual might not return to the initial baseline after the first acupuncture intervention. This is also the view held by the World Health Organisation (WHO) on single case (n = 1) studies. The WHO working group on clinical research methodology for acupuncture state that this design is “obviously not indicated in the case of acupuncture treatments that have long and-lasting or irreversible effects” (WHO, 1994, p. 34). Vincent and Furnham (1997, p. 153) also note that this design is not suitable for research questions that endeavour to determine the relative efficacies of treatments by comparing treatments.

Considering the difficulties in utilising the standard randomised controlled trial in TCA (see chapter 10), more studies using the single subject experimental design (n=1) design need to be conducted to assess the value of this research design for TCA.¹⁹⁷ While large scale RCTs can be used to indicate the therapeutic benefit of treatments ‘on average’, the n = 1 trial could be used to indicate the efficacy of treatments at the level of the individual patient (Campbell, 1994).

8.10.5 *Surveys*

Surveys can be used in TCA research and are a means by which characteristics of variables in populations can be described. The data collection methods utilised include questionnaires and structured interviews. Surveys can be used to determine the opinions, attitudes, or beliefs of people in regard to health, health care and related issues. For example, a survey could be used to compare practitioner-client interactions in Biomedicine and TCM. They can also be used to collect demographic characteristics of populations and to study the characteristics of populations on health related variables. The statistics obtained from surveys can provide an overview of the state of health, illness and treatment patterns in communities (Polgar & Thomas, 1995, p. 86). Surveys are one means by which information can be obtained from TCA practitioners and the public on TCA and related health issues. See Cassidy (1996; 1998) as examples of the use of the survey to investigate TCM.

¹⁹⁷ For a comprehensive examination of single case experimental designs, see D.H. Barlow and M. Herson, 1984 and D. Aldridge, 1993.

8.10.6 *Epidemiology*

Surveys are often utilised in the area of health science called epidemiology. Epidemiology is a type of quantitative research approach that often attempts to identify aetiological factors involved in patterns of illness and disease at the population level (Burns and Grove, 1993, pp. 295-296). This research method acknowledges that patterns of disease can change over time. Such epidemiological studies could enable the researcher of TCA to correlate aetiological factors to specific TCM 'patterns of disharmony'. The claims a researcher can make for causal links between phenomena in epidemiological studies are not as strong as in experimental designs; however, this type of research is an option where it would be unethical to conduct a randomised controlled trial.

Epidemiological studies can be classified into *retrospective* and *prospective* types. In retrospective epidemiological studies, analysis is undertaken *after* the 'causes' and the effects have occurred. This type of epidemiological study is suited to identifying correlations between aetiological factors and disease patterns in populations. It can also be used to identify commonalities between subjects and particular patterns of disease. In prospective epidemiological studies, subjects and variables are selected first, and then correlations are made back to variables as particular patterns of disease develop. Prospective epidemiological studies are considered to be more powerful than retrospective studies in inferring causality because they show that the aetiological factors actually occurred prior to the pattern of disease and are indeed involved in the production of that pattern of disease (Burns & Grove, 1993, p. 296). Such studies could be used to confirm TCA theory by demonstrating relationships between TCM aetiological factors and TCM 'patterns of disharmony' or biomedical syndromes.

8.10.7 *Meta-analysis and systematic review*

Both the meta-analysis¹⁹⁸ and the systematic review (or integrative research review¹⁹⁹) combine the results from a number of studies or clinical trials (Brown, 1999). In the meta-

¹⁹⁸ The meta-analysis is also called *quantitative synthesis* by S. Brown, 1999 p. 150.

¹⁹⁹ S. Brown (1999) uses the term *integrative research review* rather than *systematic review*.

analysis, a statistical analysis is carried out on individual statistical findings of a number of studies to provide an overall statistical value. An example of such a meta-analysis in TCA literature is the study of Patel *et al.* (1989) that reviewed the efficacy of acupuncture for chronic pain. Meta-analyses are usually difficult to perform since the individual studies that are examined usually have design differences and the research design is often poorly described in the published reports (Brown, 1991). In one study of 51 acupuncture clinical trials that evaluated the efficacy of acupuncture for chronic pain (ter Riet, Kleijnen *et al.*, 1990), it was decided by the researchers not to combine statistics from the fifty-one individual studies because the studies were regarded as being too poor and disparate to allow their findings to be combined (Vincent, 1993, p. 294). To enable meta-analyses to be made, it is essential that researchers publish their clinical results and clearly outline the research design and methodology that was used. One protocol for researchers of TCA that could allow for future meta-analyses is described in a report by the Working Group on Clinical Research Methodology for Acupuncture (World Health Organisation, 1994, pp. 30-32).²⁰⁰

Brown (1999, p. 162) claims that *integrative research reviews* have features in common with meta-analyses in that both “employ the same question asking, searching and sampling techniques”, however, “when it comes to analyzing the results, they rely on logical comparison and synthesis, rather than statistical synthesis, to reach conclusions.” Brown (1999, p. 150) notes that the meta-analysis “uses statistical techniques to combine results across studies, whereas an integrative review, relies on summations, logical synthesis, and narrative to characterize the overall findings.”²⁰¹

8.10.8 *The limitations of quantitative research methods*

While there are important roles for quantitative research methods in TCA knowledge production, it should be remembered that quantitative research methods do not always lead to certain knowledge and have been criticised on several grounds. Guzzetta (1989, p. 88), for example, claims that the quantitative method

²⁰⁰ See also chapter 13.7.5 of this dissertation for points that should to be included in published reports of TCA clinical trials.

²⁰¹ See E. Ernst (1999) for an overview of systematic reviews on the clinical effectiveness of acupuncture for a number of conditions.

does not take into account the phenomenologic nature of variables, nor does it consider the characteristics of one individual's pathway to a particular problem. It does not take into account or averages out the unique patterns and interacting variables of one individual. A flaw inherent in the deductive quantitative method is that it does not explain why one individual becomes ill and why another will not.

Other inherent strengths, weaknesses and limitations of clinical research methods are examined in chapter ten.

8.11 Summary

This chapter has examined the relationship between the methods of science and TCA knowledge production. It has been argued that the methods of science can be utilised to investigate particular TCA research questions, as long as a broad definition of science is adopted. Several quantitative research approaches including correlational research, experimental-type research, single subject experimental design, surveys, epidemiology, meta-analysis and systematic review have been outlined that are applicable to a number of TCA research aims.

CHAPTER 9

APPROACHES TO THE MEASUREMENT OF HEALTH OUTCOMES IN TRADITIONAL CHINESE ACUPUNCTURE RESEARCH

“Not everything that can be counted counts,
and not everything that counts can be counted.”

- Albert Einstein (cited in Sikorski and Peters, 1998, p. 1631)

The previous chapter examined issues related to the utilisation of the methods of science and postpositivism to examine and evaluate TCA. These ideas will be developed further in this chapter, where both philosophical and technical issues associated with health outcome²⁰² measurement in TCA clinical research will be considered. Relevant domains and parameters that can be assessed in TCA clinical research are identified and consideration will be given to some suitable instruments to assess them. This examination will provide a foundation for chapter ten which will address a number of critical issues related to the evaluation of the efficacy TCA therapy.

9.1 Measuring Health Outcomes in TCA Research

It could be argued on ethical grounds that TCA practitioners have a duty to their clients to examine the effectiveness of the health care they provide. This goal could be achieved by research that evaluates TCA practice. Such an evaluation of the effectiveness of TCA therapy would need to acknowledge and be respectful of the philosophy that underpins TCA clinical practice and the patient-centred approach that is characteristic of TCA health care. From the perspective of the TCA profession, it is important that any research design selected to evaluate

²⁰² According to A. Hutchinson, J. Hewison and M. Eccles (1996, p.10) a *health outcome* is an “effect manifest as a change in health status”.

TCA should not be compromised by any politico-philosophical demands of the biomedical paradigm: especially in ways that could reduce the meaningfulness and value of TCA research. The domains and parameters that are to be measured in order to evaluate health outcomes in TCA clinical research should, ideally, be relevant and internally consistent with the TCM paradigm. Such domains and parameters would also need to be relevant to the specific aims of the particular TCA study or clinical trial. These domains and parameters need not be restricted to only those ‘objective’ variables and signs²⁰³ that are easily measured. As suggested in chapter one (pp.13-14), the determination of health status in TCA research should not be restricted to only the measurement of data of the biological body. Such empiric and sensory data while being relatively easy to measure when compared with ‘intelligibilia’ (‘objects’ of the mind) and ‘transcendelia’ (objects of the spirit), might not be the most relevant or appropriate for particular TCA research questions.

The purported goals of mainstream Biomedicine are said to include the prevention of disease, the maintenance of health, the treatment of disease, and the management of chronic and disabling conditions. However, ‘health’ in Biomedicine is usually measured in a negative sense *via* the absence of signs and symptoms (Williams, 1992, p. 124). In contrast, health care professionals of *holistic medicine* disciplines such as TCA understand health as not merely the absence of pathology but as something that involves a positive sense of wellbeing. It is claimed by practitioners of holistic medicine that this sense of wellbeing can be attained by reducing ones exposure to health risks and by living in harmony with oneself and the environment (Edlin and Golanty, 1988, p. 3) (chapter 3). Holistic systems of medicine such as TCM often emphasise the notion of health rather than disease. A major focus of holistic TCM health care is the promotion and maintenance of health and wellbeing and not simply the treatment of disease. This last point needs to be remembered when attempting to assess the *total* benefit of TCA therapy. According to Millenson (1995, p. 4), holistic forms of medicine understand “the individual person-patient as an integral part of a larger system embracing the social, psychological and physical environment.”

²⁰³ A *sign* in the medical context refers to a physical manifestation that can be observed and/or measured by a health care practitioner or medical researcher. A sign can be contrasted with a *symptom* that is subjective in nature. Symptoms are experienced by the person who is ill and cannot be directly perceived by the health care practitioner or medical researcher. Signs are more ‘objective’ when compared to ‘subjective’ symptoms.

It should be noted that the World Health Organisation (WHO) has defined *health* as, “a state of complete physical, mental, and social well-being, and not merely the absence of disease and infirmity” (WHO, 1948) for over five decades. This definition is compatible with the holistic TCM perspective in so far that it acknowledges the interrelatedness of the physical, psychological, emotional, and social domains that contribute to the quality of a person’s life, health and wellbeing.

Holistic medicine shares with the Oriental philosophy of Daoism the belief that a person’s spiritual outlook, feelings, thoughts and experiences can affect their state of health and wellbeing. Spiritual experiences and perceptions, it is claimed, can engender feelings of contentment, compassion, tranquillity of mind, and harmony with ones environment, which, according to Oriental philosophy, are important precursors of health. The philosophy of TCM health care emphasises the unity of body, mind and spirit through its ontology, and recognises that there is no part of the mind, body or environment that is truly independent or separate (chapter 2). There is the understanding that the ‘mind’, body, society and the environment can all influence human health and illness (chapters 2, 3 & 4).

9.2 The Measurement of Data in TCA Research

The question as to which types of data and information need to be assessed by researchers to be able to evaluate the effectiveness of TCA therapy needs to be addressed. ‘Objective’ somatic signs are certainly a starting point; however, TCA practitioners often emphasise the importance of emotional and spiritual health. Therefore, when assessing the benefits of TCA therapy, researchers should not forget to assess the emotional and spiritual dimensions, even if they are ‘subjective’ and more difficult to measure. Wilber (1990, p. 39) claims that phenomena from the mental and spiritual realms should be regarded as legitimate ‘objects’ of knowledge. He claims that directly apprehended experiences can occur in each of the three realms of the body, mind (mental), and spirit. As previously mentioned (chapter 1), Wilber has termed the ‘objects’ of these three realms *sensibilia*, *intelligibilia*, and *transcendelia* respectively. Wilber (1990, p. 40) claims that what defines a datum in any of these three realms is not its simplicity or atomism but its “immediate givenness”, or “direct apprehension”. This understanding clearly

resonates with the perspective of phenomenology.

The word 'experience' is used in many ways by different authors. Wilber (1990), for example, claims that humans can *experience* sensations and perceptions (sensibilia), as well as ideas, thoughts and concepts (intelligibilia). Wilber contends that the word *experience* is used by empiricists in a very limited way: in reference only to sensory experience. Wilber suggests that people can also experience *spirit* through 'the eye of contemplation or gnosis'. Spirit, he claims, can be immediately apprehended and experienced *as spirit* (in the realm of transcendelia) (Wilber, 1990, p. 42). Wilber makes the claim that all knowledge is grounded in *experience* but not in sensory experience alone. He gives the example of 'experiencing' mathematics in the mental realm, and claims that transcendental 'truths' or spiritual experiences (e.g. the Zen Buddhist spiritual experience of *satori*²⁰⁴) are experienced in the spiritual realm (Wilber, p. 42). Wilber (1990, pp. 43-44) posits that each of the three modes of knowing allows access to real experiential data (*i.e.* sensibilia, intelligibilia, and transcendelia) in its respective realm.

9.2.1 Assessment of data in the three realms of body, mind and spirit

Wilber (1990, p. 77) has noted that one of the defining characteristics of the classic empiric-scientific method has been its use of measurement to generate data. The measurement of data in the physical sciences essentially involves only empiric or sensory data (sensibilia), which are relatively easy to measure when compared to 'intelligibilia' and 'transcendelia'. Wilber explains that

it is much harder to measure subjective intelligibilia (let alone spiritual transcendelia), the scientists simply dismissed data that could not be forced into physical measurement dimensions - and that was the horrendous crime that led to the "disqualified universe." All of this can be avoided if we simply remember that measurement in the monological [physical] sciences is primarily of extension; measurement in the dialogical sciences is primarily of intention; and measurement in gnostic sciences is primarily of transcension.' (Wilber, 1990, pp. 79-80)

²⁰⁴ A *satori* is a zen term for a type of peak spiritual experience of illumination, or enlightenment. According to E. Wood (1977, p. 91), *satori* is "the state of consciousness of the Buddha-mind. Consciousness of pure consciousness, itself, as such, without objects either mental or bodily."

Wilber (1990, p. 77) claims that Descartes explained one of the significant differences between the two realms of physical *sensibilia* and mental *intelligibilia*

the physical world is marked by *extension*, the mental world, by *intention*.
 ... For what characterizes intelligibilia is not so much their *extension* as their *intention* - their meaning, their value, their intersubjective understanding. Physical space-time no longer quite applies to them, and thus physical measurement and quantification are of rather limited use.

Wilber (1990, p. 79) adds that

[it] is not that space and time exist only in the gross realm of sensibilia. It is that in the physical realm, space and time are the densest, the grossest, the most head-knocking concrete. As we move up the spectrum of consciousness, space and time become subtler and subtler (and therefore more encompassing or transcendent), but, accordingly, measurement becomes subtler and thus infinitely more difficult to perform, until it becomes, finally, completely meaningless ... we ought to be very careful not to confuse what we mean by measurement of *extension* with measurement of *intention* with measurement of *transcension*...

Wilber's analysis has important implications for TCA research, since it suggests the need for qualitative research methods to elicit information from research informants so as to uncover meaning and intersubjective understanding in the realms of *intelligibilia* (mind) and *transcendelia* (spirit) (see chapter 12). Guzzetta (1989, p. 91) notes however that

some experiences may be ineffable. The individual who experiences certain feelings ... may not be able to conceptualize or express them or may be unable to translate or communicate these effects to another. Likewise, the researcher may be unable to interpret the effects because of a lack of experience with these feelings or because our language is limited and inadequate when describing and communicating these phenomena.

9.3 Quality of Life (QOL) Measures

In recent times, it has been claimed by some researchers that the efficacy of a therapeutic intervention should be evaluated in terms other than merely a reduction in signs and symptoms (Walker and Rosser, 1993). It has been claimed that consideration should also be given to the subjective perceptions and feelings that can result from a therapeutic intervention and which can

affect a person's 'quality of life'. As a result of this view, *quality of life* (QOL) measures are now being incorporated into pharmaceutical drug and therapy efficacy trials in response to more holistic health models (see A. Bowling, 1997a for a comprehensive review of 'quality of life' measurement scales).

'Quality of life' instruments involve the consideration and analysis of subjective data which, it has been claimed, are best evaluated by the informant (White, 1996). White (1996, p. 93) claims that, "[i]t is likely that subjective health-related quality of life will be an appropriate outcome measure for complementary medicine." Now since the concept of 'quality of life' assessment is relatively new, it is not surprising that health researchers understand the concept in different ways. Calman (1984) claimed that 'quality of life' must include all areas of life and experience and should take into account the impact of illness and treatment. A good 'quality of life' can be said to be present when the hopes of an individual are matched and fulfilled by experience. Conversely, a poor quality of life occurs when a person's hopes do not meet with experience. It should be noted that the perception of a person's quality of health will not be static but will change over time.

Schipper *et al.* (1990) have suggested that while any domain or parameter may be selected by researchers to determine 'quality of life', only those that can be expected to have specific and measurable outcomes should be assessed. Spilker (1991, p. 377) has outlined four major domains that he claims should be considered by 'quality of life' instruments and has suggested possible parameters that could be assessed in each domain:

- (i) The *psychological* domain. This category includes cognitive function, emotional state (*e.g.* depression and anger), personal productivity, intimacy and sexual function;
- (ii) The *physical* domain. This covers physical capacities and dysfunction;
- (iii) The *social* domain. This category includes things such as the number of contacts per week; the quality of social contacts at home, school and work; and the quality and quantity of social contacts with friends;

- (iv) The *economic* domain. This category includes work status and the amount of time worked. This domain remains controversial in QOL literature. It should be noted, however, that the economic domain can be correlated with health status. For example, the average life span of human beings is longer in countries at higher levels of economic development and in subpopulations at higher socioeconomic levels within countries (Brenner, 1981, p. 371).

In 1994, the World Health Organization Quality of Life Group (WHOQOLG) (1994, p. 45), in the development of its 'quality of life assessment instrument', for the measurement of health status realised that another major domain needed to be assessed: that domain was spirituality, religious and personal beliefs (see Appendix F: Domains and Facets of the World Health Organisation Quality of Life Instrument). Again, this finding is compatible with the understandings of TCM.

A related term to *quality of life* (QOL) is *health-related quality of life* (HRQOL). After due consideration and analysis of the extensive literature on this concept of HRQOL, Shumaker and Naughton (1995, p.7) state that

[h]ealth-related quality of life refers to people's subjective evaluations of the influences of their current health status, health care, and health promoting activities on their ability to achieve and maintain a level of overall functioning that allows them to pursue valued life goals and that is reflected in their general well-being. The domains of functioning that are critical to HRQOL, include: social, physical and cognitive functioning; mobility and self-care; and emotional well-being.

9.3.1 *The reasons for considering health-related quality of life (HRQOL)*

According to Shumaker and Naughton (1995, p.3):

[t]raditional indices of health are now routinely augmented with measures of HRQOL, both to characterize populations and to assess the efficacy of various interventions. In clinical trials, the exclusion of HRQOL has become rare; it is now almost unacceptable to evaluate a new treatment (behavioural, pharmacological or surgical) without attending to its influence on the day-to-day quality of an individual's life.

There are several reasons why HRQOL data are now being included in trials that attempt to

determine clinical efficacy. Spilker (1991, p. 371) suggests that consumers of health care often feel that they are being adequately treated but do not receive adequate care. He suggests that patients often see medical practitioners focusing entirely on the objective benefits of treatment and ignoring how patients feel. It has been the author's observation over recent years that clients have increasing concerns about the side effects of many pharmaceutical drugs now on the market and the possible effects that such drugs might have on their long term health and wellbeing. For many people, the subjective feeling of wellbeing is just as important as the absence of objective signs. This has relevance for TCA therapy, since it is claimed that TCA can not only reduce the signs and symptoms of disease but can also enhance wellbeing and *qi* levels.²⁰⁵ This is an important point, since much pharmaceutical drug research concentrates on the reduction of signs and symptoms and not on the positive effects of therapy such as increases in vitality (*qi* levels) and the enhancement of wellbeing. The reason for this emphasis is obvious: the focus of the biomedical paradigm is on the elimination of disease rather than on the promotion of health.

It is also important to note that 'quality of life' data are of interest to groups other than researchers, academics and patients. Regulatory authorities now realise that in certain cases 'quality of life' endpoints represent viable parameters for measuring a treatment's efficacy. According to Spilker, pharmaceutical companies now recognise that formulary committees are willing to accept QOL information as a basis for accepting a new medicine into a formulary.²⁰⁶

It is no longer sufficient to include a new medicine on a formulary based solely on safety and efficacy parameters (Spilker, 1991, p. 304).

²⁰⁵ According to Jobst (1998, p. 2), patients of TCM have reported "highly significant reductions in drug/pharmaceuticals use, diminished health insurance needs, less need for consultation with their doctor, and above all, greater energy and well being."

²⁰⁶ Formulary committees have the power to control which medicines are allowed for prescription by hospitals and other government controlled health care centres. Any decision by a formulary committee to put a new medicine on prescription will involve differentiating the new medicine from similar medicines and therapies based on a number of factors which include efficacy, safety, convenience, cost, and now in recent times 'quality of life' data.

9.3.2 When should 'quality of life' not be measured?

QOL (and HRQOL) data need not be measured where it is clear that a particular medicine or therapy has a larger benefit-to-risk ratio than other medicines and therapies. The need to measure QOL data only becomes important when a treatment is only partly curative, is expensive, has only a small benefit-to-risk ratio, or where disease symptoms are relieved but other severe adverse reactions occur (Spliker, 1991, p. 731).

9.4 The Purposes of Health Outcome Measurement in TCA Clinical Research

To measure TCA efficacy, researchers need to be able to accurately measure health outcomes.

Based on Metcalfe's (1992) ideas on the purposes of health outcome measurement, there are three important reasons for the measurement of health outcomes in TCA clinical research:

(i) to be able to assess the client's response to TCA therapy; (ii) to be able to compare the efficacy of one treatment, or therapeutic intervention with another; and (iii) to be able to assess a treatment's cost effectiveness. Metcalfe (1992) has also suggested that the quality of health care practice has three aspects, these being: (i) the *effectiveness* of the intervention; (ii) its *efficiency*, that is, the extent to which resources are conserved in obtaining effectiveness; and (iii) the *acceptability* of the the health care to the client. Metcalfe (1992, p.15) claims that the efficiency of an intervention "can only be assessed when care has been shown to be effective, and cost can only be linked to effectiveness if the latter can be measured."

9.5 Definition of a Health Outcome

Having explained the purposes of TCA health outcome measurement, it is now necessary to determine what a therapeutic outcome in TCA research could be. Metcalfe (1992, p.15) explains that an 'outcome' in general practice is

the change in health status that results either from medical interventions or from the deliberate decision not to intervene. An outcome cannot therefore, be measured unless the intervention is accurately described. The description of the intervention must include its explicit objectives so that the end state can be compared to what was intended and thus any unintended changes identified.

Metcalfe's definition would appear to be predicated on postpositivist ideas since there is an emphasis on quantification. It might also be noted that the term *health status* as the subject for endpoint assessment as used by Metcalfe conforms to the WHO definition which encompasses psychological and social well-being in addition to the presence or absence of pathophysiology. From a postpositivist perspective, Metcalfe's definition of an 'outcome' would seem appropriate when discussing changes in health status in clinical research aimed at determining the efficacy of TCA therapy.

9.6 The Distinction Between the Management of Chronic Illness and Disease and the Treatment of Acute Disease

When making decisions on which domains and parameters are to be measured in TCA clinical research, it is important for researchers to take into consideration the difference between the treatment of acute disease and the management of chronic illness and disease. Metcalfe (1992, p.18) states that *treatment* is a "relatively circumscribed range of technical interventions focused primarily on the pathophysiology". Treatment is therefore disease-centred. This approach is appropriate in situations where patients have acute conditions, or have diseases that have affected essential biological life functions, or where there is a loss of consciousness. In the case of acute conditions (as often found in hospital settings), the objective of biomedical treatment is to correct pathological processes quickly and restore normal function. The treatment in this case will be disease-centred and health outcomes will be measured by the absence or presence of pathology and the restoration of normal function.

In contrast, *patient management* describes "the range of interventions, of which *treatment* is but one part, directed to the totality of the patient's ill-health - physical, social, and psychological". Patient management is therefore patient-centred care. This distinction has ramifications for TCA research because of TCA's holistic and humanistic patient-centred orientation.

9.6.1 *Chronic disease and TCA therapy*

When patients have little or no autonomy, there is a case for a disease-centred approach in which outcomes can be measured in purely pathophysiological terms. However, when clients are autonomous, as is usually the case in TCA private practice settings, it is desirable for therapy to be person-centred. The parameters measured to evaluate health status should therefore include QOL or HRQOL data, in addition to the measurement of the signs and symptoms of particular diseases.

In the case of chronic illness and disease, that which is often managed by TCA practitioners in private practice, the aim of TCA therapy will be to promote balance between the biological, emotional, psychological and spiritual aspects of the person and their outer environment.²⁰⁷

TCA therapy in this case will be person-centred. This might also involve an attempt to restore 'normal' function, to reduce pain, and to reduce any other signs and symptoms of illness and disease. If all of these aims are not possible, the TCA practitioner will endeavour to help the client to adapt to their situation as best they can.

From a postpositivist (or neopositivist) perspective, the health outcomes that would need to be assessed should be both objective and subjective, and could possibly include measures of pathology (objective measure), the restoration of normal physical function (objective measure of function), measures of subjective experience such as pain, frustration, depression, wellbeing, and 'quality of life' data. TCA practitioners often treat and manage chronic conditions that are not 'cured', hence QOL data will be relevant to researchers wanting to evaluate the therapeutic efficacy of TCA.

9.6.2 *Treatment of acute conditions by TCA*

TCA practitioners approach the treatment of acute conditions from various perspectives. This is often a result of the different foci of the various colleges and universities that provide TCA

²⁰⁷ A survey reported by C. Vincent and A. Furnham (1997b) found that many acupuncture patients perceive acupuncture to be an effective therapy for a number of chronic conditions.

training. For example, many TCA practitioners when treating acute conditions such as low back pain, will consider all aspects of the person, that is, the somatic, psychological, the social, and the spiritual. These practitioners hold the view that all aetiological factors are interrelated and could possibly contribute to the manifesting pattern of signs and symptoms. However, there are *some* TCA practitioners who would appear to treat *some* acute conditions as circumscribed imbalances of *qi*. Therefore, when developing research designs for the evaluation of acupuncture therapy for acute conditions (*e.g.* low back pain), it needs to be decided beforehand how the measurement of health outcomes is to be attained. This will require a clear statement of the aim of the particular acupuncture research project and whether a management and person-centred orientation or a treatment orientation is to be adopted by the acupuncture practitioners involved in the research.

9.7 Deciding on which Domains and Parameters to Measure in TCA Research

Before any clinical trial is conducted to determine the therapeutic efficacy of TCA, it is first necessary to decide on which domains and parameters are to be measured to gauge the efficacy of the therapy. The domains and parameters measured in any study will depend, in part, on the hierarchical position of the discipline involved. For example, in psychology subjective mental states might be considered important to assess, whereas in endocrinological research biochemical tests that measure hormone levels could be more relevant. It must therefore be decided before any TCA clinical trial begins which domains and parameters will be the most important in assessing therapeutic efficacy. In the case of TCA, researchers will certainly want to consider the patient as a whole and will therefore need to consider changes in both psychological and physical parameters.²⁰⁸ Therefore, the evaluation of the efficacy of TCA should involve a global evaluation of domains and parameters by means of various health outcome instruments that assess clinical signs and symptoms that are both 'subjective' and 'objective' in nature.

²⁰⁸ This position is supported by a comprehensive survey of acupuncture trials conducted by Bensoussan and Myers (1996, p. 35) which concluded that there is indeed some evidence that acupuncture can produce "long-term improvements in objective and subjective indicators of health" and "may influence immunity and initiate changes in a patient's psychological state."

It is simply not practical and too expensive to measure all variables and factors that might affect health outcomes; therefore it is necessary when designing TCA clinical trials to decide which parameters are to be measured or assessed. It is possible that some parameters might be incompletely measured, while other factors that could have a bearing on health outcome might be unknown or beyond the ability of current methodologies to measure and assess. There could also be some parameters that can be measured but are not because of financial, social, political, or environmental factors (Spilker, 1990 p. 612). Dossey (1995, p. 8) has also noted that there are various 'factors of consciousness' such as empathy, love, caring, spousal support, hostility, loneliness and depression, which are often ignored in clinical trials. Dossey (1995, p. 8) claims that the primary reason that the various 'factors of consciousness' are disregarded is that our underlying assumption is "that the world is overwhelmingly physical in nature. This assumption assures us that mental effects, even if present, constitute no more than a placebo-type nuisance that will "wash out" between the treatment and control groups."

On the other hand, the research conducted by Medalie and Goldbourt (1976 cited in Dossey, 1995, p. 8) suggests that factors such as a loving and supporting relationship with one's spouse can lower the incidence of angina. Such a factor however would seldom be considered relevant or taken into consideration when deciding on which parameters to measure when designing a biomedical clinical trial since the focus of biomedicine is usually at the biological level.

9.8 Possible Domains and Parameters to Measure in Research to Establish the Therapeutic Efficacy of TCA

The domains and parameters measured to evaluate the therapeutic efficacy of TCA therapy will be dependent in part on the 'epistemological orientation to practice' adopted by the researcher (chapter 7). For example, a researcher with a 'traditional epistemological orientation to practice' might only want to measure domains and parameters associated with the TCM paradigm (e.g. changes in signs and symptoms, *qi* levels, and *shen*). In contrast, a researcher who adopts a 'neopositivist epistemological orientation to practice' could decide to measure a broader range of domains and parameters. These domains and parameters could include:

1. *Shen*. The *shen* could be considered an example of Wilber's (1990) 'transcendelia', and, like other 'spiritual' states, might be difficult to assess. It should be noted however that the *shen* of TCM should be easier to assess than some other 'transcendelia' since it can have 'physical' and behavioural manifestations.²⁰⁹ This is an outcome of the nondualistic ontology of TCM which avoids dualistic notions of mind and body (see chapter 2);
2. Psychological and emotional wellbeing;
3. *Qi* levels (or energy/vitality levels);
4. Changes in signs and symptoms / 'patterns of disharmony' (researchers' assessment). Measurement of these could be achieved through interviews, traditional TCA diagnostic means (*e.g.* pulse and tongue diagnosis) and through the use of specialised equipment (*e.g.* electrocardiogram, electroencephalogram, ultrasound, X-rays). This could require the selection and prioritisation of signs and symptoms for the evaluation of therapeutic efficacy;
5. Changes in signs and symptoms / 'patterns of disharmony' (patients' self report).²¹⁰ This could be achieved by systematic recording of case histories and client diaries;
6. Physical and physiological measures:
 - (i) Physical function (*e.g.* grip strength, mobility)
 - (ii) Histological evaluation (pathological changes);
 - (iii) Laboratory evaluation (*e.g.* urinalysis, hematology, virology, microbiological, endocrine tests, skin tests for immunologic competence);

²⁰⁹ According to T. Kaptchuk (1983, p. 46), "[w]hen Shen loses its harmony, the individuals's eyes may lack luster and his or her thinking may be muddled. A person so affected may be slow and forgetful, or perhaps suffer from insomnia. Certain Shen disharmonies are marked by unreasonable responses to the environment, such as incoherent speech. Extreme Shen disharmony can lead to unconsciousness or violent madness." Shen disturbances can therefore have both subjective symptoms and objective signs.

²¹⁰ This is especially important for research instruments that acknowledge the importance of patients' subjective perceptions of health and which focus on the measurement of function and 'quality of life' information such as the Patient Generated Index (PGI) and the Measure Yourself Medical Outcome Profile (MYMOP), see chapter 9.14.3 and 9.14.4.

7. Quality of life (QOL) or Health-related quality of life (HRQOL) data.²¹¹
8. Reduction in pharmaceutical drug use (this would be a benefit if the pharmaceutical had side-effects, or a small benefit-to-risk ratio). This could be achieved by using a Medication Record (Birch, 1997c) (See also Steedman *et al.*, 1992).

It is therefore essential that the researcher decides before a TCA clinical trial begins on the domains and the number of parameters that are to be measured. It is at this time that the domains and parameters must be prioritised. The greater the number of parameters measured, the more difficult it is likely to be to interpret the data collected. Reasons for this include the generation of an excessive number of comparisons which can lead to an increased number of false-positive results based on chance (Spilker, 1991, p. 603). On the other hand, if only a few parameters are measured, it is possible that patients could improve on one of the parameters and not on the others, which could also lead to problems with data interpretation. In the case of TCA research, the evaluation of the effectiveness of TCA therapy will be more comprehensive if a range of parameters are measured from the four domains of the physical, psychological, social and spiritual.

9.9 Research Instruments for TCA

9.9.1 *'Weighted' and 'unweighted' parameters in 'quality of life' instruments*

Spilker (1991, p. 371) has classified 'quality of life' instruments into three broad categories, these being profiles, indexes and batteries. In all of these instruments, the various parameters can be 'weighted' or 'unweighted'. When parameters are unweighted, each parameter is given an equal value. In other instruments, where parameters are weighted, parameters are given different values. It follows that in TCA research to determine clinical efficacy, it will be necessary to decide before a trial begins, the hierarchy, or the relative importance of each of the parameters to be assessed to establish efficacy and whether they should be weighted or

²¹¹ As an example, see Appendix F: Domains and Facets of the World Health Organisation Quality of Life Instrument.

unweighted.²¹²

9.9.2 *Safety parameters in TCA efficacy research*

When developing research designs to evaluate the efficacy of TCA therapy, it would seem important to consider and incorporate safety parameters at the same time. The value of TCA therapy, from a holistic perspective, should be considered in terms of not only its effectiveness for a particular 'pattern of disharmony' or medical condition, but also in terms of its overall therapeutic effect. For example, a therapy that was found to be efficacious in 75% of people with a particular condition but which also produced severe side-effects would not be considered as an extremely valuable therapy when its *total* effects were considered. For this reason, safety parameters should be determined during the development of the TCA research design so as to be able to assess the *total* effect of the therapeutic intervention.

9.9.3 *Parameters that measure both efficacy and safety*

The measurement of some parameters such as blood pressure has been used in biomedical research to evaluate both effectiveness and safety. It is therefore important to decide before a clinical trial begins how parameters are to be used. In terms of cost effectiveness, it might be desirable to use some parameters to assess *both* TCA therapeutic effectiveness and safety.

9.10 **Research Instrument Validity and Reliability**

From positivist and postpositivist perspectives, *validity*, in relation to research, refers to the correspondence of research findings with reality. A research instrument can be said to be *reliable* if it measures what it purports to measure in a stable and consistent way. If a measuring instrument is not reliable, it is certain to produce findings that are not valid (Reid, 1993, pp. 41-42).

²¹² It could be noted that there can be high correlations between weighted and nonweighted parameters in studies. For example, Zimmerman (1983) in a report that examined eighteen studies that evaluated the relationship between stress and illness, concluded that there was a high correlation between weighted and nonweighted totals.

9.10.1 *Content, face and construct validity*

Researchers of TCA need to be mindful of *content, face, and construct validity*. *Content validity* refers to the extent to which a research instrument is able to provide relevant information on the domain or phenomenon being investigated (Reid, 1993, p. 42). If, for example, a researcher wanted to evaluate the effect of TCA therapy on patients' general health and wellbeing, the research instrument would need to measure parameters from both the 'psychological' and 'physical' domains. An instrument that measured only somatic parameters would be considered to be inappropriate and lacking content validity.

Face validity refers to the acceptance of a research instrument by either research subjects or administrators (Reid, 1993, p. 42). Although some researchers regard 'face validity' as too subjective, it should not be undervalued since often the purpose of research is to influence either clinical practice or government policy. If a research instrument is not regarded as methodologically sound by both practitioners and administrators, the findings from it might be expected to have minimal impact on both TCA professional practice and government policy.

Due consideration should also be given to *construct validity* in TCA research design.

Construct validity involves the examination of the fit between conceptual and operational definitions of variables. It determines the extent to which the research instrument actually measures the theoretical construct (*e.g.* pain, wellbeing, *shen*) it purports to measure (Burns and Grove, 1993, pp. 268-270).

9.11 **Advantages of Creating an Original Instrument for a TCA study**

According to Tudiver and Ferris (1992, p. 88), there are several reasons why a researcher in the field of primary health care would want to develop an original instrument for a specific research project:

(i) The instrument produced would emanate from the conceptual framework or paradigm of the

discipline. This is an important point with regard to TCA research since many of the available instruments are based on the biomedical model of health and disease.

