Effects of Exercise and Traditional Chinese Medical Modalities on Bone Structure and Function

A Thesis Presented for the Doctoral Degree of Philosophy

by

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Declaration

I hereby certify that the work embodied in this thesis is the result of original research and has not been submitted for a higher degree to any other university or institution.

Hong Xu

March 2003

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Abstract

Bone loss often leads to osteoporosis. This is a disease characterised by low bone mass and microarchitectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk. Osteoporosis is a complicated syndrome whose treatment and prevention crosses many disciplinary boundaries: therefore it is multidisciplinary. The best form of treatment is prevention. Osteoporosis can be limited through the maximization and maintenance of bone strength and minimization of trauma.

The purpose of this study was to consider the effects of: physical activity in the form of Tai Ji (Tai Chi), acupuncture and Chinese herbal medicine on bone loss by evaluating bone structure and function in menopausal women. The effects of these modalities were objectively examined through changes in bone material properties and the biomarkers of bone metabolism. Broadband ultrasound attenuation (BUA), a measure of bone structure and density, velocity of sound (VOS), an indicater of the elastic modulus and the breaking forces of bone as provided by ultrasound parameters, were evaluated. The levels of osteocalcin (OSTN) in serum, a biomarker of bone formation and the levels of pyridinoline (PYR) and doxypyridinoline (D-PYR) in urine, which are bone resorption markers were evaluated as parameters of bone metabolism. Traditional Chinese Medicine diagnosis was also used to measure changes in participants' symptoms resulting from Tai Ji exercise, acupuncture and herbal treatment.

During an eight month paired cross-over study the effects of three traditional Chinese therapeutic strategies (as described above) on bone structure and function to prevent bone loss were evaluated. Menopausal women are considered one of the most at risk groups for bone loss. Forty menopausal women who completed treatment and testing were divided into three sub groups; 12 into the Tai Ji exercise group, 14 into the acupuncture treatment group and 14 into the herbal treatment group. The groups were

then further divided into treatment and control groups. The sub-group for each treatment underwent a four month regime while the control group maintained a normal lifestyle. At the end of the fourth month the groups changed roles with the control group undergoing treatment while the former treatment group reverted to a normal lifestyle. Relevant tests were carried out at the beginning of the study, at the end of the 4th month and at the end of the study (at the end of the 8th month).

Subjects in the Tai Ji group completed thirty-two one hour sessions of Beijing 24movements Tai Ji over sixteen weeks. These movements are designed to gather qi, focus the mind, relax the body, move qi and *blood*, exercise the muscles, joints and lumbar region. The set of movements improve the balance function of the body and strengthen the muscles and sinews.

The results of this study indicated that Tai Ji improved bone structure and increased bone density in menopausal women. There was a 7.3% increase in BUA (p=0.001) when comparing the test results of Groups A+B pre and post Tai Ji exercise. The increased BUA appears to be associated with 39.0% increased bone formation (p=0.001) rather than decreased bone resorption (p>0.05). Tai Ji exercises also relieved symptoms related to bone loss. It appears that Tai Ji exercise may not only improve balance and confidence in the elderly but also could contribute to improved bone function and structure.

The subjects who received acupuncture therapy were assessed according to the principles of traditional Chinese Medicine. Three main acupuncture points in the lower legs, KID 3, SP 6 and ST 36 were used in accordance with the common pattern of disharmony for each of the fourteen participants. Each of the subjects was treated 32 times by the researcher, twice a week for 16 weeks, the duration of each treatment was 30 minutes. The treatment involved the use of points on meridians that tonify and nourish the body. The use of specific acupuncture points on the *kidney, stomach* and *spleen* meridians meant that their related organs were tonified, nourished and regulated.

Acupuncture of points KID 3, SP 6 and ST 36 tended to increase BUA 8.8% (p=0.005) when comparing the test results of Groups A+B pre and post treatment. The balance between bone formation and resorption improved, OSTN increased 30.9% (p=0.006) which indicates an improvement in bone formation, D-PYR was reduced by 18.5% (p=0.002) indicating a decrease in bone absorption, when comparing the test results of Groups A+B pre and post acupuncture treatment. Acupuncture can also strengthen *kidney* as evidenced by the relief of symptoms reported in this study.

The participants who received traditional Chinese herbal therapy were assessed according to the principle of Traditional Chinese Medicine. "Shu Di Shan Zha formula" was selected for the treatment group in accordance with the common pattern of disharmony. The decoction (granules mixed with water) was taken twice per day over a period of four months to strengthen the *kidney* and nourish *yin*.

Chinese medical herbal therapy – Shu Di Shan Zha formula was able to affect the level of BUA (6.9% increase for Groups A+B pre and post treatment, p=0.03) and a reduction in the level of D-PYR (16.5% decrease for Groups A+B pre and post treatment, p=0.011) in menopausal women as well as ameliorating menopausal symptoms in most of the subjects. However the mechanism of herbal therapy on bone turn-over warrants_further study.

Broadband ultrasound attenuation (BUA) was higher after the treatment with these three different strategies. Increased levels of osteocalcin (OSTN) in serum and the decreased levels of pyridinoline (PYR) and doxypyridinoline (D-PYR) in the urine were all noted after the treatments and might explain the increased BUA. Results of dual energy X-ray absorbtiometry (DEXA) in the same subjects had a moderate correlation with the BUA readings (r=0.50). BUA is considered a valuable measure of bone structure and density.

The study suggests that the three modalities relieve menopausal and bone loss related symptoms. The results imply that the three traditional Chinese therapeutic strategies might delay the occurrence of bone loss by improving the balance of bone turn over and general health in menopausal women.

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CHAPTER 1

INTRODUCTION

1.1 General Introduction

Osteoporosis is a world wide problem that is increasing in significance as the global population both increases and ages (Delmas and Fraser, 1999). While osteoporosis has been extensively studied in recent years the effects of Traditional Chinese Medicine (TCM) for the prevention of this condition have seldom been examined. This study examines the effects of TCM on bone turn over in menopausal women through the mechanism of bone resorption and bone formation. The study consisted of three separate parallel trials. Each trial examined the effects of a different modality of TCM; herbal medicine, acupuncture and physical activity in the form of Tai Ji (Tai Chi) on the bone health of menopausal women. Furthermore a comparison of the three modalities of TCM, in relieving the symptoms of menopause and bone loss was made.

1.2 Background

In most countries populations are growing in size, rapidly getting older and becoming more sedentary. This combination, along with unhealthy habits such as cigarette smoking and animal-based diets, will result in chronic degenerative diseases becoming the most common cause of disability and premature death throughout the world during the first twenty-five years of this new millennium (Haskell, 2000). Increases in lifespan are likely to exacerbate the extent of morbidity in our community placing pressure upon Australian health care systems (Kendig, 1996). Conditions, which are to some extent, influenced by lifestyle such as cardiovascular disease, diabetes and obesity will become increasingly prevalent within our society unless appropriate preventative measures are implemented. As society develops more labour saving technologies the need for physical activity is reduced. This lack of physical activity quickly becomes a major risk for coronary heart disease, stroke, hypertension and non-insulin dependent diabetes mellitus. As well as these complications aging and the lack of activity will also contribute to osteoporosis (Haskell, 2000). These issues will be discussed in detail in this study.

Osteoporosis is a systemic skeletal disease characterised by low bone mass and microarchitectural deterioration of bone tissue leading to bone fragility and an increased risk of fracture (Osteoporosis: Consensus Development Conference, 1993). Essentially there is a reduction in the substance of the bones and an enlargement of bone spaces (Raisz, 1999). Osteoporosis is a painful, crippling, and life-threatening condition that, according to Stoppard (1994), is more common than heart disease, stroke, diabetes, or breast cancer. Over the past ten years, with bone fractures attributed to osteoporosis reaching almost epidemic proportions particularly among postmenopausal women, osteoporosis has rapidly become an important public health issue worldwide (Wark, 1993). It has been recognised that osteoporosis is a very common disorder affecting millions of postmenopausal women and men of various ages (Rosen, 2000). Ke (1998) claims that 16.8 million postmenopausal white women in the USA (comprising 54% of that population group) are suffering osteopenic symptoms and a further 9.4 million (30%) are suffering osteoporotic conditions. It is noteworthy that approximately 25 percent of Australia's postmenopausal women have osteoporosis, with this condition occurring in 80 percent of women after they have a surgical menopause (removal of the ovaries) (Beckham, 1995). Women, in particular, need to be informed and vigilant about osteoporosis and need to take measures which will prevent the disease from reducing their quality of life and potentially their life span. Women should take positive action to improve their bone and general health status and to remain active and healthy throughout the postmenopausal years (Beckham, 1995).

Unlike many other diseases, osteoporosis in women is preventable, through diet, exercise and hormone replacement therapy (HRT) (Ellerington and Stevenson, 1993). The development of effective prevention measures for this condition will decrease the cost of health care and enhance the quality of life for the aged community. In particular it is necessary to develop effective and economic ways to prevent or reduce the loss of bone structure and function in menopausal and postmenopausal women. To have a

universal effect any such treatment regime needs to be capable of self-administration, be inexpensive, and be capable of crossing cultural boundaries.

The currently available literature on bone health and prevention of osteoporosis in women, typically examines the relationship of healthy bones and the key modifiable factors: physical activity, diet, and hormone therapy - mainly hormone replacement therapy (HRT) for menopausal women. These three factors have been linked to the development of healthy bones in women and all three are widely discussed and advocated in societies where Western medicine is predominant. There are advantages and disadvantages in these commonly used Western therapies.

Recommendations for prolonged HRT use must be considered on an individual basis taking into account the presence of other risk factors such as a family history of breast cancer or a personal history of benign breast disease, or the presence of chronic disease (La Vecchia, Brinton and McTiernan, 2001). HRT may be considered as a preventative modality but since each woman's individual experience of menopause will vary care should be taken not to inappropriately treat a stereotype (Panidis, Rousso, Giannoulis, Mavromatidis and Stergiopoulos, 2001). The Women's Health Initiative trial by Grimes and Lobo (2002) found that the overall risk-benefit ratio recommended against using HRT for the prevention of heart disease as cardiovascular disease and breast cancer increased among users. Colorectal cancer and osteoporotic fractures however decreased among users. The priority should be the administration of appropriate medication to women to improve their individual health and quality of life. New therapeutic options could offer a substantial medical advancement for the treatment of menopausal and postmenopausal women.

Although little information exists on the role of Traditional Chinese Medicine (TCM) especially for acupuncture and Tai Ji in the treatment and prevention of osteoporosis, natural modalities and activities are increasingly being accepted as an essential part of a well-balanced and healthy life. Some of the modalities such as Tai Ji exercise can be

self-administered and are economical. Acupuncture and herbal treatments are relatively safe preventive and treatment modalities.

Wolfe (1998) summarised that there are six reasons why a woman may want to consider Chinese medical treatment for menopausal or related disorders:

- 1. It is holistic, describing and evaluating the whole landscape of the body/mind, looking at each part and piece in relationship to the others.
- 2. As a medical system, it has no inherently dangerous or troublesome side effects.
- 3. Its diagnostic techniques allow for great precision in seeing each individual quite specifically and thereby creating treatment plans which are equally precise.
- 4. It is a medicine which is more effective at manipulating energy than matter and sees energetic change in the body as more fundamental than material change. By treating energetic imbalance effectively, gross material or substantial disease need not arise. In this way TCM acts as a preventive system of medicine.
- TCM has a long, clinically verified history of effective treatment for most types of disease, including gynaecology of which menopause (which relates to bone loss) is a part.
- 6. It is an understandable and empowering system of medicine, allowing patients a chance to understand their disease process and thereby the chance to participate in their healing process.

The purpose of this study is to consider the effects of physical activity in the form of Tai Ji, TCM herbal medicine and acupuncture on bone structure and function in menopausal women.

1.3 Objectives

Osteoporosis is a multifactorial disease associated with diet, exercise, genetics and hormones. The role of Traditional Chinese Medicine related modalities in preventing and managing the disease has received little attention in well-designed laboratory research in western countries.

The objectives of this study were to determine whether exercise (Tai Ji exercise) or Traditional Chinese Medical modalities (acupuncture or herbal medicine) could influence bone structure and function in menopausal women. Additionally, the study examined the effectiveness of these modalities on bone health. It was recognised that further investigations would be required to determine that the modalities of Tai Ji exercise, traditional Chinese acupuncture therapy and traditional Chinese herbal therapy may assist in the prevention and/or treatment of problems associated with bone structure and function in other population groups. This study was limited to a specific population. Other likely target groups would be people suffering ongoing physical disability or those recovering from osteoporotic fractures and who are currently receiving other therapies.

The specific objectives of this study were:

- To investigate the effects and benefits of Tai Ji exercise, acupuncture and herbal medicine on bone structure, bone function, bone formation and bone resorption in menopausal women.
- To determine the changes in bone material properties and the biomarkers of bone metabolism induced by Tai Ji exercise, acupuncture and herbal treatment in menopausal women.
- To investigate the changes of participants' symptoms as described by TCM diagnosis induced by Tai Ji exercise, acupuncture and herbal treatment in menopausal women.

• To determine the relationship between calcaneus ultrasound (Broadband Ultrasound Attenuation), spinal bone mineral density (BMD) and compare the effects of the three modalities on bone material properties and bone turn over markers in menopausal women.

1.4 Brief Description of Research Design

In order to achieve the above objectives, a pre- and post-treatment paired group research design was used. Fifty-eight participants were recruited and divided into three groups for the study. Of the fifty-eight participants forty satisfactorily participated in the treatments and all tests. The participants were divided according to their bone structure and function as determined by their Broadband Ultrasonic Attenuation (BUA) and with reference to their menopausal status and age. Participants were first divided according to the treatment that they wished to receive, then their BUA was tested and they were divided into two sub groups within their chosen treatment modality. One sub group initially became a treatment group while the other was a control group. At the conclusion of the initial treatment period of four month, the groups "crossed over" and the control became the experimental groups and the initial experimental group became the control. The second treatment period also continued for four months.

The overall research design consisted of three individual intervention modalities - Tai Ji exercise, Traditional Chinese Acupuncture Therapy and Traditional Chinese Herbal Therapy. The 40 participants who successfully completed the study were: 12 in the Tai Ji group, 14 in the acupuncture group and 14 in the herbal group. Before and after each of the treatment interventions participants were tested for bone structure and function as well as bone turn over. They also underwent Traditional Chinese Medical assessment. The subjects also completed a bone mineral density assessment at the end of the study.

1.5 Limitations and Delimitations of the Study

The duration of each treatment was limited to four months because it was necessary that treatment be continuous. A longer period was not feasible due to the commitments of participants and the availability of resources to complete the study. Although four months is a relatively short period to effectively measure a change in bone structure it was considered sufficient given the paired design and five principal assessment tests utilised. The number of participants was limited because of the cost of analysis of data, commitments of participants and limitations imposed by the university.

In a training study of this nature and period, it was accepted that there would be a significant dropout rate of subjects. Of the 58 subjects who commenced the study only 40 completed all phases and measurement profiles. The limited numbers of completing subjects also placed some pressure on the statistics that would be used to analyse the data. Expert advice was sought which resulted in the statistical evaluations as described in Chapter 3 being utilised.

This study required that each group undergo four months of treatment and another four months as a control with no treatment. Three sets of tests were administered: at the beginning of the study, after four months and after eight months. Data collection from each participant spanned nine months. Although each participant's diet, physical activity and general health were monitored, the length of the study precluded a tight control over extraneous influences. Compliance information was elicited from the subjects' recollections during interviews at each of the three tests. The results of Broadband Ultrasonic Attenuation (BUA) in this study were compared with Dual Energy X-ray Absorbtiometry (DEXA) at the end of the study. DEXA testing was only available at the end of the study due to the lack of availability of equipment until this time and the need to restrict the number of such tests to minimise exposure to x-rays. The level of significance chosen for all statistical evaluation was 0.05.

1.6 Definitions and Abbreviations -- Biomedical

Osteoporosis	A disease characterised by low bone mass
	and microarchitectural deterioration of
	bone tissue, leading to enhanced bone
	fragility and a consequent increase in
	fracture risk.
Broadband Ultrasonic Attenuation	The trabecular orientation and pattern in
(BUA)	bone, provided by ultrasound parameters
	(expressed as dB/MHz).
Velocity of Sound (VOS) or Speed	An indication of the elastic modulus and
of Sound (SOS)	breaking forces of bone, provided by
	ultrasound parameters (expressed as m/s).
Osteocalcin (OSTN or OC) or Bone	An indication of bone formation
γ-Carboxyglutamic Protein (BGP)	(expressed as ng/ml).
Pyridinoline (PYR or HP) (urinary	An indication of bone resorption
Pyridum crosslinks)	(expressed as nmol/mmol Cr).
Deoxypyridinoline (DPD, D-PYR or	An indication of bone resorption
LP) (urinary Pyridum crosslinks)	(expressed as nmol/mmol Cr).
Dual Energy X-Ray	Two-dimensional estimation of areal bone
Absorptiometry (DEXA)	mineral density (expressed as g/cm ²)

1.7 Definitions and Abbreviations -- Traditional Chinese Medicine

Yin and *Yang Yin* and *Yang* are based on the philosophical construct of two polar complements. These complementary opposites are neither forces nor material entities but are concepts used to explain the continuous process of natural change. *Yin* and *Yang* are not only a set of correspondences but also represent a way of thinking. In this system of thought all things are seen as a part of an integrated whole. The *yin-yang* nature of phenomenon is not absolute but relative. *Yin* and *yang* exist in everything in nature, such as:

Yang	Sun	Day	Summer	Hot	Male
Yin	Moon	Night	Winter	Cold	Female

The theory of *yin-yang* permeates all aspects of the theoretical system of TCM. It serves to explain the organic structure, physiological functions and pathological changes of the human body. In brief, health is considered a balance between the *yin-yang* aspects of the whole person and disease is defined as an imbalance of *yin* and *yang*. Adjusting the balance of *yin* and *yang* is the basic principle of TCM in the prevention and treatment of illness (Yin, 1992).

Qi is functional (as compared to structural). It is *yang* in relationship to *blood* being *yin*. In the body, all physiological activity is described by and dependent upon the movements and mutations of *qi*. The five basic functions or intrinsic characteristics of *qi* are:

Propulsion/movement: *Qi* propels the *blood*, transports nutritive substances to the entire body and circulates body *fluids*.

Warming: *Qi* maintains body temperature and by its warming nature energises all the functional activities of the organism.

Defense: Qi defends the body surface against invasion by exogenous pathogens.

Transformation: *Qi* transforms the *blood* and body *fluids*. It creates these out of the raw materials derived from respiration and digestion.

Restraint or Astringency: The *qi* holds the *blood* within its vessels, the body *fluids* within the body and organs up against gravity (Liu, 1998).