- (ii) The focus of an original instrument will be directed towards the aims and objectives of the specific research project and will not contain extraneous items. As a result, an original instrument will have greater content and face validity, and will provide increased construct validity estimates.
- (iii) It can be pretested on people from the target population, that is, the same population on which the developed instrument will be used.
- (iv) An original instrument is likely to be user friendly in the sense that it will meet the specific needs of the researcher's requirements in terms of administration and clinic setting procedures.

9.12 Disadvantages of Creating an Original Instrument for a TCA Study

The main disadvantage in creating an original instrument for a particular study is the time, energy and money required to develop and test a new instrument for its content and face validity (Tudiver and Ferris, 1992, p. 88). If researchers of TCA believe that it is essential to create a new instrument for a particular project, then it should be carefully constructed following established guidelines (Tudiver and Ferris, 1992) to ensure that it will be a valuable and valid research instrument.

9.13 Creating New Instruments by Modifying or Combining Sections of Other Research Instruments

Zyzanski (1992, p.110) warns researchers that creating new instruments by 'cutting and pasting' from established instruments is not as simple as one might expect. Zyzanski claims that one cannot assume a carryover effect of the original instrument's psychometric properties to a new hybrid instrument. Zyzanski argues that the psychometric properties of a modified

instrument need to be evaluated to ensure confidence in the results obtained from it. This process can be both expensive and time consuming.

Research instruments to measure the therapeutic efficacy of TCA could be adapted from those used in other disciplines such as psychology, biomedicine and primary health care (see Appendix G: Instruments that could be used in research of TCA). If this could be done, the research findings would be less likely to be challenged by researchers working in the established medical community.

9.14 Methods and Instruments for Measuring Outcomes in TCA

9.14.1 MOS 36-Item Short Form Health Survey (SF-36)

White (1996, p. 94) has noted that, “[q]uality-of-life’ measures for use as clinical outcomes need to strike a balance between being simple and standardized so that they can operate across different diseases and treatments, and subtle and individual so that they genuinely reflect the subject’s own view.” One example of an instrument that has been used in the assessment of both primary health care and the complementary therapies is the MOS 36-Item Short Form Health Survey (SF-36) (Ware & Sherbourne, 1992).²¹³ Cox *et al.* (1992 cited in White, 1996, p. 95) believe the SF-36 to be the most appropriate research instrument currently available for evaluating complementary medicine; however, they suggest that it should be used with specific disease related instruments that have been validated. This instrument is not disease specific and hence could be used to assess general improvements in health and wellbeing in TCA clinical trials. Researchers of TCA should note that the SF-36 does not assess the areas of sleep patterns and sexual functioning, two areas often assessed in TCA practice and regarded as being

²¹³ The MOS 36-Item Short Form Health Survey (SF-36) of J. Ware and C. Sherbourne (1992) can be completed in approximately 10 minutes. The SF-36 “has been demonstrated to possess internal consistency, test-retest reliability, and construct validity” (Brazier *et al.* 1992 in White, 1996, p. 94). It consists of 36 questions which yield scores in the eight dimensions of: (i) physical functioning; (ii) role limitations which result from physical health disorders; (iii) bodily pain; (iv) general health perceptions; (v) vitality (energy levels); (vi) social functioning; (vii) role limitations which result from emotional factors; and (viii) mental health (including wellbeing). See also Bowling (1997, pp. 57-61) for a discussion of this instrument’s content, validity and reliability.

important for a comprehensive TCA diagnosis. An assumption of many instruments, including the SF-36, is that the scale on which research informants rate their health and quality of life remains constant over time.²¹⁴

9.14.2 *The World Health Organization Quality of Life Group research instrument.*

The World Health Organization Quality of Life Group (WHOQOLG) is developing another research instrument that is anticipated to have multiple uses (The WHOQOL Group, 1994, pp. 53-54) (See Appendix F: Domains and Facets of the World Health Organisation Quality of Life Instrument. The uses that are relevant to TCA research are as follows:

- (i) In TCA practice the instrument could be of use to practitioners “in making judgments about the areas in which a patient is affected by disease and in making treatment decisions”. Furthermore, when used with other measures it will allow the assessment of changes over the course of therapy.
- (ii) It could increase the TCA practitioners understanding of how illness and disease affect a patient’s quality of life. As a result, the interaction between patient (client) and the TCA care practitioner could improve;
- (iii) As a result of a comprehensive form of assessment covering a range of domains and aspects of the patient’s functioning, patients themselves might find their health care to be more meaningful;
- (iv) The routine use of ‘quality of life’ instruments such as the WHOQOL instrument could increase the recording of patient data and enable better communication of useful information between TCA practitioners and other health care professionals;

²¹⁴ This point was made in a paper titled ‘Health Outcome Measures: The evaluation of change in a primary care setting’ that was delivered by M. J. Fitter and A. J. Gould at the 3rd Symposium on Complementary Health Care, Exeter, UK, 11-13 1996. They concluded in the abstract of their paper that “most of the available measures identify 1st-order change (change assessed with a constant measuring instrument). It is claimed that complementary therapy interventions often lead to 2nd- and 3rd-order change - that is change where the measuring instrument needs to be recalibrated or redefined as a result of the intervention. This creates difficulties for assessing the full effect of interventions.”

- (v) The WHOQOL instrument could be of considerable use in clinical trials in establishing baseline levels in a range of domains and parameters, and in assessing changes in 'quality of life' over the course of treatment, particularly where the disorder prognosis is predicted to be only partial recovery or remission. A treatment plan that would be more more palliative than curative could then be determined;
- (vi) In epidemiological research, the WHOQOL instrument could allow detailed 'quality of life' data to be collected on a particular population. International epidemiological studies that could be made possible by the WHOQOL instrument might facilitate the understanding of the effects of illness and disease on patients' 'quality of life' and the development of appropriate health care interventions;
- (vii) In implementing and planning new health polices, it is important that a rationale for the effect of policy changes on the 'quality of life' of people in contact with health services is evaluated. An instrument such as the WHOQOL instrument could allow for the planning and monitoring of such changes.

9.14.3 *The Patient Generated Index (PGI): A way of measuring quality of life*

Ruta *et al.* (1994) have developed another approach to measuring 'quality of life' which they have termed the Patient Generated Index (PGI). Garratt and Ruta (1996) claim that this new PGI is a patient-centred approach to health outcome measurement. It builds on Calman's (1984) definition of 'quality of life' which attempt to "quantify the difference between individuals' hopes and expectations and reality in a way that has meaning and relevance in the context of their daily lives." This approach to measuring quality of life has three important features. First, it "allows individuals to *choose* the areas of their lives that they consider to be of the greatest importance". Second, it allows individuals to "*quantify* the extent to which reality matches expectations in their chosen areas." Third, it allows individuals to "*assess* the relative importance of their chosen areas." A strength of the PGI approach is that the domains covered by the instrument will be tailored to the perceived needs of the patient rather than being imposed by the researcher. Garratt and Ruta (1996, p. 88) claim that a sample of patients in a low back

study indicated that the PGI “satisfied validity and reliability criteria and was found to be responsive to changes in perceived quality of life”. The PGI could be used to measure intra-patient change as a result of TCA therapy in private practice and other clinical settings. Further research is required to assess the value of this approach of measuring outcomes in TCA studies.

9.14.4 *Measure Yourself Medical Outcome Profile (MYMOP)*

Another instrument that shows promise in measuring outcomes for the complementary therapies (including TCA) is the *Measure Yourself Medical Outcome Profile (MYMOP)* (Paterson, 1996). This instrument acknowledges the importance of patients’ subjective perceptions of health and focuses on the measurement of function and ‘quality of life’ information. Paterson (1996) suggests that the MYMOP could be used in the evaluation of complementary therapies such as TCM. It could possibly overcome the conceptual problems associated with the different diagnostic frameworks of the various health care disciplines since the parameters measured in the MYMOP are generated by the patient. Paterson (1996, p.1019) states that, “[t]aking the definition of the problem back to the patient’s concerns for the purpose of outcome evaluation means that complementary medicine will not be falsely constrained by the assumptions of scientific medicine.”

The MYMOP could be used to visually chart changes in health status in case studies. Further research needs to be conducted to evaluate the MYMOP’s usefulness in clinical trials, routine practice, audit, and n=1 trials. An important benefit of the use of the MYMOP might be to make the primary health care encounter more patient-centred (Paterson, 1996, p.1020).

Ruta *et al.* (1974, 1110) suggest that measures of outcome need to reflect the *patients’* perceptions and should possess the following features and characteristics:

- (i) the research instrument needs to “describe the effect of a condition on those aspects of patients’ lives that they consider to be of greatest importance”;
- (ii) the research instrument should allow patients “to rate the extent to which those aspects

of life are affected by the condition”;

- (iii) the research instrument “would be sensitive to changes in health over time, and also would allow patients to judge the value of those changes”;
- (iv) the measure of outcome should be reproducible;
- (v) the research instrument “should be suitable for a wide variety of patients in different settings”;
- (vi) the research instrument “should be brief and simple for patients to complete.”

Ideally, the instruments selected for any TCA study should be easy to administer by TCA practitioner-researchers and be simple enough for clients to complete in a short period of time.

9.15 Summary

In this chapter the purposes of health outcome measurement in TCA research have been examined. Various philosophical and technical issues associated with health outcome measurement in TCA research have been investigated. Measures of TCA therapeutic efficacy can be obtained if the most appropriate parameters from each of the somatic, psychological, social and spiritual domains are selected and assessed. Health-related quality of life instruments should be used where appropriate in TCA studies. As in all health care research, the specific parameters chosen to be measured in any given research project will be dependent on the particular research question posed. Data from the realms of ‘intelligibilia’ and ‘transcendelia’ should be assessed (if possible) if required by the research question and not *only* the more easily measured ‘sensibilia’ of the senses and the biological body. Research instruments can be constructed for specific TCA studies and should be evaluated by researchers.

CHAPTER 10

THE EVALUATION OF THE EFFICACY OF TRADITIONAL CHINESE ACUPUNCTURE THERAPY

“Healers stress that their most important qualities are love and compassion for the patient, and that true healing comes from within the patient. Love and compassion are not usually structured components in clinical trials yet they may be key factors that must accompany any and every therapeutic technique that brings about a healing response, rather than just a drug or needle effect.”

- Andrew Parfitt (1993, p. 9)

The purpose of this chapter is to examine several issues that are critical to the evaluation of the efficacy of TCA therapy. This examination acknowledges the value and strengths of postpositivist perspectives and the utilisation of quantitative research methods in relation to the determination of the efficacy of TCA therapy (see chapters 5, 7, 8 and 9). One major objective of this chapter is to determine some guiding principles for the development of appropriate research designs and methodologies to evaluate the efficacy of TCA. Such research designs and methods would ideally be congruent with the TCM paradigm, methodologically sound, useful, ethical, and economically viable considering the funding restraints placed on the planning and execution of clinical research. A second objective is to determine the significance and implications of the ‘placebo’²¹⁵ phenomenon in relation to research that endeavours to establish the efficacy of TCA therapy. In the last section of this chapter, the limitations of the randomised clinical trial for evaluating the therapeutic effectiveness of TCA are explored.

²¹⁵ H. Byerly (1976) has indicated that there are a number of ‘non-specific’ (placebo) factors that are an integral part of any therapeutic intervention regardless of the therapy employed. S. Ross and L.W. Buckalew (1985) provide one definition of the placebo in the medical context. They state that, “a placebo can be considered as any treatment or preparation given to a patient or client that does not provide any direct pharmacological or psychotherapeutic effect for the specific condition being treated”.

10.1 Evaluating the Efficacy of TCA Therapy: Some Preliminary Observations

One aim of researchers of health care is to influence and improve clinical practice. Some researchers argue that only certain types of research have the rigour and validity to provide convincing evidence to bring about change in clinical practice. *Evidence-based medicine* has been put forward as the benchmark for orthodox medical practice, where clinical practice is modelled as far as possible on the results of controlled clinical trials (Black, 1996 cited in Vincent & Furnham, 1997, p.152). In Biomedicine, the *randomised clinical trial* (RCT), a quantitative research design, has become the benchmark in medical research to determine a therapeutic intervention's effectiveness (Kiene, 1996a; Filshie & White, 1998, p. 4).

Quantitative research designs such as the RCT (see chapter 8.9.2), which have been derived from positivistic ideas, have one advantage over other methods in relation to the evaluation of the efficacy of TCA: they can be used to make predictions about the efficacy of treatment for groups of patients. The researcher working within a postpositivist mode (*e.g.* neopositivism, see chapter 7.4.3) may *acknowledge* the idea that all people are to a degree different; however, postpositivist perspectives emphasise the notion that human beings like other worldly phenomena are subject to common laws. TCA practitioners also acknowledge the idea that all people are different and in some ways unique; however, there is also the notion that similar TCM 'patterns of disharmony' can be observed in people when they are ill.

Although the therapeutic outcome for any one patient in a research program can never be predicted with absolute certainty because of the unique properties of the individual and other variables, it is still thought possible, using the RCT, to calculate a probability of health outcome for a group of patients that experience a particular medical disorder. It is often claimed that the RCT provides the best means by which the most effective and efficient type of therapy for particular syndromes and diseases can be determined. Health policy, based on such research, has the potential to determine the most efficient distribution of health care funding according to clinical evidence.²¹⁶

²¹⁶ This idea is derived from the understandings of evidence-based medicine (EBM), which posits that doctors and patients should make decisions about health care based on the best available scientific evidence (see R. Moynihan, 1998, p. 213).

In relation to the determination of the efficacy of TCA, postpositivism might provide the best epistemological orientation to adopt when attempting to answer questions for groups of people. The analysis of clinical studies, based on postpositivism, can often involve the calculation of a probability of therapeutic outcome for groups or subpopulations. However, it should be remembered that no matter how exhaustive the scientific or clinical investigation, there are often limitations imposed in health care research that make it extremely difficult to make definitive knowledge claims. Absolute truths in some areas of health care may never be found regardless of the method used (including the RCT), since it is impossible to control for all variables that are involved in the therapeutic encounter. The best that can be hoped for is a description of relationships between variables which have a high probability of occurrence.

In most biomedical research that involves the evaluation of pharmaceutical drugs, an attempt is usually made to keep the therapeutic intervention constant. However, Patton (1990, p. 42) points out that it is extremely difficult to keep practitioner treatments and interventions controlled and standardised during programs that involve human intervention. He states that, “[p]rograms, treatments, and interventions frequently change as practitioners learn what works and what does not, as they experiment and grow and change their priorities.” Patton (1990, p.42) explains that according to Parlett and Hamilton (1976), experimental evaluation designs are most suited to studies where it is “possible to limit program adaption and improvement so as not to interfere with the rigour of the research design.” This point should be kept in mind in regard to TCA research, since TCA therapy is ‘tailored’ to the requirements of each individual client. The TCA practitioner will routinely change the ‘treatment principle’ and consequently the acupuncture points used, as the pattern of a client’s signs and symptoms changes throughout the course of treatment (chapter 2). TCA therapy is not a static therapy like some forms of pharmaceutical drug therapy, where the same dose of a particular pharmaceutical drug is prescribed at intervals during a course of treatment without modification.

Some researchers could view the ‘tailored’ approach of TCA therapy as interfering with the rigour of the conventional RCT design in that the therapeutic intervention is not kept constant. In pharmaceutical trials, the efficacy of a particular drug is usually determined by prescribing the *same* therapeutic agent to all research subjects; however, to conduct a TCA clinical trial in

which the same set of acupuncture points were needed repeatedly without modification (according to the changing client pattern of signs and symptoms) would amount to *not* evaluating TCA. In TCA clinical trials that attempt to determine TCA therapeutic efficacy, the research design should allow for the utilisation of appropriate acupuncture point selection based upon individual TCA diagnoses that will result in individualised patient treatment. Richardson and Furnham (1997, p. 147) have claimed that some complementary practitioners who value the individual approach of the complementary therapies could believe that the RCT “may not do justice to complementary medicine and perhaps should be avoided. This might also be the view of some TCA practitioners.

Sivan (1990, p. 35) suggests that the definition of therapeutic efficacy should be broader and more comprehensive. He claims that the evaluation of a therapy’s efficacy should consider how well it *prevents* disease in *addition* to the extent to which it alleviates the signs and symptoms of disease. Sivan’s point is important in regard to TCA research, since it is claimed by TCA practitioners that TCA can *prevent* disease by enhancing the body’s innate healing processes (through strengthening the *zheng qi*) in addition to treating the signs and symptoms of disease. Konner (1993, p.117 cited in Moynihan, 1998, p. 247) has argued that in the current health care system there has been an emphasis on treatment rather than prevention. As a result, preventative medicine and health promotion have become neglected areas of health research. This is perhaps due to the domination of Biomedicine in the field of health care, with its high use of pharmaceutical drugs that often aim to eliminate ‘pathogenic’ disease factors (*e.g.* microorganisms) rather than attempting to enhance health and the body’s own innate healing processes. Konner (1993, p. 117) claims that patients and “people in general - have relentlessly insisted on abdicating responsibility for their health and their own treatment, choosing in almost every case the quick fix, only to be bitterly disappointed when the quick fix doesn’t really work.”

10.2 The Randomised Controlled Trial (RCT)

Many biomedical researchers believe the randomised controlled trial (RCT) to be a necessary step in the determination of the efficacy of a pharmaceutical drug, or therapy (see chapter 8.10.2).

The RCT is the research design favoured by the majority of medical journals that publish the findings of pharmaceutical drug efficacy trials. Lynn Payer has noted that if a clinical trial is not performed as an RCT that it is unlikely to be accepted for publication in English medical literature (Payer, 1990, p. 9). The reason for this, she claims, is that the RCT is regarded as the essence of the scientific approach to medicine. Although the use of the RCT might not always lead to correct medical decisions, many biomedical researchers believe that in the long term, medical decisions based on this methodology will be accurate more often than not and generate medical knowledge. (Charmers, 1982, p.19).

The difference in therapy effectiveness estimates between controlled and uncontrolled clinical trials is significant, with the medical research literature suggesting that the best way to obtain a positive result in a clinical trial is to leave out the controls (Charmers, 1982, p.15). This is one reason why many researchers do not regard anecdotal reports of the benefits of particular medical interventions as convincing evidence for a therapy's efficacy. For these reasons alone, a persuasive case could be developed for the continued use of the RCT to evaluate the efficacy of TCA therapy.

In a randomised controlled trial (RCT), a 'treatment' group is compared with a 'control' group so as to determine the efficacy of the *specific* medical intervention. A control group is included in the design so as to account for the 'non-specific' (placebo) effects of therapy. Byerly (1976) has noted that there are a number of 'non-specific' factors that are an integral part of any therapeutic intervention regardless of the therapy employed. It is now generally accepted that these 'non-specific' effects are responsible for part of the therapeutic outcome of *all* therapies that involve a clinical encounter between a practitioner and a patient.

Ross and Buckalew (1985), in one review, outlined the most researched 'non-specific' factors that are involved in the so called placebo effect: (i) the doctor-patient relationship (Sleisenger, 1958; Gelbman, 1967); (ii) the patient's expectations and needs (Beecher, 1952; Rosenthal and Frank, 1956; Affleck, 1966; Tetreault and Bordeleou, 1971; Hurst, Weidner, Radlow & Ross, 1973; Ehrenwald, 1974; Aletky and Carlin, 1975); (iii) suggestion (Buckalew, 1969, 1972); (iv) the patient's personality and psychological state (Ray, 1978; Buckalew, Ross and Star,

1981); (v) symptom or discomfort severity (Aletky and Carlin, 1975; Ray, 1978); (vi) the instructions given to the patient (Lyerly, Ross, Krugman and Clyde, 1964; Ross *et al.*, 1972; Buckalew, 1972); (vii) preparation characteristics (Jacobs and Nordan, 1979; Morris and O'Neil, 1974; Buckalew and Ross, 1981; Buckalew and Coffield, 1982a, 182b); and (viii) the environmental milieu (Fisher, 1970; Beck, 1977). This information is relevant for any researcher wanting to investigate the efficacy of TCA therapy who desires to separate out and account for the effects attributable to the acupuncture needling procedure and those that result from other elements of the clinical encounter.

10.3 The Placebo Effect in Traditional Chinese Acupuncture Research

If we accept the finding from a number of studies that the placebo effect is inherent in any form of therapy that involves a clinical encounter (Bok, 1974; Berg, 1977 and Vrhovac, 1977), it is not surprising that there has been strong interest by researchers of TCA in the placebo phenomenon. It has become apparent that an understanding of the placebo phenomenon will be essential for the development of appropriate controls for RCTs that can be used to evaluate the efficacy of TCA. Before World War Two, clinical outcomes were all that were required to demonstrate effectiveness. Placebo controls only came to be regarded as essential when it became obvious that non-specific (placebo) effects were ubiquitous in clinical experiments (Kaptchuk, Edwards and Eisenberg, 1996, p. 42). The RCT methodology developed in response to the recognition of these ubiquitous placebo effects in clinical trials.

10.4 The 'Double-blind' Randomised Controlled Trial

The RCT can be 'single' or 'double-blinded' (Vincent & Furnham, 1997, p. 156). In a properly conducted 'double-blind' RCT, the researchers do *not* know if they have administered a 'real' therapy or a placebo (which in pharmaceutical drug trials is often in the form of a pill). In addition to this, the 'subjects' in the clinical trial are not told if they have received the 'real' drug (or therapy) or a placebo. In Biomedicine, the double-blind RCT has become the 'gold standard' in medical research to determine a medical intervention's effectiveness (Kiene, 1996a;

Filshie & White, 1998, p. 4).²¹⁷

The 'double-blind' RCT is a planned experiment designed to evaluate the efficacy of a therapeutic intervention on human beings. This is done by comparing health outcomes of a group of patients treated with a new drug or therapy with those of a comparable group whose members do not receive treatment (*i.e.* the control group). Many biomedical researchers claim that a drug or therapy can only be said to be efficacious if its effect in a clinical trial differs significantly from that of the control group. The control group is used to distinguish the 'placebo'/'non-specific' effects involved in the therapeutic encounter from those that result from the *direct* therapeutic effect of the drug, or medical intervention. Much of the medical literature regards the placebo phenomenon as a 'nuisance' variable in inadequately designed experiments (Brody, 1980, p. 8). However, Shapiro and Shapiro (1997, p. 230) note that "the double-blind method is not infallible."

Vincent and Richardson (1986, pp.10-11), following Lewith and Machin (1983), argue that "double-blind trials of acupuncture, while technically possible, are inherently flawed in that by definition a truly blind procedure must be carried out by a naive and inexperienced practitioner who may not produce an adequate standard of treatment." They make the point that appropriate and adequate acupuncture therapy can only be administered by a skilled acupuncture practitioners who are fully conscious of the therapy that they are providing. TCA clinical research that is to be regarded as being ethical would require TCA practitioner-researchers to be comprehensively trained in the theory and practice of TCA.

TCA therapy does not lend itself to double-blind RCTs since the acupuncturist must be aware of the treatment that they are administering, whether it be 'real' or 'sham' acupuncture.²¹⁸

Acupuncture clinical trials by necessity have to be conducted as 'single-blind' clinical trials

²¹⁷ A.K. Shapiro & E.S. Shapiro (1997, p. 229) state that [in the United States] "the double-blind method has since the 1960s been a requirement for NIH [National Institutes of Health] funding of studies and for FDA [Food and Drug Administration] approval of new drugs or experimentation".

²¹⁸ 'Sham' acupuncture is one control that has been devised to account for the non-specific effects of acupuncture therapy. Specifically, it is an attempt to account for the placebo effect of acupuncture *and* the non-specific physiological effects of needling (see chapter 10.5.1).

(Choi & Tweed, 1996).²¹⁹ The only possible role for a double-blind RCT is in the evaluation of the efficacy of laser acupuncture, where instead of using traditional acupuncture needles, a laser is used to activate the acupuncture points. In such a RCT, the laser could be turned on and off by a researcher other than the TCA therapist who delivers the therapy. In such a research methodology, the acupuncturist delivering the treatment would *not* be aware of any difference in the treatment procedure used in the 'treatment' and control groups.²²⁰

10.5 The 'Single-blind' Randomised Clinical Trial

The 'single-blind' RCT is one research design available to TCA researchers that provides a degree of control when a double-blind RCT is either impossible or difficult to conduct (Vincent & Richardson, 1986a; Watson, 1991; Choi & Tweed, 1996). In this research design, practitioner-researchers *are* aware of whether they are administering a 'real' or 'sham acupuncture' treatment, while the 'subject' is *unaware* of which treatment ('real' or placebo) is being received.

It has been claimed that single-blind clinical trials do not always yield more 'objective' data and interpretations than uncontrolled trials (Spilker, 1991, p. 616). Spilker (1991) also suggests that a clinical trial does not have to be 'double-blind' to be regarded as a 'well-controlled' clinical trial. He suggests that the 'double-blind' is but one feature of a well-controlled clinical trial. Clearly, in single-blind RCTs it is important to have an adequate control group.

Vincent and Richardson (1986a, pp. 10-11) suggest that single-blind RCTs with an

²¹⁹ It could be noted that there is much compelling evidence from double-blind controlled studies that acupressure on the classical acupuncture point *neiguan* (pericardium 6) is effective in the treatment of nausea (Ernst, 1996b). This conclusion was drawn from an analysis of studies that used double-blind controlled trials in which studs in wrists bands were used to stimulate the acupuncture point. Acupressure is *not* acupuncture; however, the findings of the studies reported in the review by Ernst (1996b) provides some evidence for TCA classical theory and the therapeutic value of 'activating' classical acupuncture points in the treatment of nausea.

²²⁰ The laser is perceived by patients as no more than a light beam and cannot be distinguished from a conventional red light beam that could be used as a control. The laser beam used in laser acupuncture therapy cannot usually be felt by patients.

independent outcome assessment are adequate for evaluating the efficacy of acupuncture, provided efforts are made to monitor independently the impact of non-specific effects and/or ensure that they do not vary between groups.²²¹ Spilker (1991, p. 615) suggests that the validation process in any 'blinded' clinical trial should involve the evaluation of the integrity of the blind with an 'end-of-trial' questionnaire or interview. Ideally, patients involved in TCA clinical trials would need to be asked after the trial if they were able to determine from practitioner cues if they were in the 'treatment' or the placebo group. Obviously, if patients in a clinical trial were able to break the 'blind' there would be a dramatic loss of internal validity.

In single-blind RCTs, TCA practitioner-researchers could be routinely video taped by an independent committee to assess if they treated the 'treatment' and placebo groups in the same manner. This would help to ensure that cues (whether conscious or unconscious) were not given to patients that would indicate the group ('treatment' or placebo) to which they had been assigned. Single-blind RCTs of TCA would seem to provide a defensible means of assessing the efficacy of TCA therapy when compared with uncontrolled trials in which no blind is used and where both researchers and subjects know the nature of the therapy delivered.

10.5.1 '*Sham*' acupuncture controls in TCA clinical research

Many researchers who have attempted to evaluate the efficacy of acupuncture have used what is known as 'sham' acupuncture as a control (Vincent & Richardson, 1986; Vincent, 1993).

Wood and Lewith (1998, p. 79) claim that credible placebo controls are "an essential element of randomised, controlled trials of acupuncture." A 'sham' acupuncture control is one that involves the needling of the skin with acupuncture needles at loci on the body other than classical acupuncture points.²²² Points adjacent to known acupuncture points that are not on acupuncture channels are used for this purpose. This approach assumes that '*ah shi*' points²²³

²²¹ For strategies to maintain the credibility of the sham acupuncture control see C. Zaslowski *et al.*, 1997.

²²² An early example of this approach was that of C.A. Vincent, 1989.

²²³ *Ah shi* points are acupuncture points that can be located anywhere on the body that become tender in some disorders and which have a therapeutic effect on that disorder when needed.

or unidentified acupuncture points are not needed.

Several types of acupuncture control have been used in clinical trials that have involved acupuncture. For example, Macdonald *et al.* (1983) used 'mock' transcutaneous nerve stimulation (TENS) as a 'sham' acupuncture control.²²⁴ This method would not be a suitable control for TCA where needles are used since it would be obvious to many subjects that TENS is not a traditional acupuncture procedure. Another 'sham' acupuncture control termed 'minimal acupuncture' has been used in other acupuncture clinical trials (see Vincent and Richardson, 1986). This control procedure involves minimal skin surface stimulation by acupuncture needles. One strength of the 'minimal acupuncture' control is that it would appear identical to 'real' (*e.g.* TCA) acupuncture from the point of view of the clinical trial subject (Vincent & Furnam, 1997, p. 183).²²⁵ It should be noted, however, that 'minimal acupuncture' might still have physiological/therapeutic effects which could reduce its value as a control. The most recent development of the 'sham' acupuncture procedure involves a new 'sham needle'. When used, the shaft of the 'sham needle' telescopes into the handle, giving the impression that it is penetrating through the skin and underlying tissues (Streitberger and Kleinhenz, 1998). This relatively new sham procedure would appear to have some potential in future randomised controlled trials involving TCA.

As early as the mid 1980s, Vincent and Richardson (1986b) reported that acupuncture studies that used 'sham' acupuncture controls yielded mixed findings with regard to clinical efficacy, with some studies suggesting that acupuncture had a significant therapeutic effect while others found no significant difference between 'real' acupuncture treatment and 'sham' acupuncture. Vincent and Richardson (1986, p. 29) suggested that the failure to find significant differences between 'real' and 'sham' acupuncture in those trials if they were present (assuming that the trials were in all other ways well conducted) could be explained by any one of three hypotheses:

²²⁴ See C. Vincent (1993, p. 295) for a full account of this type of 'sham' acupuncture control.

²²⁵ See R. Wood and G. Lewith (1998) for an examination of the credibility of placebo controls in acupuncture trials.

- I the effects of both the ‘real’ acupuncture and ‘sham’ acupuncture are due to non-specific/placebo factors;
- II ‘real’ acupuncture and ‘sham’ acupuncture are equally efficacious treatments for particular health problems. If this were the case, then a knowledge of traditional Chinese acupuncture point function would not be necessary for TCA practice²²⁶;
- III there *is* a difference in the therapeutic efficacy between ‘real’ acupuncture and ‘sham’ acupuncture but this difference is not easily detected by researchers due to some aspect of the research design (*e.g.* the sample size being too small).

Hypotheses (I) and (II) are unlikely to be true since there is now a substantial and growing body of evidence in the form of many well conducted clinical trials using a ‘single’ RCT methodology that would indicate that acupuncture *is* an effective therapy for particular conditions such as pain, vomiting and nausea (Bensoussan & Myers, 1996, p. 34).²²⁷

Hypothesis (III), above, is a credible possibility when one considers the relatively small samples of patients who have been examined in most controlled acupuncture clinical trials.

10.5.2 Possible problems associated with the ‘sham’ acupuncture control

As early as the 1970s, Moore and Berk (1976) claimed that it could be difficult to determine a therapeutic difference between ‘real’ acupuncture and a ‘sham’ acupuncture control. In one

²²⁶ If indeed the TCA theory of specific acupuncture point function is valid, then there should be a significant difference between the outcomes of TCA and ‘sham’ acupuncture. If this were found not to be the case, it would have disturbing ramifications for TCA theory and practice, since it is a common understanding of traditional acupuncturists that classical acupuncture points have specific ‘energetic’ effects. It could also be noted that while the classics of TCM do refer to some specific functions of some acupuncture points there is some controversy as to whether specific point functions can be ascribed to all classical acupuncture points. P. Deadman and M. Al-Khafaji (1998, p. 8) suggest that the ascription of specific acupuncture point functions has increased in modern times (20th century) from the ideas of Chinese herbal medicine.

²²⁷ A. Bensoussan and S. Myers (1996, pp. 33-34), in their comprehensive survey of acupuncture clinical trials also concluded that there is evidence that acupuncture “has a marked action on a range of physiological functions, and may be of benefit in hypertension and other cardiovascular disorders, asthma and bronchospasm, digestive disorders, obstetrics, and drug addiction”. It could be noted that Bensoussan & Myers (1996, p. 33) used the NHMRC’s (1995a) quality of evidence ratings to evaluate the quality of the acupuncture clinical trials that they surveyed in their comprehensive study (see Appendix B).

study, Moore and Berk (1976) attempted to compare acupuncture therapy with a 'sham' acupuncture procedure for chronic shoulder pain. The placebo control procedure consisted of pricking the skin superficially with acupuncture needles without actually inserting them deeply (this is a form of 'minimal acupuncture'). This type of 'sham' acupuncture procedure might, however, not be a totally suitable control to account for placebo effects since research by

Melzak and Wall (1965) has found that any type of cutaneous stimulation can promote pain relief.²²⁸ Diffuse noxious inhibitory control (DNIC) is a model developed by Le Bars *et al.* (1979) from an earlier theory called 'counter-irritation' to account for how pain or noxious stimulation in one part of the body can relieve pain in another (Birch, 1997). Birch (1997, p. 36) explains that:

The basic theory of 'counter-irritation' and DNIC is that if one provides a painful or noxious stimulation to part of the body it can block pain in other parts of the body regardless of the site of stimulation or site of pain. ...the stronger the (noxious) stimulus, the stronger the analgesic effect... .

If this is correct, 'sham' acupuncture might not be *physiologically* inert and hence might not be an inappropriate control in some TCA clinical trials where *pain* is the variable measured to assess therapeutic effectiveness. Any statistical analysis of data using this type of 'sham' acupuncture control could indicate that TCA therapy is not significantly better than the control because of the therapeutic effect (*i.e.* analgesic effect of the cutaneous needling) in the 'sham' acupuncture procedure. If 'sham' acupuncture is not physiologically inert, large numbers of subjects would be required to demonstrate a statistically significant difference between the therapeutic effects of 'real' acupuncture' and the 'sham' acupuncture control if they were present (Pomeranz, 1987). DNIC might not pose a problem in TCA clinical trials (that use a 'sham' acupuncture control) where the disorder examined does not involve pain: in such trials the variable of pain would not need to be assessed.

If 'sham' acupuncture is not physiologically inert, then it could be understood as an active

²²⁸ For other physiological effects of needling see D.E. Kendall, A scientific model for acupuncture, *American Journal of Acupuncture*, 7, 1989, 251-268 and D. Le Bars *et al.*, Diffuse noxious inhibitory control (DNIC) in man and animals. *Acupunct. Med.*, 9, 1991, 47-57. .

treatment rather than a control. If 'sham' acupuncture is regarded as an active treatment, then there are a range of possible explanations as to why researchers might find both 'real' TCA therapy and 'sham' acupuncture to be clinically effective²²⁹:

- (i) Both therapies could be therapeutically active in the same type of patient;
- (ii) One treatment ('real' TCA or 'sham' acupuncture) could be active in one type of patient and the other treatment could be active in different types of patients;
- (iii) One treatment ('real' TCA or 'sham' acupuncture) could have been more active in a few patients, and the other treatment less active in a larger number of patients; and
- (iv) Both treatments ('real' TCA or 'sham' acupuncture) had false-positive responses.

Conversely, there are possible explanations as to why both 'real' TCA therapy and 'sham' acupuncture could appear to be ineffective treatments:

- (i) Changes in clinical signs and symptoms in patients were nonspecific and resulted from the placebo effect;
- (ii) Both 'real' TCA therapy and 'sham' acupuncture had false-negative responses; and
- (iii) One treatment ('real' TCA or 'sham' acupuncture) produced a false-negative response and the other was actually ineffective.

10.6 Are the Therapeutic Effects of the TCA Needling Technique and the Non-specific (placebo) Effects of Therapy Additive?

One assumption that is often made by biomedical researchers is that the therapeutic effects of a medical intervention and any associated non-specific effects are additive. If this were the case then the total therapeutic effect of TCA therapy could be simply calculated by subtracting the

²²⁹ These reasons have been adapted from the work of B. Spilker (1991, p. 721) on the interpretation of clinical response.

therapeutic effect of non-specific (placebo) effects from the total therapeutic outcome.

Conventional biomedical research assumes no synergy between the specific therapeutic effect of a medical intervention and the non-specific (placebo) effects of therapy. This might not be true if the holistic maxim that the 'whole is greater than the sum of its parts' is applied to a therapy.

Spilker (1991, p. 617) notes that the calculation of the placebo influence by subtraction rests on several unproven assumptions: in particular that the placebo and specific therapy responses are linear and that the placebo response is relatively constant in magnitude throughout the duration of the clinical trial. Spilker suggests that the interaction of the trial medicine (or therapy) and the placebo is probably complex and that some of the assumptions of biomedical placebo action are probably not valid.

In the case of some therapies such as psychotherapy, it is often difficult, if not impossible, to separate practitioner induced placebo effects from the actual therapy. This same difficulty is encountered with TCA therapy which often has a component of Oriental health counselling. Since it appears that the placebo effect is involved in *all* therapeutic encounters and is an important factor in healing, it would seem unethical to attempt to minimise its effect in TCA clinical research designs. It might eventuate, through further research, that the placebo effect is far from being a 'nuisance' variable but rather an important part of the healing process that needs to be better understood and utilised by practitioners.