Qi

- **Blood** (Xue) Blood is described as the substance which flows through the vessels, the main function of *blood* is to nourish. It is more material, physical or yin than qi. In the Nei Jing Su Wen (Inner Classic Simple Questions), one of Chinese medicine's first classics (which was written around the period of the Warring Staes, 403 BC - 221 BC, over 2400 years ago according to Cheng, 1985), it is said that the *qi* commands the *blood*, the blood is the mother of the qi. If qi is responsible for movement, warmth, transformation and restraint of the blood, blood is the underlying nourishment which fuels these functions of qi. Without *blood* or nourishment (*yin*), the *qi* (*yang*) has no root, no material or substantial foundation or mother. Without *qi* (*vang*) to move, warm and transform the *blood* (vin), the *blood* is inert, without force or direction. As always *vin* and *vang* are completely interdependent (Liu, 1998).
- **Body** *Fluids* Body *fluids* are also a part of the *yin* of the body, body *fluids* are a general term for all normal water/*fluids* within the body. The functions of the body *fluids* are to moisten the skin, hair, joints, organs and tissues of the body and to facilitate smooth movement of joints and other body parts. *Blood* and body *fluids* are derived from a common source and may affect each other. For instance, consumption of *blood* may injure the body *fluids* and vice versa.

It is the *qi* which is responsible for the movement and transformation of body *fluids*. *Qi* moves and transports the body *fluids* to all parts of the body. Therefore, an insufficiency of *qi* may result in body *fluids* accumulating somewhere in the body as pathologic dampness.

Essence Essence refers to the vital physical *essence* of the body, its seminal basis. It is the primary substantial element responsible for determining physical growth and development and maintenance of life activity and metabolism. It is the most primal stuff from which our being unfolds. The outward physical manifestation of *essence* in women is (menstrual) *blood*; in men it is semen. It is the material base necessary for the creation of a new being, the creation of life. Therefore *essence* is *yin* in relationship to *spirit* (mind and spiritedness), which is the nonmaterial or *yang* impetus necessary for the creation of life. In Chinese medicine there are two types of *essence*, pre and postnatal (acquired before and after birth) (Liu, 1998).

Bian Zheng The TCM principle for the treatment of disease. Before the practitioner selects treatment methods the pattern of disharmony Lun Zhi must be identified. In TCM a disease will have a name but it may occur as a result of more than one pattern of disharmony within the body. When the principle of differentiation of syndromes is used to guide clinical practice several different patterns (syndromes) may be found in the same disease and the same syndrome may appear in a variety of diseases in the course of their development. This observation leads to two maxims of clinical relevance: applying different methods of treatment to the same disease and treating different disease with the same method (Yin, 1992). Menopause is an example of a disharmony with a number of different syndromes. The most common syndrome results from *yin* deficiency in specific organs and treatment is based on nourishing yin in the affected organ.

CHAPTER 2

LITERATURE REVIEW

2.1 General Summary of Literature on Osteoporosis

This chapter outlines the literature reviews that summarize recent major advances in the understanding, diagnosis and management of osteoporosis and also refers to relevant Traditional Chinese Medicine sources. Section one includes a brief introduction on the background for this osteoporosis study; factors associated with bone loss, populations at high risk of bone loss, possible prevention and treatment. Section two considers the Traditional Chinese Medicine view of menopause and bone loss. Section three looks at diagnosis and treatment mainly based on Traditional Chinese Medicine.

2.1.1 Background

Pocock, Culton and Harris (1999) claim that, based on the incidence of current ageadjusted hip fracture and population projections for New South Wales, a 90% increase in hip fractures by the year 2021 is expected. The number of men reaching the high risk age group for osteoporotic hip fracture could contribute significantly to this increase. After the age of 60 years about 60% of women and 30% of men suffer from an osteoporotic fracture (Beckham, 1995). Sanders, Nicholson, Ugoni, Pasco, Seeman and Kotowicz (1999) also predicted that the number of fractures per year in Australia is projected to increase by 25% from 83,000 fractures in 1996 to 104,000 in 2006. Hip fractures are projected to increase 36% in that ten year period (from 15,000 to 21,000), because of a substantial rise in the number of elderly who are aged 85 years and over. It is anticipated that hip fractures will double by 2026 and increase fourfold by 2051. In contrast to Europe and North America, where the numbers of hip fractures are expected to double by 2026 and then stabilise, in Australia hip fractures will continue to place a growing demand on healthcare resources for many decades. A forecast of the extent of osteoporosis within the female segment of the Australian community predicted a global rise from the current figure of 1.66 million to 3.94 million by the year 2025 (Lindsay,

1993). On the bases of the above information, it can be said that Australia has an aging population; therefore, treatment of osteoporosis-related conditions such as hip fractures will impose an increasing burden on the HealthCare system.

2.1.2 Factors Associated with Bone Loss

Major risk factors for osteoporosis are age, genetics, lifestyle (especially nutrition) and menopausal status (North American Menopause Society, 2002). According to Ellerington and Stevenson (1993), the eventual development of osteoporosis depends upon two main factors:

- the peak bone density achieved by the individual before thirty years of age, and
- the rate at which this density is subsequently lost as the person ages.

New (2001) also stated that maximum attainment of peak bone mass and the rate of bone loss with advancing age are the two mechanisms that principally determine adult bone health.

Peak bone density appears to be achieved during early adult life soon after linear skeletal growth has stopped (Ellerington and Stevenson, 1993). Evidence gathered by Ellerington and Stevenson, 1993 from the study of twins suggests that this is largely genetically determined. For example, there is more variation in bone mass between non-identical twins than between identical twins. As well as genetic factors, common causes of bone loss are (according to Stevenson and Marsh, 1993); ovarian failure due menopause, age-related factors. hypoparathyroidism, hypercortisolism, to hyperthyroidism, hypogonadism, reticuloendothelial disorder, connective tissue disorder, drugs (eg. corticosteroids, heparin, alcohol), cigarette smoking, and Guthrie, Ebeling, Dennerstein and Wark (2000) described the immobilisation. prevalence of risk factors for osteoporosis in a population-based cohort of Australianborn midlife women; the results showed that:

"At baseline, 52% reported a calcium intake of less than 800 mg/day and 46% reported a caffeine intake of more than 360 mg/day; 29% exercised less than 1.5 hours/week; 5% had a body mass index (BMI) of less than 20; 14% were current smokers; 23% were past smokers; 10% reported abnormal menstrual histories; and 25% reported a family history of osteoporosis".

Although there are many factors that can cause bone loss, Mundy (2001) stated that osteoporosis is the disease of progressive bone loss that is most often associated with aging and the postmenopausal state in women. This author further explained that:

"All people, men and women, lose bone mass with advancing age, but in some the loss is so great that the skeleton is unable to maintain optimal structural integrity and the result is susceptibility to fractures, particularly of the hip and spine. The condition is increasing dramatically in prevalence as the numbers of elderly in the population increase".

To determine the age and menopause-related changes in BMD, Zhang, Kushida, Atsumi, Kin and Nagano (2002) indicated that an accelerated bone loss was seen in the early postmenopausal stage. The first year after menopause and physiological age were the most important factors that affected the rate of bone loss. Their study of healthy postmenopausal Japanese women showed that there was a significant decrease of BMD (-1.59% /year) in the early postmenopausal women when compared with the pre and late postmenopausal women (p<0.0001).

It would appear that the balance between blood calcium levels and bone mass is another important issue in osteoporosis, Aloia (1989, p7) states that:

"Bone mass was sacrificed to maintain blood calcium levels in the optimal range. The loss of bone was an undesirable effect of a homeostatic mechanism. When excess calcium is lost to the environment or when adequate calcium cannot be obtained from the environment, bone will be lost. If there is insufficient dietary calcium, a loss of calcium through the urine, or an inability to increase production of calcitriol so that calcium absorption cannot increase appropriately, parathyroid hormone will produce bone loss. This sequence of events occurs in old age because aged kidneys cannot generate sufficient calcitriol when the intake of dietary calcium is inadequate".

Guthrie et al. (2000) also indicated that there are multiple risk factors for osteoporosis in the Australian-born population of midlife women, but only anthropometric variables were associated with BMD at baseline. Significant changes during the menopausal transition in anthropometric variables and calcium intake were in the direction that could decrease the risk of osteoporosis but were not found to affect menopausal bone loss.

It is not known why and which women lose more bone mass than others and which develop osteoporosis. Rosen (2000) stated that osteoporosis manifests as painful fractures of the spine, hip or radius and that the underlying pathogenesis is complex and multifactorial. "Genetic factors play an enormous role in defining the height of acquisition of bone mass; however, these factors also interact with environmental and hormonal determinants". "Systemic factors such as oestrogen deprivation and parathyroid hormone strongly activate remodelling and can, in several circumstances, lead to imbalances in the remodelling cycle" (p181-193). Ziegler, Scheidt and Scharla (1995) suggested that one factor causing bone loss could be latent hypoandrogenism. Optimal bone mass depends on sufficient sex hormones, building materials, and physical loading. Sex hormones add to bone mass, but the female sex loses oestrogen at menopause.

2.1.3 High Risk Population

Osteoporosis which has its highest rate of occurrence in postmenopausal women, increases the risk for fractures, these injuries are often associated with particularly high morbidity and mortality (North American Menopause Society, 2002). Ellerington and Stevenson (1993), also claim that postmenopausal osteoporosis is the most common metabolic disease in the developed world and results in considerable morbidity and mortality.

According to modern Western medicine, natural menopause is described as the transitional phase of a woman's life when menstrual function ceases due to age-related declining ovarian function usually occurring between the ages of 40 and 50. Mackay, Beischer, Pepperell and Wood (1992) indicated that as a woman ages into her forties the ovarian follicles become progressively fewer in numbers and more refractory to hormonal stimulation. Hacker and Moore (1998) explained that eventually the production of oestrogen, progesterone and the other ovarian hormones is reduced. There is a resultant loss of feedback inhibition of the hypothalamus-pituitary causing the levels of follicle-stimulating hormone and luteinizing hormone to rise. Receptors for oestrogen are widely distributed including in the vagina, cervix, uterus, ovary, pelvic fascia, bladder, skin, bone, heart, arteries, liver, brain, muscle, breasts and other endocrine glands. When oestrogen levels are low or absent, cells within these tissues become relatively inactive. The net result of the inactivity in target cells is an increase in general body dysfunction.

Menopausal bone loss is a composite of loss caused by oestrogen deprivation and age per se for the hip and total body but is caused by oestrogen deprivation alone for the spine (Recker, Lappe, Davies and Heaney, 2001). Menopause normally occurs in women around 51 years of age. The average female life expectancy in industrialised nations is about 81-83 years this means that many women could spend 30 years or more, perhaps a third of their lives, in a postmenopausal state. This state of oestrogen deficiency can have profound effects on their skeleton (Ellerington and Stevenson, 1993).

Stevenson and Marsh (1992), stated that oestrogen deficiency produces an increase in bone turn-over in which osteoplastic activity dominates leading to a net loss of predominately trabecular bone, accelerating bone loss after menopause. Consequently older women may suffer from fractures or other health problems that result in a lowered quality of life and/or lower life expectancy. In addition to the classic vertebral crush,

hip, and Colles' fractures osteoporosis probably contributes to almost all fractures experienced by elderly people, according to Lindsay (1993).

Bone mass controlling mechanisms include bone growth, bone absorption and bone resorption. Before the age of thirty-five bone growth and absorption dominate the bone mass controlling mechanism and have a direct influence on peak bone mass. Bone resorption dominates the bone mass controlling mechanism after the age of forty-five and has a direct influence on the rate of bone loss. Factors influencing peak bone mass include genetics and environmental factors such as nutrition, smoking, exercise, skeletal trauma and gonadal status. Factors such as menopause, aging, alcohol, drugs, nutrition, smoking and exercise greatly influence the rate of bone loss. Decreases in peak bone mass and/or increases in the rate of bone loss after the fifth decade lead to decreases in total bone mass below the fracture threshold and are a direct cause of osteoporotic fractures according to Ke (1998). In general, during the time of transition from peri to post menopause, women have an accelerated bone material density (BMD) loss at both the hip and spine (Guthrie, Ebeling, Hopper, Barrett-Connor, Dennerstein, Duddley, Burger, and Wark, 1998).

2.1.4 Rate of Bone Loss

Bone mass changes with age. It reaches a maximum (peak bone mass) during the 30s in both males and females and begins to decrease after the age of forty-five. By the age of eighty, bone mass declines to 50% of its maximum value (Ke, 1998). Another opinion from Xue (1998) states that bone loss begins from between the ages of thirty and forty and continues throughout the aging process. Bone loss slows 10 to 15 years after menopause. Nattiv, Agostini, Drinkwater and Yeager (1994) found that normally bone mass peaks in women at age thirty-five and then tends to be lost at the rate of about 1% of bone mass every year (or 10% over 10 years). After menopause bone loss is typically 5% per year.

Bone loss is most likely in menopausal and postmenopausal women (Xue, 1998). There is some disagreement amongst researchers about the rate of bone loss for menopausal or postmenopausal women. Table 2-1 indicates the bone loss rate reported by some researchers. It is clear that bone loss increases as people age and that this loss begins to accelerate at menopause. Peak bone mass and aggregate bone loss both contribute to low bone mass in later life (Preisinger, Alcamlioglu, Saradeth, Resch, Holzer and Metka, 1995).

Researcher(s) and year	Menopausal status	Bone density loss rate / year
Xue (1998)	Around menopause	Stratifying the participants according to menopausal status revealed that the fastest bone loss occurred at the time around menopause when the annual rate of bone loss (-0.66%) was almost twice as rapid as that in postmenopausal women (-0.39%).
Guthrie, et al. (1998)	After menopause	After menopause, BMD declined with age at all sites although the rate of bone loss was faster at the femoral neck (-0.62% per year) and Ward's triangle (-0.84% per year) than at the spine
Riggs and Melton (1986)	Menopause and after menopause	(-0.49%). The fastest bone loss coincided with menopause. For 5 to 10 years after menopause the rate of loss accelerates to between 3% and 6%, this means that more than 15% of bone mass is likely to be lost in the early postmenopausal years.
Szejnfeld, Atra, Baracat, Aldrighi and Civitelli (1995)	Sixth decade	The greatest decrease occurred at the spine, an average of 11.4% bone loss compared with the previous decade.
Hanson, Overgaard and Christiansen (1995)	After menopause	Bone loss averaged 20-25% over the initial 16 years of menopause.

Table 2-1 Bone Loss Rates in Menopausal and Postmenopausal Women

2.1.5 **Prevention and Treatment**

Generally, prevention of disease is better than treatment and it is especially important when no generally satisfactory treatment exists (Avioli, 1993). This is particularly relevant to osteoporosis as there is no satisfactory treatment, the disease is so debilitating and it is very common in our society. It is therefore much better to use preventive modalities in the early stages of menopause and in the postmenopausal years. Ellerington and Stevenson, 1993 claim that for reasons that are poorly understood the rate of bone loss begins to slow down approximately eight to ten years after menopause so any preventive measures should be taken earlier since they would be of reduced benefit after this time. "Given the health implications of osteoporotic fractures, the primary goal of osteoporosis therapy is to prevent fractures by slowing or preventing bone loss, maintaining bone strength, and minimizing or eliminating factors that may contribute to falls" (North American Menopause Society, 2002).

Osteoporosis as a result of bone loss often leads to painful fractures of the spine, hip or radius; the underlying pathogenesis is complex and multifactorial (Rosen, 2000). It has been suggested that an imbalance between bone resorption and bone formation during bone remodelling might be responsible for the occurrence of osteoporosis (Ke, 1998).

Pharmacological treatments for osteoporosis are classified as anti-resorptive agents that primarily decrease bone resorption and anabolic agents that primarily stimulate bone formation thus restoring bone mass previously lost. Therapeutic agents such as oestrogen (with or without progesterone), calcitonin, bisphosphonates (alendronate), and selective oestrogen receptor modulators (raloxifene) have been approved as anti-resorptive agents for the prevention of osteoporosis (Ke, 1998). Hormone replacement therapy (HRT) has shown a strong correlation with increasing bone mineral density and lowering fracture incidence. However, definitive measures for the prevention of bone loss are still required (Genazzani and Gambacciani, 1999).

These agents however, have both advantages and disadvantages. The major issue is the relationship between HRT and breast cancer. Long-term and current HRT use is followed by a slight though significant increase in the risk of breast cancer. Progestogens can modify the cellular response of normal as well as cancerous breasts (Genazzani and Gambacciani, 1999). La Vecchia, et al. (2001) found that there are many potential benefits to the use of HRT even though there is a higher risk of cancer. Combined HRT may be associated with a higher risk of breast cancer as compared to oestrogens alone. Panidis, et al. (2001) stated that although HRT has beneficial clinical effects and a positive benefit to risk ratio, awareness of the side effects such as weight gain and especially a fear of cancer, limit compliance. den Tonkelaar and Oddens (2000) reported that ovariectomy, hysterectomy and opinions about benefits and disadvantages of HRT were the most important determinants of long-term use, whereas women themselves mentioned side effects and weight gain most frequently as reasons for discontinuing it. New data from long-term controlled prospective studies on the effects of different HRT schedules on cancer, cardiovascular disease and osteoporotic fracture risk are needed.

Most gynaecologists recommend HRT during menopause. Gupta and Aronow (2002) stated that HRT has long been a staple of management of the postmenopausal life phase. They indicated that:

"Over time, and after estrogen therapy was modified to include progestin, an increasing number of observational reports suggested that HRT conferred benefits well beyond those of managing or minimizing hot flashes, mood swings, and vaginal dryness. In short, HRT was believed to improve women's health and even extend life. One of the most significant theorized benefits was protection against cardio- and cerebrovascular events. Other benefits – protection against osteoporosis, reduction in incontinence symptoms, and improved cognition – have also been linked with HRT".

Whitehead (2000) indicated that occasionally new data is released that challenges established beliefs, it was thought that HRT would reduce the risk of coronary heart disease. This still applies to apparently fit and healthy women but data from the Heart
and Estrogen/progestin Replacement Study (Grodstein, Manson and Stampfer, 2001) has shown that the use of HRT in women with established risk factors for coronary heart disease increases in the short term. Kaplan, Aschkenazi-Steinberg, Yogev, Nahum, Sulkes and Phisher (2002) suggested that until definitive guidelines became available, an individualised approach should be applied with careful consideration of both the benefits and risks of treatment.

The levels of oestrogen in women decline as ovarian function decreases due to menopause. The fall in oestrogen levels causes reductions in basal bone mass and increases the risk of osteoporosis. Although this situation could be improved to some extent with hormone replacement treatment (HRT) the treatment cannot be used in all situations e.g. Western medicine advises women with breast cancer to avoid HRT. Potential side effects of the long-term use of HRT include endometrial carcinoma and breast cancer. The application of HRT is of limited value for postmenopausal women and patients who already suffer from osteoporosis (Chen, 2002).

Bone loss can be treated with different regimes. Lifestyle adaptations, separately or in combination, have been suggested to prevent, delay, or attenuate bone loss via osteoporosis. Yamaguchi, Truman and Cameron (2000), indicated that dietary factors, as well as physical activity, influence bone characteristics as assessed by Quantitative Ultrasound (QUS). In this study, the strongest predictors of decreased bone density, as measured by Broadband Ultrasound Attenuation (BUA) and Speed of Sound (SOS), were increased age and menopausal status. Higher body mass index and current participation in exercise or sports were significant predictors of increased BUA, and SOS in a multivariate model. Higher calcium intake predicated increased BUA and missing meals predicated a lower SOS. Ellerington and Stevenson (1993) also stated that certain lifestyle factors eg. immobilisation, cigarette smoking appear to affect bone density which is also dependent on menopausal status. Strategies for the prevention and treatment of osteoporosis are directed at maximizing peak bone mass by optimizing physiologic intake of calcium, vitamin D therapy, exercise, and maintenance of normal menstrual cycles from youth through adulthood (Lane and Nydick, 1999).