10.7 Problems of Adapting the Randomised Clinical Trial Methodology to Evaluate the Efficacy of TCA Therapy

A number of authors have discussed the methodological problems associated with the use of controlled clinical trials to evaluate the complementary therapies (including acupuncture) that require the therapy to be 'tailored' to individual patient needs (Pocock, 1993; Lewith, 1993; Wiegant, Kramers & van Wilk, 1993; Canter & Nanke, 1993; Anthony, 1993; Vincent, 1993; Lewith & Aldridge, 1993; Diebschlag, 1993; Vincent & Furnham, 1997).²³⁰ Many of the points made by these authors for the complementary therapies in general are applicable to the

²³⁰ The focus of the examinations of C. Vincent (1993) and F. Diebschlag (1993) were on acupuncture, whereas the other authors cited examined the complementary therapies in more general terms.

evaluation of the efficacy of TCA:

- (i) Treatment strategies of TCA practitioners acknowledge the personal traits of the individual in addition to the signs and symptoms of particular diseases or TCM 'pattern of disharmony'. While RCTs usually attempt to evaluate the efficacy of medical interventions for specific diseases, optimal TCA therapy requires practitioners to endeavour to assist individuals as persons, rather than merely treating circumscribed diseases.
- (ii) In controlled clinical trials, the emphasis is usually on *average* group responses to therapy rather than on individual responses. As a result, insufficient attention could be given to patient 'outliers', who have extreme positive or negative responses to the therapy being evaluated.²³¹
- (iii) Human illness and disease have a natural history and as a consequence TCA therapy plans need to be continuously modified in response to changes in a patient's health status. TCA therapy is not static, and as a consequence no set protocol or treatment plan can be determined for the entire course of therapy before treatment is begun. For example, if a patient was not responding to standard TCA therapy using points on the body, the practitioner might decide to use another approach such as auricular acupuncture. It should be noted that in conventional biomedical RCTs, the intervention that is being evaluated is usually restricted and manualized to be delivered in a predetermined manner and order. If TCA practice were to be standardised in clinical trials in the same way, the outcome might have little relevance to TCA practice in the field, that is, there could be a loss of external validity.
- (iv) the 'double-blind' RCT is difficult (if not impossible) to utilise in the evaluation of the efficacy of TCA (using traditional needling) because of the 'hands on' physical nature of the therapy. At best, a 'single-blind' RCT design can be used assuming a suitable placebo control is available.

²³¹ It could be noted that qualitative research that utilises dialectic reasoning can actually use patient 'outlier' information to develop rival theories and provide explanations of clinical phenomena (see chapter 12).

- (v) In TCA clinical trials that use placebo controls, there could be a reduction in client compliance because patients might believe that they are receiving a placebo treatment (e.g. 'sham' acupuncture) rather than 'real' TCA therapy.
- (vi) As a result of trying to account for non-specific/placebo effects in clinical trials, researchers could neglect, or not give due recognition to TCA practitioner characteristics and qualities that could be important determinants in client compliance and therapy outcomes.
- (vii) TCA practitioners acknowledge that the practitioner himself (or herself) is an integral component of TCA therapy. TCA therapy involves a therapeutic two way encounter between a practitioner and a client and is not merely a medical technique involving the insertion of acupuncture needles. This understanding of TCA therapy could require the evaluation of TCA therapy as a *whole*, rather than the evaluation of only the needling component.²³² The TCA practitioner's 'effect' (which can be an aspect of the placebo effect) should not be minimised in TCA clinical trials since it is the role of the TCA practitioner to stimulate the patient's self-healing through dialogue, education, and Oriental health counselling. This is a consequence of the ontology of TCM which assumes no intrinsic difference between the 'substance' of the body and the mind (chapter 2).
- (viii) there are also problems with the selection of relevant domains parameters and endpoints to assess health outcomes. In clinical trials that endeavour to evaluate the efficacy of TCA, researchers would want to measure a variety of domains and parameters and not only those easily measured objective signs of the biological body. It would be desirable in many cases to assess subjective parameters such as changes in emotional wellbeing and *qi* (or energy) levels. Multiple endpoints do, however, tend to make analysis more difficult.
- (ix) If there is too great an emphasis on the assessment of 'objective' domains and parameters

²³² *The pragmatic randomised controlled trial (PRCT)* can be used to evaluate TCA therapy as a whole (see chapter 10.18).

rather than 'subjective' ones, the client's perspective of what constitutes beneficial change in health status might not be reflected.

- (x) Ethical dilemmas can also arise in some controlled clinical trial contexts as a result of the use of placebo controls (see chapter 11).

Seligman (1995, p. 966) has claimed that the controlled clinical trial is the wrong method for evaluating psychotherapy because it omits too many crucial elements of how it is actually conducted in the field. The points Seligman makes for psychotherapy apply equally to controlled clinical trials that endeavour to evaluate the therapeutic efficacy of TCA:

- (i) TCA clients in the field often seek out TCA practitioners by *active* shopping. They enter into therapy after choosing a particular practitioner. In contrast, people who enter clinical trials enter by a *passive* process which results in the random assignment to a treatment or control group. There is acquiescence with regard to who the practitioner is and what happens to be offered in the study (Howard, Orlinsky and Lueger, 1994 cited in Seligman, 1995, p. 967). This process could result in samples that are not representative of people who attend private TCA practices.
- (ii) Clients seeking TCA therapy in the field usually have *multiple problems*. TCA practitioners commonly attempt to relieve parallel and interacting health problems. In contrast, patients who are selected into clinical efficacy trials usually have the signs and symptoms of a single disease diagnosis which has been determined by an extensive set of exclusion and inclusion criteria.
- (iii) TCA, like psychotherapy, is generally concerned with improvement in the general functioning of the client, in addition to the amelioration of the signs and symptoms of specific diseases. In contrast, controlled clinical trials in Biomedicine often focus on specific sign and symptom reduction and whether a disease is cured.

10.8 Other Issues in the Evaluation of the Effectiveness of TCA

In the endeavour to evaluate the effectiveness of TCA, many researchers have attempted to adapt the RCT as it is used in pharmaceutical drug research. One difficulty with such an approach is that there is not a one-to-one correspondence between biomedical diseases and TCM 'patterns of disharmony'. For example, 'arthritis', a biomedical syndrome, cannot be equated with a *single* TCM 'pattern of disharmony'. This is to be expected, since the two medical systems have different understandings of health, illness and disease, and different ways of classifying human health problems. In TCM, there are several 'patterns of disharmony' known as *painful obstruction syndrome (bi)* that can manifest with signs and symptoms similar to those of 'arthritis'.²³³ This is clearly the reason why some contemporary TCM authors have correlated 'arthritis' with painful obstruction syndrome since there can be common signs and symptoms such as pain, stiffness, and bone deformity.

It is the differences, rather than the similarities between biomedical and TCM syndromes that present methodological difficulties in research designs aimed at evaluating the efficacy of TCA. For example, Maciocia (1989) claims there are several types of painful obstruction syndrome which involve different TCM aetiological factors (*e.g.* damp, cold, wind, and heat). The point to note here is that there are *several* TCM 'patterns of disharmony' that have similarities with the *one* biomedical syndrome of arthritis. Each of these TCM 'patterns of disharmony' would require different treatments, and the utilisation of different sets of acupuncture points. This one example illustrates why the TCA therapeutic intervention cannot be kept constant while evaluating the efficacy of TCA for any one biomedical syndrome or disease. This is to be expected since medical paradigms inevitably have their own distinct ontology, clusters of assumptions, tenets, concepts, and language.

10.9 Overcoming Clinical Research Problems Associated with the Different Languages of TCM and Biomedicine

The outcome of any clinical study is dependent on the research question posed and the

²³³ For a comprehensive account of painful obstruction syndrome (*bi*), see G. Maciocia, 1989, pp. 561-604.

theoretical framework within which it is formulated. This raises the question of which conditions, syndromes, and diseases, researchers will decide to study when conducting clinical trials to determine the efficacy of TCA therapy. Should researchers of TCA attempt to evaluate the efficacy of TCA therapy for biomedically classified syndromes and diseases, *or* TCA 'patterns of disharmony'? Researchers of Biomedicine usually examine biomedical diseases and syndromes by investigating particular sets of signs and symptoms that have been classified according to the understandings of the biomedical paradigm. In contrast, TCA practitioners claim to treat 'energetic patterns' that result from a disharmony of the *whole person* rather than only physiological dysfunction of the biological body. The TCA orientation therefore strikes at the very basis of biomedical research protocols which often assume that the sign and symptom pattern of a disease is that of a limited and circumscribed disorder rather than a manifestation of an imbalance of the *whole* human being. Researchers when endeavouring to determine the efficacy of TCA must therefore determine which patterns of signs and symptoms should be investigated - biomedical syndromes such as 'arthritis' or TCM 'patterns of disharmony' such as painful obstruction syndrome.

One solution to the question posed has been suggested by Wiegant, Kramers and van Wilk (1993, p. 87) for the complementary therapies in general, a solution that could be utilised by researchers of TCA. They suggest that subjects could be selected for inclusion into a clinical trial through a two-step process. In the first stage of selection, an 'homogeneous' group of subjects is formed using orthodox biomedical diagnostic criteria and randomisation. This group is then subjected to a second round of selection conducted according to the diagnostic criteria of TCM. The resultant groups are then divided into treatment and placebo groups as is done in the standard randomised clinical trial (see Fig. 10.1).

The patient selection approach of Wiegant, Kramers and van Wilk (1993) has one important strength. Researchers might be able to determine whether *some* subgroups of 'arthritis' patients respond better than others with 'tailored' TCA therapy. There is also the possibility that a better understanding of the biomedical syndrome in terms of TCM theory could be attained through the differentiation of the biomedical disease, or syndrome through the analysis of the TCM sub-

groups. If the patient selection protocol of Wiegant, Kramers and van Wilk (1993) were to be adopted by researchers of TCA, TCA therapy could be more fairly assessed and would be less likely to be dismissed as a result of the diagnostic classification of Biomedicine.

A possible design weakness of the patient selection approach of Wiegant, Kramers and van Wilk (1993), from the point of view of the TCA profession, lies in the research protocol having to attract subjects into a research trial that first classifies health disorders according to the disease classification of Biomedicine. This could be seen as indirectly perpetuating the dominance of the biomedical paradigm, since the researcher's initial classification of disease in terms of the biomedical paradigm can direct the selection of variables that are thought to be relevant and which are measured to evaluate the therapeutic outcome of the therapy being

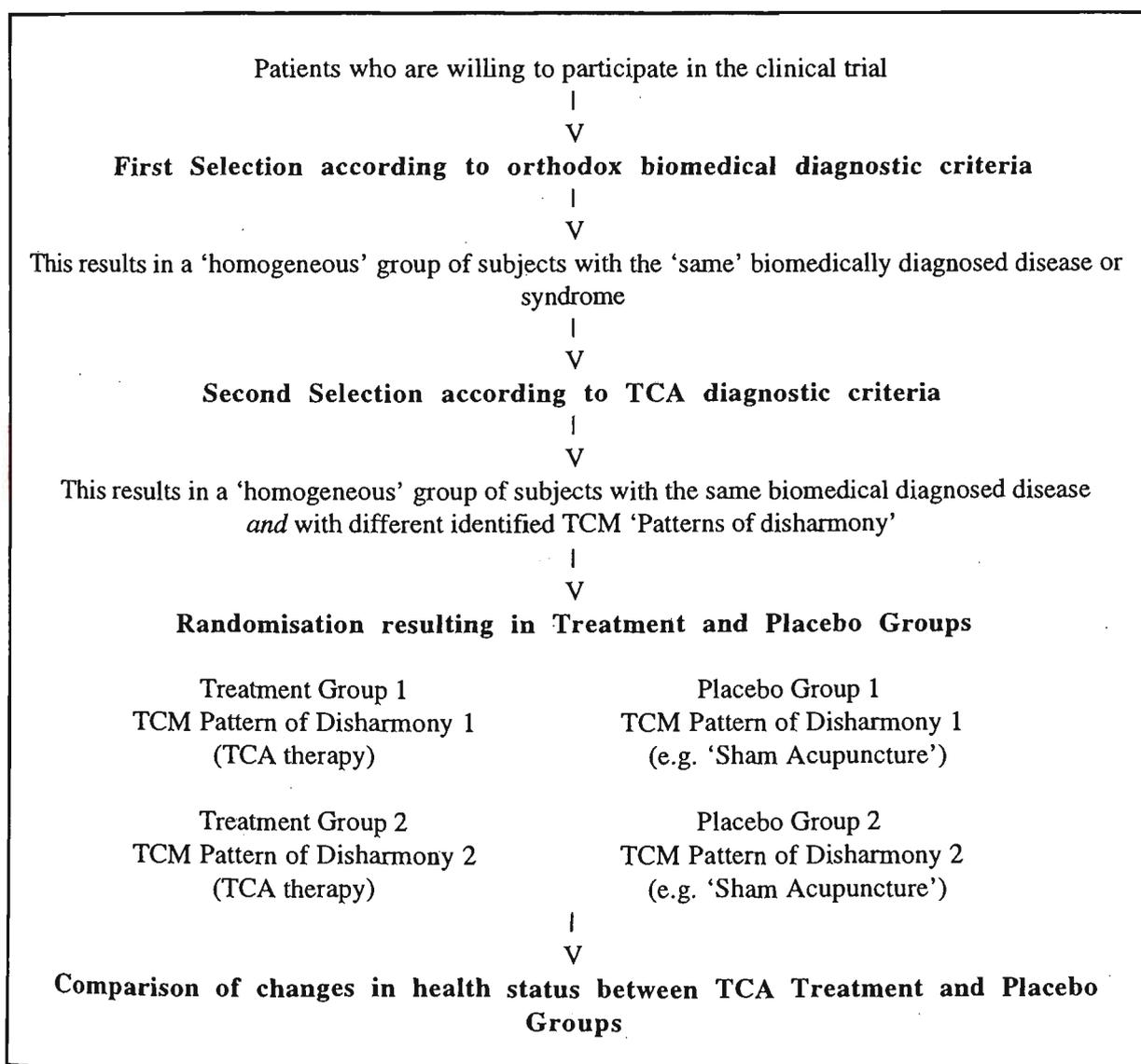


Figure 10.1 A Selection Procedure for a TCA Clinical Efficacy Trial
(Based on Wiegant, Kramers & van Wilk, 1993, p. 87)

investigated. This could affect the evaluation of TCA efficacy, since some signs and symptoms that might be regarded as important to measure in one paradigm might be considered to be irrelevant in another. This problem could be accentuated in clinical trials where different therapies, derived from different health care paradigms, are evaluated and compared in the one clinical trial.

Using the biomedical syndrome of 'arthritis' again as an example, a researcher with a background in biomedical research might decide to measure levels of pain and mobility, while a TCA practitioner-researcher might want to assess, in addition, a range of parameters that includes *qi* (vitality/energy) levels, wellbeing and 'quality of life' information. If it were found through clinical trials that both TCA and pharmaceutical drug therapy reduced pain and increased mobility equally in people with 'arthritis' but that only TCA therapy increased patients' energy levels and their sense of wellbeing, then one might conclude that TCA is the preferred therapy. This conclusion might only be reached if a broader range of domains and parameters were assessed. Biomedical researchers might have no reason to measure these broader parameters since 'arthritis' can be seen as a self contained syndrome. From the biomedical perspective, the measurement of a broader range of parameters might be believed to be unnecessary, only making analysis more difficult. This again emphasises an important distinction between the two medical systems: Biomedicine aims to cure circumscribed diseases of the body, while TCA attempts to enhance the health and wellbeing of the whole person, in body, mind, and spirit.

An alternative patient selection protocol for TCA clinical trials to that outlined by Wiegant, Kramers and van Wilk (1993, p. 87) would be to first classify peoples' health problems according to TCM diagnostic criteria and then treating those identified TCM 'patterns of disharmony' using TCA therapy. Such a patient selection protocol, while being politically desirable from the point of the TCA profession, might not be feasible owing to problems of communicating TCM concepts to a Western population that generally has knowledge of Biomedicine, and at best, only a little knowledge of the concepts and theory of TCA. At the level of practicality, research participants are usually recruited into clinical trials through advertisements in the media and the terminology that is usually used is that of Biomedicine. As

a result, subject recruitment has posed no real problems for researchers of Biomedicine. Individuals have volunteered for clinical trials because they wished to have their *particular* medical condition (that had previously been diagnosed and named by their medical practitioner) treated. Obviously, if researchers advertised in Western societies for volunteers for a research project using the terminology of TCA (*e.g. spleen qi xu*, a TCM 'pattern of disharmony'), there would be little if any response because Western populations are not familiar with the terminology and concepts of TCM.

10.10 Which Diseases and Syndromes Should the TCA Profession Consider for Research?

Owing to the differences between the illness and disease classifications of TCM and Biomedicine, the TCA profession should be careful as to which diseases and syndromes it decides to study. A syndrome such as 'stress' is a suitable condition to research from the perspective of the TCA profession, since both the TCM and biomedical frameworks would require the measurement of a broad range of parameters from the physical, psychological and social domains.²³⁴ The TCA profession should be wary of 'comparative' trials where TCA is evaluated with Biomedicine, where the disease evaluated is understood from the perspective of Biomedicine to affect only the biological body. In such cases, the variables selected to determine therapeutic efficacy would most likely only be selected from the 'physical' domain, and any benefits of TCA in the psychological domain might not be assessed - hence the total therapeutic effect of TCA therapy would not be determined. When comparing the relative efficacies of different therapies (*e.g.* TCA, pharmaceuticals, physiotherapy) for the treatment of biomedically classified syndromes and diseases, it is important from the TCM perspective to use a general health instrument such as the *MOS 36-Item Short Form Health Survey* (chapter 9.15.1) to assess a broad range of domains and parameters in addition to any tests or instruments to measure those of the specific biomedical syndrome or disease. If this is not done, an accurate evaluation might not be achieved because of the classification system of Biomedicine (see chapter 10.18 - 10.19 below).

²³⁴ The syndrome of stress has been studied by the TCM unit of the University of Technology - Sydney. See C. Rogers *et al.*, *The UTS College of Acupuncture Clinical Research - Stage 2*, 1996.

10.11 'Non-specific' (placebo) Factors in TCA Clinical Trials

In the next section, the placebo phenomenon will be examined in detail. It will be shown that an understanding of the placebo phenomenon is central to the development of research designs to evaluate the efficacy of TCA therapy. This examination provides a rationale for the *pragmatic* RCT (PRCT) which can be used to evaluate TCA therapy as a whole (see chapter 10.18). This examination will also provide further insights into the placebo and its relationship with the role of healing in TCA therapy.

From a conventional health care research perspective, if placebo effects can be accounted for, the actual efficacy of the *specific* medical intervention being evaluated can be determined. This type of clinical approach has been termed an *explanatory* trial by Pocock (1993, p.33). The explanatory trial attempts to separate out the various components of a therapy so as to determine the effect of the individual components. The net therapeutic response of the *specific* medical intervention is calculated by subtracting the therapeutic effect of any 'non-specific' (placebo) aspect of the therapy from its *total* therapeutic effect. This idea is based on the *fastidious* efficacy model²³⁵, which assumes that treatment-specific effects (TSE) and non-specific effects (NSE's) are separable and that the total therapeutic effect (TTE) of a medical intervention or therapy is equal to the sum of the active treatment effects of the specific therapeutic intervention and its 'non-specific' (placebo) effect (Beecher, 1955; Feinstein, 1985 and Kaptchuk, Edwards and Eisenberg, 1996). It should be stressed however that this model has never been subjected to scrutiny. It is theoretically possible that there could be a synergistic rather than a simple additive relationship between the therapeutic technique (or medicine) and non-specific (placebo) effects.

Kaptchuk, Edwards and Eisenberg (1996, p. 43) suggest that the fastidious model of efficacy attempts to account for the placebo effect in quantitative, precise, and objective terms that are characteristic of and required by a 'mechanistic-orientated biology'. Kaptchuk, Edwards and Eisenberg (1996, p. 42 citing the work of Sullivan, 1993) explain that

²³⁵ According to T. Kaptchuk, R. Edwards, and D. Eisenberg (1996) the term 'fastidious' was first applied to the randomised clinical trial by A. Feinstein, 1985.

[n]on-specific effects are intentionally diminished in placebo controlled trials if ethically possible, in order that the specific effect can be more efficiently observed. ... Expectation, persuasion, anticipation, belief, faith, suggestion, cultural beliefs, patient doctor relationship dynamics, imagination and conditioning are all reduced by the blinding processes (especially if double blinding is possible). ... This approach considers non-specific causation inconsequential and ultimately embodies an implicit value judgement that is dismissive of placebo effects... .

10.12 The Mega-placebo Effect

Kaptchuk, Edwards and Eisenberg (1996) have explored what they term the 'mega-placebo effect'. The mega-placebo effect can be that therapeutic effect of an 'unproven', or 'fringe' therapy that is found to be greater than the total therapeutic effect of a 'scientific' medical treatment. Kaptchuk, Edwards and Eisenberg (1996, p. 54) state that

[a] false 'unscientific' treatment could have a larger total outcome effect for a particular condition than a 'proven scientific' treatment. It may be possible in some conditions that the non-specific effects of a complementary therapy and alternative medicine therapy have a greater total outcome effect than its scientific counterpart.

While Beecher's (1955) meta-analysis has suggested an *average* placebo effect of $35\% \pm 2\%$, the placebo effect could theoretically vary between zero and one hundred percent (Ernst & White, 1997, p. 3). Spilker (1991, p. 718) has suggested several reasons for the placebo response being greater than expected. These include:

- (i) the majority of patients entering into the clinical trial are more sensitive to a placebo response because the disease being evaluated is mild;
- (ii) the participants entering the clinical trial have a severe or chronic disease and as a result the phenomenon of regression to the mean (that is known to occur during the natural course of chronic disease) produces an apparently large placebo response;
- (iii) the population studied might have been more susceptible to psychological suggestion compared with populations previously studied;
- (iv) the 'blind' used in the trial was better maintained than in previous trials and as a result a

more accurate placebo response was determined;

- (v) the subjects in the clinical trial had been withdrawn from all treatment and therapy for a relatively long period of time, and were, as a result, more sensitive to any treatment or therapy;
- (vi) since the placebo is always given to research patients prior to the medicine or therapy in a crossover design trial, a greater response (relative to the medicine or therapy effect) was found to occur.²³⁶

Clearly, the reasons for why the placebo response could be greater than expected need to be considered carefully by researchers of TCA when designing studies if they are to draw valid conclusions from controlled clinical trials that involve the evaluation of the efficacy of TCA.

Further to this, Spilker (1991, p. 718) provides other reasons for how a therapeutic outcome from a placebo could be found to be actually greater than an 'active' treatment when evaluated:

- (i) the active medicine being evaluated actually makes the disease worse;
- (ii) randomisation was not successful and there were differences in base-line values in the treatment and control groups;
- (iii) there were confounding factors such as prior treatment or surgery;
- (iv) the sample size of the trial was too small;
- (v) the variables and parameters that were measured were inappropriate;
- (vi) the trial was conducted over too short a period of time;
- (vii) there were environmental factors in the clinical setting that may have influenced the magnitude of the placebo response.

If 'mega-placebo effects' were frequently found in clinical trials to be greater than 'proven scientific' treatments then this could pose a serious threat to the biomedical research paradigm

²³⁶ Spilker (1991, p. 718) notes that Cormia and Dougherty (1959) provide an explanation of this finding.

and conventional biomedical understandings of the factors involved in illness, disease and therapy. It also suggests that researchers need to devote more attention toward understanding the nature of the placebo phenomenon and its role in healing.

10.13 The Importance of the Mind and Psychological Factors in Health and Disease

Brody (1985, p. 432) claims that psychological factors such as symbolic processes, imagination, beliefs and emotions might well be significant causal factors in both health and illness and should not be precluded when discussing and analysing medical practice and research. Hahn (1985, p. 167) has claimed that the biomedical paradigm does not fully account for many of the sociocultural factors involved in the processes of both illness and healing. Hahn suggests that the placebo phenomenon is an anomaly for the biomedical paradigm and is a prime exemplar of sociocultural causation. This is in contrast to the usual biomedical perspective in which the placebo is seen as is a 'nuisance' variable that needs to be controlled, or at least accounted for. Hahn believes that there is a need to develop what he calls an 'anthropological paradigm', in which sociocultural causative factors (*e.g.* the placebo phenomenon) have a central role instead of being relegated to the periphery of medicine.

10.14 Understanding the Placebo Phenomenon

The word *placebo* comes from the Latin word which means 'I shall please'. The word 'placebo' was first used by the Roman Catholic church as a title for a form of vespers for the dead (Jospe, 1978). Shapiro (1971) states that the word was first used in a medical context in 1785, where it was used to describe a commonplace medicine or method. Shapiro notes that in 1811 the term placebo was described as a 'medicine' prescribed to patients 'to please' them rather than for its therapeutic effectiveness.

There have been many attempts to define the placebo phenomenon in the medical context. Pepper (1945) defined the placebo as a therapeutic effect produced by a biomedically inert substance. Later, Modell (1955, p. 55) suggested that the placebo effect is that which all

treatments have in common. Wolf (1959) believed that the placebo effect is a therapeutic effect, or side effect, attributable to drug therapy but not to the drug's pharmacologic properties. Later, Shapiro (1968) defined a placebo as any therapy (or that component of any therapy) that is deliberately used for its non-specific, psychologic or psychophysiological effect, or presumed effect, on a patient, symptom, or illness, but which, unknown to patient and therapist is without specific activity for the condition being treated. The placebo when used as a control in clinical studies is often defined as a substance or procedure that is without specific activity for the disorder being studied. Ross and Buckalew (1985, pp. 68-69) state that a placebo can be considered "as any treatment or preparation given to a patient or client that does not provide any direct pharmacological or psychotherapeutic affect for the specific condition being treated." From reviewing the literature on the placebo, it is apparent that there are many different understandings of what the placebo is.²³⁷

10.14.1 *Placebo effects on illness and disease*

It has been noted previously (chapter 3) that a distinction can be made between *illness* and *disease*. Disease is a condition of the body in which its structure and function are disturbed or deranged; whereas illness is the subjective state that is experienced by individuals when they suffer from disease (Wood, 1986, p. 62). Spiro (1986, p. 88), over a decade ago, claimed that there appeared to be little evidence that placebos affect disease states other than those that are subjective in nature. Spiro, at that time, claimed that while illnesses that manifest as subjective complaints can benefit from placebo, there was little persuasive evidence that the placebo can improve disease states where there is pathology that can be objectively measured.²³⁸ It is now clear, however, that placebos can relieve more than just subjective experiences such as pain and anxiety. Placebos can in fact influence virtually any condition or

²³⁷ A. Grunbaum (1981) argues that the definition of the 'placebo' is critical for any discussion of the placebo phenomenon since any formulation employing inappropriate terminology will not only be linguistically inept, but will in fact engender conceptual confusion in therapeutic research. Grunbaum (1985), in a later analysis of the placebo, suggested that the term 'non-specific' should be replaced by the term 'incidental causes' when discussing placebo effects, since the causes of the placebo effect, while often unidentified, are not intrinsically unknowable.

²³⁸ A paper by H. Haas, H. Fink and G. Hartfeld (1959) cited by Spiro (1986, p. 88) lists a number of conditions that can be helped by the placebo. These conditions include migraine, rheumatism, dysmenorrhea and seasickness, all of which are 'subjective' and/or functional disorders.

symptom in relation to which they have been tested or controlled. Wolf (1950), as early as the 1950s, claimed that the placebo could affect nausea and gastric motility. Wolf claimed that both the subjective symptoms and the associated physiological signs of this condition can be changed at the same time by the placebo. Bourne (1971), in one review of placebo literature, concluded that the placebo can ameliorate the subjective symptoms *and* objective signs of conditions that include angina pectoris, hypertension, cough, headache, anxiety and depression. In a later examination of the placebo, Richardson (1997, p. 136) concluded that an

“[e]xamination of the available evidence suggests that “placebos administered in an orthodox medical context may induce relief from symptoms in an impressively wide array of illnesses, including allergies, angina pectoris, asthma, cancer, cerebral infarction, depression, diabetes, enuresis, epilepsy, insomnia, Meunier’s (*sic*) disease, migraine, multiple sclerosis, neurosis, ocular pathology, Parkinsonism, prostatic hyperplasia, schizophrenia, skin diseases, ulcers and warts”.

Richardson (1989; 1994; 1997) argues that placebos have been demonstrated to impact on objective measures of physical bodily processes, including lung function, postoperative swelling, gastric motility and blood pressure. If these findings are correct, placebos can affect not only subjective symptoms but also *objectively measurable physiological processes*.²³⁹

Various investigators have searched for personality factors that could identify the so called placebo ‘reactor’. It has been suggested by some researchers that only neurotic personality types respond to placebos; however, this has been found to be incorrect and there would appear to be no single personality type that characterises placebo reactors (Kurland, 1960; Shapiro, 1968). It is very likely that anyone could respond to a placebo given the right conditions or setting.

10.14.2 *Theories of placebo action*

Many theories of placebogenesis have been proposed (Richardson, 1995; Shapiro and Shapiro, 1997).²⁴⁰ These various theories have been derived from different schools of thought and the

²³⁹ It could also be noted that a study by Honzak, Horackova and Culik (1972) reported that patients can also experience side-effects from placebos. These side-effects include palpitations, temporal headache, itching, weakness, somnolence, insomnia, diarrhoea and irritability.

²⁴⁰ See also Jospe, 1978; Brody, 1980 and White, Tursky & Schwartz, 1985.

concepts of classical conditioning, transference effects, hope, faith, expectancy effects, cognitive dissonance, suggestion, misattribution, role demands, guilt reduction, operant conditioning, persuasion and anxiety reduction. Byerly (1976) classified the theories that have attempted to explain placebo action as being either mentalistic, behaviouristic, or a combination of the two. At the physiological level, the placebo appears to evoke its effects by increasing endogenous opioids (Levine *et al.*, 1979; Levine *et al.*, 1978; Grevert and Goldstein, 1985; Benedetti and Amanzio, 1997). This conclusion was drawn from the evidence that placebo effects can be reversed by the administration of naloxone which is an endorphin antagonist.²⁴¹

Mentalistic theories account for the placebo phenomenon by reference to the patient's subjective states of awareness. One example of a mentalistic explanation is 'patient expectation theory' (Rosenthal and Frank, 1956). This is the idea that the patient's expectation of sign and symptom change is held to be causally connected with the change or outcome that occurs. Another type of mentalistic theory used to explain the placebo phenomenon arises from the Freudian tradition and is based on the concept of transference (Ferrer, 1964). According to Shapiro (1968), a good doctor-patient relationship can invite the patient to unconsciously trust the physician, that is, to submit to their wishes with the expectation that the doctor will heal the illness or 'make it better' in a way similar to the parent-child relationship.

In contrast, behaviourist conditioning theories have attempted to account for the placebo effect through the study of observable behaviour. Behaviourist conditioning theories take a stimulus-response form and make no reference to the internal mental states of the patient. Bourne (1971) has claimed that it is difficult to select from the many competing theories, since most of them provide an acceptable account for the observable placebo phenomenon. Richardson (1995, p. 46) claimed that "it is unlikely that a single winner will ever be declared from among the rival theories of placebo action. Each is likely to have some part to play in accounting for changes occurring after placebo administration as a result of incidental features of a non-placebo treatment".

²⁴¹ An endorphin antagonist is a chemical that can block the effects of endorphins.

10.14.3 *The placebo effect: a psychological phenomenon*

It is clear from the list of non-specific factors involved in the placebo phenomenon that placebos can come in many forms (Ross & Buckalew, 1985). Placebos are *not* limited to physical things such as pills and capsules but can be psychological in nature and act directly on the mind. When one considers the ‘non-specific’ factors that are involved in the placebo effect as previously outlined (chapter 10.1) (*e.g.* the doctor-patient relationship; the patient’s expectations and needs; suggestion; the patient’s personality and psychological state), it becomes apparent that the placebo effect must be fundamentally and primarily a psychological phenomenon (Plotkin, 1985). Plotkin (1985, p. 244) states clearly that the placebo’s

explication is found within the domain of psychology, in terms of psychological concepts such as “faith,” “(mis)understanding”, and “intentional action.” Even when the placebo effect involves a physiological change as a primary outcome (as with psychosomatic or biofeedback therapy), the explanation is primarily psychological.

Even in the case of ‘physical’ placebo pills, the mode of action would seem to be necessarily psychological, even if there were accompanying physiological changes.

10.14.4 *The placebo is not psychotherapy*

The placebo could be likened to psychotherapy in that both can affect the health status of a person through psychological means. However, Spiro (1986, p. 224) argues that while both the placebo and psychotherapy involve psychological processes there are important differences

the psychotherapist is a trained socially sanctioned healer who tries to produce certain changes in his patient’s emotional state, attitude, and behaviour. In this account, the placebo changes the perception of pain but does little to change attitudes or personality. Placebos and psychotherapeutic words both provide symbols, but one is an icon and the other a sign pointing toward the resolution of disturbances. In a sense the placebo functions on the irrational side of the relationship, magically or intuitively, whereas psychotherapy tries to work on the more mature and rational side of the therapeutic alliance.

Spiro, in the passage above, suggests that psychotherapy tends to act on the rational aspect of the mind, whereas the placebo tends to affect the irrational, or unconscious aspect of the human

being. In Spiro's exposition, the placebo is associated with that which is unknowable, or at least that which is not yet known through rational means.

Jerome Frank (1973) in his attempt to synthesise the factors common to psychotherapy and other healing practices, concluded that there are several common features in all effective therapeutic relationships:

- (i) the patient believes and feels confident that the healer is competent;
- (ii) the healer conveys empathetic understanding of the patient;
- (iii) the therapeutic encounter occurs at a socially sanctioned place of healing;
- (iv) a rationale is provided to explain the presence of the illness; and
- (v) there is a method or plan of treatment.

If Frank (1973) is correct, it follows that the relationship that exists between the TCA practitioner and the patient will influence the effectiveness of therapy. It has also been claimed that the faith and confidence that the patient has in the healer, and their belief in the therapy employed, play a key role in the outcome of the therapeutic encounter. James Fosshage (1978, p.16), after consideration of Frank's (1973) research, remarks that

[w]hat emerges is that despite the most varied explanations of the illness, from the possession of an evil spirit to an unresolved Oedipus complex, healing proceeds on the basis of the powerful, socially sanctioned, two-person interaction in which both the sufferer and the practitioner exude the utmost faith and confidence in the healing rationale and methodology.

This emphasises the therapeutic importance of the clinical encounter. In TCA practice there is a therapeutic dialogue between the TCA practitioner and client and in TCA clinical research between the researcher-practitioner and the 'patient'. No medical intervention or therapy, can ever be seen as simply a technique administered by an automaton like researcher to a passive recipient (the patient). If the findings of Frank (1973) are correct, they provide further support for the humanistic therapeutic orientation and practice of the TCA practitioner. Some researchers, however, do not consider the doctor-client relationship to be an important subject for investigation. Stoeckle (1987, p. 385) has suggested that one reason for this is that

Biomedicine is more interested in medical technique than in the process of care itself. The assumption in Biomedicine is that illness and disease are alleviated predominately by a range of medical techniques and not by the therapeutic encounter *per se*.

10.14.6 *The 'meaning model'*

One of the several theories of placebo action reviewed by Brody (1980) is the *meaning model* of Adler and Hammett (1973). This model provides a theoretical explanation of the placebo effect in symbolic-cultural terms. In this model, the subjective meaning of the illness experience is factored into what the authors call 'system formation'. It is this that provides a coherent explanation of illness that is consistent with the patient's world view. A second factor involved in this model is 'group formation', which is the gathering of a supportive and caring group around the patient. According to Adler and Hammett (1973, p. 597), these two factors are "invariably used in all successful interpersonal therapies, and are the necessary and sufficient components of the placebo effect." This model directs health care research toward cultural and social aspects of health and disease and the patient's system of belief, in addition to the more often studied personality and emotional variables.

Brody (1980, p.122) would seem to support, in part, the Adler and Hammett model but does not view it as being complete. Brody claims that the placebo effect is most likely to occur when the following three conditions are met:

- (i) The patient is given an explanation for their illness which is consistent with their preexisting world view. Stoeckle and Barsky (1981, p. 226 citing the work of Kleinman, 1973; 1975) claim that "*explanation* is one of the major functions of any system of medical care" regardless of whether it be folk, primitive or scientific medicine;
- (ii) There is a group of individuals available to the patient who can assume socially sanctioned caring roles and who can provide emotional support; and

iii) The healing intervention leads to the patient's acquiring a sense of mastery and control over the illness (Siegler and Osmond, 1973). Stoeckle and Barsky, 1981, p. 225) claim that *"causal explanations provide control because they give personal meaning to bodily discomfort as well as suggesting actions to take."*

Byerly (1976) believes that the challenge for researchers is to develop a framework that avoids both 'materialistic' and 'mentalistic' reductionism. One way to resolve the problem as to how the mental and biological realms interact with respect to the placebo phenomenon is to adopt a Daoist philosophical framework: a framework that does not separate the mind and body at the level of ontology (chapter 2).

Some authors have pointed to the positive therapeutic potential of the placebo effect and the insights it might offer for our understanding of the processes of healing and the treatment of psychosomatic disease. For example, Brody (1985) argues that the current exclusion of placebo effects from contemporary medical practice derives from the dominance of a biological reductionist matrix that is dismissive of symbolic processes. Capra (1983) contends that medical science must transcend its narrow view of health and illness and reincorporate the idea of 'healing' into its theory and practice of medicine. Leder (1992, p. 24) has suggested that modern biomedical practice "demands an almost schizophrenic shift between, at one moment, examining the machine-body, and at the next, acknowledging the person to whom it belongs." This schizophrenic behaviour of Biomedicine can also be found in biomedical research where the placebo is understood as a 'nuisance' variable, rather than something that should be studied in its own right to increase our knowledge of the processes involved in healing. This view is an outcome of Biomedicine's emphasis on the mechanistic medical intervention over the interpersonal component of therapy, and objective data over subjective information.

The studies of Frank (1973) and Shapiro and Morris (1977) have shown that the placebo is one of the most powerful factors in healing, and in some cases the most powerful therapeutic agent. The placebo effect must be acknowledged as an important factor in healing regardless of whether researchers can differentiate its effects from those of specific therapeutic techniques or medical interventions (Fosshage, 1978, p. 17).

10.15 Care and Cure: The Effect of the Physician in the Healing of Human Illness and Disease

The study of the placebo is important not only because an understanding of the phenomenon is necessary for designing sound research designs for the evaluation of the efficacy of TCA, but also for the light it sheds on the effect of the health care practitioner in the healing of human illness. Jay Katz (1984, p.191) remarks that, “[i]f placebos were to be acknowledged as effective in their own right, it would expose large gaps in medicine’s and doctors’ knowledge about underlying mechanisms of care and relief from suffering.” This observation by Katz is important because it suggests that there is a split between ‘care’ and ‘cure’ in modern biomedical practice (Spiro, 1986). The emphasis of modern biomedical practice is generally on the understanding and treatment of human disease through a scientific approach, with its associated pharmaceutical drug and technologically based medical interventions.

Western medical schools have tended to concentrate on the treatment of acute diseases which are most often seen in hospital settings, rather than on the less exotic and chronic conditions that are often encountered in private practice. It is because of this emphasis on the *cure* of diseases by specific medical interventions that the role of *care* in biomedical practice is sometimes undervalued. It is a common criticism by patients of Western medical practitioners that they receive adequate treatment but inadequate care (Willis, 1994). This perceived lack of care by western medical practitioners is perhaps one reason why TCA practitioners can maintain practices outside of mainstream medicine. Complementary health practitioners are often perceived by patients as providing more care than many biomedical doctors (Vincent & Furnham, 1997). Complementary health practitioners, with their holistic person-centred approach, can often appear to provide more care because they focus on the *person* who has an illness rather than on disease states *of* the person. The author does not suggest that TCA practitioners are more caring and compassionate than Western medical practitioners; however, it does highlight the public’s perception of the way the two forms of medicine are practised.²⁴² In one review by Hewer (1983 cited in Vincent & Furnham, 1997, p. 127), it was claimed that

²⁴² See C.M. Cassidy (1998). Chinese Medicine Users in the United States. Part II: Preferred Aspects of Care. *Journal of Alternative and Complementary Medicine*, 189-202.

complementary health practitioners tend to spend considerably more time with their clients than medical practitioners. Hewer (1983) found that the average consultation between a complementary practitioner and a patient was twenty minutes, whereas general practitioners spent on average seven minutes. In Australia, Bensoussan and Myers (1996, p.108) have reported that the average face-to-face contact time between a TCM practitioner and patient during a consultation is 25.0 minutes, with the average TCM treatment time being 42.0 minutes (this average does not include the initial consultation). While diagnosis and treatment by general practitioners might not be compromised by the period of time spent on consultations, patients often report as feeling rushed, and somewhat stressed because they perceived that they could not provide, or receive a full explanation of their health problems. The time factor alone could account for the perception that complementary health practitioners provide superior care. A seven minute therapeutic encounter is probably insufficient for a general practitioner to establish rapport with a client, let alone deal with any emotional or psychological factors that might be involved in an illness or disease.

Spiro (1986) suggests that a problem for Western medical practitioners lies with the varied concepts of the role of the physician. Over the last century, physicians have found themselves in several different roles. These roles include the general practitioner at the bedside, the clinician in the hospital, and the scientist in the laboratory setting. Jewson (1976, cited by Spiro, 1986, p. 5) believes that some of the misunderstandings that arise between medical practitioners and patients result from the conflict between the various roles of the physician with their associated foci. The general practitioner 'sitting at the bedside' is more likely to see their patient as a whole person than as a person with a disease that must be cured. On the other hand, the clinician working in a hospital setting is more likely to see the patient as a case, and will tend to focus on the pathology of a disease rather than spending time gauging the effect of psychological and social factors that could be implicated in the genesis of the disease. Finally, there is laboratory medicine which involves understanding illness and disease in terms of biochemical and subcellular processes.²⁴³ The effect of a shift towards laboratory medicine could result in the

²⁴³ The growth in this area of medicine is perhaps not surprising considering the recent developments in the understanding of DNA structure and the possible future use of recombinant DNA therapy to correct cell dysfunction.

transformation of physicians into scientists. With this could come a focus on the micro level of disease at the biochemical and cellular levels at the expense of the macro level of the person.

10.16 Placebo Healing in Randomised Controlled Trials

Considering the placebo's reported therapeutic effects, it is surprising that doctors and researchers have not studied the placebo phenomenon more than they have. Beecher (1961) calculated the *average* baseline placebo effectiveness for nonsurgical procedures to be around 35 %, although it can rise to 60% or more depending upon the circumstances (Spiro, 1986, pp. 86-87). Medical researchers seldom talk of increasing therapeutic effectiveness by enhancing the factors involved in the placebo effect. It is more usual for the placebo phenomenon to be discussed in derogatory terms. One reason for this could be that researchers tend to value the therapeutic effects of specific medical techniques or procedures above those non-specific therapeutic factors that might be able to be maximised by health care providers themselves during consultations (Lewith, 1993). This attitude is partly due to the biomedical paradigm which encourages medical practitioners and researchers to strive for certainty and objective understanding of therapeutic interventions.

In contrast, TCA practitioners generally have no difficulty with the concept of 'practitioner as healer', since the counselling that occurs during the TCA therapeutic encounter is believed to affect healing processes. From the perspective of TCM, words are *qi*, and, as such, can affect the configuration of *qi* of the patient and subsequently the health status of the patient. Perhaps the biomedical researcher's discomfort with the placebo phenomenon could stem from a conscious, or unconscious desire to distance themselves from primitive, unscientific, or magical medical practices of the past. Burt (1979, p.106, 116 cited in Spiro, 1986, pp. 32-33) remarks that

[t]he rigour with which the placebo effect must be eliminated before any medical intervention can be viewed as efficacious points to two critical aspects of contemporary physicians' views of themselves: first, that the magical "laying on of hands" which had such prominence in earlier physicians views of their calling is now widely seen as inconsistent with the highest aspirations

of medical practice... Normative valuation of objectivity in the modern practice of medicine have not only affected physicians' views of themselves. These facts have also dramatically altered physicians' views of their interpersonal relations with patients... A physician who aspires to scientific objectivity can properly assert that, insofar as the efficacy of his therapy depends on his personal will, he has transgressed the norms of his profession.

An important finding from the examination of the placebo phenomenon is that healing can result from factors other than the specific technique used by the practitioner. The implication for TCA practice and research is that more attention should be given to the various factors involved in the therapeutic relationship so that more effective 'treatments' can be developed.

10.17 The Therapeutic Effect of Individual Health Care Practitioners is Not Always the Same

It would appear from a number of controlled clinical trials that the 'healing' or therapeutic effect of individual health practitioners is not the same. In a French study that involved the treatment of duodenal ulcers it was found that individual physicians had different placebo healing rates (Sarles, Camatte and Sahel, 1977). It was also discovered in this same study that 'placebo' healing rates of individual physicians tend to be constant over time. This point is seldom discussed in medical literature but could have relevance for any analysis of data from controlled clinical trials where multiple practitioners are involved in a clinical study.

10.17.1 The Role of Practitioner Intention in TCA Practice

Diebschlag (1993) has noted the importance of practitioner *intention* in certain styles of acupuncture. Diebschlag claims that the *intention* of the acupuncturist is part of traditional acupuncture therapy and that this concept can be traced back as far as the *Nei Jing* (c. 200 B.C.).²⁴⁴ Some TCA practitioners claim that the practitioner's state of mind and *qi* when consulting and needling can affect the *qi* of the client and consequently the outcome of TCA therapy.

²⁴⁴ The importance of practitioner intention is discussed in one of the classics of TCM, the *Nei Jing* (*Su Wen*, chapter 54). There it states that the "right hand should be very firm, as if restraining a tiger. The *shen* should be free of all outside preoccupations, contemplating the patient calmly and brooking no distraction".

Another factor that could influence the therapeutic outcome of a medical intervention is the physician's *belief* in a therapy. Dossey (1993, p.135) contends that

[i]n single-blind studies, in which the patients do not know whether they are taking the active medication or a placebo pill, the doctor can unconsciously show more interest and enthusiasm in the 'treatment' group than the control group. This can lead, through suggestion, to a heightened response on the part of the treatment group, all due to the doctor's *belief* that they should do better.

Jerry Solvvin (cited in Dossey, 1993, p.135) has examined the therapeutic power of the physician's underlying beliefs. In three 'double-blind' studies where the use of vitamin E for the treatment of angina pectoris (a coronary artery disease) was evaluated, it was found that the degree of pain reduction was a function of the doctor's *belief* in the treatment. In one of these studies which was conducted by an enthusiastic doctor who *believed* in the therapeutic value of vitamin E, the treatment was found to be significantly more effective than a placebo, while in the other two studies conducted by 'skeptics', there was found to be no effect. In an earlier study (Uhlenhuth, Cantor, Neustadt, and Patson, 1959 cited in Dossey, 1993, p.136), the results of the drug meprobamate proved significantly more powerful than the placebo - but only for those doctors who *believed* in it. There was found to be no therapeutic drug effect for the skeptical physician's patients. Solvvin (1984 cited in Dossey, 1993, p. 10) contends that

[s]tudies with a wide variety of treatments have conclusively affirmed that the administering physician or researcher is not independent of the results in ... double-blind ... studies. ... As a general rule, the double-blind cannot any longer be assumed to guarantee the exclusion of the nonspecific effects of the treatment, especially when the actual treatment has a weak or variable effect.

While 'double-blind' RCTs cannot be easily applied to evaluate TCA, the findings of Dossey suggest that even the 'double-blind' RCT cannot guarantee certain medical knowledge.

From the previous examination of non-specific (placebo) effects (which can include the influence of the practitioner-patient relationship), it is apparent that that it is not easy to draw clear boundaries between medical 'techniques' and the clinical encounter *per se*. It is also not clear that one can assume that the 'placebo effect' can be simply calculated by subtraction from the total therapeutic effect which rests on several unproven assumptions.

10.18 Pragmatic randomised controlled trial (active control equivalence study)

As previously noted, TCA therapy as it is practised in Australia, England, the United States and other Western countries is an integrated therapy that involves the interpersonal and healing skills of the practitioner in addition to the acupuncture needling procedure (chapter 2). Given this, what seems necessary to be able to assess the efficacy of TCA therapy is a research design that evaluates TCA therapy as a *whole*, rather than a methodology that assesses only a part of TCA therapy (*i.e.* the acupuncture needling procedure). A candidate for this task is the *pragmatic randomised controlled trial* (see chapter 8.10.2.2).²⁴⁵ The *pragmatic randomised controlled trial* (PRCT) can be utilised to evaluate the efficacy of TCA therapy as a whole, where TCA therapy is compared with the current medical treatment of choice.²⁴⁶

According to Coates and Jobst (1998, p. 241)

[t]he pragmatic RCT takes place under everyday conditions to aid decision making. It is used to evaluate the efficacy, safety, cost effectiveness, and acceptability of treatments or services. ... Because the aim of pragmatic trials is to mimic normal treatment and allows practitioners to individualise treatment as required, blinding of patient or practitioner may not be required but evaluator blinding is still recommended.

The PRCT is related to the concept of *pragmatic efficacy*, a term coined by Schwartz and Lellouch (1967) to describe a research approach that compares two or more treatments or therapies as they would be applied in clinical practice. This approach can provide the means to determine clinical effectiveness which is not particularly concerned with the theory and mechanism of a therapy (Kaptchuk, Edwards and Eisenberg, 1996). Kaptchuk, Edwards and Eisenberg (1996, p. 44) claim that a “pragmatic perspective provides less scientifically useful

²⁴⁵ It should be noted that the *pragmatic randomised controlled trial* (PRCT) approach has been discussed in research literature using a variety of terms. Spilker (1991) has used the term *active control* to describe the use of an established therapeutic drug or therapy when compared with a new therapy or drug. The ‘active control’ allows researchers to determine if a new drug or therapy has clinical advantages (*e.g.* fewer side-effects) over the best currently known treatment for the specific condition being studied. Hammerschlag and Morris (1997) note that such a clinical research design has been termed a ‘positive control trial’ by Temple (1989) and an ‘active control equivalence study (ACES)’ by Makuch and Johnson (1989). Pocock (1993, p. 33) refers to this general approach as a *pragmatic trial*.

²⁴⁶ As an example of this approach, see Meade *et al.*, Low back pain of mechanical origin: Randomised comparison of chiropractic and hospital outpatient treatment, *BMJ*, 300, 1990, 1431-1437.

information but potentially more clinically relevant information.” In respect to the placebo phenomenon, this model accepts that there might be interactions between the specific effects of the treatment technique, or therapy, and the various ‘non-specific’ effects of the clinical encounter. In the ‘interactive’ placebo model of Uhlenhuth *et al.* (1966), it is argued that there can be a synergistic relation between the specific effects of the therapeutic technique or intervention and the non-specific effects of therapy which produces the total therapeutic effect.

Spilker (1991 cited in Kaptchuk, Edwards and Eisenberg, 1996, p. 44) draws the important conclusion that if there is a synergistic relation between the non-specific and specific effects of a therapy, then the assumptions of the ‘fastidious’ model, which assumes that non-specific and specific effects of treatment are separable, linear, stable and relatively constant during a clinical trial must be questioned.

The PRCT can be contrasted with what Pocock (1993, p. 33) terms the *explanatory* [randomised controlled] trial, where the researcher attempts to determine which components, or aspects, of a therapy are effective.²⁴⁷ Coates and Jobst (1998, p. 241) explain that

[t]he explanatory RCT under controlled conditions is appropriate for determining the efficacy of a single active intervention. For example, one may want to know if a specific herbal remedy or an acupuncture treatment is more effective than placebo treatment for a particular clinical condition. The methodology also require blinding of evaluator, patient, and practitioner, where possible, to minimise the likelihood of factors other than the component under test having a causative effect on outcome.

To date, it has been the explanatory trial that has been generally used in most acupuncture clinical trials rather than the PRCT which is more congruent with the way TCA is actually practised in clinics.

10.19 Two-arm and Three-arm Pragmatic Trials that Use Active Controls

Spilker (1991, p.720) has claimed that there are two categories of clinical trial design that utilise active controls:

²⁴⁷ When the double-blind RCT is discussed in acupuncture literature, in most instances the authors are referring to the *explanatory* trial model.

- (i) The first is the 'two-arm' trial in which the test medicine or medical procedure is compared with an active medicine (or medical procedure) control in either an 'open-label' (in which there is no blinding), single-blind or double-blind manner;
- (ii) the second type of design is the 'three-arm' trial in which the test medicine (or medical procedure) is compared with a placebo, in addition to an active medicine (or medical procedure) control in a single-blind or double-blind manner.

Spilker (1991, p.720) claims that there are fewer problems interpreting data from a 'three-arm' clinical trial when compared with a 'two-arm' trial since "data from the active medicine group can be compared with placebo responses to confirm that the active medicine control yielded a positive response." Temple (1982) argues convincingly that a placebo group is necessary in addition to an 'active control' to establish a measure of a therapy's efficacy, since if this is not done, there is no valid statistical test that can be applied to show if the active control was effective due solely to its placebo effect. While Temple's (1982) reasoning might very well be correct from the perspective of the 'fastidious' model, Hammerschlag and Morris (1997, p.133) claim that once a therapy has outperformed a placebo and has become standard medical care, it can then be compared to other treatments (*i.e.* active controls) such as acupuncture without a placebo:

An important feature of this type of study ['two-arm' trial] is that, provided the biomedical care has previously been proven more effective than a placebo, a control group for acupuncture is not required. Thus, in these trials, the demonstration of acupuncture efficacy lies not in outperforming a control treatment, but in performing at least as well as the standard care.

If we acknowledge that all therapeutic interventions that involve a clinical encounter share placebo benefits, researchers could dispense with the placebo control group once standard care is identified and then aim to determine the more effective therapies by comparing therapies and thereby establishing relative measures of efficacy. An example of this approach is the study by Loh *et al.* (1984) in which acupuncture was compared with standard pharmaceutical drug therapy for the treatment of migraine and muscle tension headaches.²⁴⁸

²⁴⁸ It could be noted that this study indicated that acupuncture can produce greater relief than the standard pharmaceutical drug therapy in patients that have long term histories of chronic headache.

The only potential weakness of the PRCT design is that TCA practitioners can use different approaches that draw on diverse subsets of TCA theory and practice. For example, some TCA practitioners use the *bian zheng lun zhi* style which involves treatment based on the ‘discrimination of patterns’, while others use auricular acupuncture. If the various acupuncture approaches were found to have different overall efficacy rates, then this could distort the findings of any TCA study that did not acknowledge the possible range of effectiveness of the various acupuncture styles. This poses no real problem if the research study specifies the type, or style of acupuncture that is to be assessed.²⁴⁹ In fact, it is possible that a sub-group analysis of the different methods could be used to determine the more effective acupuncture styles. Clinical TCA research that utilised active controls could be seen to have greater external validity because it mirrors the way therapy is conducted in private practice, that is, practitioners usually treat patients by selecting from a number of active treatment procedures rather than by prescribing a placebo.

If researchers, when attempting to evaluate therapeutic effectiveness, were to dispense with the placebo control when standard care had been determined, and compare only active treatments (e.g. TCA, biomedical care, osteopathy, physiotherapy) there would be a clear ethical advantage in that no person would be denied a treatment that has some chance of alleviating their health problem (Shapiro, 1989). In fact, by using active controls, ethical problems could be avoided by allowing patients to select the treatment they preferred. Clinical trials involving human beings now require informed consent from the clinical trial participants, and the author suspects that more subjects would take part in clinical trials if they knew that they were to be given one of a number of alternative treatments thought to possibly benefit their condition rather than a placebo that is believed to be therapeutically inert. Hammerschlag and Morris (1997, p.133) note that a “distinctive feature of active control trials is their ethical appeal since there is an intent to heal all patients in the study.”²⁵⁰ Some TCA practitioners consider the use of

²⁴⁹ Birch (1997c, pp. 68-71) has devised what he calls the *Birch Relevant and Irrelevant Treatment Selection* (BRITS) method that can be used to describe and justify the type of acupuncture used and the associated sets of acupuncture points that are being tested in acupuncture clinical trials. Birch claims that such a method will improve the generalisability of results from acupuncture clinical trials.

²⁵⁰ Temple (1982, cited in Spilker, p. 722) claims that two-arm tests cannot be avoided in patients with conditions such as terminal cancer or severe bacterial infections for which adequate medicine or therapy currently exists and where it would be unethical to test a new medicine against a placebo.

placebo controls in clinical trials to be unethical, or somewhat dissonant with their desire to reduce human suffering. This has probably contributed to some TCA practitioners being reluctant to become involved in controlled clinical trials to evaluate TCA.

10.19.1 *Does TCA therapy result in better therapeutic outcomes than 'formula' acupuncture or standard biomedical treatment?*

With a variety of biomedical, natural and traditional medicines being used for a whole range of human health disorders, the PRCT could be used to answer the socially important question of: Which therapies are the most effective and efficient therapeutic options for ameliorating particular illnesses and diseases? The PRCT can also be used to answer the question: Do traditional acupuncture approaches result in better therapeutic outcomes than 'formula' acupuncture and other forms of 'scientific' acupuncture where points are selected based on biomedical physiological understandings of disease rather than TCA theories of *qi* and acupuncture point function? These question could be addressed and possibly answered by clinical trials which compare the various therapies and forms of acupuncture for particular syndromes (*e.g.* stress, back pain). For example, research participants with a syndrome such as 'stress' could be randomly assigned to one of three groups and acupuncture points needed in the first two groups as follows:

Group 1

Classical acupuncture points are needed by TCA practitioners who select points according to TCM theoretical understandings of diagnosis, treatment principles and acupuncture point function (refer to Maciocia, 1989; Lade, 1989; Zhiya, 1995; Deadman & Al-Khafaji, 1998; Birch & Felt, 1999);

Group 2

Classical acupuncture points are needed which have *not* been selected according to TCM theoretical understandings (examples of this type of acupuncture point selection are 'formula' acupuncture and some types of Western medical acupuncture²⁵¹ or 'scientific' acupuncture where point selection is based on

²⁵¹ See J. Filshie and M. Cummings (1999) for an account of Western medical acupuncture.

biomedical physiological understanding, such as trigger points or muscle motor points, rather than on TCA theories of diagnosis, treatment principles, and traditional acupuncture point function;

Group 3

Standard biomedical care.

By comparing the therapeutic outcomes of groups 1 and 2 above, it could be determined if traditional acupuncture approaches result in better therapeutic outcomes than 'formula acupuncture' and other forms of 'scientific' acupuncture where points are selected based on biomedical understandings of disease rather than on TCA theories of diagnosis, treatment principles, and traditional point function. It should be noted that such a comparison does not necessarily answer the question: Do classical acupuncture points have particular energetic and therapeutic functions as claimed by TCA practitioners? It is possible that differences in health outcomes between groups 1 and 2 could be due to other components of the particular therapeutic approach (*e.g.* differences in interpersonal skills of practitioners or time spent with patients). By comparing the therapeutic outcomes of groups 1, 2 and 3, it could be determined which therapy should be the preferred therapeutic option for ameliorating the particular syndrome or condition studied.

Shapiro (1989, pp. 182-183) stresses that with limited government funds and resources, treatment decisions should take into consideration the cost of the therapy as well as its effectiveness. Therefore, if different active therapies are compared by using active control trials, a cost-benefit analysis could be determined in terms of effectiveness per unit cost. Since what is often required by health administrators in government health departments for the allocation of funds is a measure of the *relative* efficacy of a therapy rather than its *absolute* efficacy, an active control trial methodology would enable the various biomedical and complementary therapies (including TCA) to be compared so as to determine the more cost effective therapeutic interventions for the various types of human illness and disease. Such an approach acknowledges that it is the efficacy of the *total* therapy that is important (*i.e.* the sum of the therapeutic effects of the medical technique or intervention and the associated non-specific

effects) rather than only the therapeutic effect of the 'objective' medical component of the therapy.

The research design of a proposed clinical trial on low back pain by (Fitter & MacPherson, 1995, pp. 46-50) meets many of the requirements that would seem necessary for an appropriate PRCT. In the Fitter and MacPherson trial, it is planned that the final stage will involve a comparison between the services of traditional acupuncturists and orthodox medical practitioners. This study is to involve the co-operation of traditional acupuncturists, general practitioners of Biomedicine, and the NHS (UK). This study will be a 'service evaluation' rather than a 'treatment evaluation' which will allow practitioners to treat each case to the best of their ability. This research design will allow TCA practitioners to practise in a way that is congruent with standard TCA clinical practice. It could also be noted that a review of clinical trials (Hammerschlag & Morris, 1997, p.138) that compared acupuncture with biomedical standard care reported that "[d]espite the low scores on quality of study design and reporting, 20 of the 23 studies reported that acupuncture was at least as effective as standard care." While only 3 of the 23 studies evaluated were rated as 'adequate' on at least 60% of the research quality criteria of Hammerschlag and Morris, the review still suggests that further well designed PRCTs are warranted.

10.20 The Quest for Certainty: Problems Associated with the Randomised Controlled Trial

The 'double-blind' randomised controlled trial (RCT) is held up as the 'gold standard' in clinical research to establish a therapy's effectiveness (Pocock, 1993; Kiene, 1996a; Filshie & White, 1998, p. 4). It is a method that many believe furnishes the researcher with a way to obtain medical knowledge and avoid self deception. Behind the insistence that this is the best way in which to obtain medical knowledge is perhaps a fear, or a sense, that so called facts and knowledge are not as concrete and certain as one would like. Polanyi (1958) claimed that not even the methods derived from positivism can protect the researcher from the fear of uncertainty.

In studies involving factory workers at the Western Electric Hawthorne Works in Chicago in the late 1920s, it was found that workers' efficiency improved as a direct result of the increased attention that they received during the studies. This phenomenon has been termed the 'Hawthorne effect' (Polgar and Thomas, 1995, p. 78) and has been found to occur in medical research. For example, medical diagnoses of acute abdominal emergencies were found to improve while doctors were being monitored during a study but were found to decrease again back to the baseline level after the completion of the study (De Dombal, Leaper, Horracks *et al.*, 1984). These findings are significant, since the level of attention given to people in clinical research settings during controlled RCTs could be significantly different from that which clients receive when treated in private practice. If this is so, the efficacy rates determined from randomised clinical trials might not be the same as in private practice: they might be better or they might be worse. This suggests that effectiveness rates of therapeutic interventions could be dependent on the therapeutic context. If this is the case, the findings from controlled trials of TCA might not be able to be generalised with confidence to treatment interventions that occur in private TCA practice. In research terminology, this could mean that randomised clinical trials might have poor external validity.

For some TCA practitioners, the problem with 'double-blind' RCTs is the context that they create.²⁵² The design of such trials often denies the patient information and subjects them to experimental control. For many biomedical researchers, knowledge is dependent on control. The structure of the 'double-blind' RCT encourages the patient to be passive, and in one sense powerless. Similarly, the pharmaceutical drug therapies of biomedical practitioners could be seen to *act upon* the patient, with the patient not usually having to contribute significantly to the restoration of their own health. In contrast, TCA practitioners in private practice encourage their clients to fully participate in therapy (see chapter 2).²⁵³

²⁵² This point was examined by the author at the Second Australasian Acupuncture and Chinese Herbal Medicine Conference, 14 July 1996 and reported in B.W Nester (1997). *The Limitations of Randomised Clinical Trials in Traditional Chinese Acupuncture Research (Learning to live with uncertainty)*. In Department of Health Sciences, Victoria University of Technology (1997). *Proceedings of the Second Australasian Acupuncture and Chinese Herbal Medicine Conference, 14 July 1996, 63-76.*

²⁵³ The reason that some TCA practitioners refer to the people whom they try to help as *clients* rather than as *patients* stems from an altered health care provider relationship. The term 'patient' can connote a passive reception of therapy by a dependent person. The term 'client', in contrast, suggests that a person is essentially independent and capable of making judgments based on the advice given to them by their health care provider.

10.20.1 *'Helplessness' in research*

Human beings can feel extremely stressed when they feel that they are not in control, or feel that they are being controlled. According to the literature in this field, stress can result from 'being acted upon' and can induce what has been termed 'helplessness' (Black, 1988 p. 54). Scientists can induce this state of helplessness in animals, and it has been claimed that this state can also be induced in humans. When this state of helplessness exists, physiological changes from the norm can be detected. When helplessness is induced in animals, stress can result that can be detected by changes in the animal's internal biochemistry. Studies have shown that stress can result in changes in physiology that can cause a weakening of the immune system.²⁵⁴ Black (1988, p. 54) claims that research has shown that this 'helpless' physiology is involved in many diseases, including high blood pressure, cancer, diabetes, arthritis, depression and epilepsy.

The question that could be asked is: does the context of medical research, where the patient submits to the control of the researcher produce similar feelings of helplessness with an accompanying weakening of the body's immune system? It is well known for example that blood pressure can increase due to the clinical environment in which it is taken, and it is also possible that there could be other negative effects that could result from cold, impersonal and controlled clinical research environments. As an example, Norman Cousins (1983, cited in Black, 1988, p. 55), outlined the principles he applied to recover from a near-fatal heart attack. At one point in Cousins' story he describes taking a diagnostic treadmill test for a doctor. The doctor, after examining the results of the test, recommended immediate heart bypass surgery. Cousins disagreed with the doctor's 'therapeutic solution' because he had previously walked distances that the test results suggested were impossible for him. Cousins refused surgery and asked the doctor if he could be retested on the treadmill in pleasant, non-clinical surroundings. The results of the second test indicated that surgery was not required. This example suggests that changes in human physiology could be caused by stress and that helplessness could be induced by impersonal and controlled clinical environments. While helplessness might be balanced by the Hawthorne effect, it does suggest a possible inherent problem with overly controlled and impersonal clinical trials.

²⁵⁴ See J. Millenson, *Mind Matters: Psychological Medicine in Holistic Practice*, 1995

10.21 Could the RCT Reduce the Effectiveness of Complementary Therapies such as TCA?

Black (1988) has argued that the effectiveness of a therapy can be a function of the context in which the therapy is delivered. Black cites the study of Ewan Cameron and Linus Pauling (both Nobel prize winners), which involved a non-blinded study of the effects of vitamin C on terminal cancer patients (Cameron & Pauling, 1976). Cameron and Pauling found vitamin C to be of value in the treatment of patients with advanced cancer. At the end of the study 18% of subjects were alive and 16% recovered. No person in the untreated control group survived. In a later *double-blind* controlled trial on the effects of vitamin C on cancer patients by Creagan *et al.* (1979), only one person was alive at the end of the trial. The conclusion that was drawn from this double-blind controlled trial by the researchers was that vitamin C had no role in the treatment of cancer. Assuming that the uncontrolled study of Cameron & Pauling (1976) and the double-blind controlled trial of Creagan *et al.* (1979) were conducted as reported, which conclusion is the more credible?

To determine what could have produced the two different sets of results one needs to look at how the two treatment groups differ (Black, 1988). There are two important differences that can be noted that relate to the *context* of the research. The first difference is that the physicians in the Cameron and Pauling (1976) study *believed* in the therapy that they were using to strengthen their patients' natural resistance and healing processes. In contrast, the researchers in the Creagan *et al.* (1979) double-blind trial were unaware of which treatment they were giving their subjects (vitamin C or placebo) and hence might not have conveyed the same belief in the therapy to their patients. Secondly, the physicians in the Cameron and Pauling (1976) study involved their patients by telling them exactly what they were trying to do; whereas the researchers in the double-blind study deliberately withheld information from their research subjects regarding which intervention was being administered to them (*i.e.* treatment or placebo), which is a requirement of the double-blind RCT research design.

Black (1988, pp. 59-61) suggests that the differences in the sets of results in the above studies

are attributable to the contexts of the two research approaches. If double-blind RCTs deliberately keep patients in a state of helplessness and uncertainty, then it is conceivable that the vitamin C that could have been stimulating the immune system was actually being used to modulate the stress response. Also, in clinical settings where there is human caring, anxiety might be reduced which could have a positive effect on the function of the body's natural healing processes. It is feasible that it was the very nature of the double-blind RCT that actually prevented the therapy from working rather than proving that it did not work. This should be kept in mind when interpreting the findings of RCTs involving complementary therapies such as TCA. The discrepancies between effectiveness rates reported by TCA practitioners in private practice and those from RCT's could be a function of the context in which the TCA therapy is delivered.

10.22 It is Impossible to Eliminate all Possible Explanations by Using the Randomised Controlled Trial

The objective of the 'double-blind' RCT is to eliminate every possible alternative explanation for the therapeutic outcome except the one that is being assessed. Patients are 'randomised' at the start of the study in the attempt to make the two groups as similar as possible. The reason for randomisation is that any variable in which the groups differ might be a possible cause of the clinical outcome. It follows that if the control and treatment groups are 'matched' through randomisation, any differences in therapeutic outcome between the two groups could not be attributed to any of the variables that are the same in both groups. Treatment and control groups can be matched on the basis of sex, age, economic class, nutrition, *et cetera*. The problem is that the list of variables to be controlled is endless. It is simply not possible in practice to produce homogeneous groups by randomisation to eliminate all of the alternative explanations for differences in therapeutic outcome between treatment and control groups. Guba and Lincoln (1994, p.106) remark that, "such exclusionary designs [including the RCT], while increasing the theoretical rigour of a study, detract from its relevance, that is, its applicability or generalizability, because their outcomes can be properly applied only in other similarly truncated or contextually stripped situations". In most clinical trials it will be too expensive or impractical to control or measure all relevant factors. Spilker (1991, p. 612) states that

[i]f fully adequate information is not available on all relevant factors (which it rarely is), then the interpretation must be considered as incomplete and even possibly as flawed. This is unfortunately the situation with almost all clinical trials. Interpretations are rarely perfect explanations of all data from a clinical trial.

10.23 Further Difficulties of Accounting for Non-specific (placebo) Effects in Randomised Controlled Trials

In one particular controlled controlled trial, an anti-ulcer drug was evaluated by comparing its therapeutic effect with a placebo. This trial, using the same research design, was carried out in two hospitals, one in London and the other in Dundee (Littman, Welch, Fruin *et al.*, 1977). The results of this study were extremely interesting because the healing rates that resulted from the placebo were significantly different at the two hospitals. At the hospital in London, the ulcers were healed by the placebo in 44% of cases, compared with 73% at the hospital in Dundee. The differences in response to the placebo might be explained in terms of differences in physicians, patients, or both. What should be noted here is that the rate of placebo response is setting dependent and does not appear to be solely a function of the actual therapeutic intervention. Littman *et al.* (1977), in the same study, found that in one hospital the same antacids relieved pain in 17% of cases, while at another hospital the rate was 79%. It was claimed that the same research design and selection criteria were used at the two hospitals and yet the responses to treatment were significantly different. This finding weakens the argument that the controlled RCT is in fact the 'gold standard' for determining the efficacy of a medical intervention since different efficacy rates can be found in different settings using the same research design and methodology. This finding also suggests that the efficacy rate of a particular medical intervention cannot always be generalised to other settings or populations, since the actual response to therapy can be setting dependent. If this is the case, proponents of RCT's might not be able to claim that RCTS are far superior to well conducted qualitative studies that acknowledge that their findings are setting dependent.

According to Anthony (1993), an important limitation of the RCT is that often patient recovery is "influenced as strongly by the patient as by the treatment." This factor is now being recognised in conventional medicine. This realisation suggests that a particular treatment will

not always benefit *all* patients equally, even if they all have the 'same' disease. Characteristics of the individual can influence the outcome of any treatment and this needs to be considered in future TCA research design. This suggests that researchers of TCA will need to take detailed and comprehensive case histories of every patient entering a clinical trial so that personal factors can be identified and correlated with the extremes of highly successful or poor therapeutic outcome.

While the RCT will probably continue to be employed by researchers to evaluate the efficacy of acupuncture, it should be remembered that no matter how exhaustive the scientific or clinical investigation, absolute truths will *not* be found using this method since it is impossible to control for all variables that are involved in the therapeutic encounter.

10.24 All New Medical Procedures Should be Evaluated, Not Only the Complementary Therapies

It is easy to obtain the impression from advocates of Biomedicine through the media that all new medical procedures are evaluated by controlled clinical trials before they are used on the public. Glasziou (1995) has reported that contrary to popular opinion, there are many pharmaceuticals that have not been evaluated by randomised controlled trials. In Australia, Moynihan (1998, p. 7) suggests that "approximately 95 per cent of medical devices have been introduced without any requirement for evidence of their safety or effectiveness." Taylor (1979, p. 235) had previously argued that there has been a premature and uncritical incorporation of new forms of diagnosis and treatment into medical practice. Taylor claims that the advocates of many new methods of biomedical diagnosis and treatment rely on *ex cathedra* statements based on clinical impressions, or on elaborate theoretical justifications rather than on randomised clinical trials.

Hiatt (1977) stated in the *New England Journal of Medicine* that

some constraints on the spread of new procedures must be accepted. Well designed trials should *precede* widespread dissemination, as is done to a considerable extent for drugs. Why not for surgical procedures? Why not for costly procedures of all kinds?