A comprehensive approach to exercise and fall prevention should be coupled with drug therapy (Lane and Nydick, 1999). Physical activity is a determinant of peak BMD. Weight bearing exercise, as has been suggested by a number of researchers, has a beneficial effect on bone mineral density and hence osteoporosis (Xu, Long and He, 1997; Chilibeck, Sale, and Webber, 1995). Physical activity leads to greater bone density in children and adolescents and to a minor extent in adult. Weight bearing activities, such as walking, have a greater effect than non-weight bearing activities, such as cycling and swimming (Branca, 1999). There is also evidence that activity during growth modulates the external geometry and trabecular architecture, potentially enhancing skeletal strength. During the adult years physical activity may reduce age related bone loss. The magnitude of the effect of a 7% to 8% increase in peak BMD, if maintained through the adult years could translate to a 1.5-fold reduction in fracture risk (Henderson, White, and Eisman, 1998).

At the post menopause, physical exercise contributes to protecting bone mass and may be associated with a decreased risk of oestrogen-dependent breast and endometrial carcinomas (Gaspard, Buicu and Creutz, 2001). Cheng, Sipila, Taaffe, Puolakka and Suominen (2002) indicated that both HRT and exercise have local effects on bone mass. Estadiol plus noretisterone acetate (Kliogest) acts primarily at the bone marrow interface; jumping and bounding activities contributed to the maintenance of bone mass. They suggested the change in bone mass distribution induced by HRT and exercise may play an important role in the alteration of bone strength. Walker, Klentrou, Chow and Plyley (2000) indicated that for the postmenopausal women with osteoporosis who participated in weight-bearing aerobic activities of moderate intensity and muscle strengthening exercise using free weights, it was possible to stabilize their height and the BMD of the lumbar site and to reduce fractures over the five year study period. Yamaguchi, Truman and Cameron (2000) indicated that the strongest predictors of decreased BUA, SOS and stiffness index (SI) were increased age and menopausal status. Higher body mass index and current participation in exercise or sports were significant predictors of increased BUA, SOS and SI in a multivariate model.

The optimal form of exercise varies with age, to achieve the objectives that reduce the risk of falling and thus further reduce fracture risk requires a particular type of exercise. Vigorous physical activity during childhood (including weight-bearing, resistance, and impact components) may maximize peak BMD. This type of activity seems optimal through the young adult years as well, but as inevitable age-related degeneration occurs, limiting the impact component of exercise may become necessary (Henderson, et al., 1998). In the elderly, progressive strength training has been demonstrated by Henderson, et al. (1998), to be a safe and effective form of exercise that reduces risk factors for falling and may also enhance BMD. In the frail elderly, activity to improve balance and confidence may also be valuable. Group activity such as Tai Chi may be cost-effective. Stretching, strengthening, impact, and balance exercise are effective. Lane and Nydick (1999) stated that: Coupled with drug therapy should be a comprehensive approach to exercise and fall prevention. Stretching, strengthening, impact and balance exercise are effective. Those authors believe that of the balance exercises, Tai Chi Chuan has proved to be the most successful in decreasing falls.

Early in 1959, Qu, Jiang, Pu, Gao, Jin and Ji investigated the effects of Tai Ji in general. They summarised that Tai Ji in particular has been shown to have a positive effect on bones and joints, calcium and phosphorus metabolic functioning and the prevention of early aging. In 2001, Li, Hong and Chan reviewed the characteristic effects of Tai Ji on metabolism and cardiorespiratory response and measured its effect on cardiorespiratory function, mental control, immune capacity and the prevention of falls in elderly people. They indicated that Tai Ji is a moderate intensity exercise that is beneficial to cardiorespiratory function, immune capacity, mental control, flexibility and balance control; it improves muscle strength and reduces the risk of falls in the elderly. Wolf (2001) investigated centre of pressure feedback using computerized balance machines. A series of experiments ultimately led to the finding that Tai Ji as an exercise form for older adults can have a substantially favourable effect in delaying the onset of fall events. Wong, Lin, Chou, Tang and Wong (2001) evaluated the effects of coordination exercises on postural stability in older individuals using Tai Ji, the results indicated that

the elderly people who regularly practiced Tai Ji showed better postural stability in the more challenging conditions than those who do not (eg. The condition with simultaneous disturbance of vision and proprioception). Tai Ji as a coordination exercise may reduce the risk of falls through maintaining the ability of posture control.

Prevention of bone loss is obviously preferable to any remedial measures but new therapeutic strategies provide a means of restoring deficient bone (Lane and Nydick, 1999). Many therapies that exist are new to the Western world but are well established alternative remedies including diet, tea, bathing cures, tranquillisers and drugs for the autonomic nervous system. Homeopathic therapy and acupuncture also have their place (Ledermair, 1985). The optimal model for the prevention of osteoporotic fractures includes maximization and maintenance of bone strength and minimization of trauma probably utilising a variety of strategies. Numerous determinants of each have been identified but further work to develop preventive strategies based on these determinants needs to be undertaken (Henderson, et al., 1998).

Clearly there is a growing need and plenty of scope for new treatments, preventative therapies and strategies that prove to be safe, effective and economical. Liu (1998) notes that osteoporosis is a complicated syndrome whose treatment and prevention crosses many disciplinary boundaries: therefore it is multidisciplinary.

2.2 The Traditional Chinese Medicine View on Menopause and Bone Loss

The theories of TCM and its various therapies have a great deal to offer the menopausal woman. These theories can be applied in relation to menopause and osteoporosis leading to the use of TCM as a means of alleviating the possible physical and emotional discomforts / disorders which too often attend it. TCM offers a number of easily preformed and self-help ideas and disciplines to reduce bone loss, hot flushes, night

sweats, stress, create purpose and self-esteem and improve quality of life during menopause or at any other time which is emotionally or physically trying.

If TCM is used as a means of health enhancement prior to menopause, to harmonise the body, this period of a woman's life could be less difficult. TCM treatment can also be used to prevent and treat osteoporosis with limited side effect in all situations. This treatment can be applied broadly to prevent and treat menopausal symptoms, osteoporosis symptoms and improve general well-being.

In Traditional Chinese Medicine (TCM), health is considered to be a function of the smooth flow of qi through a series of pathways (the *meridian* system) which link and unite all parts of the body, including internal organs, into a single integrated whole. If this smooth flow of qi is disrupted the result is disease. Disease is defined as an imbalance of, or disruption to, the movement of qi (Watson, 1991).

At around the age of 35-40, the production cycle begins to slow down with the natural process of aging. The digestion becomes less efficient, therefore producing less *qi* and *blood*. This is relevant to menopause for two interrelated reasons. First, it means that, over time, there is not the production of the super-abundance of blood required for menstruation. Second, it means that less *postnatal* or *acquired essence* is available to supplement *prenatal essence*. This leads to the consumption of *prenatal essence*, which describes the aging process (Wolfe, 1998).

Wolfe (1998) further explained this aging procedure according to TCM physiology:

"One of the reasons why menopause is a necessary, vital homeostatic mechanism in women's bodies is that by ending the monthly loss of *blood*, the consumption of both *blood* and *prenatal essence* is slowed down. This is because, as it is said in the classics, *essence* and *blood* share a common source, the *kidneys*. When *blood* is lost with the menses each month, some *essence* is also lost, since the menstrual *blood* is the physical manifestation of *essence* in woman. As the body metabolism

slows down and less *blood*, *qi*, and *postnatal essence* is created, the body can ill-afford the monthly loss of *blood* (and *essence*) of menstruation. The body's wisdom slows and then stops the menstrual flow, allowing the body to hold onto the *blood* and *essence*, which are now more precious since less is being created" (p26).

Thus, the menopause allows a woman the possibility for another 20 to 30 years of relative good health, with a much slower decline than would be the case if menstruation continued. Menopause, while itself a sign of aging, actually slows down the aging process by preventing the unnecessary loss of *blood* and *essence* according to TCM thoughts.

It is a disruption of the function of *qi* combined with an imbalance between yin and yang in the *zang-fu* organs that causes osteoporosis. Deficiency of *qi* is a syndrome that occurs when the functions of the *zang-fu viscera* (TCM internal organ systems) are weakened due to constitutional weakness and/or over use of the energies of internal organs. Yang (1998) explains that the clinical manifestations of this are: shortness of breath, lassitude, dizziness, spontaneous sweating, loose stools and bleeding. All of these symptoms are aggravated by physical exertion. *Kidney qi* deficiency symptoms include: shortness of breath and dyspnea (more severe with physical activity), cough causing perspiration and urinary dysfunction, oedema of the face, pale complexion, pale tongue with thin coating, and weak pulse (Tian, 2000).

The *Plain Questions in Nei Jing* – one of the most important TCM classic books states: Calm *yin* and steady *yang* result in good vitality. The separation of *yin* and *yang* result in a depletion of vitality. Therefore the dynamic balance between *yin* and *yang* was regarded as the standard of health by the ancients (Yang, 1998).

Each of the five *zang-viscera* has its own *yin* and *yang*. So each of the *zang-viscera* may be deficient in *yin* and/or *yang*. The *yin* deficiency syndrome involves *yin* and body *fluid* shortage, which leads to deficient *fire* in the interior. This deficient *fire* causes a

number of menopausal symptoms related to a lack of oestrogen, for example hot flushes and night sweats. The *yang* deficiency syndrome results in *yang* and *qi* insufficiency that leads to cold manifestations. This is evident in the elderly osteoporosis patient who is always cold. Yang (1998) claims that *yin* deficiency and *yang* deficiency result from deficiency of vital *yin* and vital *yang* that in TCM terms involves deficiency of *kidney yin* and *kidney yang*. The *kidney* is responsible for the congenital foundation of life so congenital deficiencies as well as improper innate development and afterbirth feeding can give rise to the insufficiency of *kidney yang* or *kidney yin*.