Hiatt's remarks should be noted by government health departments, health insurance funds,

medical consumer groups, politicians, economists and medical journalists. Many new medical procedures are expensive and it would be wise to determine if they are in fact safe, efficacious and not iatrogenic. Taylor (1979) restates that old adage, “that health is too important to be left in the hands of doctors.” With limited funds allocated to health care by government authorities, it is important that it should be spent wisely for the benefit of the public rather than to appease and benefit the practitioners of any one system of medicine. It is for this reason that Western government health departments and other relevant agencies should provide sufficient funds to researchers of both Biomedicine and the complementary therapies (including TCA) so that research can be conducted to evaluate the claims made by the proponents of the various systems of medicine.

10.25 Summary

In this chapter the uses and limitations of the controlled clinical trial for evaluating the therapeutic benefits of TCA have been examined. It was argued that the *pragmatic randomised controlled trial*, using active controls, should be further utilised for evaluating the efficacy of TCA therapy as a whole (*i.e.* both the interpersonal and healing skills of the TCA practitioner and the acupuncture needling technique). Such an approach could be utilised to determine the ‘relative’ efficacy of a therapy rather than its ‘absolute’ efficacy. Comparative studies using the *pragmatic randomised controlled trial* methodology provides the means of enabling the various biomedical and complementary therapies (including TCA) to be compared so as to be able to determine the most effective and efficient therapeutic approaches for the various types of human illness and disease.

While the RCT, a product of positivist assumptions and tenets, will probably continue to be employed by researchers to evaluate the efficacy of TCA, it should be remembered that no matter how exhaustive the clinical investigation, *absolute* truths will *not* be found using this method since it is impossible to control for *all* variables that are involved in the therapeutic encounter.

CHAPTER 11

ETHICS AND TRADITIONAL CHINESE ACUPUNCTURE RESEARCH

“The principle of medicine is the principle of humaneness.
Its basis is innate compassion, and help is its duty.”

- Chang Jen (preface to Wan Ch'uan's *Wan Mi-chai shu*
cited in P. Unschuld, 1979, p. 99)

The aim of this chapter is to outline some of the ethical issues that should be addressed when designing and conducting TCA research that involves human beings. When researchers of TCA begin to develop a research design to achieve a particular research objective, ethical issues should be considered concomitantly with the design and not reflected on later as an afterthought.

Bertrand Russell (1945 quoted by Wilber, 1990, p. 27) once claimed that “[t]he sphere of values lies outside science”. Such a view is no longer a tenable position in contemporary societies and research communities. The conduct of clinical research is now guided by the guidelines of ethics committees, while qualitative research methods are now being used in medical research to uncover beliefs, attitudes and values that relate to the understanding of health and disease (see chapter 12).

11.1 The Conflicting Obligations between the TCA Practitioner's Roles of Therapist and Clinical Researcher

The first ethical issue that will be addressed is the problem of conflicting loyalties. It is possible that with TCA practitioners and TCA post-graduate students desiring to conduct research in the area of TCA, that some individuals might be confronted with an ethical dilemma that results

from a conflict of loyalties between their roles of therapist and researcher. As a TCA practitioner, care for the wellbeing of the client is always a primary concern; however, the demands of postpositivist research designs such as the randomised clinical trial (RCT), with its demand for a placebo control group, could be seen to contravene a fundamental ethical principle of TCA practice. McConnell (1982, p. 93) claims that “[d]oing what will lead to advances in one’s area of expertise may require that one violate one’s obligation to the patient.” It is important that the TCA practitioner-researchers’ desire for knowledge will not displace their obligations as therapist. Older TCM texts do not explicitly discuss clinical research ethics, since controlled clinical trials are a relatively new development of Western medical science²⁵⁵; however, they do discuss the proper conduct and behaviour of a good physician (Unschuld, 1979).

11.2 Ethics in TCM Practice

Confucian philosophy has influenced the practice of TCM practitioners. This philosophy has emphasised two essential points: the first is cultivating humaneness (*ren*), and the second is mastering skill (*ji*). Chiang Shih in the preface of the *I-ts’ui ching-yen* by Hsu Yen-tso (Unschuld, p.108) claimed that

Medicine consists of humaneness and skill. Some [physicians] master the skill and are wanting humaneness. These are the greedy physicians. Others possess humaneness, yet they lack skill. These are the ‘common’ physicians. Commonness and greed are apt to harm man.

For Confucians, the physician’s skill is believed to be essential for practice; however, humaneness is always regarded as being primary. Christakis (1992, p.1084) states that the Chinese notion of humaneness “encompasses the notions of beneficence towards the ill and the duty to treat those in need. It is an obligation to do good to sick people. And [*sic*] it involves the injunction to treat others as one would oneself.” This emphasises the notion that the primary concern of the TCM practitioner is the welfare of the client, and that other things, including the possible advancement of medical knowledge and the advancement of the researcher through

²⁵⁵ C. Vincent and A. Furnham (1997, p. 155) note that the randomised controlled trial was developed for medical research during the 1940s.

gaining this knowledge should be secondary. A similar idea is found in Kung T'ing-hsien's 'Ten Maxims for Physicians', where he lists adopting a disposition humaneness and grasping Confucianism in first and second places, which is then followed by the mastery of medical knowledge. (Unschuld, 1979, pp. 71-72).

11.3 Ethics in Clinical Research

There are several codes of ethics that address the ethical issues related to research that involves human experimentation. The ideas contained in these codes are relevant for researchers of TCA. The two codes that are most often cited are the Nuremburg Code and the Declaration of Helsinki, both of which consider the relationship between the permissibility of using human subjects in research experiments and the nature of informed consent. The Declaration of Helsinki was adopted by the World Medical Association in 1964 and was revised in 1975. In Australia, the National Health and Medical Research Council (NHMRC) has published its guidelines for all research workers and administrators of institutions in which research is undertaken with human subjects. It deserves to be noted that the NHMRC's guidelines were originally written with an awareness and an acceptance of the recommendations of the Declaration of Helsinki.

The NHMRC's Statement on Human Experimentation Guidelines (1987, p. 2) states clearly that, "in the conduct of research the investigator must at all times respect the personality, rights, wishes, beliefs, consent and freedom of the individual subject." To ensure this end, the NHMRC has made the recommendation that institutions in which human experimentation is undertaken should have a committee concerned with the ethical aspects of research projects. The role of such committees is to approve only those research proposals that conform to accepted moral and scientific principles.

Wulff, Pedersen and Rosenberg (1986) suggest that controlled clinical trials involve several related ethical issues. They argue that some researchers justify the use of controlled therapeutic

trials from the theory of *utilitarianism*.²⁵⁶ From the perspective of utilitarianism, an action is judged in terms of its consequences. If the consequences are good, so are the actions. Goodness, in turn, is judged in terms of the total amount of happiness that an action produces. According to the utilitarianism philosophy of David Hume [1711-1776], this is how humans make ethical judgments (Vesey & Foulkes, 1990, p. 289). From the perspective of utilitarianism, the total benefit of controlled trials must be calculated by considering the benefit to future patients and not only those benefits and risks for those individuals that enter clinical trials.

Researchers of TCA involved in RCTs should remember that conducting research does not relieve them of their duty to do the best for their patients. Researchers cannot know in advance the outcome of a clinical trial. Therefore they cannot know beforehand if a new therapy or medical intervention will be found to be better than the best currently known therapy, or if the new therapy will be found to have unexpected side-effects. On this point, the Declaration of Helsinki states that, “[i]n any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method”. If this statement is taken literally, it forbids controlled trials of this nature, as the therapy that is being evaluated does not qualify as the best therapeutic method. Most researchers, however, interpret the above statement to mean that patients should not be given a treatment that is *known* to be inferior (Wulff, Pedersen and Rosenberg, 1986, p. 200).

11.4 Therapeutic and Non-therapeutic Research

The Declaration of Helsinki clearly defines the distinction between a *therapeutic* and a *non-therapeutic* research experiment. A therapeutic experiment (or clinical trial) is one in which the researcher uses a new untried technique or treatment regime with the sole aim of helping the patient (subject). In this case, any medical or scientific knowledge that results from the treatment or therapy will be valuable but incidental. In contrast, in non-therapeutic research

²⁵⁶ R. Audi (1995, p. 824) explains that *utilitarianism* is “the moral theory that an action is morally right if and only if it produces at least as much good (utility) for all people affected by the action as any alternative action the person could do instead. Its best-known proponent is J.S. Mill who formulated the greatest happiness principle: always act so as to produce the greatest happiness.”

experiments, the primary aim is to gain medical knowledge. In the case of the non-therapeutic research experiment, some research subjects might be expected not to benefit directly from participating in clinical trials. The Declaration of Helsinki makes three statements with regard to clinical research on human beings:

- (i) when treating a patient, the practitioner must be free to use new therapeutic techniques if, in the practitioner's assessment, the new untried regime offers the possibility of saving life, alleviating suffering, or reestablishing health;
- (ii) the researcher should obtain the patient's freely given and fully informed consent. If the subject is legally incompetent then the consent should be obtained from the subject's legal guardian;
- (iii) the practitioner-researcher may only combine clinical research with professional care to the extent that the clinical research is justified by its expected therapeutic value for the patient.

One conclusion that could be drawn from point (iii) above is that TCA practitioner-researchers should not use their patients in non-therapeutic experiments. Although the Declaration of Helsinki does not state this consequence explicitly, it is a logical conclusion that could be drawn from statements in the document. Some TCA researchers might agree with this idea because of the notion that the value of knowledge is a function of the way it is obtained. Other researchers of TCA, with a more postpositivistic orientation, might argue that non-therapeutic research is ethical as long as participants are fully informed of the details of the research design and consent to take part in the trial.

Some researchers might believe that the study of the physiological effects of needling specific acupuncture points on the human body could increase TCA knowledge and subsequently improve TCA practice. Clinical research in which the primary aim is to determine the physiological effects of needling specific acupuncture points would have to be regarded as non-therapeutic research, since this is not how TCA therapy is normally practised by members of

the TCA profession. If it is decided that non-therapeutic research needs to be conducted, it is important that the research objectives are worth achieving considering the time, effort, cost and possible pain and discomfort that could occur. While this type of basic research might possibly lead to a better understanding of acupuncture point function in biomedical terms, it is quite possible that this kind of acupuncture treatment is not the best and most appropriate treatment for those people being treated in the clinical trial if they are ill.

Non-therapeutic research will not necessarily be beneficial for research participants (subjects) and in some cases might cause actual harm. The NHMRC (1987, p. 3), in its *Statement on Human Experimentation*, state that “the investigator must stop or modify the research program or experiment if it becomes apparent during the course of it that continuation may be harmful”. The NHMRC claims that it is essential that any subject must be free to withdraw consent from further participation in a clinical trial at any time.

Another potential danger of the randomised clinical trial (RCT) when used to evaluate TCA is that the TCA person-centred approach could be undermined by reducing TCA therapy to a mere technique, where therapeutic outcomes are attributed solely to the mechanical technique of needling. It is important that the interpersonal aspect of TCA therapy is not minimised in TCA research designs that aim to determine the outcome attributable to the needling component of TCA practice.

11.5 Informed Consent in Clinical Research

In the past, some medical researchers working in a positivistic mode have not fully informed their subjects as to the true purpose of the research that they were conducting. This has sometimes been done because of the belief that the scientific validity of the study would be jeopardised by fully informing the subjects. Such research is clearly not ethical based on current guidelines.

Ethical TCA research requires researchers to obtain informed consent from all patients participating in any research project. The features of informed consent have been clearly

outlined in the Nuremburg Code:

The voluntary consent of the human subject is absolutely essential... This means that the person involved should have *legal capacity* to give consent; should be situated as to be able to exercise *free power of choice*, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient *knowledge* and *comprehension* of the elements of the subject matter involved as to enable him [or her] to make an understanding and enlightened decision (Nuremburg Code, 1986, p. 425, cited in Burns and Grove, 1993, p. 105).

Burns and Grove (1993, p. 105) state that the definition of informed consent as provided by the Nuremburg Code emphasises four important points: (i) the researcher needs to disclose essential information to the subject; (ii) the subject needs to comprehend the information given; (iii) the subject needs to be competent to make an informed decision; and (iv) consent is given voluntarily.

In TCA clinical research that involves the use of a placebo control (*e.g.* 'sham' acupuncture) to determine TCA efficacy, it is important that subjects are fully informed and comprehend that they have an equal probability of receiving either 'real' TCA therapy or a placebo. If this is not done, the research could be regarded as being unethical because of the element of deception.

Giles (1983, p.76) has remarked that

the more deception that is made part of medical practice in a therapeutic and research setting, the more likely people will become disenchanted with it. Eventually, they may become so mistrustful of medical research that they will refuse to volunteer themselves as experimental subjects.

Research that allows any element of deception can only be justified by a utilitarian philosophy that regards the growth of scientific and medical knowledge to be an important end product that exceeds the undesirable but necessary deception. Such a position could only be justified where there was no serious threat of harm to the subject, and where the benefits for society and future patients could not be achieved in any other way. This utilitarian argument, while persuasive for some, would seem to be inconsistent with the Helsinki Declaration (p. 428) that states that "the interests of the subject must always prevail over the interest of society and science". This last

statement seems to be more in accord with Kantian ethics²⁵⁷ and the Hippocratic oath²⁵⁸, which both emphasise respect for each and every patient, rather than with the philosophy of utilitarianism.

11.6 Other Ethical Issues Associated with TCA Clinical Trial Designs

A major criticism of clinical research designs that involve a placebo control is that patients will be deprived of real treatment (Hammerschlag, 1998). In some TCA clinical trials, people in control groups have not been given treatment that could benefit their condition, that is, there has not been the “intent to treat” (Hammerschlag, 1998, p.161). Examples of controls that have been used in clinical research where it is the intention of the researcher *not* to provide treatment because it is a requirement of the research design are the ‘wait-list control’, the placebo control and the ‘sham’ control (Hammerschlag, p. 166).²⁵⁹ Ethical concerns vary with each of these controls.

TCA clinical research that utilises the ‘wait-list control’ could be regarded as ethical where the condition being studied is chronic but stable. This control would seem to be ethical since the control group can be given ‘real’ TCA treatment (if it is found to be effective) or biomedical standard care at the end of the study without a significant reduction in health status as a result of being denied treatment for a period of time (Hammerschlag, p. 166). A design weakness of this type of control, from a neopositivist perspective, is that it cannot provide a measure of the non-specific or placebo effects of acupuncture needling.

Ethical concerns have also been raised in relation to TCA clinical trials where a placebo control or ‘sham’ acupuncture control have been used (Hammerschlag, 1998). Some researchers

²⁵⁷ G. Vesey and P. Foulkes (1990, p. 56) note that Kantian ethics is centred around Kant’s notion of the categorical imperative which he regarded, “as the central CRITERION for right conduct: always act in such a way that the principle underlying the action could be conceived as turned into a general law.”

²⁵⁸ According to M. Charlesworth (1996, pp. 8-9), the “older Hippocratic tradition of medical ethics saw medicine largely in individual, asocial terms”.

²⁵⁹ See R. Hammerschlag (1998) for examples of acupuncture research that has utilised these different types of control group.

contend that in these cases there is no “intent to treatment” and hence the control group is denied ‘real’ treatment that could ameliorate their condition. In addition, in the case of the placebo control (*e.g.* inactive TENS and mock needling), the control does not account for the non-specific effects of needling. The ‘sham’ acupuncture control, while having similar ethical problems as the placebo control, is methodologically more sound in that it could account for the non-specific effects of acupuncture therapy.

Ethical issues can be minimised by conducting clinical trials that utilise ‘active controls’ (*i.e.* actual therapies) rather than placebo controls (see chapter 10). If researchers were to dispense with placebo controls and compare only active treatments when attempting to determine therapeutic effectiveness, there would be a clear ethical advantage in that no person would be denied a ‘real’ treatment that has some chance of alleviating their health problem (Shapiro, 1989). Comparative clinical trials where TCA is compared with ‘standard care’ (which might be biomedicine, physiotherapy, osteopathy etc.) would appear to be an ethical research strategy. This assumes that the standard care has been previously shown to be superior to a placebo (Hammerschlag, 1998, pp.166-167).

Another ethical research design, that has been termed the ‘adjunctive care comparison’, involves assessing the efficacy of acupuncture therapy plus standard care relative to standard care alone (Hammerschlag, 1998, p. 159). This research design is clearly ethical since all groups receive standard care. Such a design could determine if TCA therapy enhances standard care. Little is known, however, of the possible synergy of standard biomedical care and TCA. A possible weakness of this research design is that the standard care (*e.g.* a pharmaceutical drug) may reduce the efficacy of the TCA therapy, that is, there might be adverse interactions between the two treatments. Another permutation of this research approach is to compare TCA therapy with ‘sham acupuncture’ with standard care being given to both groups.

11.7 When Should Placebo Controls Not be Used in TCA Clinical Research

There are certainly times when the use of placebo controls would be clearly unethical. Spiro

(1986, p.16) claims that placebo controlled clinical trials are not indicated when: (i) death or disability could result if no treatment is given; (ii) other forms of therapy are known to be effective; and (iii) a drug, or other therapy, is already known to be effective and the research is designed only to measure the magnitude of the therapeutic benefit. To these three could be added contraception studies where ineffective contraception could result in pregnancy (Finkel, 1985, p. 420).

11.8 The Monitoring of TCA Clinical Trials

It would be expected that any ethical problem related to TCA research could be adequately dealt with by an institutional ethics committee as recommended by the NHMRC's Statement on Human Experimentation (1987, pp. 5-6). The role of a properly constituted institutional ethics committee would be to approve research projects before they begin and ideally, to give guidance to researchers on the complex ethical issues in health care research that involves human experimentation.

It would also be the responsibility of institutional ethics committees to ensure that any planned research project be completed within a defined period of time. In some cases it might be unethical to continue a clinical trial for the full period that was planned by the researchers (NHMRC, 1987, p.12). It would be obviously unethical to continue a clinical trial if a high frequency of side effects were encountered in an experimental group. It would also be unethical to continue a trial where one of several treatments or modalities being compared, proved as the trial progressed to be much better or worse than others, and where it was clear that continued adherence to the research protocol would disadvantage or harm some of the people in the study.

It is highly desirable that all TCA clinical trials be monitored, especially in 'single-blind' randomised clinical trials. Monitoring should be conducted by an independent person or small committee. The independence of the monitoring body would be necessary to minimise researcher/subject bias. The researchers conducting the trial should not monitor the same trial because of their access to the trends of the trial which could lead to researcher bias and thereby reduce the validity of the study. The monitoring committee, according to the NH&MRC (1987,

p.13), should also have the power to terminate any clinical study where it could be concluded that a treatment was deleterious to the health of the subjects in one or more of the experimental or control groups.

11.9 Summary

Ethical issues cannot be divorced from TCA clinical research design and methodology. Researchers need to carefully consider all of the ethical issues associated with particular research designs when developing TCA studies. Ethical issues can be minimised by conducting clinical trials that utilise 'active' controls (*i.e.* actual therapies) rather than placebo controls.

The relationships developed between researchers and research participants are crucial, not only on ethical grounds but also because they impact on the quality of data obtained in the research process. Research of TCA is an ethical necessity if the TCA profession is to improve TCA practice so as to maximise the outcomes for clients. Regardless of the therapeutic intervention that is being evaluated in a study, it is essential, given limited community funds, that research funds are not wasted on poorly designed research programs. Although there can be no guarantee that any TCA research project will produce useful clinical findings, it is important to minimise poor research with its subsequent proliferation of misleading ideas in professional literature. In fact, it could be argued that, given the existence of limited research funds, well designed and executed research programs are an ethical necessity.

CHAPTER 12

QUALITATIVE METHODS AND OTHER RESEARCH APPROACHES FOR TRADITIONAL CHINESE ACUPUNCTURE

“Knowledge is a function of being. When there is a change in the being of the knower, there is a corresponding change in the nature and amount of knowing.”

- Aldous Huxley (1972, p.1)

“Consciousness grows. It develops new concepts and categories. It finds itself torn between one “form of consciousness” and another, and it learns to reconcile them or, in any case, move beyond them. Consciousness and knowledge are dynamic, a dialectic. They grow through confrontation and conflict, not by way of mere observation and understanding.”

- Solomon & Higgins (1997, p. 96) on the philosophy of G.W.F. Hegel [1770-1831]

In the first section of this chapter, consideration will be given to several qualitative and interpretive methods of inquiry for generating TCA theory, understanding the nature of TCA, and increasing TCA knowledge. This will be followed by an outline of other research methods that could be used to address particular research questions in the field of TCA but which are not generally classified as being either qualitative or quantitative.

12.1 Naturalistic Inquiry and Qualitative Research Methods

Egon Guba (1978) once described *naturalistic inquiry* as a discovery-oriented approach that minimises researcher manipulation of the study setting and which places no prior constraints on what the outcomes of the research will be. Often naturalistic inquiry involves the use of

qualitative research methods.²⁶⁰ Guzzetta (1989, p. 86) has defined *qualitative research* as “a form of research that studies the context and meaning of interactive variables as they form patterns reflective of the whole.” Often interviews are utilised by qualitative researchers to obtain information from informants.²⁶¹ Kvale (1994, p. 1) notes that the qualitative research interview “attempts to understand the world from the subjects’ points of view, to unfold the meaning of peoples’ experiences, [and] to uncover their lived world prior to scientific explanations.” This can be contrasted with experimental, or clinical research, which often attempts to control the conditions of a study in an attempt to hold external influences constant while measuring a limited number of outcome parameters or variables. Stake (1995, p. 37) has noted three important differences between qualitative and quantitative research approaches: (i) the distinction between *understanding* and *explanation*; (ii) the distinction between the personal and the impersonal roles of the researcher; and (iii) the distinction between knowledge that is *constructed* and knowledge that is discovered.²⁶²

According to Morse and Field (1995, p. 6), qualitative inquiry “is a process of documenting, describing, identifying patterns and concepts, identifying the relationship between concepts, and creating theoretical explanations that explain reality.” One of the aims of qualitative research is to generate theory. Morse and Field (1995, p.18) claim that an important purpose of qualitative research is to “construct valid theory that guides knowledge development within a discipline.” Naturalistic inquiry and qualitative research methods are also concerned with determining the *meaning* of particular phenomena that affect human beings. This type of research usually involves inductive and dialectic reasoning processes (see chapter 6. 3).

Qualitative research methods allow the researcher to study selected issues in depth and detail.

Qualitative fieldwork is often conducted without being constrained by predetermined categories

²⁶⁰ According to Morse and Field (1995, p. 6), qualitative inquiry “is a process of documenting, describing, identifying patterns and concepts, identifying the relationship between concepts, and creating theoretical explanations that explain reality.” For a comprehensive account of qualitative research methods see N. Denzin and Y. Lincoln (eds.). *Handbook of Qualitative Research*, 1994.

²⁶¹ For an account of the role of the interview in qualitative research see S. Kvale, *Interviews: An introduction to Qualitative Research Interviewing*, 1996.

²⁶² Refer also to chapter 5.4.6.

of analysis which can increase the depth, openness, and detail of an inquiry. According to Leininger (1985), qualitative research can be a subjective and systematic approach that can be used to describe and to give *meaning* to the life experiences of people. This approach could be used in TCA research to gain an understanding of the experiences of both TCA practitioners and their clients. Qualitative research methods could be of use in understanding changes in human experiences such as pain and psychological states during illness and therapy. Human experiences such as emotional states can be difficult to quantify by the assignment of a numerical value, and because of this it is often argued that qualitative approaches are more appropriate for examining some types of subjects, phenomena and research questions.

Spiritual and transpersonal dimensions of health and wellbeing might also be best studied by qualitative research approaches. Qualitative research interviews, a common method used in qualitative research, would seem to be one of the few means by which a researcher could access information from an informant on their perceptions of the spiritual and transpersonal domains that relate to health and wellbeing.

12.2 Similarities between the Themes of Qualitative Research and TCA Theory and Practice

Qualitative research methods might be expected to have an important role in TCA research because of the similar themes and features of qualitative inquiry and TCA. To discern these similarities, it is first necessary to consider the important features of qualitative inquiry. Miles and Huberman (1994, pp. 6-7) note several features of qualitative research:

- (i) It is conducted through a deep and/or prolonged contact with a phenomenon in the 'field' or life situation. These situations are typically 'banal' or commonplace, being reflective of the everyday life of individuals, groups, societies, and organisations;
- (ii) The aim of the researcher is to gain a 'holistic' (systemic or integrated) overview of the phenomenon under investigation in context, including its logic and its explicit and implicit rules;
- (iii) The researcher attempts to capture data in the form of the perceptions of the 'local actors', 'from the inside', by the process of deep attentiveness and empathetic

understanding. This can require the suspension or 'bracketing' of preconceptions about the phenomenon under study;

- (iv) The researcher, after analysing transcripts and other materials, attempts to isolate certain themes that can be later reviewed with informants. For the purpose of validating findings, the transcripts or raw data are maintained in their original forms throughout the study;
- (v) A main task of the qualitative researcher is to explicate the ways "in which people in particular settings come to understand, account for, take action, and otherwise manage their day-to-day situations.";
- (vi) In qualitative research, there can be many possible interpretations of the informants' material but some will be "more compelling for theoretical reasons or on grounds of internal consistency.";
- (vii) The researcher is essentially the main measurement instrument in the study. There is relatively little standardised instrumentation used initially;
- (viii) Data generally consist of words in the form of dialogue, statements and descriptive summaries of the researcher. The analysis involves looking for themes, identifying categories and looking for patterns in the data.

Patton (1990 pp. 40-41) has also outlined several themes and features of qualitative inquiry.

These themes and features would seem to resonate with TCA philosophy and practice:

- (i) Both study real world situations as they unfold naturally. They are non-manipulative and non-controlling, with an openness to whatever emerges (refer to the nature of the TCA therapeutic encounter in chapter 2);
- (ii) Both are case oriented and assume that each person is special and unique;
- (iii) There is an immersion in details and specifics of the data to discover important categories, dimensions, and interrelations. There is exploration by genuinely open questions rather than testing theoretically derived (deductive) hypotheses;
- (iv) Both hold a holistic perspective. Morse & Field (1995, p.18) maintain that "the qualitative perspective is holistic and primarily inductive." The focus of both TCA and

qualitative inquiry is on complex interdependencies, rather than on a few discrete variables and linear, cause-effect relationships. Much TCA knowledge has developed through induction by the careful observation of human beings and the natural world;

- (v) The data collected are detailed. Quotations capturing people's personal experiences are regarded as important;
- (vi) The qualitative researcher has direct contact with, and gets close to the people, situation, or phenomenon under study. The researcher's personal experiences and insights are an important part of the inquiry and critical to understanding the phenomenon studied. Similarly, the TCA practitioner needs to get close to their clients and gain their confidence so as to be able to obtain information essential to understanding their clients. In both cases, understanding requires the interpretation of data and relies, in part, on intuition;
- (vii) In qualitative research, as in the TCA therapeutic encounter, participants are dealing with dynamic systems. Some qualitative researchers hold the belief that 'truth' is not static but dynamic, and maintain that it can only be discovered by studying people as they interact in their various socio-historical settings (Tinkle & Beaton, 1983). This understanding would be supported by Daoist philosophers who claim that the only constant in the world of phenomena is change itself. Change is constant, regardless of whether one is considering a disease state, a client, or an entire society;
- (viii) There is context sensitivity. In the clinical encounter, as in qualitative inquiry, there is a social and temporal context that decreases the likelihood of meaningful generalisations being extrapolated to other settings;
- (ix) In both TCA practice and qualitative research there is empathetic neutrality. Complete objectivity is impossible and pure subjectivity undermines credibility. An objective of the qualitative researcher is to understand people and the world in all of their complexities, while taking a neutral nonjudgemental stance toward whatever content may emerge;
- (x) In naturalistic inquiry there is an openness to adapting the method of inquiry as

understanding deepens and/or situations change. Design flexibility avoids getting locked into rigid designs that eliminate responsiveness. This allows the pursuit of new paths of discovery as they emerge. Flexibility is also a feature of TCA practice. TCA therapy is not static and no set protocol for a course of therapy can be stated before treatment is begun. A TCA therapy plan is continually modified in response to changes in a client's health status.

The common themes of naturalistic inquiry, qualitative research and TCA philosophy and practice would suggest that qualitative research methods are congruent with the paradigm of TCM and could have a more important role in future TCA research.

12.3 The Roles of Qualitative Methods in TCA Research

The National Health and Medical Research Council (NHMRC) (1995b, p. 13) have attempted to summarise the uses of qualitative research methods in health care research. All of the NHMRC's suggested uses could be employed by researchers of TCA:

- (i) to examine, analyse and interpret the economic, political, social, and cultural factors that can influence health and disease. Qualitative inquiry enables health researchers to apply theoretical understandings to concepts such as participation and empowerment. This has particular relevance to critical social theory (see chapter 5). Qualitative studies are important for obtaining in-depth understandings of the complex ways in which a variety of factors can affect health outcomes and health care;
- (ii) qualitative inquiry enables researchers to understand how communities, and individuals within them, interpret health, illness and disease. This method of research allows researchers to document and interpret the different ways individuals and groups make sense of their experiences of health and disease, and how these experiences can influence health care delivery and health outcomes;
- (iii) to examine the interactions between the various participants and stakeholders in any

particular public health issue. For example, the correlative link between alcoholism and liver disease might be established by experimental and quasi-experimental methods; however, these approaches are not suitable for understanding *why* some people drink excessively.

- (iv) qualitative inquiry can be used to elicit contextual data so as to improve the validity of survey instruments that can be used to pursue quantitative research. Qualitative studies have enabled the improvement of epidemiological survey instruments;
- (v) qualitative inquiry can be used to develop causal hypotheses for the findings emerging from epidemiological studies. For example, while it has been found through quantitative studies that there is a correlation between income levels, morbidity and mortality, the method does not explain the nature of the relationships.²⁶³ Qualitative research could be used to explore the *reasons* for correlations between variables. Similarly, researchers of TCA could use qualitative research to determine the reasons for correlations between TCM 'five phase' theory and human phenomena (see chapter 2.3.3);

Morse (1989, p. 9) claims that qualitative research can also be used to challenge the status quo and to identify new paradigms, or directions of inquiry. Further qualitative research of TCM might provide insights that could lead to a more integrated holistic health care paradigm.

12.4 Data Collection and Analysis in Qualitative Research

Data collection in qualitative research is varied; however structured, unstructured, and in-depth interviews are often used in addition to observation. The data collected are usually subjective, and can consist of the subjective perceptions of both the informants and researchers. It follows that many of the data from qualitative research consist of words in the form of dialogue, statements, and descriptive summaries of the researcher.

²⁶³ According to Brenner (1981, p. 371), the average life span of human beings is longer in countries at higher levels of economic development and in subpopulations at higher socioeconomic levels within countries.

12.4.1 *The qualitative research interview*

Kvale (1994, p. 5) claims that *conversation* can be a type of research, “[c]onversation is a basic mode of human interaction. Human beings talk with each other—they interact, pose questions, and answer questions. Through conversations we get to know other people, get to learn about their experiences, feelings, and hopes and the world they live in.” Lyotard (1984) argues that in these postmodern times, there is a move from formalised knowledge systems to narrative knowledge as embodied in storytelling. Kvale (1994, p. 2) asserts that the *qualitative research interview* as used by researchers can be “a construction site of knowledge”. The TCA clinical encounter between the practitioner and client could similarly be understood as a construction site of knowledge, since it involves a type of open interview where the client tells a story and provides a narrative about their life.

Kvale’s (1994) account of the qualitative research interview has important implications for the role of the researcher and the way knowledge can be produced. Kvale (1994, pp. 3-4) provides a theoretical understanding of his position through the two contrasting metaphors of the research interviewer as *miner* or *traveller*:

In the *miner metaphor*, knowledge is understood as buried metal and the interviewer as the miner who unearths the valuable metal. Some miners seek objective facts to be quantified, others seek nuggets of essential meaning. In both conceptions the knowledge is waiting in the subjects’ interior to be uncovered, uncontaminated by the miner. ... the value of the end product, its degree of purity, is determined by correlating it with an objective, external, real world or to a realm of subjective, inner, authentic experiences.

This can be contrasted with the *traveller* metaphor, which understands the interviewer as

a travel[l]er on a journey that leads to a tale to be told upon returning home. The interview travel[l]er wanders through the landscape and enters into conversations with the people encountered. The travel[l]er explores the many domains of the country, as unknown territory or with maps, roaming freely around the territory ... What the travel[l]ing reporter hears and sees is described qualitatively and is reconstructed as stories to be told to the people of the interviewer’s own country, and possibly also to those with whom the interviewer wandered. ... The journey may not only lead to new knowledge; the travel[l]er might change as well. The journey might instigate a process of reflection that leads the interviewer to new ways of self-understanding, as well as uncovering previously taken-for-granted values and customs in the travel[l]er’s home country.

While the *miner* metaphor captures a modern social sciences' understanding of knowledge as 'given' (Kvale, 1994, p. 5), the *traveller* metaphor emphasises the postmodern notion of the construction of knowledge through the interaction of people *via* conversation and dialogue. (Kvale, 1994, p. 11).

In qualitative inquiry, attempts are often made to understand and give *meaning* to observed and/or experienced phenomena. This orientation acknowledges that human phenomena are complex and that the *meaning* of a phenomenon being investigated can be determined only by obtaining data from informants that have multiple subjective understandings. In this framework, there is the recognition that informants have knowledge that can be imparted to the researcher, and that informants are not merely subjects to be observed and studied at a distance.

12.4.2 *Common features of qualitative data analysis*

According to Miles and Huberman (1994, p. 9), common features of qualitative data analysis include:

- (i) the affixing of codes to a set of field notes or transcripts drawn from observations or interviews;
- (ii) reflection by the researcher on the data collected;
- (iii) review of the raw data to seek various interpretations. This involves the identification of "similar phrases, relationships between variables, patterns, themes, distinct differences between subgroups, and common sequences" in the data;
- (iv) the isolation of "the patterns and processes, commonalities and differences", and taking them out into the field in the next wave of data collection. For example, after each interview with an informant, the researcher will often reflect and analyse the information which can lead to the modification of the questions that will be asked in subsequent interviews;
- (v) in some types of qualitative inquiry, an attempt is then made to determine a small set of

generalisations that cover the consistencies discerned in the data;

- (vi) the generalisations determined are confronted with a formalised body of knowledge consisting of constructs or theories.

Clearly, data collection and its analysis in qualitative research is not a simple two step process as in some quantitative research methods. The collection and analysis of data can often occur at the same time. Qualitative data gathering and analysis is often a cyclic process that continues until the researcher reaches a point of 'saturation' where the process stops. The term 'saturation' in some types of qualitative research refers to that point in the research process where the researcher believes that enough information has been collected and analysed so that a *meaningful* interpretation of the phenomenon, or life experiences of the people involved in the study, can be made. Tentative conclusions can then be drawn and organised according to particular issues for the final report.

It should be noted that the findings of a single qualitative research project are unique to the phenomenon studied in its unique sociocultural-historical setting. When writing up a qualitative research report, the researcher will often make no claims that the findings can be generalised to a larger population of people. It is possible, however, that the *meaning* of a phenomenon obtained in one setting could give other researchers insights into the phenomenon of study occurring in a *similar* setting (Burns & Grove, 1993, p. 29).

12.5 The Role of Theory in Naturalistic Inquiry and Qualitative Research

In the study of any particular TCA phenomenon, it could become apparent over time that the theory offered to account for the phenomenon is poorly developed and does not explain the phenomenon accurately. In such instances, naturalistic inquiry and qualitative research designs might be suited to generate new theory which could provide a better account, or understanding, of the phenomenon being investigated (De Poy & Gitlin, 1993, p. 29). The overall sequence of the process is summarised in Figure 12.1.

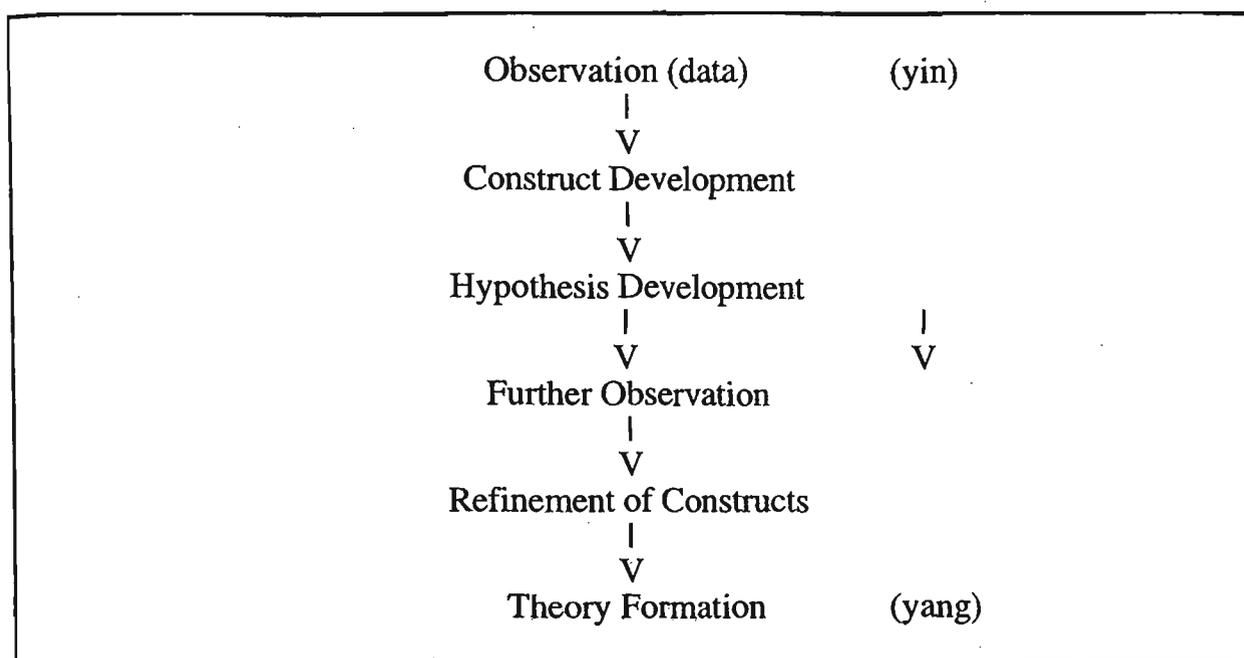


Figure 12.1 The Role of Theory in Naturalistic Inquiry/Qualitative Research (based on De Poy & Gitlin, 1993, p. 38)

The decision to use an experimental-type research design or qualitative research methods depends, in part, on the *level* to which the theory has been developed for the phenomenon being investigated (De Poy & Gitlin, 1993, p. 39). If current theory provides a poor account of a particular TCA phenomenon, then a qualitative research strategy might be appropriate to generate a more sophisticated or comprehensive theory to explain or understand the TCA phenomenon.

Qualitative inquiry can develop theory through the process of induction. One of the purposes of qualitative research is to develop theory from careful observation and empirical data. In some forms of qualitative inquiry, theory is said to *emerge* from the data. This is in contrast to experimental-type research, where a theory while it is being evaluated is assumed to be true. Qualitative inquiry cannot be said to be atheoretical since all researchers come to research phenomena with some preconceived beliefs, assumptions and ideas. It is, however, desirable that these theories be suspended if possible, until a theory 'emerges' from the data. In some forms of qualitative inquiry, as in Glasser and Strauss's (1967) *grounded theory*, attempts are made to link the emergent abstract concepts and constructs developed by the researcher to the observations and other data recorded during the research.

12.6 Types of Qualitative Research that can be Employed in the Field of TCA

12.6.1 *Grounded theory*

Grounded theory is a type of qualitative research method developed by Glasser and Strauss (1967) that principally uses the inductive process of *constant comparison* to generate theory. In this research method, data collection often involves observation and interviews with informants. The purpose of this method is to develop theory, the theory being 'grounded' in the context in which the phenomenon occurs. The theory that is developed by the researcher is said to *emerge* from the data collected and is 'grounded' in the data. This method is used to compare data to discover differences and similarities within the phenomenon being examined. The method of grounded theory allows categories to be determined and enables the exploration of differences within categories. Using the language of Chinese philosophy, the process of constant comparison looks for the *yin* within the *yang* and the *yang* within the *yin*. Such analyses enable relationships to be found within data. This is accomplished through a cyclic process of 'coding', analysis, and recoding until a theory is obtained. Morse and Field (1995, p. 6) state that the "end product of grounded theory is to develop midrange theory that describes a *process*." Glasser and Strauss claim that the method of *grounded theory* can be used to both generate and verify theory. The method of *grounded theory* would seem congruent with the philosophy and practice of TCA in the sense that the theory generated is derived from careful observation, empirical data, experience and reflection.

12.6.2 *Phenomenological research*

Phenomenological research is a general term for an approach to research derived from the phenomenological philosophy of people including Husserl, Kierkegaard, Schutz, and Merleau-Ponty.²⁶⁴ According to Van Manen (1990 cited in Morse and Field, 1995, p. 22) the "phenomenological tradition seeks to understand the lived experiences of individuals and their

²⁶⁴ For accounts of phenomenology and phenomenological research, see J. Cheek *et al.*, 1997; S. Toombes, 1992; N. Burns & S.K. Grove, 1993; J.M. Morse & P.A. Field, 1995, and J.A. Holstein & J.F. Gubrium, 1994.

intentions within their 'life-world'." (see also chapters 5 & 7). The phenomenological research approach could be used in the discipline of TCA to gain a better understanding of human subjective experiences such as pain, illness, health and wellbeing.

One goal of the phenomenological research method can be to provide an accurate description of the phenomenon being studied and *not* the development of theory as in 'grounded theory' (Morse and Field, 1995, p. 22). Sometimes phenomenological researchers attempt to find the *essence*, or meaning of a phenomenon without reference to a prior theoretical framework. The phenomenologist believes that for a phenomenon to be fully understood, it is first necessary to temporarily suspend one's own beliefs about the subject in order to fully comprehend the situation of which one is a part. This is accomplished through 'bracketing', which divests the subject studied of its accepted meanings and values so that only 'pure' phenomena remain. For example, Toombes (1992) achieved this in one study by removing the medical values and meanings demanded by the biomedical-positivist model of health and disease and examining the phenomena that remained for the patient experiencing the effects of illness.

In the discipline of TCA, a phenomenological research approach could be utilised to gain a better understanding of the nature of *qi* during the TCA practitioner-client encounter. This could be achieved by interviewing and monitoring clients while they are being needled during TCA therapy, so as to gain insight into the sensations that can be experienced when *qi* is manipulated through needling. Researchers have already conducted some work in this field and have found that a range of sensations can be experienced by both the client and the practitioner when acupuncture points are needled and a *de qi* sensation is obtained (O'Conner and Bensky, 1981, p. 411). Research of this type could be of value in determining the suitability of points on the surface of the skin for use as placebo controls in randomised controlled trials. For example, in single-blind randomised controlled trials in which a 'sham' acupuncture control is used (see chapter 10), points on the surface of the skin are needled that are believed to be therapeutically inactive in terms of TCM theory. A comparison of the sensations *experienced* by the patient when classical and 'sham' acupuncture points are needled could help to determine if the 'sham' acupuncture control is indeed a suitable control that can be used in research to determine the efficacy of TCA. If patients could distinguish different sensations between

classical acupuncture points and other points on the skin when needled, this could result in the 'blind' being broken. On the other hand, if it was found that there are distinct differences in sensation between the two types of points when needled, this might provide some support for the TCA theory that classical acupuncture points have particular 'energetic' functions.

A phenomenological approach could have been used by TCA practitioners in China to originally map the acupuncture channels. It has been claimed that a small percentage of people (approximately 5%) are sensitive to acupuncture needling and have the ability to feel sensations along the theoretical courses of acupuncture channels after classical acupuncture points are needled (Buck, 1986). This phenomenon has been observed in 'naive' subjects with no prior knowledge of the theoretical location of the acupuncture channels or acupuncture points (Buck, 1986, p. 15). TCA practitioners explain this sensation experienced by patients as the movement of *qi* along the acupuncture channel. This perception of the movement of *qi* along acupuncture channels has been termed *propagated needle sensation* and can be induced by traditional acupuncture needling techniques such as the '*green dragon wags its tail*' (Buck, 1986). The acupuncture channel system could have been originally mapped by the Chinese by using such needling techniques and monitoring the sensations and experiences reported.

Alternatively, the course of the acupuncture channels could have been determined through meditation.²⁶⁵ The original method of mapping the acupuncture channels in China would seem to have required a phenomenological approach involving subjective data. It would appear that many of the qualities of *qi* can only be known by *experiencing* them through changes in subjective states of consciousness. Confirmation of the pathways of the acupuncture channels might be achieved by researchers measuring *qi* 'objectively' by using radioactive tracers or

²⁶⁵ It has been suggested that the course of the acupuncture channels could have been determined by 'highly evolved sages' through meditation. Tsung Hwa Jou (1983, p.143) claims that Daoists could increase their vitality and health by circulating the *qi* through meditation. He suggests that for a person who practises one type of Daoist meditation, the *qi* can be felt passing along the *Du* and *Ren* channels, and as the *qi* passes through each of the acupuncture points on these channels a "distinct physical phenomenon" can be experienced.

using electronic measuring instruments (*e.g.* ohm-meter).²⁶⁶

12.6.3 *Hermeneutics*

Hermeneutics is an interpretive method that the researcher of TCA could use to *understand* or discover the *meaning* of a TCM text or a phenomenon in human terms. The term, hermeneutics, is now used to describe a way of inquiry into the understanding of human behaviour and action. Rowan (1981b, p. 132) remarks of modern hermeneutics that it

is not a special process, totally different from everyday human understanding; it is just one example of an everyday process through which persons make sense of their world. *All* understanding is hermeneutical, taking place, and to a very large extent determined by, our finite existence in time, history, and culture.

One of the aims of hermeneutics is to understand the *meaning* of a phenomenon rather than to give an account or explanation of it in scientific empirical terms. Dilthey (cited in Little, 1995, p. 154) claims that *understanding* involves a “process of comprehending the parts through an appreciation of the whole.” This process can be contrasted with the seeking of *explanations*, as in postpositivism, enabling the prediction and control of phenomena. Miller and Crabtree (1992) claim that hermeneutics “is a movement beyond phenomenology in that the goal of hermeneutic research is to use interpretation of lived experience to better understand the political, historical and sociocultural context in which it occurs.”

Hermeneutics was first used in the interpretation of biblical texts (Makkreel, 1992) and could be used to study classical Chinese medical texts. A premise of hermeneutics is that the parts of a text can be fully interpreted and understood only in the context of the text as a whole. The hermeneutical interpretation of *meaning* is characterised by what has been termed a *hermeneutical circle*. Kvale (1994, p. 47) explains that

²⁶⁶ Electronic instruments have been used to locate acupuncture points because of a lowered electrical resistance on the skin at the acupuncture point compared to the surrounding skin (Helms, 1995, pp. 20-21). Dr Koosnadi Saputra at a seminar “Acupuncture and Modern Science” at the Victoria University of Technology (Footscray Campus), 20 February 1998 reported that his research team has partly mapped some traditional acupuncture channels using radioactive isotopes. Other research that has attempted to trace the acupuncture channels ‘objectively’ has been reported by Helms (1995, pp. 22-25), as an example, see Darass *et al.*, 1993.

[t]he understanding of a text takes place through a process in which the meaning of the separate parts is determined by the global meaning of the text, as it is anticipated. The closer determination of the meaning of the separate parts may eventually change the originally anticipated meaning of the totality, which again influences the meaning of the separate parts, and so on. In principle, such a hermeneutical explication of the text is an infinite progress, while it ends in practice when one has reached a sensible meaning, a valid unitary meaning, free of inner contradictions.

This approach has relevance for the study of classical traditional Chinese acupuncture texts, since from a hermeneutic perspective, the individual chapters of Chinese medical texts such as the *Nei Jing* can be interpreted *meaningfully* only in the context of the *whole* text.²⁶⁷ There is also the acknowledgement in hermeneutics that the interpretation of a text will be formed and influenced by the theories, beliefs and understandings of the interpreter. Little (1995, pp.154-155), in his examination of Gadamer's hermeneutic philosophy, suggests that

[i]nterpreters inevitably hold beliefs and conventions inherited from the past and expressed by the present. Each act of interpretation is irretrievably involved with this synthesis of values, and the romantic notion of hermeneutics as an objective and timeless science of interpretation is not adequate. The prejudices of interpreters are part of the context of a society. Interpreters expand their own horizon of understanding by their work of interpretation. Their success as interpreters depends on their imaginative capacity to find the questions posed by the text or the work of imagination being studied.

Little's claims have implications for the use of classical TCM literature, since it reminds us that translations of texts such as the *Nei Jing*, and commentaries on them, will be coloured by the beliefs and preconceptions of the interpreter. Also, in terms of the hermeneutical approach, not all interpretations of a text will be equal. Kvale (1996, p. 245) explains that Ricoeur (1971) rejected

the position that all interpretations of a text are equal; the logic of validation allows us to move between the two limits of dogmatism and skepticism. Invoking the hermeneutical circle of falsifiability, he [Ricoeur] describes validation as an argumentative discipline comparable to the juridical procedures of legal interpretation. Validation is based on a logic of certainty and of qualitative probability, where it is always possible to argue for or against an interpretation, to confront interpretations and to arbitrate between them.

²⁶⁷ It could also be noted that, in a similar way, individual Chinese characters can only be meaningfully interpreted in the context of their surrounding characters.

Kvale (1994, p. 51) notes that the qualitative research interview has been handled from a hermeneutical perspective by Carson (1986) and Weber (1986). It is possible that written case studies of TCA clinical encounters could be treated in a similar way. Kvale (1994, pp. 47-51) however notes some important differences between literary and interview texts:

(i) Traditionally, hermeneutics has been used for the interpretation of finished texts, whereas a research interview, or TCA case study involves the generation and interpretation of a text. Therefore interviewers are “cocreators of the texts they interpret, and they may negotiate their interpretations with their subjects. The interview text is thus not a pre-given literary text, but emerges in the same process as its interpretation; it involves both the creation and the negotiated interpretation of the text.” (Kvale, 1996, p. 50);

(ii) A literary text is a finished work of communication which originates outside of the situation in which it was created. In contrast, the interview is “tied to a specific interpersonal situation, it develops more or less spontaneously, the subjects addressing themselves to the interviewer by words but also through gestures and implicit references to their common situation.” The transcribed interview will hence be an “incomplete account of the wealth of meanings expressed in the lived interview situation.” (Kvale, 1996, p. 50);

(iii) Literary texts are highly condensed expressions of meanings which are well-articulated. In contrast, transcribed interviews are often repetitious, vague, and with many digressions. To arrive at the meanings intended by the interviewee, it may be necessary to go through a process of clarification and condensation. However, Kvale notes that what might appear from the standpoint of a ‘pure’ meaning interpretation to be ‘noise’, might produce “important information through the deeper psychological interpretation of nonintended meanings as a form of ‘depth hermeneutics’.” (Kvale, 1996, pp. 50- 51).

12.6.4 *Case study*

The case study has been used extensively in the discipline of psychology and a form of case study can be found in TCM research literature. This is not surprising considering that a focus

of TCM is on the unique treatment needs of individual clients. Single case studies are usually qualitative in nature; however they can take on the nature of quantitative research (see chapter 8.14.4, single subject experimental design $n=1$).

Volker Scheid (as reported by Gould, 1996, p. 57), at the first Acupuncture Research Symposium suggested that the “systematically recorded single case study could be posited as the ‘gold’ standard in Chinese medical research.” Scheid (1994, p.19) had previously noted that research had generally attempted to assess “‘Chinese medicine’ as a therapeutic system, rather than evaluate the treatments of individual practitioners.”

A focus on case study research by TCA practitioners-researchers could be expected to improve the recording and documentation of clients’ medical history and responses to TCA therapy. Stake (1994, p. 238) claims that to determine what is unique and of interest in a single case, the case researcher should collect data on the following: (i) the nature of the individual case; (ii) the historical background of the case; (iii) the physical setting of the case; (iv) the contexts of the case including the political, legal, economic and aesthetic; (v) other case studies through which the particular case is recognised; and (vi) other informants through whom the case can be known.

Diebschag (1994, p. 55) notes two advantages of single case studies. First, case studies “do not create a conflict between clinical and research priorities, as the research is applied as part of the clinical treatment, and reflects actual clinical practice.” Second, there is no problem of recruiting large numbers of clients which could result in prohibitively high costs. Canter and Nanke (1993, p.104) note that the case study also allows a more detailed inclusion of the experience of both the therapist and the patient being treated. Kazdin (1982) claims that the detailed analyses of individual cases can: (i) provide a focus for discussion as to how particular problems can be managed; and (ii) generate hypotheses as to the significant factors involved in illness processes and treatment procedures which could inform subsequent larger controlled studies.

The single case study also has value in TCA teaching settings where it can be used to integrate

TCA theory with clinical practice. Many TCA texts specifically focus on case studies which provides some evidence of the perceived value of the single case study by both academics who teach TCA and members of the TCA profession.²⁶⁸

12.6.4.1 *Intrinsic and instrumental case studies*

Stake (1994), in his examination of case study research, differentiates between two types of case study, the *intrinsic* case and the *instrumental* case. He claims that the *intrinsic* case study is undertaken when one wants to better understand a particular case. Stake (1994, p. 237) notes that the intrinsic case

is not undertaken primarily because the case represents other cases or because it illustrates a particular trait or problem, but because, in all its particularity and ordinariness, this case itself is of interest. The researcher temporarily subordinates other curiosities so that the case may reveal its story.

The intrinsic case study would seem to relate to Lyotard's (1984) idea of knowledge production through open interviews where people tell stories about their lives. The intrinsic case study can be contrasted with what Stake (1994, p. 237) calls the *instrumental* case. In the instrumental case study

a particular case is examined to provide insight into an issue or refinement of theory. The case is of secondary interest; it plays a supportive role, facilitating our understanding of something else. ... The choice is made because it is expected to advance our understanding of that other interest.

Canter and Nanke (1993, p.104) suggest that the main limitation of single case studies (from a postpositivist perspective) is that they

may be unrepresentative and reflect the idiosyncrasies of a particular therapeutic intervention in a way which cannot be generalized to other contexts. This does not invalidate single case studies provided they are not used to address general questions such as the efficacy of particular treatments.

Diebschag (1994, p.55) suggests that a series of single case acupuncture studies could be designed and analysed collectively to generate predictive data. Similarly, Stake (1994, p. 237)

²⁶⁸ As examples see MacPherson and Kaptchuk, 1997 and Dengbu, 1994.

suggests that researchers could study a number of cases jointly in order to examine a population or phenomenon. This he calls *collective case study*. This is not the study of a collective, but rather an instrumental study extended to several cases.

The case study could be seen as a first step toward generalization (Campbell, 1975); however, Stake (1994, p. 238) warns researchers that damage can occur “when commitment to generalize or create theory runs so strong that the researcher’s attention is drawn away from features important for understanding the case itself.” Stake (1994, p. 245) adds that while one or a few case studies are a poor representation of a population, and poor grounds for advancing “grand generalization”, a single case as a negative example can establish limits to grand generalization. Stake believes that case studies to be of value in suggesting complexities for further investigation, refining theory, and helping to determine the limits of generalisability.

12.6.4.2 *Forms of generalisability*

Kvale (1996, pp. 232-233) suggests that in relation to case studies it is useful to identify three types of generalisation : (i) statistical generalisation; (ii) naturalistic generalisation; and (iii) analytical generalisation.

(i) Statistical generalisation is formal and explicit and requires subjects to be selected at random from a population. Statistical generalisation cannot often be used with case studies because usually the subjects are not selected at random but by some other criterion (*e.g.* accessibility).

(ii) Naturalistic generalisation depends on personal experience. Kvale (1996, p. 232) states that naturalistic generalisation “develops for the person as a function of experience; it derives from tacit knowledge of how things are and leads to expectations rather than formal predictions; it may become verbalized, thus passing from tacit knowledge to explicit propositional knowledge.” (see chapter 6). This is one method that could have been utilised by TCA practitioners in China’s distant past to make predictions for TCA therapy.

(iii) Kvale (1996, p. 233) states that *analytical generalisation*

involves a reasoned judgment about the extent to which the findings from one study can be used as a guide to what might occur in another situation. It is based on analysis of the similarities and differences of the two situations. ... By specifying the supporting evidence and making the arguments explicit, the researcher can allow readers to judge the soundness of the generalization claim

Kennedy (1979, cited in Kvale, 1996, p. 233) suggests that the clinical practitioner can draw on “knowledge of the general case to form interpretations of and actions in the specific case.” According to Kennedy this can only be done if the attributes compared are relevant and the descriptions of the cases are rich and thick enough for comparisons to be made. Kennedy (1979, p. 672) states that, “[I]ike generalizations in law, clinical generalizations are the responsibility of the receiver of information rather than the original generator of information, and the evaluator must be careful to provide sufficient information to make such generalizations possible.”

12.6.5 *Etymological studies*

Etymology is the study of a word’s origin and development. Examples of etymological studies in TCM are those studies of Claude Larre and Elizabeth Rochat de la Vallee (1995) that have provided insights and a better understanding of Chinese medical terms through the examination of Chinese characters that symbolise Chinese concepts. In the field of TCA, further etymological research could generate a fuller understanding of TCA concepts through the study of Chinese characters of classic TCM medical texts. For example, an examination and analysis of the names and *meanings* of the Chinese characters of traditional acupuncture points could result in the ascription of new energetic functions to the acupuncture points.²⁶⁹ This type of research could develop new theory and inform TCA practice

12.6.6 *Ethnography*

Historically, the method of inquiry known as *ethnography* evolved from cultural anthropology. Many of these studies tended to focus on the cultural patterns of people living in villages.

Morse and Field (1995, pp. 25-26) note that “[e]thnography is always informed by the concept

²⁶⁹ For an account of this idea, see P. Ferrigno, 1997, p. 95.

of culture and attempts to develop concepts and understanding of human behaviours from the insider's point of view." The ethnographer uses multiple methods to gather data, including participant observation, interviews, and field notes.

In this research method, the researcher lives or works in a particular cultural setting so as to obtain information and data about that setting. This process involves the systematic collection and analysis of qualitative data. Ethnographic analysis ideally "moves beyond description to reveal or explain aspects of social patterns or observed conduct." (Morse and Field, 1995, p. 27). The aim of the ethnographer is to develop a theory of cultural behaviour that explains the phenomena that occurs in that setting (Leininger, 1985).

Spradley (1979) notes that ethnographers can learn from people rather than studying them as subjects. Ethnographies are holistic, contextual, and reflexive (Boyle, 1994). Ethnography is hence a method that is congruent with the nature of TCA practice and suited to particular TCA research questions. Ethnography could be used by researchers in the field of TCA to obtain a more comprehensive understanding of traditional acupuncture practice by comparing and contrasting the different forms of TCA that are practised in various countries and in different cultural settings. The result of such research could contribute to an understanding of the effect of culture on the practice of TCA.²⁷⁰

12.6.7 *Critical social theory*

Critical social theory started in the 1920s and has been influenced by the writings of the philosopher Karl Marx [1818-1883] and later by Habermas (1971).²⁷¹ The thrust of critical social theory is that social phenomena can only be understood when examined within a historical context. Some philosophers contend that societies operate as 'closed systems' of thought that can lead to constraints that impede the personal growth of individuals and their free and uncoerced participation in that society (Burns and Grove, 1993, p. 83).

²⁷⁰ As an example, see J. Farquar, *Knowing Practice: The clinical encounter in Chinese Medicine*, 1994.

²⁷¹ For an account of critical social theory and its relevance to health workers, see J. Cheek *et al.*, *Society and Health: Social theory for health workers*, 1997.

In regard to TCA and health policy, researchers using critical social theory might attempt to construct a picture of Biomedicine that exposes its prevailing methods of domination in the field of health care. Through such a critical analysis, change could be encouraged to improve the weaknesses in the current health care system (see chapter 1.10). Such an analysis could involve showing that the current 'crisis' in health care is due to the dominance of Biomedicine with its limited (or flawed) philosophical premises and conceptions of health and illness. Through the use of critical social theory, changes to government health care policy could be achieved by challenging the tacit philosophical assumptions of the biomedical paradigm. Such research could suggest a greater role for TCA in future mainstream health care.

12.6.3 *Focus groups*

A focus group involves the examination of a subject by a group of participants who are knowledgeable about the subject under investigation (see Morse & Field, 1995, pp. 31-33). Focus groups often involve unstructured interviews with small groups of people that are facilitated by the researcher. Focus groups can be used to explore beliefs about health and disease or cultural values (Bowling, 1997b). They could also be utilised to obtain information from TCA practitioners on guidelines to improve TCA practice, factors that they regard as impacting on therapeutic outcomes, and their understandings of the application of TCM theory in practice. According to Kitzinger (1996), the group process can enable people to explore their views in ways that might be more difficult in face-to-face interviews.²⁷²

12.7 **The Role of Qualitative Research Methods in the Improvement of TCA Clinical Practice**

There are many styles of TCA practised within China and Western countries (Ernst & White, 1997; Dale, 1997a; Dale, 1997b; Birch 1997a; Birch 1997c) that might have different rates of clinical effectiveness. From a neopositivist (or postpositivist) perspective, the relative effectiveness of different sets of TCA clinical practice guidelines could be determined through a

²⁷² See also R. Krueger, *Focus groups: A practical guide for applied research*, 1993.

cycle as outlined by Mosey (1992, pp. 193-216).²⁷³ Figure 12.2 summarises the steps involved in this process. Through such a cyclic process, the adequacy of sets of guidelines for clinical TCA practice could be developed, refined, and assessed.

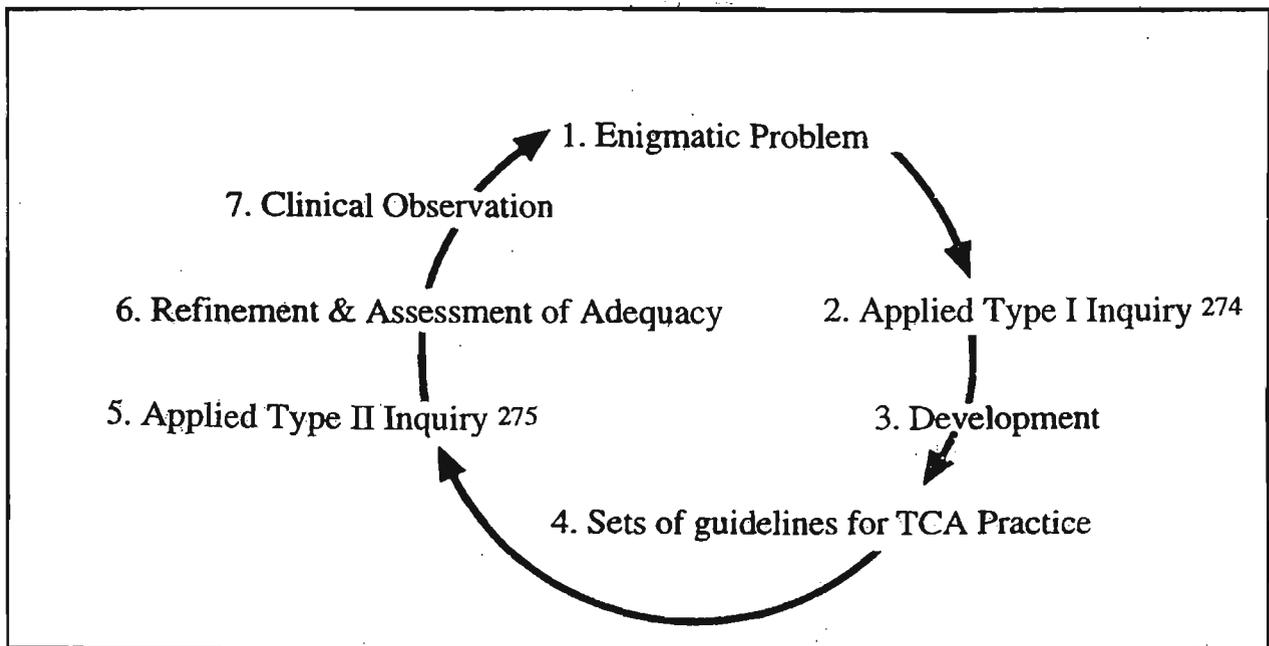


Figure 12.2 A schematic representation for the development, refinement, and the assessment of the adequacy of sets of guidelines for TCA practice (Adapted from Mosey, 1992, p. 194, for TCA).

- (i) The first step involves the identification of a problem that needs to be solved. This could be accomplished through a qualitative method utilising qualitative research interviews or a focus group.

²⁷³ According to the Institute of Medicine (1990, p. 8), *clinical practice guidelines* are systematically developed statements to assist practitioners and patients to make decisions about appropriate health care for specific clinical circumstances. See also the National Health and Medical Research Council, Quality of Care and Health Outcomes Committee. *Guidelines for the Development and Implementation of Clinical Practice Guidelines*, 1995a.

²⁷⁴ Applied Type I Inquiry involves “the use of the methods of science and of theoretical information to formulate some sort of guidelines for action. In relation to health professions, these guidelines are referred to as *sets of guidelines for practice*” (Mosey, 1992, p. 4)

²⁷⁵ Applied Type II Inquiry in this case refers to the refinement and assessment of the adequacy of sets of guidelines for practice (Mosey, 1992, p. 195).

- (ii) Relevant TCA theories and empirical data that relate to the problem are identified.
- (iii) A selection and synthesis of postulates is undertaken to form a theoretical foundation.
- (iv) Guidelines and treatment principles are derived for problem resolution from the theoretical foundation of TCM.

The guidelines developed could then be evaluated using a quantitative experimental design such as the pragmatic randomised clinical trial (PRCT) using active controls (chapter 10.18). It should be noted that such an approach has value only from a neopositivist (or postpositivist) perspective. Some acupuncturists with a more phenomenological orientation to practice might claim that no set of guidelines can be developed to guide the TCA practitioner through their unique encounters with clients (see chapter 7).

12.8 Other Research Methods for TCA

12.8.1 *Clinical audit*

The clinical audit is one practical and low cost method for TCA practitioners to conduct meaningful research in their own clinics, or in university TCA teaching settings.²⁷⁶ In the field of TCA, clinical audit can be used to assess the quality of TCA practice, evaluate its therapeutic effectiveness, and, where necessary, suggest recommendations to change TCA clinical procedures so as to improve patient outcomes. Lewith and Davies (1996) claim that clinical audit is a process that involves four steps: (i) the determination of what you think is happening (*i.e.* in a particular process, program or practice); (ii) the decision as to what needs to happen (or what needs to be improved); (iii) the introduction of a change that might bring about the desired outcome; and (iv) evaluation of the result. This audit cycle can be repeated as many times as is necessary to bring about the desired objective. Through this process TCA practice could be developed and improved (see Figure 12.3 below, p. 367).

The clinical audit can take several forms depending on its purpose:

²⁷⁶ See R.W. Rees, 1997.

- (i) it can be used to generate statistics and profiles of TCA patient populations. Such audits could reveal the types and numbers of patients presenting with particular conditions, and could provide some indication of the outcome of TCA therapy for these conditions (Diebschag, 1994, p. 52). The analysis of such data could suggest conditions and syndromes that could be further investigated by controlled clinical trials;
- (ii) it could be used to inform TCA practitioners of the types of conditions and treatment approaches used by TCA practitioners and the perceived effectiveness of these approaches;
- (iii) the collection of statistical data through the clinical audit could determine the extent of use of TCA, which could be of value to government health policy officers in making decisions in relation to TCA (Diebschag, 1994, p. 52).

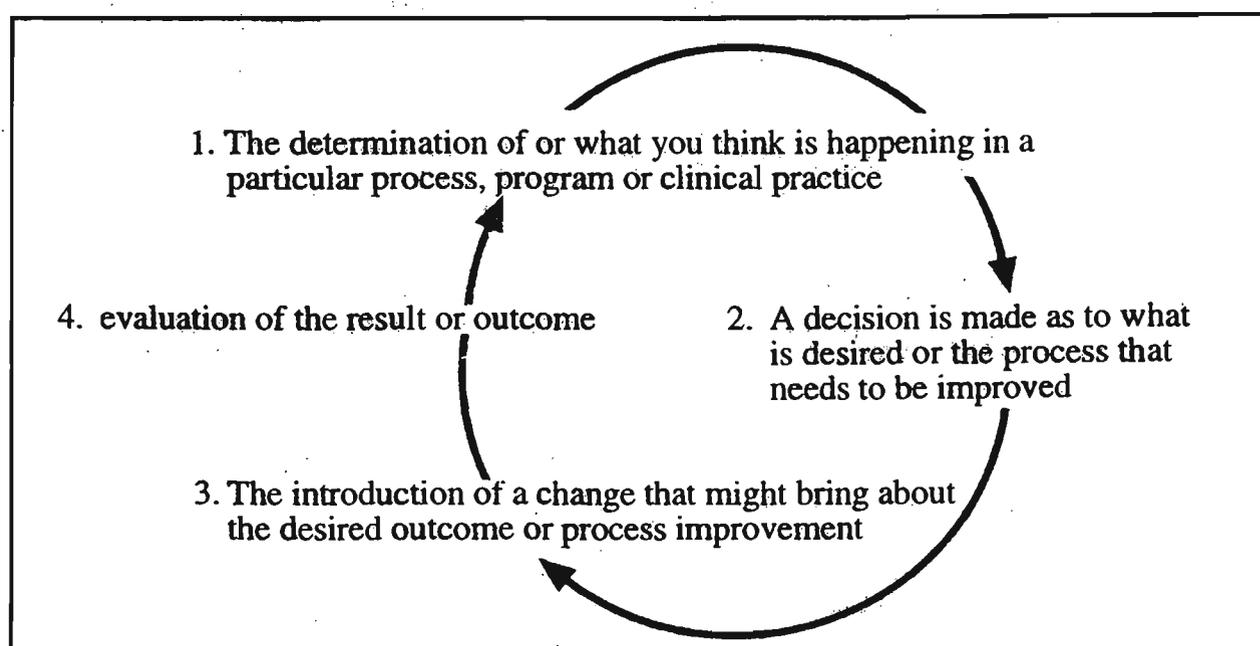


Figure 12.3 The Audit Cycle (based on G. Lewith and P. Davies, 1996, p. 233 from J. Hughes and C. Humphrey, 1990)

12.8.2 *Philosophical inquiry*

Philosophical inquiry is directed and guided by the philosophical questions posed (Burns and Grove, 1993). Philosophical inquiry can involve the interpretation of many types of data and often uses dialectical reasoning. This form of inquiry can involve the examination of an idea,

subject or phenomenon by examining conceptual meanings, raising questions, proposing answers, and then suggesting the implications of those answers. The purpose of philosophical inquiry is often to examine and develop theories of meaning through concept analysis. This approach can be used in TCA research to further examine the nature of TCA, TCA knowledge production, and to study ethical issues related to TCA practice and research.

12.8.3 *Historical research*

Historical research methods have been utilised by some researchers of TCM. While historical research is similar in some respects to qualitative research, there are major differences between the two approaches. The focus of historical research is on the interpretation and narration of past events, while most qualitative studies focus on current events. The data of historical research can be obtained from written records, diaries, verbal reports and artifacts (Krampitz, 1981). Burns and Grove (1993, p. 31) state that through historical research, past mistakes can be “examined to facilitate an understanding of an effective response to present situations.” They also suggest that “this type of research has the potential to provide a foundation for and direct the future movements” of a profession. Examples of historical studies in TCM include those by Paul Unschuld (1985) and Lu Gwei-djen and Joseph Needham (1980).

12.8.4 *Primary prevention and health promotion studies*

Primary prevention and health promotion studies could also be used by researchers of TCA.²⁷⁷ Such studies attempt to measure the effect of primary prevention by recording reductions in variables that are termed *indicators*. For example, the effectiveness of regular TCA therapy to maintain wellbeing and prevent stress could be evaluated by comparing a treatment group with another group in the community which does not use TCA. Longitudinal studies using extremely large samples and suitable research instruments would be required to measure appropriate indicators.

²⁷⁷ See Burns and Grove (1993) for an account of primary prevention and health promotion studies.

12.9 Summary

In this chapter, the uses of qualitative inquiry and other research methods for examining TCA have been examined. Consideration has been given to the various qualitative and interpretive methods of inquiry for generating TCA theory, understanding the nature and meaning of TCA , and improving TCA practice. Considering the common features and themes of qualitative research and TCA philosophy and practice, qualitative research methods deserve to have a more important role in the future development of TCA knowledge.

CHAPTER 13

CRITERIA FOR EVALUATING THE QUALITY OF TRADITIONAL CHINESE ACUPUNCTURE RESEARCH

In this chapter the criteria for evaluating the quality of TCA research will be explored. It will become evident through the examination that the concept of 'validity' has diverse meanings in the various paradigms of research. It will be argued that the criteria for evaluating the quality of TCA research are to an extent dependent upon the paradigm of research to which one subscribes. Positivist conceptions of truth and validity will be considered, as will other, postmodern notions which have led to the idea of validity as social construction. This analysis will draw on the validity concepts examined by Kvale (1996). Attention will be also be given to the defensibility of TCA knowledge claims in terms of 'communicative' and 'pragmatic' validity.