In the *Neijing* (The Inner Classic), the first classic of Chinese medicine, it is stated that at 14 years of age the *kidnevs* are mature, the *ren mai* (*ren* channel) is free flowing, the chong mai (chong channel) is exuberant, the tian qui (menstrual water/blood) arrives. This is based on a Chinese medical theory that describes the physiological growth, maturation, and decline of reproductive function in women in terms of seven year cycles. Each seven year segment describes a state in the natural history of an individual's *kidney* function, the foundational viscus of Chinese medical physiology. It is said that at seven times seven years (i.e., at 49 years of age) the kidney qi is debilitated, the tian qui is exhausted and thus the chong and ren vessels are not nourished and menstruation ceases (Wiseman and Ye, 1998). Menopausal symptoms have long been well known and documented in Chinese medicine, menopausal syndrome is described as *jing* (menstration) *duan* (stop) *qian* (pre) *hou* (post) *zhu* (various) *zheng* (symptoms) (Wang and Guo, 2000). The main symptoms have these traditional names: xin ji (palpitations), shi mian (insomnia), xuan yun (dizziness), tou tong (headache), zang zao (visceral agitation) and beng lou (flooding and spotting) (Si Tu and Yang, 2000). This traditional description includes various diseases arising before or after the cessation of menstruation.

According to fundamental Chinese medical theory it is stated that *yin* and *yang* must remain in dynamic balance and that *blood* and *qi* are a *yin/yang* pair so they must also remain in dynamic balance. Therefore, as less *blood* and body *fluids* (*yin*) are produced through the digestive function with age the dynamic balance of *qi* to *blood* and *yin* to

yang begins to move out of balance. *Qi* and *yang* become excessive in relation to *blood* and *yin*. This imbalance can be compounded by a person's constitutional weaknesses which are responsible for most of the problems and disease associated with aging (Wiseman and Ellis, 1995). Furthermore, when this process of decline is accompanied by stress, overwork, emotional upset or any organic dysfunction in the body this disequilibrium between *yin* and *yang* is typically worsened (Wolfe, 1998).

This type of disequilibrium often manifests initially as *kidney yin* deficiency/vacuity. The statement *yang* tends to become excessive easily while *yin* tends to deficiency is attributed to the greatest doctor of the *Jin/Yuan* Dynasty, Zhu Dan-Xi (1281-1358). The statement describes the typical imbalances of *yin/yang* which he saw in most of his patients. In TCM it is said that by 40 years of age, *yin* is half used up. Since the *kidneys* are the root of all *yin* and *yang* in the body, *kidney* vacuity, whether *yin* or *yang*, may give rise to vacuity and insufficiency in other viscera or bowels. Any viscus may be affected, although different constitutional types tend to manifest the imbalance in different but fairly predictable ways (Yang, 1998).

According to Western medicine menopause may occur naturally, prematurely or artificially as a result of oophorotomy, chemotherapy, irradiation or disease (Mackay, et al, 1992). Early or premature menopause, or menopause prior to age 40, may occur for a variety of reasons. The most common of these include response to viral infection, inherited chromosomal abnormality, defects in gonadotropin secretion, autoimmune disorders, enzymatic defects, excessive smoking, or cancerous growths (Berkow and Fletcher, 1987).

Menopausal symptoms in TCM terms occur due to *qi*, *blood*, *yin and yang* disorders. Some women experience few or no symptoms and others suffer severe discomfort with menopause. This, on top of the problems associated with the simple facts of aging, can make life extremely difficult. Sometimes the reason is purely genetics. Some people have a stronger constitution, better digestion or stronger *kidneys*. Other causes include poor lifestyle, may relate to recreational drug use, drinking to excess, smoking, eating poorly and lack of exercise. This can result in a more difficult menopause than that of their more health conscious sisters. According to TCM, unhealthy lifestyle choices as well as sociocultural stressors can make the difference between symptoms and no symptoms during menopause. These choices result in liver *qi* stagnation or depression which lead to menopausal symptoms (Wolfe, 1998). Although the transition period of menopause may occur without symptoms, at least 75% of women experience the most common menopausal symptom – hot flushes (McVeigh, 1990).

Other common menopausal symptoms are stress and depression, these are due to liver *qi* stagnation in TCM theory. Stagnation/depression is a concept in Chinese medicine, which describes any substance or *qi* in the body which is not flowing or being transformed properly and hence getting stuck. Six things can become stagnant or depressed in the body according to TCM: *qi*, *blood*, food, *dampness* (result of water metabolism disorder), *phlegm*, or *fire* (extreme heat). This stagnant or depressed *qi* and other substances can cause different types of problems in the body with one type of stagnation leading to or exacerbating another (Deng, 1999).

In the case of menopausal problems, qi stagnation is paramount. This results as, of all the organs, qi stagnation most strongly affects the *liver* and will worsen any problem related to the *liver*. Since the *liver* is strongly connected to the *uterus*, the *chong* and *ren* channels (damage and detriment to these channels are the main cause of gynaecological disorders according to Flaws, 1997) and the menstrual cycle, any *liver* disharmony caused by qi stagnation will have a strong impact upon menopause. When *liver* problems are combined with the normal decline of organ function associated with the simple fact of being 45 to 50 years old, the process of menopause is likely to produce symptoms. Stress, anger, worry, fear, frustration, boredom, or any emotional stress for which a woman has no solution will cause the qi to stagnate. Common symptoms include irritability and depression, erratic body pains that come and go, fibrocystic breast disease and chronic digestive disorders (Wolfe, 1998).

Emotions are the subjective mental experience of various manifestations of qi flow as they relate to various organs. This is important as qi and the mind or emotions are not separate and what happens to one will happen to the other. As Wolfe (1998) indicated, if some aspect of our lives continually makes us feel struck, dissatisfied, or limited, then over time that is what will happen to our qi as well. This means that the mental/emotional state is most important in either producing or preventing qistagnation/depression symptoms.

Stagnation of qi alone can cause many problems – including distension and bloating, cramping pain and emotional lability. It will usually complicate other problems that already exist or destabilize any delicate energetic transition that the body is going through, such as menopause. This is because all physiological transitions or transformations, of which menopause is a major example, are dependent upon what is called the qi mechanism. The qi mechanism can only function properly if the qi flows freely. Qi stagnation inhibits this necessary free flow of qi (Deng, 1999). Wolfe (1998) suggested this fact alone explains why liver depression/qi stagnation complicates any transformation such as menopause and leads to symptoms where they might not otherwise arise.

Warmth is an inherent quality of *qi* and of life itself, so that if enough of it stagnates in one place for a long enough period of time, it will become hot or transform to (stagnant/depressive) *fire*. Excessive heat such as this can cause a number of problems. It can dry out the *blood* and *yin* of the body, which in menopausal women, are already compromised by the fact of aging. This leads to further imbalances of *qi* to *blood* and *yin* to *yang*. Further, since *blood* and *yin* are required to root or anchor *qi* and *yang*, if this imbalance becomes too great, the *qi/yang* will rise up to the surface of the body. This is how hot flushes, night sweats, headaches, irritability, dry eyes and certain types of vertigo and insomnia arise (Deng, 1999).

A third possible way in which *qi* stagnation can aggravate the menopausal situation is if there is already a tendency to *kidney* yang/*spleen* yang vacuity. Deng (1999) explained this according to the TCM theory of the five elements or five phases (this relates the *zang* organs to nature and explains their relationship accordingly), *liver* (*wood*) dominates *spleen* (*earth*). Beinfield and Korngold (1992, p98) explain this relationship, "As *Wood* dominates *Earth*, so the activating power of the *Liver Qi* awakens the transformative function of the *Spleen*". If the *spleen* is already weak, then the *liver* may overexert this control on the *spleen*, making it even weaker. The *spleen* is the organ which, when weak, is responsible for the production of pathogenic phlegm and dampness. If the *spleen* is made weaker by over control or invasion from a stuck and overheated *liver*, there will tend to be even more phlegm and dampness, leading to oedema, loose stools, obesity and more seriously, lumps and bumps in the flesh or in the organs. Furthermore, according to Yu (1997) if the *liver* is overheated, these lumps and bumps can become solidified, like gooey dumplings, which harden into bread when steamed or boiled. This is one way that tumours, both benign and malignant, develop.

According to modern Western medicine, hot flushes are due to instability of the brain's relay system, its neurotransmitters, which are affected by the lowered levels of oestrogen in the blood stream as menopause progresses. Wolfe (1998) indicated that "It can take a while for this brain relay system to readjust itself to a new level of blood oestrogen. For the average woman this usually means about a year of hot flashes, although some women experience them for much shorter or longer periods of time and some not at all" (p5).

This instability affects the autonomic nervous system (ANS). It is the ANS that is responsible for the body's thermostatic control, contraction and dilation of the blood vessels and skin pores, perspiration and other automatic physiological responses of our body. Another way to think about the ANS is that it is responsible for all the many things that go on in our bodies, without our conscious awareness (Wolfe, 1998).

Night sweats which are related to hot flushes but are experienced at night often involving a complete drenching of bed clothes and feelings of being chilled instead of being overheated. These are often more problematic than hot flushes because they disturb a woman's sleep, thereby causing other problems. In fact, some sources feel that the fatigue, irritability, and insomnia which some menopausal women reports are merely side effects of frequent night sweat episodes (McVeigh, 1990).

Another common symptom of menopause is irregular periods with extremely heavy bleeding. Again, this seems to be related to the erratic brain relay system and lack of ovulation, which results in irregular levels of oestrogen in relationship to progesterone. Fibroid tumours, endometriosis, and uterine cancer are also possible causes. Excessive stress can make this problem worse. Excessive menopausal or postmenopausal bleeding is usually treated with oestrogen replacement therapy (ERT) (Wolfe, 1988).

Other symptoms which can affect women during menopause include depression, palpitations, numbress and tingling in the limbs, urinary frequency or incontinence, back pain, vaginal dryness or irritation, and various gastrointestinal disorders (Berkow and Fletcher, 1987). Further problems may occur after menopause including postmenopausal bleeding, serious bone decalcification (osteoporosis) and an increased incidence of heart disease.

Chen, Hsue, Chang and Gee (1999) evaluated the association between postmenopausal osteoporosis and *kidney* deficiency syndrome. The results showed that patients with *kidney qi* vacuity and *kidney yin* vacuity were more likely to suffer from osteoporosis than those without these problems. No significant difference in the rates of osteoporosis between the *kidney yang* vacuity group and non-*kidney yang* vacuity group was found. The *kidney qi yin* vacuity group had a higher probability of developing osteoporosis than the *kidney qi* vacuity or *kidney yin* vacuity group.

One of the maxims in TCM is, the *kidneys* control the bones. The *kidneys* store vital *essence*, take charge of reproduction, growth and development, regulate water circulation, help the lungs receive air (inhale), supply the bones with marrow and determine the condition of the bones (Xie and Liao, 1993). The *kidneys* in TCM comprise one of the five organ systems of TCM *Zang Fu* (internal organs) theory. In this system the *kidney's* role only partly corresponds with the role accorded to them in western physiology. The *kidneys* control the bones resulting in *kidney* and bone being closely related physiologically (Yin, 1992).

The vital *essence* stored in the *kidneys* (the chief constituent of *kidney yin*) is the basis of reproduction, growth and development, formation of marrow, nourishment of bones and functioning of the brain. If the vital *essence* in the *kidneys* is insufficient the following symptoms may occur in adults according to Xie and Liao (1993): premature senility, sterility, slow reactions, dizziness, tinnitus, hypomnesia, softening of the bones, weakness of the legs and luxation of the teeth.

Kidney yang warms the body, heats up the *spleen* to assist in food digestion, helps the *lungs* receive air, regulates the water metabolism, assists the urinary bladder in storing and discharging urine and acts as the dynamic force behind reproduction (sexual potency). Xie and Liao (1993) list symptoms associated with deficiency of *kidney yang* as: chilliness, intolerance to cold, cold limbs, diarrhoea with fluid stools containing undigested food or diarrhoea occurring before dawn daily, dyspnoea or asthma, oliguria, oedema, dysuria, incontinence of urine, impotence and hyposexuality.

Osteoporosis exhibits many different patterns related to the *kidney*. Diseases of the *kidneys* involve another typical symptom that is related to pathoanatomy rather than pathophysiology, that is, pain in the lumbar regions. Ailments of the *kidneys* often cause pain in the lumbar region, these problems can be exacerbated by external factors. Exogenous pathogenic factors (such as *cold-damp* or *damp-heat*, where *damp* is a disorder of the water mechanism resulting in fluid accumulation in the body) attacking

meridians and collaterals or stagnated *qi* and *blood* due to muscle strain or traumatic injuries cause lumbago of excess pattern. In these cases, the practitioner must tonify the *kidneys* as well as remove *cold-damp*, *damp-heat* or *blood stasis*. If *cold-damp* causes lumbago it manifests as pain characterised by an association with cold sensations. It will be aggravated by cold damp weather. A heat sensation in the lumbar region accompanies lumbago due to *damp-heat*. If *blood* stasis causes the lumbago it is usually accompanied by a history of trauma and the pain is characteristically in a fixed location, there is difficulty in turning over and local tenderness (Xie and Liao 1993).

2.3 Diagnosis and Treatment

Western medicine looks for an organic dysfunction that is responsible for problems such as high blood pressure and thyroid or pituitary disorders. Most often, however, the medical texts counsel the doctor to try and evaluate how many of these symptoms are psychogenic in origin (Berkow and Fletcher, 1987). "In other words, modern Western medicine often tends to dismiss some aspects of menopausal syndrome as psychological or emotionally induced. While there is no doubt that psychoemotional factors play a role in many modern women's health problems, this attitude on the part of Western practitioners may also be because Western medicine posits no clear etiology or cause for many of these signs and symptoms other than estrogen deficiency" (Wolfe, 1998, p6).

Western medicine essentially defines menopausal problems as a lack of oestrogen production. The main Western therapy prescribed for menopausal women is oestrogen replacement therapy (ERT). While not a panacea for the symptoms of aging, ERT can diminish or eliminate many of the troublesome symptoms of menopausal syndrome, at least for a period of time. Especially hot flushes, night sweats, and joint or back pain due to bone decalcification are often positively affected by ERT. ERT also seems to have a positive effect on the elasticity of the arteries, thereby reducing the risk of heart disease (Gambrell and Don, 1990). Oestrogen creams are also used locally to reverse

vaginal inflammation and sensitivity as well as some cases of urinary incontinence (Wolfe, 1998).

ERT therapy, however, does have risks. It has been implicated as a factor in certain types of breast cancer. It is also linked to higher rates of endometrial cancer (cancer of the uterine lining). However, preliminary research indicates that the use of lower doses of oestrogen with progesterone added for part of the month reduce or negate this latter risk (Greenwood, 1989). Additionally, ERT is usually not prescribed for women who smoke due to the possible increased risk in these women of blood clots and stroke, or for women with gallbladder disease. Finally, some women will have to discontinue ERT due to excess vaginal bleeding, sore breasts, nausea and vomiting, uterine cramps, or abdominal bloating (Gambrell and Don, 1990).

Brynin (2002) indicated that both animal and human studies demonstrate that phytoestrogenic soy isoflavones favorably impact bone health, however the exact mechanism is still unclear. Additional research is needed to determine if isoflavones are an effective alternative to hormone replacement therapy for the prevention and treatment of osteoporosis. The effects of soybean protein intake on bone metabolism in postmenopausal Japanese women were studied by Horiuchi, Onouchi, Takahashi, Ito and Orimo (2000). The results suggest that a high soy protein intake is associated with a higher bone mineral density and a lower level of bone resorption, but further studies are needed to confirm the causal dynamic mechanisms.

Li, Miyahara, Tezuka, Namba, Suzuki, Dowaki, Watannabe, Nemoto, Tonami, Seto and Kadota (1999) reported that they isolated berberine from aqueous extracts of tsu-kangan, a Kampo formula used for the treatment of osteoporosis. They found that berberine caused an inhibitory effect on parathyroid hormone (PTH) – stimulated bone resorption in neonatal mouse bone. Oral administration of the berberine (30 and 50 mg/kg/d) to ovariectomized rats prevented a decrease in bone mineral density (BMD) of the lumbar vertebra without affecting the weight of the uterus and plasma concentration of estradiol. They suggested that berberine prevented a decrease in BMD in vivo by inhibiting osteoclastic bone resorption. This study was followed by another trial undertaken by Li, Miyahara, Tezuka, Namba, Nemoto, Tonami, Seto, Tada and Kadota (1998), they indicated that the inhibitory effect of tsu-kan-gan on bone resorption was at least partly attributed to the inhibitory action of this compound. A number of studies on bone density utilizing Chinese medical modalities are further reviewed in Section 2.4.

Chinese medicine does not segment health problems as either physical or psychological entities. One of the most enlightened aspects of Chinese medicine is that it never creates a mind/body dualism. To a practitioner of TCM, an emotional or mental event or experience is only another piece of diagnostic information no different or less important than a physical sign or symptom. Treatment plans using acupuncture or herbal medicine typically include certain emotional tendencies or experiences as part of the overall pattern of disharmony being treated. While some practitioners of Chinese medicine may suggest the support of psychotherapy, just as many others may feel that acupuncture treatment is often as effective a method of working with certain emotional states. Classically, Chinese medical theory expects specific mental/emotional conditions to go along with certain disease patterns, and expects these emotional symptoms to respond to treatment as well as any physical symptom (Wolfe, 1998).

In Chinese medicine each and every sign and symptom is considered in relation to all other signs and symptoms. A menopausal woman may suffer hot flushes, night sweats, lower back pain, insomnia, irritability and constipation. A good practitioner of TCM would see and understand the whole pattern of this patient as if she were a landscape painting with various aspects – water, trees, mountains - a holistic approach. The practitioner would then prescribe one of or a combination of acupuncture, herbs, dietary/nutritional advice, exercise and/or massage therapies to work effectively with the entire pattern that each patient presents. Done skilfully, Chinese medicine need not, indeed cannot, separate a person into segmented parts treating one symptom or part at the expense of another. Each part is only relevant in relation to the whole of each patient's personal "landscape". Further, any change of even one sign or symptom may

change the entire pattern and therefore the entire treatment plan. In this way TCM is indeed a holistic and human system of medicine (Wolfe, 1998).

In Chinese medicine, however, a person with a Western diagnosis of menopausal syndrome and bone loss symptoms must undergo a complete TCM diagnosis before TCM treatment commences. This diagnosis can reveal any one of five or six simple patterns and a myriad of individualized complex patterns of disharmony, which can account for a specific person's menopausal and bone loss symptoms. Each of these patterns requires a different kind of treatment from the others, each of the herbal or acupuncture formula can be modified, eg. add or omit herb(s) or acupuncture point(s), making it more specific to that particular person's or groups' need and imbalance. Such personally tailored treatment lessens the possibility of that person or group experiencing unnecessary side effects (Wolfe, 1998).

This is significant because it means that a good practitioner of TCM can treat disease at a more fundamental level, which then helps prevent the onset of more serious disease. As such Chinese medicine is a good preventive medicine, as well as being able to treat symptoms and signs which Western medicine sees as subclinical and therefore does not recognize as disease (Xu, 1995). This is especially important in the treatment of gynaecological disorders, so many of which involve functional, emotional and from the Western medical point of view, often subclinical signs and symptoms.