13.1 Modern and Postmodern Understandings of Validity

Kvale (1996, p. 236) has noted that in ordinary language dictionaries, the term *validity* refers to the "truth and correctness of a statement". A valid statement is one that is "sound, well grounded, justifiable, strong, and convincing." Kvale (1996, p. 236) claims that as a consequence, ascertaining validity involves issues of both knowledge and truth: therefore, what constitutes valid knowledge is dependent upon the answer to the philosophical question of what is truth. Kvale (1996, p. 238) claims that

[w]ithin philosophy, three classical criteria of truth are discerned - correspondence, coherence, and pragmatic utility. The *correspondence* criterion of truth concerns whether a knowledge statement corresponds to the objective world. The *coherence* criterion refers to the consistency and internal logic of a statement. And the *pragmatic* criterion relates the truth of a knowledge statement to its practical consequences.

Kvale (1996, pp. 238-239) explains that

[a]lthough the three criteria of truth do not necessarily exclude each other, they have each obtained strong positions in different philosophical traditions. The correspondence criterion has been central within a positivist social science where validity of knowledge is expressed as a degree of correspondence with an objective reality. The coherence criterion has been strong in mathematics and hermeneutics. The pragmatic criterion has prevailed in pragmatism and to a certain extent in Marxist philosophy.

13.1.1 *Validity and positivism*

The correspondence criterion has been fundamental to positivist and postpositivist understandings of what constitutes valid knowledge. Denzin and Lincoln (1994, p.100) claim that in positivist and postpositivist paradigms the criteria for judging the quality of an inquiry are the four conventional benchmarks of rigour:

- (i) *internal validity*. This is the degree to which research findings correctly map the phenomena of the 'one objective reality' (*i.e.* isomorphism of findings with reality).
- (ii) *external validity*. This is the extent to which research findings from one setting can be generalised to other similar settings.
- (iii) *reliability*. This is the extent to which research findings can be replicated by other researchers using the same research design.
- (iv) *objectivity*. This relates to the degree to which research findings are free of bias. The assumption made here is that the researcher can be neutral or value free, and study phenomena at a distance.

Guba and Lincoln (1994, p.114) claim that the positivist and postpositivist paradigms

depend on the realist ontological position; [for] without the assumption, isomorphism of findings with reality can have no meaning, strict generalizability to a parent population is impossible, the stability cannot be assessed for inquiry into a phenomenon if the phenomenon itself can change, and objectivity cannot be achieved because there is nothing from which one can be 'distant'.

Kvale (1996, p. 231) claims that

[f]rom a postmodern perspective issues of reliability, validity, and generalizability are sometimes discarded as leftovers from a modernist correspondence theory of truth. There are multiple ways of knowing and multiple truths, and the concept of validity indicates a firm boundary line between truth and nontruth.

13.1.2 *Validity and constructionism*

From the perspective of *constructionism* (see chapter 5.4.7), the concept of validity as it is understood in positivism and postpositivism is too narrow to acknowledge the achievements made by many researchers that can be deemed to be significant contributions to human knowledge. Some researchers of TCA might be expected to reject the positivist ‘correspondence theory of truth’ that understands knowledge as a mirror of nature, and which assumes that there are ‘facts’ out there in the real world to which theories of them can correspond. As C. Taylor (1979) has argued, empirical epistemology cannot provide an account for those ‘objective’ facts of human experience that are socially constructed. Salner (1989, p. 69) explains that

[o]nce a ‘correspondence theory of truth’ is challenged, as it is by human science epistemological arguments, the concept of validity must be redefined. From the perspective of human science epistemology, it makes more sense to talk in terms of *defensible knowledge claims* rather than validity per se.

From the perspective of the constructionist paradigm, the quality of research needs to be judged by somewhat different criteria from those of positivism and postpositivism. Constructionists have proposed two sets of quality criteria for their research. The first is that of ‘trustworthiness’ which consists of (i) credibility (paralleling internal validity); (ii) transferability (paralleling external validity); (iii) dependability (paralleling reliability), and (iv) confirmability (paralleling objectivity) (Guba, 1981; Lincoln & Guba, 1985). Kvale (1996, p. 231) suggests that Lincoln and Guba (1985) “have gone beyond the relativism of a rampant antipositivism and have reclaimed ordinary language terms to discuss the truth value of their findings, using concepts such as trustworthiness, credibility, dependability, and confirmability.” A second set of quality criteria that has been proposed is the *authenticity criteria of fairness*, which includes ontological authenticity (enlarges personal constructions),

educative authenticity (leads to improved understanding of constructions of others), catalytic authenticity (stimulates action), and tactical authenticity (empowers action). (Guba & Lincoln, 1989).

Guba (1981) contends that qualitative studies should not be judged by the same standards as those of quantitative studies. He suggests that the canons by which quantitative studies are evaluated are simply inappropriate for qualitative studies. Whereas Strauss and Corbin (1990, p. 250), in a discussion of *grounded theory* (a qualitative method of inquiry, see chapter 12.6.1), claim that most grounded theorists would agree that “the usual canons of ‘good science’ should be retained, but require redefinition in order to fit the realities of qualitative research, and the complexities of social phenomena that we seek to understand.”

13.2 Knowledge Validation: Conviction, Truth and Evidence

Thompson (1972) has raised the question of whether belief, opinion and knowledge are in fact “distinct categories with differing levels of guarantee and truth.” (quoted in Higgs & Tichen, 1995, p. 130). The concepts of truth, conviction and evidence are debated terms. Higgs and Tichen, p.130.) state that, “[k]nowledge (of the individual) is defined as *an awareness of the individual which has current conviction for the individual, gained through the testing of acquired or self-generated understanding*. The individual’s claim to knowledge, therefore, needs to be accompanied by a personal commitment to that claim.” Higgs and Tichen (1995, p. 130) suggest that

[t]o know something is to have a conviction about the validity of what is claimed to be known. Thus knowledge (or the product of knowing) involves an understanding about something which carries with it a high level of conviction. ... an individual may be able to remember information, data or facts but not be convinced of their validity.

On the other hand, Ayer (1956, p. 222 quoted in cited in Higgs & Tichen, p.131) has claimed that when attempting to verify knowledge claims, skepticism of claims should be taken seriously since this will enable one to “to distinguish the different levels at which our claims to knowledge stand”. Therefore, the process of knowing is a continual process of generating,

refining and understanding knowledge (Higgs & Tichen, 1995). Researchers of TCA therefore need to operate like alchemists, separating out the dross from the essence so as to continuously create evermore sophisticated constructions and understandings.

Kvale (1996, pp. 244-245) puts forward a concept that he terms *communicative validity*. Communicative validity involves the testing of the validity of knowledge claims through dialogue. Valid knowledge, according to the concept of communicative validity, is determined as conflicting knowledge claims are debated through dialogue. Salner (1989, p. 52) claims that it is the universal human capacity to “cognitively evaluate, to choose, and to communicate via language” which provides the “fundamental ground from which we proceed to examine the comparative validity of knowledge claims in human science research.” Salner (1996, pp. 52-53) explains that

[t]he outcome of human reasoning is not necessarily “truth”. Rather, the outcome reflects interpersonal (social) agreements to follow certain agreed-upon procedures and forms in making and communicating decisions. These procedures may vary considerably from society to society. Their outcome, however, is not simply an agreement about how to use language. We are not merely producing communally satisfying statements about options. Rather, the outcome is rooted in reality by virtue of the necessity to act decisively in practical situations which have consequences. Thus, innate and universal reasonableness as an avenue to knowledge is inextricably intertwined with trial and error learning which serves as a corrective to the distortion introduced into the free exercise of human cognitive capacities by procedural conventions, language limitations, or the constraints of political force.

The points Salner makes are relevant to TCA practice and research, since if TCA practice is examined, it would appear that many medical decisions that are made by TCA practitioners are pragmatic, based on ‘trial and error’ and draw on innate human reasonableness and an agreed consensus on TCA ideas and procedures.

13.3 Evaluating Competing Knowledge Claims

Like Karl Popper (1968), Polkinghorne (1983) claims that the quest for absolute or certain knowledge through verification needs to be replaced by the conception of defensible knowledge claims. This would change the emphasis from knowledge *verification* to knowledge *falsification*. As Kvale (1996, p. 240) explains

when giving up a correspondence theory of truth as the basis for understanding validity, there is, following Popper, a change in emphasis from verification to falsification. The quest for absolute, certain knowledge is replaced by a conception of defensible knowledge claims. Validation becomes the issue of choosing among competing and falsifiable interpretations, of examining and providing arguments for the relative credibility of alternative knowledge claims.

Polkinghorne (1983) has identified four ways of evaluating competing knowledge claims:

(i) innate and universal human reasonableness; (ii) universal trial and error learning; (iii) tacit knowledge; and, (iv) epistemological pluralism.²⁷⁸ All are congruent with TCM understandings.

In relation to the notion of 'innate and universal human reasonableness', Salner (1989, p. 52) claims that there is substantial evidence from anthropological studies that

human beings, irrespective of the particular society of which they are part, evolve personal and collective strategies and means for making decisions and choosing between competing options for action. These decision making strategies involve reasoning skills which are an outgrowth of universal cognitive capacities (e.g. the abilities to visualize, to imagine, to abstract general categories from particulars, to perceive structural connections).

Salner (1989, p. 53) indicates that there are several implications of the notion of 'human reasonableness' in relation to the validity of human science research: (i) there can be no reasonableness without a "particular cultural form which in effect structures the utilization of human cognitive abilities"; (ii) there can be no 'reasonableness' without a particular language: both language and the cultural form can create and outline the boundaries of a particular discourse; and (iii) the notion of 'reasonableness' is "always naturally constrained by its dependence on a particular human social context (universe or discourse) for its intelligibility; however, some constraints which are the result of human social dynamics (e.g. forceful exclusion, deceit, limited access to information) distort human reasoning and produce results that are un-reasonable." Salner's claims have relevance for the findings of TCA research, since the notion of 'reasonableness' will be conditioned by the credibility and persuasiveness of the TCM discourse.

²⁷⁸ Epistemological pluralism is based on James Ogilvy's (1977) idea as explained by D. Polkinghorne (1983, p. 250) that "there is not *one* truth which corresponds to 'reality'. Instead, there are some truths which hold within communities".

13.4 Verification Principles for the Collection of Data in the Three Realms of Body, Mind and Spirit

The idea that communication and discourse provide the fundamental ground from which people advance to examine the comparative validity of knowledge claims in human science research can be related to Wilber's (1990) verification principles. In chapter one, the idea was introduced that the domains of body, mind and spirit can require different methods of inquiry. Wilber (1990, p. 44) argues that the principles of data accumulation and verification are essentially identical in each realm (body, mind and spirit), but that it is the actual *methodologies* of data accumulation and verification that differ in the three realms. According to Wilber (1990, pp. 31, 32 & 44), valid data accumulation has three basic strands regardless of the domain being investigated:

- (i) The first is an *instrumental* or *injunctive* strand. This takes the form of: if you want to *know* about a particular phenomenon or process, you must *do* certain things or follow a particular set of instructions (Wilber, 1990, p. 31);
- (ii) Wilber (1990, pp. 31 & 44) claims that there also needs to be an *intuitive* or apprehensive strand: “[t]his is a cognitive grasp, prehension, or immediate experience of the object domain (or aspect of the object domain) addressed by the injunction; that is, the immediate *data* - apprehension. He claims that “this is an illuminative *seeing* by the particular eye of knowledge evoked by the injunctive strand.” (Wilber, 1990, p. 32);
- (iii) The *intuitive* or *apprehensive* strand can then allow the possibility of a *communal confirmation* strand. This is a checking of findings, apprehensions or data with others who have adequately completed the injunction and apprehensive strands. Wilber (1990, p. 32) claims that, “[i]f the shared-vision is agreed upon by others, this constitutes a communal or consensual proof of *true seeing*.”

Wilber (1990, p. 45) claims that the three strands mentioned above contain a way to reject any data that are apparently erroneous. The three strand procedure provides a “potential ‘disproof

mechanism””. Wilber’s (1990) verification principles can be understood as a form of communicative validity .

Wilber (1990, p. 49) notes that “a ‘bad’ phenomenological apprehension will simply not mesh with the ground of other phenomenological facts, as embedded and disclosed in intersubjective consensus.” Wilber’s examination of verification principles has relevance for TCA research, since TCA practitioners claim that TCA therapy can affect the mind-body complex that is often referred to in the West as body, mind and spirit. As noted in chapter nine, it is easier to examine the biological body and the rest of the physical realm through the research methods of the natural sciences than it is to investigate the realms of mind, spirit and *shen*. Wilber also correctly notes that it is far easier to find consensus on knowledge of the physical realm than that of the mind. As Wilber (1990, p. 34) notes, “everybody is given the same eye of flesh but different mental outlooks.”

13.5 Pragmatic Validity and TCA

For the pragmatist, truth is that which can assist one to take action that will produce the desired results. According to Kvale (1996, p. 248), the ‘knowledge’ of the pragmatist is “action rather than observation”, with the worth of knowledge claims being demonstrated by the effectiveness of one’s action. From the perspective of the pragmatist, *justification* is replaced by *application* in relation to the validation of knowledge claims. Kvale explains that

[a] pragmatic concept of validity goes farther than communication; it represents a stronger knowledge claim than an agreement through a dialogue. Pragmatic validation rests on observations and interpretations - “actions speak louder than words.” With the emphasis on instigating change, a pragmatic knowledge interest may counteract a tendency of social constructionism to circle around in endless interpretations and a plunge of postmodern analyses into infinite deconstructions. (Kvale, 1996, p. 248)

Pragmatism is a recurring motif of TCM, and it would seem that the notion of pragmatic validity is one that might be embraced by the TCA profession and TCA practitioner-researchers. As Kvale (1996, p. 248) has noted, “[a] pragmatical knowledge interest in helping patients change is intrinsic to the therapeutic interview, where communication of interpretations serves to instigate changes in the patient.” This is often the case with TCA practitioners where

they are involved in counselling with clients to facilitate a change in their clients' health. Also, many TCA practitioners are more likely to ask a question such as: *does* a particular TCA therapeutic approach work? - rather than endeavouring to find out *how* a particular therapy works. TCA practitioners have historically been pragmatic, more focused on the effectiveness of action (*i.e.* therapy) than on theoretical knowledge that provides an account of the effectiveness of that action.

Salner (1989, p. 54) explains that 'truth' for the pragmatist can be understood as

whatever assists us to take action that produce the desired result. The shared and accumulated experience of human individuals, built up memory of various trials and errors, becomes part of the stock of knowledge of a community and forms part of the background against which new knowledge claims are evaluated. ... In the human domain, the pragmatic usefulness of knowledge is determined by community consensus.

The important idea to note with pragmatic validity is that an understanding does not have to be 'factually correct' to be useful. Salner claims that

[i]n the domain which human science researchers study, a knowledge claim is substantiated by the extent to which it can be linked to the community's pattern of experience in applying its understanding to a particular issue. The understanding does not need to be factually correct (truthful) in order for it to have value to a community. If a particular understanding facilitates action that has the desired effect, then it takes the temporary status of a fact. (Salner, 1989, p. 55).

This has relevance for the practice of TCA. While some might doubt the validity of some traditional TCA theories, there are few who now doubt the pragmatic effectiveness of the actual therapy for the treatment of various syndromes and disorders.

13.6 Criteria for Evaluating the Quality of TCA Research

While qualitative and quantitative research might have different evaluation criteria, there are some general guidelines for judging any type of research. Marshall (1990) outlines some general criteria by which research can be evaluated. The main points that are applicable to TCA research are as follows:

- (i) The research design and methodology should be explicated in detail so that the consumer of the research can judge if it is appropriate for answering the stated research question. The methods for obtaining research informants should be outlined, as well as the methods of data collection, sampling, recording, and analysis. In the case of research which aims to evaluate the efficacy of acupuncture, the type or style of acupuncture being used in the study should be specified. This would allow comparisons of TCA clinical trials to be made for sound meta-analyses;
- (ii) A rationale should be given for the research design and methodology selected;
- (iii) The research design needs to be regarded by researchers and the TCA profession as being ethical. Researchers and their methods should demonstrate humane sensitivity towards those participants, or informants, involved in the research;
- (iv) Philosophical and theoretical assumptions should be acknowledged and stated;
- (v) In the collection and analysis of data, the researcher should attempt to minimise personal value judgments if that is required by the research design (as would be the case in some positivist type research designs);
- (vi) There should be adequate evidence from the data to demonstrate a relationship between the research findings and the 'real world';
- (vii) The study should extend the knowledge base by exploring phenomena or relationships not previously researched. The relationship between the present study and previous related studies needs to be made explicit;
- (viii) The written report of the research should be accessible to the audience(s) for which it was intended, whether it be TCA practitioners, researchers, or policy makers;
- (ix) Findings that are presented should indicate that the researcher was tolerant of ambiguity, and did not dismiss 'negative' instances or cases that did not support the hypothesis being examined;

- (x) Ideally, triangulation²⁷⁹, using a variety of methods should be used to enhance validity;
- (xi) The written report should acknowledge the difficulties in generalising the findings to other populations and settings;
- (xii) Raw data should be preserved for future reanalysis if required (this could be limited by ethical considerations, that is, the consent of informants);
- (xiii) The quality of data should be assessed. For example, informants' ulterior motives, truthfulness, and knowledgeability should be checked;
- (xiv) Research informants should gain some benefit from the research (This might involve reimbursement of travel costs or a copy of the published report);
- (xv) The research design with its associated data collection methods should be the most appropriate and efficient so as not to waste research funds; and
- (xvi) The findings of the study should be put into a context of larger systems. For example, the findings of a TCA efficacy study should be placed in the context of larger societal objectives.

In the remainder of this chapter, the 'quality criteria' for quantitative and qualitative research will be examined in the main separately; however, it should be remembered that they are not mutually exclusive research methodologies. Qualitative and quantitative research methods involve differing strengths and weaknesses and constitute alternative, but not mutually exclusive, strategies for research. As Patton (1990, p. 14) has noted, both qualitative and quantitative data can be collected in the *one* study.

13.7 The Validity of Quantitative TCA Research

From a postpositivist perspective, the validity of TCA research that involves quantitative methods will be dependent on careful instrument construction so that instruments measure what

²⁷⁹ Triangulation in relation to research is the use of multiple research methods in the one study to examine a phenomenon (N. Denzin, 1989). See also chapter 13.8 and Appendix H: Types of Triangulation.

they purport to measure. Instruments must be administered in a standardised manner according to appropriate and prescribed procedures.

13.7.1 *Validity and bias in TCA clinical trials*

The objectives of any TCA clinical trial need to be clear, concise, unambiguous, and determined before a clinical trial is conducted. If this is not done, the data generated by the trial might not be useful. The uses and limitations of clinical research designs (see chapter 8 & 10) need to be understood, since many research designs have inherent weaknesses due the types of control and subject selection procedure used. It is also important that the research design protocol is adhered to so that the actual trial is not adversely affected by bias. Monitoring of the clinical trial is desirable, to ensure that the researchers involved in the trial followed the clinical trial protocol. This would require an acceptable degree of compliance by both researchers and the participants involved. Any deviations from the clinical trial protocol would need to be noted by monitors and evaluated before any data could be meaningfully interpreted.

From a postpositivist perspective, clinical researchers endeavouring to determine the efficacy of TCA for any disorder or illness need to ensure that their interpretation of data is as objective and as free from bias as possible. Sackett (1979) has classified clinical bias into six categories: (i) bias in the examination of literature in the field of study; (ii) selection of an inappropriate clinical trial sample; (iii) failure to properly conduct the clinical trial protocol in the way it was intended; (iv) mistakes in the measurement of changes and outcomes in research subjects; (v) incorrect analysis of clinical data; and (vi) misinterpretation of the analysis. Researchers of TCA should endeavour to avoid bias by reflecting on Sackett's six categories.

There are several reasons why a clear interpretation of TCA clinical data might not be possible.

For example:

- (i) The aim or objectives of the TCA clinical trial were not clearly stated, or terms used in the stated objectives were ambiguous. When this occurs it is not possible to determine if the data support or refutes the hypothesis being tested. If the research aim is too general,

this can also result in difficulties in the interpretation of results.

- (ii) If a number of variables are being assessed to determine the clinical efficacy of TCA, it is conceivable that some outcome measures would indicate a positive result for the therapy while others might suggest the contrary. This would not pose a problem for a clinical trial if the parameters that were to be assessed were hierarchically ordered at the time the clinical trial design was developed (Spilker, 1991, p. 602). In the case of a global evaluation, it would also be desirable that each domain and parameter being assessed be given a weighting so that an overall efficacy assessment could be made. If this is not done, researchers would find the interpretation of data difficult since the different domains and parameters could suggest different interpretations.
- (iii) Meaningful conclusions might not be possible because of sample size, which can affect the power of statistical analysis. Quantitative research designs should be evaluated by a statistician prior to their use to ensure that the research design does not have design flaws that will lead to difficulties in statistical analysis. Calculations of statistical 'power' need to be completed before the commencement of a clinical trial to ensure that the sample size is adequate to yield an answer to the stated research question (Crichton, 1993, Bowling, 1997b).

13.7.2 *Maintaining internal validity in TCA clinical research*

Researchers conducting clinical research to determine the efficacy of TCA therapy would want to be able to claim that it is indeed the treatment administered to the research participants (patients) that has resulted in the observed differences between treatment and control groups (chapter 10). According to Cook and Campbell (1979) there are several ways that the internal validity of experiments can be threatened: these include (i) maturation, (ii) history, (iii) selection or assignment errors, (iv) practice effects, (v) regression to the mean, and (vi) measurement error (see Appendix E). If these factors are not accounted for, then the researcher cannot really make the claim that the experimental outcome is attributable to the medical intervention being evaluated.

13.7.3 *Maintaining external validity in TCA clinical research*

External validity refers to the extent to which the results of a study can be generalised to another group or setting. Huck *et al.* (1974) have classified external validity into two types: (i) *population* and (ii) *ecological*. According to Huck *et al.*, *population validity* refers to the generalisation of findings from a sample to the population from which it was drawn. For example, it is possible that some trait or characteristic could be present at a higher frequency in a sample of people in a clinical trial than in the general population. Obviously if this did occur an incorrect conclusion could be drawn from the findings of the TCA clinical trial.

Huck *et al.* (1974) discuss a second type of external validity which they term *ecological validity*. They claim that the results of studies conducted in laboratory or clinical settings can differ from those conducted in different settings such as a private practice. For example, it might be found that a particular syndrome can be treated successfully with TCA therapy in private practice but not in a hospital ward. A possible explanation of such a finding could be that the people attending the two *different* settings might in fact be quite different, possessing particular sets of characteristics which might have some bearing on the outcome of therapy. Polgar and Thomas (1995, p. 49 citing the research of Beecher, 1959) provide such an example. It has been found that the drug morphine is not useful in reducing levels of pain induced by electric shocks in laboratory studies; however, it has been found to be an effective analgesic for pain that results from injury in other clinical settings.

13.7.4 *The evaluation of the quality of clinical evidence*

In Australia, the National Health & Medical Research Council (NHMRC) (1995) have introduced a grading system that can be used to evaluate the quality of clinical evidence (see Appendix B: NHMRC (1995) Quality of Evidence Ratings).²⁸⁰ This system hierarchically orders evidence obtained from, at the top, the systematic review of all relevant randomised

²⁸⁰ According to Bensoussan & Myers (1996, p. 32), these ratings were adapted from US Preventative Services Task Force (1989), *Guide to clinical preventive services: an assessment of the effectiveness of 169 interventions* (ed. M. Fisher). Williams & Wilkins, Baltimore, Appendix A, p. 388.

controlled trials, down to, at the bottom, the opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees. This ranking would seem to assume that the randomised controlled trial is indeed the 'gold' standard for the evaluation of medical interventions (see chapter 10). Researchers of TCA who support a postpositivist position could adopt this grading system to evaluate the quality of TCA clinical evidence.

13.7.5 The criteria for the evaluation of TCA clinical trials

The criteria for the evaluation of TCA clinical trials has been previously examined by Vincent and Richardson (1986); Ter Reit, Kleijnen and Knipschild (1990) and Birch (1997c, pp. 33-42). When these criteria and insights are combined with the generic criteria of Polgar and Thomas (1995, pp. 343-350) for the evaluation of published research, the following list of criteria can be formed, which, in the opinion of the author, should be considered when evaluating published TCA clinical trials:

1. The research design, methodology and results should be adequately described in the published report. A report of a TCA clinical trial needs to be in accord with the guidelines for quantitative research, that is, there should be a title, abstract, introduction, methods section, results, discussion, references and appendices.²⁸¹
2. *Critical evaluation of the introduction of a report*
 - (i) The introduction should provide a rationale for the chosen research design and methodology;
 - (ii) There should be clear aims and hypotheses. If the aims or hypotheses are not clear, the study will lack direction and the interpretation of evidence might be ambiguous;
 - (ii) There needs to be an adequate literature review that reflects the current state of knowledge in the area of study. The literature review can provide a context and a conceptual basis for the current study;

²⁸¹ See Polgar and Thomas, 1995, pp. 333-339.

- (iii) Appropriate domains and variables need to be selected. If this is not done measurements will not be related to the concepts being investigated. 'Health-related quality of life' should be assessed in addition to the measurement of the signs and symptoms of specific biomedical syndromes and diseases if required by the research design. Domains and parameters must be prioritised before the start of a study.

3. *Critical evaluation of the methods section of a report*

The documentation of the *methods* section of a paper will help one to evaluate the internal and external validity of an investigation (Polgar and Thomas, 1995, p. 344).

(a) *Subjects*

- (i) The sampling method selected should be appropriate given the aim of the TCA study. The sampling model employed should optimise the representativeness of the sample if required by the research design;
- (ii) There needs to be an adequate description of the sample. Key sample variables (*e.g.* age, gender) should be stated;
- (iii) A power calculation has been made to ensure that the sample size is sufficient to demonstrate any significant differences between treatment and control groups (see Bowling, 1997, pp. 148-149);
- (iv) Adequate descriptions of inclusion and exclusion criteria.

(b) *Instruments*

In this section, the researcher should demonstrate the adequacy of the instruments used for data collection.

- (i) Appropriate, validated, and reliable instruments should be used to measure changes in variables;

- (ii) Details of any new instrument and the way it is to be used should be presented so that the study can be replicated by other researchers.

(c) *Procedure*

In this section, the researcher should adequately describe the way the study was conducted so that it can be replicated. It also enables one to evaluate the internal and external validity of the investigation (Polgar and Thomas, 1995, p. 345).

- (i) The methodology should be appropriate and adequate given the research design;
- (ii) The treatment interventions that are being evaluated should be adequately described to allow for study replication. Treatment types, techniques, treatment times and frequency should be provided. The qualifications and experience of the practitioners who conducted the treatments should be stated. This is important since it is likely that the outcome of TCA therapy is partly a function of the skills, experience, and characteristics of the individual TCA practitioner-researcher;
- (iii) Rosenthal effects²⁸² and Hawthorne effect²⁸³ need to be controlled or accounted for. Where possible, RCTs should be double or single blind;
- (iv) There needs to be adequate control groups (such as ‘sham’ acupuncture, no treatment, standard care) if required by the research design;
- (v) Where a placebo control such as ‘sham’ acupuncture is used, the control should be credible to the patients in the study;
- (vi) Diffuse noxious inhibitory control (DNIC) needs to be avoided or controlled for if required by the research design (see chapter 10.5.2);
- (vii) There is randomisation of research subjects. The aim of randomisation is to eliminate,

²⁸² According to Polgar and Thomas (1995, p. 372), the Rosenthal effect is “the phenomenon where the expectations of the researchers in a study influence the outcome.”

²⁸³ Polgar and Thomas (1995, p. 365) state that the Hawthorne effect is “[a]n effect which results in the improvement of peoples’ performances through being observed and/or social contact.”

or at least reduce, the effect of extraneous variables on the outcome (dependent) variable (see chapter 8.10.2);

- (viii) There is adequate subject assignment when control groups are used. Patient populations in treatment and controls should be homogeneous with comparable baseline measures of relevant variables. For example, if evaluating the efficacy of TCA for a particular biomedical condition, it is desirable that the severity of the condition being studied be determined in the study population. This is especially so if treatment and control groups are used. A table should be included comparing the demographics of the randomised groups;
- (ix) In TCA studies where variables are measured, a rationale for their selection should be provided;
- (x) There is prestratification on key variables.²⁸⁴ If this is not done the researcher will not be able to determine the impact of variables such as age and gender on treatment outcome;
- (xi) In single-blind RCTs involving TCA, the 'blinding' of patients should be adequate;
- (xii) In single-blind RCTs, the evaluator of treatment needs to be 'blinded' as to whether a patient was in the treatment or control group. This will enhance validity in single-blind RCTs;
- (xiii) There needs to be inter-rater reliability. This is the extent to which practitioner diagnoses or evaluators of treatment outcomes agree with each other. In the case of traditional acupuncture (of which there are many styles), it is desirable that traditional diagnoses and treatment plans are confirmed by another practitioner-researcher;
- (xiv) The research setting needs to be described to enable the findings to be generalised to other settings;
- (xv) There is sufficient follow-up after the course of treatment to evaluate long term benefits.

²⁸⁴ The sample is divided into strata or groups using some identified variables.

The means by which this is to be accomplished needs to be stated (*e.g.* post-trial validation²⁸⁵).

4. *Critical evaluation of the results section of the report*

The *results* section should contain a statistically accurate summary of data and its analysis. This will allow for correct inferences to be drawn from the data analysis.

- (i) There needs to be a suitable presentation of data and descriptive statistics;
- (ii) Appropriate statistics should have been used to analysis data²⁸⁶ ;
- (iii) Any adverse side effects of treatment should be noted;
- (iv) The use of, and any reduction of medication during the study should be noted if required by the research design.

5. *Critical evaluation of the discussion section of the report*

In this section, the researchers need to demonstrate that they have drawn the correct inferences from the data analysis in relation to the initial aims or hypotheses of the study.

- (i) The limitations of the study should be stated and any protocol deviations noted (*e.g.* the 'blind' is broken by participants). To the extent that they are known, variation in or lack of control of treatment parameters should be stated;
- (ii) inferences should acknowledge the limitations of descriptive and inferential statistics;
- (iii) There is no confusion between statistical and clinical significance;
- (iv) There is no overgeneralisation from the findings;
- (v) Any ethical issues are considered and examined. An ethical principle governing

²⁸⁵ As an example of post-trial validation see C. Vincent, 1990.

²⁸⁶ Wang and Zhang (1998, p. 283) claims that while "[t]he use of statistical methods in Chinese medical journals is improving ... the lack of or inappropriate use of statistics remains a serious problem."

research is that participants should not be harmed as a result of participating in a clinical trial (chapter 11);

- (vi) The findings of the study should be related to previous relevant findings that have been identified in the literature review. This allows the determination of the theoretical significance of the clinical trial.

13.8 Maintaining Validity in Naturalistic Inquiry and Qualitative Research

The issues of validity, reliability and rigour in naturalistic inquiry and qualitative research have been debated by many researchers (see Guba 1981; Miles and Huberman, 1984; Lincoln & Guba, 1985; Guba & Lincoln, 1989; Guba, 1990; Patton, 1990; Denzin & Lincoln, 1994; Grbich, 1999). Patton (1990, p. 461) for example, argues that the *credibility* of qualitative inquiry depends on three distinct but related elements:

- (i) the use of rigorous methods of data collection and analysis, where attention is given to the issues of validity, reliability, and triangulation (see below);
- (ii) the credibility of the researcher. Patton (1990, p. 14) claims that, “[i]n qualitative inquiry the researcher *is the instrument*.” This is to say that the validity of qualitative research is dependent “to a great extent on the skill, competence, and rigor of the person doing the fieldwork.”;
- (iii) the researcher has a “philosophical belief in the phenomenological paradigm and an “appreciation of naturalistic inquiry, qualitative methods, inductive analysis, and holistic thinking.” Patton (1990, p. 483) makes the point that “[q]ualitative data will tend to make the most sense to people who are comfortable with the idea of generating multiple perspectives rather than absolute truth.”

Due to its nature, naturalistic inquiry and qualitative research is often conducted by individuals rather than groups of researchers, and as a result there is the possibility of bias and threats to research quality if precautions are not taken. Miles and Huberman (1984) outline several

important strategies for examining the validity of qualitative research. All of these strategies are relevant to research of TCA that utilises qualitative research methods (see chapter 12):

(i) *Checking for representativeness*. To ensure that the data obtained are representative of the targeted population, it is important that the researcher has attempted to access sources of data, or participants, that typically are not easily accessible. This is necessary not so as to be able to generalise the findings to other populations, but rather to minimise bias through insufficient data from all sources that are relevant to the phenomenon being examined. In *purposeful sampling*²⁸⁷, for example, the sample is not meant to be representative of the whole population; however, it is important that the sample is adequate to reveal all of the aspects of the phenomenon being investigated. Purposeful sampling should ensure that extreme cases are included and examined.

(ii) *Checking out the meaning of 'outliers'*. Qualitative research that uses dialectical reasoning will often uncover 'outliers', which are exceptions to general findings. These need to be examined and can be used to confirm general conclusions. These 'outliers' can be compared with the theoretical model developed by the researcher to determine if the theory can account for or can be modified to account for them. The search for negative cases naturally follows from the dialectic method which attempts to search for rival explanations or interpretations of phenomena. Such an approach requires researchers not to settle on any one theory or interpretation of the phenomenon studied until all of the data has been analysed. This is sometimes difficult for qualitative researchers to do, especially towards the end of a study, because often the data strongly suggest one theory or interpretation. For this reason, it is desirable that one person on the research team, or a colleague, act as 'devil's advocate' until the study is completed.

(iii) *Obtaining feedback from informants*. The findings and conclusions of a study should be made available to informants for feedback or confirmation. This step is important after a model

²⁸⁷ *Purposeful sampling* involves the conscious selection by the researcher of certain subjects or elements to include in a study (see M. Q. Patton, 1990, p. 169).

or theory is generated and provides another way to verify research findings.²⁸⁸

(iv) *Increasing validity through 'triangulation'*. The term 'triangulation' is taken from land surveying, whereby an object's location can be determined on a two dimensional plane from the intersection of three fixed points or landmarks (Fielding & Fielding, 1986 cited in Patton, 1990 p.187). Triangulation, in relation to research, is the use of multiple research methods in the one study to examine a phenomenon (Denzin, 1989). This method could be used in the field of TCA where researchers are investigating a phenomenon that is complex. Triangulation allows different aspects of complex phenomena to be better understood by using a variety of research methods that are derived from different philosophical or theoretical perspectives (See Appendix H: Types of Triangulation). The author endorses Guba's (1990, p. 21) claim that

[i]f human sensory and intellectual mechanisms cannot be relied upon, it is essential that the 'findings' of an inquiry be based on as many sources-of data, investigators, theories and methods-as possible. Further, if objectivity can never be entirely attained, relying on many different sources makes it less likely that distorted interpretations will be made.

Patton (1990, p. 470) states that "[t]riangulation is a process by which the researcher can guard against the accusation that a study's findings are simply an artifact of a single method, a single source, or a single investigators's biases." Triangulation in the field of TCA would be desirable because of the various epistemological orientations to practice that have been identified in the TCA profession.

It could be noted though that some researchers believe that *investigator* and *theoretical* triangulation could be used to unite quantitative and qualitative methods by building a bridge between the philosophical differences that exist between the two orientations (Porter, 1989). Guba and Lincoln (1988), on the other hand, have suggested that it might be unwise to mix the various methodological approaches derived from the different modes of inquiry, since they are derived from fundamentally different paradigms that have different and incompatible theoretical assumptions and premises. They suggest that this would amount to trying to interpret the data from two different philosophical perspectives. Mitchell (1986) claims to have identified major difficulties in analysing data in studies that use both quantitative and qualitative methods.

²⁸⁸ This relates to *face validity* and *member checking* where researcher interpretations are checked by presenting them to a focus group of participants.

Mitchell contends that there is a problem in combining and interpreting quantitative data that are often expressed as a numeral value with qualitative data that are often textual in the form of written narrative or verbal statements. Secondly, there is the difficulty of deciding how to weight the two sources of quantitative and qualitative data. Does the researcher weight the results from the two types of methodology equally, or is the study theoretically driven by one of the methods? Patton (1990, pp. 193-194) acknowledges Guba and Lincoln's (1988) concerns, but suggests that it is possible to creatively combine methodologies that are derived from two inquiry modes or paradigms. Patton contends that "the practical mandate in evaluation to gather the most relevant possible information for evaluation users outweighs concerns about methodological purity based on epistemology and philosophical arguments."

Myers and Haase (1989) believe that quantitative and qualitative methods can only be effectively combined if at least two researchers are involved in the study. One researcher would need to be experienced in quantitative methods and another well versed in a qualitative inquiry. One assumption here is that both 'subjective' and 'objective' data are recognised as legitimate sources for gaining understanding and knowledge of the phenomenon being studied. In their guidelines for the merging of quantitative and qualitative methods, they recommend that the world and its phenomena should be viewed as a whole, and that quantitative and qualitative methods can be understood as two interactive systems that look at different levels of the one 'reality'. To accomplish this end, both atomistic (reductionist) and holistic thinking would have to be used in both the development of the research design and the subsequent analysis (Myers & Haase, 1989, p. 300).²⁸⁹

Duffy (1987, p.133) makes the important point that if triangulation is used appropriately, it should "produce richer and more insightful analyses of complex phenomena than can be achieved by either method separately". If researchers do use both quantitative and qualitative methods in a single study, both construct and external validity should be enhanced. If it is accepted that *all* research methods have their inherent strengths and weaknesses then it would seem desirable that multiple methods be used to investigate TCA and related phenomena.

²⁸⁹ See chapter 17 of A. Bowling (1997b) for some research methods that use a combination of qualitative and quantitative data gathering approaches.

13.9 Summary

In this chapter the quality criteria for both quantitative and qualitative research have been examined. While positivist, constructionist and other naturalistic paradigms might have different evaluative criteria, some general guidelines for judging any type of TCA research have been determined. Quantitative and qualitative research methods involve differing strengths and weaknesses and constitute alternative, but not mutually exclusive, strategies for research.

Triangulation, using a variety of research methods derived from different theoretical perspectives, has the potential to provide a better understanding of complex TCA phenomena.

The issues of research rigour, validity, reliability, and generalisability are still highly contentious in the world of academic research and debates will no doubt continue because of the different assumptions and tenets of the various paradigms of research.

CHAPTER 14

SUMMARY AND CONCLUSIONS

14.1 A Summary of Research Findings

In this dissertation many of the critical issues associated with inquiry and research in the field of Traditional Chinese Acupuncture (TCA) have been examined. A focal point of this study has been the determination of the forms of inquiry, research designs, and methodologies that are appropriate for increasing our understanding of TCA and for the further development of TCA knowledge and practice. It has been argued that at this point in time there are still many significant research questions in the field of TCA that need to be addressed. Some of these important questions might be difficult to answer; however, any attempts that are made should utilise the most appropriate research approaches and designs.

In chapter one, it was concluded that it is the particular *aim* of the TCA research question that should guide the researcher in determining the most appropriate type of research design and methodology for any particular study. It was argued, from a contemporary postmodern position, that no single method of inquiry has a privileged status. The various research approaches and methods examined in this study can produce different types of knowledge, all of which can be of value and useful for particular TCA research goals. It was also concluded that, from the perspective of the TCA profession, it is desirable that the research methods used by researchers to investigate TCA are congruent with the TCM paradigm.

It was established that much contemporary research in the field of TCA has been directed toward the determination of the effectiveness of TCA. Since many of the research approaches, designs and methodologies that have been used to evaluate the effectiveness of TCA therapy

were originally developed for Biomedicine (chapter 2), it was found necessary to consider the system of Biomedicine (chapter 3) to determine if its research methods could be adapted to meet the needs of researchers of TCA.

In chapter two, the nature of TCA and the core philosophical concepts, characteristics, and recurring themes of Traditional Chinese Medicine (TCM) that underpin TCA practice were identified. It was concluded that TCA therapy must be seen as a therapeutic approach that is used by a TCA practitioner rather than merely a medical technique. This initial explication and analysis of the nature and features of TCA therapy provided the foundation for the later determination of the types of research methods that are congruent with the philosophy, theory and practice of TCA.

In the second part of chapter two, the domain of TCA inquiry and research was outlined. Attention was given to how a researcher of TCA could determine what is an appropriate research design or method of inquiry for any given TCA research question. It was argued that the research design selected for any particular TCA study is, in part, dependent upon the nature of the research question that is to be addressed. Contemporary acupuncture research literature was also reviewed and analysed from a TCM perspective so as to make explicit the flaws in contemporary acupuncture research that made this study necessary.

In chapter three, sociocultural and philosophical aspects of medical systems and their implications for research were examined. TCM, with its associated concepts of health, illness and disease, was compared and contrasted with Western forms of health care including Biomedicine. It became evident through the analysis that the concepts of the different medical systems have implications for how they are to be assessed and how research of them is to be conducted. It was also found that what constitutes health and disease in any system of medicine has a direct bearing on the domains and parameters that are assessed and measured in health care research involving that system of medicine.

It was established that a key feature of any system of medicine is its conception of what a human being is. It was concluded that the substance and nature of the human being are

understood somewhat differently within the models of Biomedicine and TCM. These differences in conception can have profound ramifications for how health care practitioners of different systems of medicine interact with their patients in the therapeutic encounter, and how research of them is to be conducted and evaluated. While both medical and TCA practitioners attempt to ameliorate health disorders at the level of the individual, the system of TCM tends to place a greater emphasis on social and spiritual determinants of health and disease compared with mainstream Biomedicine. This is an outcome of TCM's 'holistic' orientation, with its central tenet that phenomena at all levels (the physical, psychological, social and spiritual) are interdependent and constitute a single whole.

The focus of chapter four was on aetiological models of health and disease. It was found that one core feature of any system of medicine is its concepts of the determinants of health and disease. The concepts of determinism and causality were subsequently explored in relation to TCM and the implications of these concepts for TCA research were examined. All societies have developed aetiological models to explain the presence of illness and disease. It was found that aetiological models can be classified broadly into two categories or types: supernatural/magical and naturalistic/systemic, with contemporary TCA drawing usually on the concepts of the naturalistic/systemic category. It was also established that health and illness are defined as members of a society inform each other as to the name, effect, the believed cause, and the appropriate responses to the various forms of illness and disease.

It was argued that the biomedical paradigm has found it difficult to account for many sociocultural factors involved in the processes of both illness and healing. It also appears that Biomedicine has downplayed the importance of psychological determinants in health and disease, just as it has done with many sociocultural factors. This stance is in keeping with Biomedicine's primary focus at the level of the biological body. This can be contrasted with the approach of the holistic TCA practitioner, who understands that psychological processes can be aetiological and therapeutic in the formation and treatment of disease in the same way as surgery or a pharmaceutical drug.

Another finding was the avoidance of dualisms in Chinese philosophy and medicine. This is an

outcome of the non-dualist Chinese philosophical concept of *yin/yang*. This is exemplified in the Chinese philosophical conception of the human being which avoids dualistic notions of mind and body. From the Daoist perspective, both so called psychological and physiological processes are understood as manifestations of the one *qi*: hence there is not the need to explain *how* mind and body interact since they are *both* expressions of the one complex which is *qi*. Researchers of TCA should also be beware of dichotomies. They need to avoid pernicious dualisms as exemplified by the passionate debates of Western philosophers examining the so called 'mind-body' problem and by obsessive proponents of either quantitative or qualitative research methods.

It was found that TCA therapy can be seen as being holistic in the sense that no single sign or symptom can be understood by the TCA practitioner except in relation to the whole person and the sociocultural environment in which the person is embedded. According to TCM theory, there are numerous factors that can contribute to a client's pattern of signs and symptoms. It is seldom possible to trace the 'cause' of a TCM 'pattern of disharmony' to a single aetiological factor because human biological functions are influenced by cultural and social aetiological factors operating at different levels or subsystems within a hierarchy of systems. It was demonstrated that TCA assumes a 'systems' orientation that needs to be taken into consideration when attempting to decide how TCA is to be studied. TCM is an example of and supports the transition from a bioreductionist model of disease to a 'systems' orientation in health care.

Chapter five examined several research paradigms and perspectives on health care that have relevance for the determination of appropriate forms of inquiry and research methods for TCA. It was argued that researchers within a discipline usually attempt to use research approaches that they judge to be congruent with the ontology of that paradigm. It became apparent that research approaches for TCA would need to be compatible with the TCM paradigm if they are to be acceptable to both TCA practitioners and researchers.

Researchers of TCA should remain open to the various research perspectives, since the various approaches have the potential to reveal different facets of any given TCA phenomenon studied.

Researchers of TCA who restrict themselves to any *single* research paradigm, or way of knowing, could place limitations on the domains of knowledge and the depth of understanding that could be obtained. TCA researchers need to continue to foster discourse and consider different points of view from beyond the boundary of their own world view. Researchers of TCA need to embrace research plurality and abandon the forced choice between the various paradigms and perspectives of research.

In chapter six, the nature of TCA knowledge was examined. This was accomplished by identifying the forms of knowledge found in Chinese philosophic and TCM texts and through an examination of the ways TCA practitioners actually transform their clinical experiences into knowledge. It was demonstrated that in the discipline of TCA, knowledge has developed through a variety of traditional and contemporary methods including the study of classical Chinese texts, authority and tradition, mentorship, trial and error, reflection on clinical practice and personal experience, and in other instances through the utilisation of methods that have been appropriated from other disciplines.

In chapter seven, Mosey's (1992) topology of 'epistemological orientations to practice' was examined so as to determine the epistemological orientations to practice that are, and have been, used by practitioners of TCA. This analysis provided a means to understanding the ways that knowledge has been obtained by practitioners and researchers of TCA. It was argued that to accommodate the reality that TCA practitioners have adopted several epistemological orientations to practice, the notion of epistemological purity will need to be replaced with one that acknowledges the value of a plurality of inquiry and research perspectives.

In chapter eight, the relationship between the methods of science and TCA knowledge production was investigated. The nature of science was examined to see if TCA *is*, or *can be*, scientific. It was argued that the methods of science can be utilised to investigate particular TCA research questions, as long as a broad definition of science is adopted. Several quantitative research methods were outlined that are applicable to a number of TCA research aims.

Chapter nine examined the purposes of health outcome measurement in research aimed at

establishing the effectiveness of TCA therapy. Various philosophical and technical issues associated with health outcome measurement in TCA research were investigated. Domains and parameters deemed relevant to assessing the efficacy of TCA therapy in clinical research were determined. It was argued that the evaluation of TCA therapeutic efficacy can be achieved if the most appropriate domains (physical, psychological, social and spiritual) and parameters are selected and assessed in each particular TCA study. Data from the realms of 'intelligibilia' ('objects' of the mind) and 'transcendelia' (objects of the spirit) should be assessed if required by the nature of the TCA research question and not *only* the more easily measured physical 'sensibilia'. Suitable TCA instruments should also be constructed and evaluated.

Chapter ten developed the ideas and issues introduced in chapter nine and focused on the critical issues related to the evaluation of the effectiveness of TCA therapy. One important issue explored in this chapter was the significance and implications of the so called 'placebo' phenomenon in relation to TCA clinical research. It is now evident that placebo ('non-specific') effects are involved in *all* therapeutic encounters and are an important factor in healing. It might eventuate through further research that the placebo phenomenon is far from being a 'nuisance' variable (as it is often considered from positivistic perspectives), but rather an important part of the healing process that needs to be better understood by health care practitioners. An important implication for TCA practice and research is that more attention should be given to the various factors involved in the therapeutic relationship so that more effective TCA 'treatments' can be developed.

It was argued that the *pragmatic randomised controlled trial* (PRCT), using 'active' controls, should be further utilised for evaluating the efficacy of TCA therapy as a whole (*i.e.* both the interpersonal and healing skills of the TCA practitioner and the acupuncture needling technique). Since what is often required by health administrators in government health departments for the allocation of funds is a measure of the 'relative' efficacy of a therapy rather than its 'absolute' efficacy, the 'active control trial' methodology could provide one means of enabling the various biomedical and complementary therapies (including TCA) to be compared so as to be able to determine the most effective and efficient therapeutic approaches for the various types of human illness and disease.

The limitations of the randomised controlled trial for evaluating the therapeutic benefits of TCA were also examined. While the RCT (a product of positivist ideas and assumptions) will probably continue to be employed by researchers to evaluate the efficacy of acupuncture, it should be remembered that no matter how exhaustive the clinical investigation, *absolute* truths will *not* be found using the RCT since it is impossible to control for *all* variables that are involved in the therapeutic encounter.

Chapter eleven outlined a number of ethical issues that need to be considered concurrently with other research issues when designing and conducting TCA clinical research. It was argued that Chinese humanist notions of the person should be considered in relation to TCA research design. It was concluded that ethical issues cannot be divorced from TCA clinical research design and methodology. The relationships that are developed between researchers and research informants are also crucial, not only on ethical grounds but because they impact on the quality of data obtained in the research process. Research of TCA is an ethical necessity if the TCA profession is to improve TCA practice so as to maximise health outcomes for clients.

In chapter twelve, the uses of naturalistic inquiry and qualitative research methods for examining TCA were explored. Consideration was given to the various qualitative and interpretive methods of inquiry for generating TCA theory, understanding the nature and meaning of TCA and related phenomena, and improving TCA practice. Given the common features and themes of TCA and naturalistic inquiry, it is likely that qualitative research methods will have a more important role in the future development of TCA knowledge. Both hold a holistic perspective and adopt a case orientation in which contextuality is emphasised. A number of qualitative research methods were outlined that are applicable for particular TCA research aims.

Chapter thirteen examined the 'quality criteria' by which the quality of TCA research can be evaluated. While positivist and constructionist paradigms and their associated research methods might have different evaluative criteria, some general guidelines for judging any type of TCA research were determined.

From the examination of the issues addressed in previous chapters, it is clear that appropriate research approaches and methods for particular TCA research questions can only be determined if researchers are cognizant of the philosophy, theory, and practice of TCM. From a postmodern perspective, it has been argued that no single method of inquiry has a privileged status, and that it is the specific TCA research question that should dictate the type of research approach, design and methodology for any particular TCA study. An important conclusion that can be drawn from this study is that there is the requirement for a plurality of research methods to examine the many facets of TCA. This conclusion is supported by the different epistemological orientations to practice that are drawn upon by contemporary TCA practitioners.

14.2 The Implications of this Study for Future TCA Research

From a Chinese philosophical vantage point, the interpretive paradigms (*e.g.* phenomenology and constructivism) and postpositivism (in its many forms) could be seen as the *yin* and *yang* of research orientations. In regard to TCA research design, the interpretive paradigms and postpositivism can be seen as being complementary perspectives rather than two epistemological orientations that are mutually exclusive. If one has a true understanding of Chinese philosophical thought, one is more likely to arrive at a balanced position on issues related to TCA research without having to take up an extreme position. Chinese philosophers often suggest that it is better to take a ‘middle path’ and avoid extremes, since extreme positions are often not fruitful and can at times even be detrimental. This idea is poetically expressed in Laozi’s *Dao de Jing* (chapter nine), “[b]etter stop short than fill to the brim. Over sharpen the blade, and the edge will soon blunt.” If this advice is heeded by researchers of TCA, there will not be the need to create false research dichotomies. In relation to TCA research design, this will mean acknowledging the strengths and weaknesses of different research orientations without having to argue for an extreme position. It means in essence avoiding ontological, epistemological and methodological dualism.

Many quantitative and clinical research designs are based on the assumptions of the positivist (or postpositivist) paradigm. In contrast, many qualitative research methods are derived from

other interpretive research paradigms which are often used to understand and to give *meaning* to the life experiences of people. It is a mistake to suggest that one type of research approach is superior to the other, since the reasons for their use differ. While a distinction is often made by researchers between quantitative and qualitative research methods, from the TCA perspective the quantitative/qualitative dichotomy is no longer useful. Both quantitative and qualitative research methods should be utilised to develop TCA knowledge, with the selection being determined by the particular type of research question to be addressed. Quantitative and qualitative research methods complement each other and can generate *different* types of knowledge, both of which are important for the development of TCA knowledge and the TCA profession.

In Chinese philosophical terms, qualitative and quantitative research methods could be viewed as the *yin* and *yang* of research design. Chinese philosophers maintain that the *yin* cannot exist without the *yang*, and that *yang* cannot exist without the *yin*, since these two agents are but two aspects of one whole. From this perspective, qualitative and quantitative research methods provide researchers of TCA with two complementary ways of obtaining TCA knowledge. If the *yin* and *yang* analogy is extended further, it can be understood how aspects of both approaches could be incorporated into the one research design for a specific project (see chapter 13.8), since *yin* and *yang* are not intrinsically different. Within the *yang* there is always *yin*, and within the *yin* there is *yang*. Therefore, qualitative and quantitative research methods should not be viewed as 'pure' methods that must be kept separate from each other, and which must compete for the attention of potential researchers. The author, following Patton (1990, p. 39), advocates a paradigm of choices and rejects methodological orthodoxy in favour of methodological appropriateness as the primary criterion for judging methodological quality. Subsequently, the question for researchers of TCA then becomes not whether one has uniformly adhered to the prescribed canons of either positivism, phenomenology, constructionism, or any other paradigm, but whether one has made sensible decisions given the purposes of the inquiry, the questions being investigated, and the resources available.

This study also has implications for the training of TCA researchers. Novice researchers should be exposed to different paradigms of health care research and their associated methodologies.

Researchers need to appreciate paradigm differences, and in that context to learn the purposes and the uses of both qualitative and quantitative research methods. A knowledge of naturalistic inquiry is essential because it is required to be able to utilise dialectical and hermeneutical methodologies. On the other hand, quantitative research methods are needed to evaluate the efficacy of TCA therapy so as to be able to determine its role in the treatment and management of the various health disorders and diseases that humans experience.

14.3 Priorities for Future TCA Research

Researchers of TCA should endeavour to develop research designs that acknowledge the particular decision making context. This will require being cognizant of all stakeholders, including decision makers, policy makers, funders, program managers, professional groups, program participants, and the general public who may be affected by the results of the research. Clearly, a variety of approaches drawn from the research methods that have been examined in this dissertation will be required to address the many issues and questions that currently confront the TCA profession. Priorities for future research in the field of TCA include the following:

1. The continued exploration of the concepts of health, illness and healing from the holistic perspective of TCM. Such research needs to be conducted to evaluate the implications of holistic models of health and health care for government health policy.
2. The development of research instruments to assess TCA therapeutic outcomes that take into consideration the holistic orientation and practice of TCA therapy. These instruments should assess 'quality of life' (or health related quality of life) data and should not be purely disease focused. Such instruments would need to consider the assessment of data from the psychological, social and spiritual domains in addition to the somatic. The proper measurement of health outcomes is necessary to determine the relative effectiveness of different types of therapy for the various health problems that human beings experience.
3. The increased use of naturalistic inquiry and qualitative research methods for:

- (i) understanding the nature and practice of TCA so that it can be placed in relation to other bodies of health care knowledge;
- (ii) understanding the *meaning* of health and illness for TCA practitioners and their clients;
- (iii) improving guidelines for TCA practice;
- (iv) generating TCA theory;
- (v) determining which variables TCA practitioners and their clients believe are indicators of health, wellness and illness.
- (vi) understanding the interactive nature of variables.

4. The determination of TCA interventions that are beneficial in health promoting behaviours and wellness in specific client populations. For example, further studies should be conducted which aim at evaluating the effectiveness of TCA therapy for particular types of health disorders, and for various vulnerable groups such as the elderly, children with congenital health problems, the mentally ill, and the poor.
5. The design and evaluation of alternative models of delivery and administration of health care. This could result in the integration of TCA into mainstream health care delivery if TCA is found to be safe, efficacious and cost-effective.
6. The identification and analysis of historical and contemporary factors that have influenced, and continue to influence and shape, the TCA profession's involvement in national health policy development.
7. The determination of the effectiveness of the various forms of acupuncture. Is there a 'best' way to practise acupuncture? Are general guidelines and protocols for TCA practice appropriate or desirable? These questions could be answered through a comparative evaluation (*i.e.* using active controls) of the different forms of acupuncture therapy (*e.g.* 'formula', 'scientific', auricular, traditional, laser therapy).

8. Exploration of the reasoning processes involved in making TCA clinical judgments and decisions. Such studies could determine the factors involved in determining TCA diagnoses, management and therapy plans.
9. The determination of clients' compliance with prescribed programs of TCA therapy. For example, researchers could explore the possible associations between clients' psychological characteristics and their degree of compliance with different TCA programs. Research of this type could determine how various factors are related to the adherence to adjunctive TCM food therapy programs, suggested changes in lifestyle and herbal medication regimens.
10. Research to assess the importance of TCA theory in the practice of TCA therapy.
11. The determination of the safety of TCA therapy. Is the effect of TCA always positive, or does it have side-effects like many of the drug therapies of Biomedicine?
12. More qualitative research to further the understanding of the nature of TCA therapy and the factors that contribute to its effectiveness. Which conditions facilitate the effects of TCA therapy and which retard them?
13. The determination of the relations between the consciousness, qualities and skills of the TCA practitioner and the therapeutic outcome. Is there an important synergy between the skills and qualities of the individual TCA practitioner and the successful application of the acupuncture technique?
14. Social constructivist based research could be utilised to further study the concepts of the 'person' and the 'body' in TCM.
15. Research should continue in different TCA settings with the objective of developing a holistic account of the therapy. This could involve cross-cultural comparisons.

TCA practitioners and researchers of TCA who reflect on the discussion of this study should be better placed to address the above issues and research questions.

14.4 Towards an Integrated Model of Health Care

Illsley (1977 cited in Illsley & Svensson, 1986, p. 100) has identified a number of long-term changes that are occurring in the health systems of developed countries. This movement can be seen to be centred around a change in models of health and disease that are characterised by a shift in focus: (i) from illness to health; (ii) from cure to care; (iii) from treatment to prevention; (iv) from disease to behaviour that produces disease; (v) from the individual as the 'unit of treatment' to the population; (vi) from illness as the concern and domain of doctors and health care professionals to 'health' as the concern of all; and (vii) from the right to treatment to a duty to remain healthy. Illsley and Svensson (1986, p. 101) have noted that the changes listed above (i-vii) "have affinities with the changes of direction proposed in the WHO strategy for health for all by the year 2000". If one examines the TCM paradigm closely, it can be seen that its holistic theoretical framework and practices could fulfil a WHO aim, and could contribute to and provide insights into a more comprehensive, cost effective and efficacious system of health care. Subsequently, TCA therapy could have a significant role to play in future systems of health care that are based on a more comprehensive and holistic model of health and disease.

The emphasis of TCM has always been on health rather than disease, with prevention being regarded as being just as important as the treatment and cure of disease. The TCM model also recognises that illness is the concern of all people, not just doctors and health care professionals. As a result of this view, TCA practitioners believe that clients must participate in and contribute to overcoming their own health problems, since in some cases their thoughts and behaviour have been contributing aetiological factors. The TCM model also accepts that not all health problems can be helped by the practices of individual health care practitioners working with their clients. In many instances there are social (*e.g.* unreasonable work practices and expectations) and environmental factors (*e.g.* environmental pollutants) involved in the production of health and disease that cannot be controlled by either the client or the practitioner. In such cases, all that can be expected of TCA practitioners is that they will attempt to help their clients to adapt to their situation.

The TCM paradigm acknowledges that illness is a part of life that will always be faced by

humanity. Health and disease are like *yin* and *yang*: one cannot exist without the other; the two form a continuum. People and societies do not always make the best choices, which can result in poor health status. There will always be people with painful chronic illness and diseases that will require adequate care since cures are not available. It is of little value to demand medical treatment as a right if no treatment exists. This is why the TCM paradigm stresses prevention over cure, because for some diseases, no curative treatments exist once they have progressed beyond a certain point. Where a cure cannot be found, all that can be given is adequate care, which requires the TCA practitioner to treat the patient as a person rather than a body that has a disease.

Dalenoort (1986, p. 31) has stated that “[t]he medical profession have (*sic*) concentrated on the biological aspects of disease, whereas we now increasingly realise the importance of the psychological and social aspects.” Most TCA practitioners would concur with Dalenoort’s sentiments. The focus of Biomedicine has generally been at the level of the individual and more often at the biological level. While TCA practitioners also intervene at the level of the individual, there is a greater acknowledgement by the TCA practitioner of the psychological, social and spiritual determinants of health, illness and disease. Future models of health care will no doubt incorporate some of the ideas of the holistic TCM model that acknowledges the interaction and interdependence of the biological, environmental, psychological, social and spiritual domains. Inquiry and research are the means by which the theory and practice of TCA can be appraised and evaluated. It will be through research, using appropriate methods of inquiry, that the future role of TCA in contemporary health care systems will be determined.

APPENDIX A

The Therapeutic Techniques of the Contemporary Practitioner of Traditional Chinese Acupuncture

The contemporary practitioner of traditional Chinese acupuncture uses some, or all of the following therapeutic techniques:

- * acupuncture (*zhen jiu*)
- * moxibustion (*jiu fa*)
- * cupping (*ba guan fa*)
- * dermal hammer/plum blossom (*mei hua zhen*) techniques
- * three-edged needle (*san leng zhen*) technique
- * point injection therapy
- * pressure (pushing needle) technique
- * threading needle technique
- * embedded needle technique
- * embedded suture technique
- * hooking technique
- * magneto-therapy
- * modern technologies applied to acupuncture points and meridians
- * bone righting (*zheng gu*)
- * massage (*tui na*)
- * *qua sha*
- * *shi liao*
- * prepared Chinese herbal medicines
- * Oriental/TCM Health counselling;
- * meditation
- * *dao yin*
- * *tai ji quan*
- * *qi* cultivation (*qi gong*)

(Source: Department of Health Sciences, Victoria University of Technology, 1997).

See also Bensoussan, A. & Meyers, S. (1996). *Towards a Safer Choice: The Practice of Traditional Chinese Medicine in Australia*, Sydney: Faculty of Health, University of Western Sydney Macarthur, pp. 26-27.

APPENDIX B

What Respondents Said Chinese Medicine Care Does and Why they Liked It

Theme 1: Chinese Medicine care relieves symptoms and improves function

- * Relieves physical pain
- * Relieves or releases emotional pain
- * Decreases the frequency, intensity or duration of chronic complaints

Theme 2: Chinese medicine improves physiological coping or adaptive ability

- * Increases “energy”
- * Induces sensations of calm, relaxation
- * Helps reduce reliance on prescription drugs
- * Reduces the frequency of “cold” and “strengthens the immune system”
- * Speeds healing, as from surgery
- * minimizes side-effects of drugs

Theme 3: Chinese medicine improves psychosocial coping or adaptive ability

- * Increases self-awareness
- * Engenders a sense of wholeness, balance, centeredness, well being
- * Increases self-efficacy
- * Changes lives

Theme 4: Chinese medicine involves a close patient-practitioner relationship

Theme 5: Chinese medicine treats the “whole” body/mind/spirit/social person

Table from C.M. Cassidy (1998). Chinese Medicine Users in the United States. Part II: Preferred Aspects of Care. *Journal of Alternative and Complementary Medicine*, p. 195.

APPENDIX C

Quality of Evidence Ratings

(Quality of Care and Health Outcomes Committee,
National Health and Medical Research Council)

- I. Evidence obtained from a systematic review of all relevant randomised controlled trials.
- II. Evidence obtained from at least one properly-designed randomised controlled trial.
- III-I. Evidence obtained from well-designed controlled trials without randomisation.
- III-2. Evidence obtained from well-designed cohort or case-control analytical studies preferably from more than one centre or research group.
- III-3. Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.
- IV. Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees.

Source: National Health and Medical Research Council, Quality of Care and Health Outcomes Committee) (1995a). Guidelines for the development and implementation of clinical practice guidelines. Australian Government Publishing Service (AGPS), Appendix A, p. 39. These ratings were adapted from US Preventative Services Task Force (1989), *Guide to clinical preventive services: an assessment of the effectiveness of 169 interventions* (ed. M. Fisher). Williams & Wilkins, Baltimore, Appendix A, p. 388.

APPENDIX D

The Mitroff and Kilman Typology of Scientists

The Mitroff and Kilman typology of scientists includes the 'analytical scientist,' the 'conceptual theorist', the 'conceptual humanist', and the 'particular humanist' (see Reason, 1981, pp. 45-50).

Characteristics of the 'Analytical Scientist'

	<i>Evaluative Categories</i>	<i>Attributed characteristics</i>
<i>External Relations</i>	Status of science as a special field of knowledge in relation to other fields.	Occupies a privileged and a preferred position: value-free, apolitical, cumulative, progressive, disinterested, clearly separable from other fields, clear lines of demarcation, autonomous, independent, strict hierarchical ordering of scientific fields from precise to less precise fields.
<i>Internal Properties</i>	A. Nature of scientific knowledge.	Impersonal, value-free, disinterested, precise, reliable, accurate, valid, reductionistic, causal, apolitical, cumulative, progressive, clear standards, for judgment, realistic, anti-mystical, unambiguous, exact.
	B. Guarantors of scientific knowledge.	Consensus, agreement, reliability, external validity, rigour, controlled nature of inquiry, maintenance of distance between scientist and objects studied.
	C. Ultimate aims of science.	Precise, unambiguous, theoretical and empirical knowledge for their own (disinterested) sake.
	D. Preferred logic.	Aristotelian, strict classical logic, non-dialectical, and indeterminate.
	E. Preferred sociological norms (ideology)	Communism, Universalism, Disinterestedness, Organised Skepticism (CUDOS)
	F. Preferred mode of inquiry	Controlled inquiry as embodied in the classic concept of the experiment.
	G. Properties of the scientist	Disinterested, unbiased, impersonal, precise, expert, specialist, skeptical, exact, methodical.

Source: Mitroff and Kilmann, 1978. Table from Reason, 1981, p. 46.

APPENDIX E

Threats to Internal Validity (Cook and Campbell, 1979)

According to Cook and Campbell (1979) there are several ways that the internal validity of experiments can be threatened: these include (i) maturation, (ii) history, (iii) selection or assignment errors, (iv) practice effects, (v) regression to the mean, and (vi) measurement error.

(i) *Maturation*. During any study involving human beings it has been found that internal physiological changes can occur within subjects. This is obvious since all living things have a constantly changing form that is time-dependent. It is possible that an illness could clear up without any intervention since many illnesses are self limiting: *e.g.* many viral infections will clear in a few days.

(ii) *History*. It is possible that the research subject will change some aspect of their lifestyle, environment, or social situation during the interval between the pretest and the post-test, which could have an effect on the condition or phenomenon being investigated.

(iii) *Selection or Assignment Errors*. If subjects are not assigned randomly to 'treatment' and 'control' groups, then the outcome can not with certainty be attributed to the differential treatment of the groups since the groups were not similar at the outset.

(iv) *Practice Effects*. A subject may appear to improve as a result of becoming familiar with the testing or assessment procedure (*e.g.* readministration of health assessment tests or instruments could lead to a better performance without any real improvement in the patient).

(v) *Regression to the mean*. Clinical research often involves the selection of subjects that have a particularly high or low level of signs and symptoms for the condition being investigated. Such groups when retested can show an apparent improvement. This occurs because on post-testing the measurement error tends to be less. This is a special effect due to the 'regression toward the mean'.

(vi) *Measurement error*. During the period between the pretest and the post-test, there could be a change in the evaluation instrument or the person measuring the sign and symptom changes for one of the groups. This would result in an apparent improvement or deterioration, when in fact no change had occurred.

Source: Cook, T. & Campbell, D. (1979). *Quasi-experimentation: design and analysis issues for field settings*. Chicago: Rand McNally.

APPENDIX F

Domains and Facets of the World Health Organisation Quality of Life (WHOQOL) Instrument (WHOQOL Group, 1994, p. 45)

The WHOQOL Group (1994, p. 45) claim that the WHOQOL instrument:

... provides a balanced and holistic assessment of a person's quality of life, where both positive and negative aspects of life are assessed together. The overall coverage of quality of life that results from this methodology ensures a conceptual coherence, or Gestalt, missing from many other measures of health status.

Domain I: The Physical domain

- 1 Pain and discomfort
- 2 Energy and fatigue
- 3 Sexual activity
- 4 Sleep and rest
- 5 Sensory functions

Domain II: The Psychological domain

1. Positive feelings
2. Thinking, learning, memory and concentration
3. Self-esteem
4. Body image and appearance
5. Negative feelings

Domain III: The Level of Independence

- 1 Mobility
- 2 Activities of daily living
- 3 Dependence on medicinal substances and medical aids
- 4 Dependence on non-medicinal substances (e.g. alcohol, tobacco, drug)
- 5 communication capacity
- 6 Work capacity

Domain IV: Social Relationships

- 1 Personal relationships
- 2 Practical social support
- 3 Activities as provider/supporter

Domain V: Environment

- 1 Freedom, physical safety and security
- 2 Home environment
- 3 Work satisfaction
- 4 Financial resources
- 5 Health and social care: accessibility and quality
- 6 Opportunities for acquiring new information and skills
- 7 Participation in and opportunities for recreation/leisure activities
- 8 Physical environment (e.g. pollution, noise, traffic, climate)
- 9 Transport

Domain VI: Spirituality, Religion and Personal Beliefs

APPENDIX G

Instruments that Could be Used in Research of Traditional Chinese Acupuncture

The instruments listed below could be used or adapted for specific TCA studies.

The MOS 36-Item Short Form Health Survey (SF-36)

Key Reference: Ware, J. Jr. and Sherbourne, C. (1992). The MOS 36-Item Short-Form Health Survey, *Medical Care*, Vol. 30, (6), 473-483.

World Health Organization Quality of Life Assessment Instrument

Key Reference: World Health Organisation Quality of Life (WHOQOL) Group (1994). In Orley, J. & Kuyken, W. (eds.) (1994). *Quality of Life Assessment: International Perspectives (Proceedings of the Joint-Meeting Organized by the World Health Organization and the Foundation IPSEN in Paris, July 2-3, 1993)*. Berlin: Springer-Verlag, 41-57.

The Patient Generated Index (PGI): A way of measuring quality of life

Key Reference: Ruta, D.A., Garratt, A.M. and Leng, M., Russell, I.T., MacDonald, L.M. (1994). A new approach to the measurement of quality of life: The patient-Generated Index. *Medical Care*, 32, (11), 1109-1126.

Measure Yourself Medical Outcome Profile (MYMOP)

Key Reference: Patterson, C. (1996). Measuring outcomes in primary care: a patient generated measure, MYMOP, compared with the SF-36 health survey, *British Medical Journal*, 312, 1016-20.

There are other psychosocial instruments that could be used for specific TCA studies: see S. H. Frank (1992). Appendix: Inventory of Psychosocial Measurement Instruments Useful in Primary Care. In Stewart, M., Tudiver, F., Bass, M.J., Dunn, E.V., Norton, P.G (eds.) (1992). *Tools for Primary Health Care*, Newbury Park: Sage Publications, pp. 229-270.

APPENDIX H

Types of Triangulation

Denzin (1989) has identified four types of triangulation: (i) data triangulation; (ii) theoretical triangulation; (iii) investigator triangulation; and (iv) methodological triangulation. Kimchi, Polivka, and Stevenson (1991) suggest a fifth type of triangulation which they term *analysis triangulation*. Each of these types of triangulation could be utilised by researchers to examine TCA.

Data triangulation

This involves obtaining data from multiple sources. This could involve the collection of data from different groups of people who live in different settings and who might experience the phenomenon under study in different ways.

Theoretical triangulation

In *theoretical triangulation*, the same data can be analysed in the one study by testing hypotheses and ideas based on different theoretical frameworks. Such an approach could increase the validity of the study by acknowledging the strengths and inherent weaknesses of each individual research design. A better understanding of health, illness and disease could be achieved by adopting different theoretical perspectives (e.g. using *both* the biomedical and TCM models).

Investigator triangulation

Investigator triangulation requires the involvement of at least two investigators (preferably more) who have divergent backgrounds (possibly from different disciplines), and who can explore the phenomenon under investigation from their preferred perspective. For example, a study that looked at the experiences of people with the biomedical syndrome of 'arthritis' (which has similarities to 'Bi syndrome' in the TCM paradigm) might involve researchers with

backgrounds in Biomedicine, TCM and psychology. Since the various health professions often have a preference for particular research methods, it is possible that the researchers from the various disciplines would investigate the phenomenon in different ways, which could reveal different aspects of the phenomenon. It also reduces the probability of bias that is more likely to occur in single investigator studies (Duffy, 1987). This last point is very important in regard to research that attempts to determine the efficacy of TCA therapy, which often involves a 'single-blind' randomised controlled trial methodology.

Methodological triangulation

In *methodological triangulation* different research designs can be used in the one study that are based on the same theoretical perspective. This could involve using more than one data collection method or instrument.

Analysis triangulation

In *analysis triangulation*, the data collected by the researcher(s) are analysed using two or more methods (e.g. quantitative and qualitative methods). This process can help verify the validity of a study's conclusions by comparing and looking for similarities between different sets of analyses.

Triangulation is a research strategy that would seem suited to examining subjects such as the TCA practitioner-client encounter which involves a multitude of factors and issues. Using only one research design to investigate such a process might reveal only one facet or dimension of the subject.

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