In Traditional Chinese Medicine (TCM), herbal medicine and acupuncture have long been used for gynaecological and obstetric problems. As early as the Qing Dynasty (AD1644), Chinese physicians prescribed a special herbal formula named *Zhi Bai Di Huang Pill* for treating women who suffered from *yin* (body fluid) deficiency and heat hyperactivity. This condition manifests with the following major symptoms: severe deficient heat steaming from the bones (a feeling of severe internal heat), spinal sore/pain, irritability and night sweating (Li, Liu and Jiang, 1998). These manifestations describe menopausal symptoms.

The *kidneys* and bones are very closely related, *Su Wen. Liu Jie Zang Xiang Pian* in *Neijing* recorded: *Kidney* strength manifests in strong bones. The TCM classics use a number of terms such as *Gu Suo Bing, Gu Bi, Gu Wei, Gu Ku, Gu Zhou*, and *Gu Ji* to describe a range of bone conditions. Among these, *Gu Suo Bing* most accurately corresponds with bone atrophy and pain, these are the clinical symptoms of osteoporosis. In the Song dynasty (AD 960) the book *Bian Que Xin Shu* was written and gave the following description to explain bone loss. This is due to *kidney qi* deficiency and exhaustion, the *kidneys* are in charge of bones, *kidney water* has already dried up, thus all bones are dry, then gradually shorten and shrink. Treated late the patient may die. Moxibustion should be used and internally medicate with "*Dan Fu*" and similar herbs. Commonly used grass and plants are not effective. All aged people gradually shorten and may suffer from *Gu Suo* disease.

According to TCM theory, the *spleen* is in charge of transportation and transformation of food and water. If the *spleen* cannot preform the function of transportation and transformation then *postnatal essence* will gradually deplete and the bones will lack nourishment and waste away (Yang, 1998). As a result of this mechanism *spleen* deficiency can be another pathogenesis of osteoporosis.

Poor circulation of body *fluids* and *blood* stagnation can become pathogenic (a TCM pattern of disharmony). The treatment principles of tonifying the *kidney*, strengthening the *spleen*, invigorating the *blood* and removing *phlegm* (a thick pathologic and pathogenic product of body fluid metabolism disorder) (Yang, 1998) should provide prevention and treatment for osteoporosis.

Western medicine offers only limited satisfactory treatments for menopausal syndrome. Traditional Chinese Medicine, on the other hand, has many safe, tried and effective treatments for menopausal complaints and much wisdom concerning the whys and wherefores of these complaints, TCM considers different complaints in terms of patterns of disharmony (see Section 2.4 for further details). Different TCM treatment strategies are adopted to treat the different patterns of disharmony. In this way common symptoms as well as individual specific symptoms can be treated by TCM. This approach has been used in China for about three thousand years and Western people are now seeing the benefits of this methodology.

In summary, Traditional Chinese acupuncture, herbal therapy and Tai Ji exercise may provide a solution by preventing or reducing the loss of bone density and reducing related disorders. Subsequently these therapies may be used as a treatment and/or as a preventative in maintaining women's general health during menopause.

2.4 Traditional Chinese Medicine Strategies

2.4.1 Tai Ji (Tai Chi)

Tai Ji Chuan or Tai Ji exercise, as it is commonly known, is an art and science (Mackie, 1981) as well as a form of physical activity. It was originally developed from martial arts and has existed for centuries in China. Tai Ji has become increasingly widely known and practiced by western communities. It is a science of control of physical and mental functions that improve the health and outlook of the performer (Liu, 1994).

It is now widely recognised that physical activity plays an important role in maintaining the physical health and psychological well-being of the whole community (Taylor, 1995). Public health approaches will be needed to reverse the trend of increasing "hypokinetic" disease as the computer/communication revolution becomes worldwide (Haskell, 2000). Thus there is a need to find alternative activities that will attract large elements of the community to participate in physical activity. It is important to demonstrate that such alternative activities do have physical and psychological health benefits. It is also important to know what activities or substances deplete bone mass or speed up its loss. There is a need to attract sedentary individuals to participate in physical exercise to improve their health.

Longitudinal training studies have shown that strength training and high impact endurance training increase bone density (Chilibeck, Sale, and Webber, 1995). A significant increase in lumbar bone mineral density was seen in gymnasts following twenty-seven weeks of training (Nichols, 1994). Female athletes who exercised (including gymnastics exercise) significantly increased bone mineral density (Xu, et al., 1997). Exercise such as resistance training or weight-bearing activities like running or walking have an osteogenic effect on increasing BMD in young people with the decrease in BMD being slower in postmenopausal women who exercise. Nevertheless, the influence of the length and intensity of such physical activities remain to be determined (Barlet, Coxam and Davicco, 1995).

Studying exercise and BMD, Ellerington and Stevenson (1993, p71) stated:

"There is no evidence that exercise alone will halt osteoporosis, but it will strengthen muscles and generally improve fitness, which will minimise damage to bones in the event of a fall. Weight-bearing exercise may directly benefit the femur bones, but how much exercise should be done, and how often, is unclear. In general, exercise is, of course, of great benefit to the whole body functions".

Athletic amenorrhoea has a hypothalamic origin and is postulated to relate to an exercise induced disturbance in the pulsatile release of gonadotrophin – releasing hormones. This disturbance results in attenuated gonadotrophin and oestrogen levels and may consequently provoke an undesirable skeletal adaptation to sports training in young females (Hirchberg and Hagenfeldt, 1998). This indicates that over exertion may

badly affect bones. Tai Ji is a gentle form of exercise and should not produce these side effects.

Tai Ji exercise is a branch of Chinese traditional sport. Medical observations of older adults who practise Tai Ji exercise in China have shown favourable effects on the cardio-vascular system; lipid metabolism; bone and joint function; calcium and phosphorus metabolic functioning; and the prevention of early aging (Qu, et al., 1959).

Tai Ji has been practised in China since ancient times, Tai Ji is becoming extremely popular in the west due to its beneficial effects on physical and mental well-being. The words "Tai Ji" or "Tai Ji Quan" means "Supreme Ultimate Fist", "Chuan" (fist) this is much more than a clenched hand. To a Chinese person, it means "studies and training associated with a martial art". However, Tai Ji, as it is generally called, is frequently used for improving and maintaining health (Crompton, 1996).

Participation in Tai Ji is increasing in Australia (Han, 1993). In a study of 380 new Tai Ji participants in twenty Melbourne Tai Ji schools it was found that most of the participants were mature and older adults, that the majority were female and that many had never played competitive sport. Their main motivation in taking up Tai Ji was that they liked the gentle and graceful nature of Tai Ji, the opportunity to exercise and to relax the mind and body together as well as for the treatment of existing medical conditions (Han and Morris, 1991).

Tai Ji exercise has been widely practised since the 16th century as a means of keeping fit and preventing and curing disease. Its popularity has further increased since the adoption of a simplified set of exercises (24 styles) in 1956. It has formed an important part of treatment often prescribed in hospitals and sanatoriums in China for different kinds of diseases. Early in 1959, Qu, et al. used spinal x-ray to observe the reduction of bone structure in older males, aged from 59 to 89, comparing members who participated in a Tai Ji program with a control group, it showed that the control group without Tai Ji

exercise had a greater reduction in bone structure. They also indicated that from their clinical observation Tai Ji has proved its efficacy in reducing the rate of bone loss and treating chronic diseases such as high blood pressure and neurasthenia.

The positive effects of Tai Ji have much to do with its characteristic features, namely:

- 1. the requirement of a high degree of concentration, with the mind free from distractions;
- 2. the execution of movements that are slow and uninterrupted like a flowing stream; and
- 3. the utilisation of breathing that is natural, sometimes involving abdominal respiration in rhythmic harmony with body movements.

From a Western physiological point of view, Tai Ji is a moderate intensity exercise that is beneficial to cardiorespiratory function, immune capacity, mental control, flexibility and balance control; it improves muscle strength and reduces the risk of falls in the elderly as explained in Section 2.1.

The combination of these attributes makes systematic performance of Tai Ji exercise an excellent method for strengthening the bodies of older adults.

"In view of the uniqueness of the Tai Ji exercise method, especially the results of the slow but brisk movements and their favourable action on the cardio-vascular system, we may assert that Tai Ji exercise constitutes one of the best methods for strengthening the body and preventing disease in the aged" (Qu, et al. 1959, p49).

The gentle unhurried movements of Tai Ji and the emphasis on deep breathing and relaxing the muscles directly relieve cramps. Tai Ji movements are fluid and the body is in motion from the start to the completion of the exercise session. Often the greater part or all of the body weight is supported on one leg; transitions from one posture to the next are made very slowly; the knees are bent all the time. These characteristics

mean that Tai Ji can be ideal for the elderly as they can gain leg strength and improve body static balance.

Another advantage that Tai Ji has as an exercise is its convenience. Only ten minutes exercise is all that is required for a practice session (Pang and Hock, 1984). (Note: The Beijing twenty-four style of Tai Ji used in this study requires only five minutes to complete; therefore, it can be repeated according to a person's available time.) It can be practiced solo in a relatively small area with no special equipment. Tai Ji is not only an exercise, participants can receive benefit not only physically but also mentally and spiritually. Learning the movements and postures is just the very beginning of the practice of Tai Ji. The real benefits of this exercise occur when the participant is able to make *qi* circulate smoothly and balance *yin* and *yang*.

Most observational and epidemiological studies suggest that physical activity is beneficial in reducing the risk of falling due to improved balance, flexibility and coordination skills. It might well be that the effect of exercise on fall reduction is more important than any effects on bone density (Australian National Consensus Conference, 1996).

Wolf, Kutner, Green and McNeely (1993) indicated that subjects who participated in Tai Ji exercise had less loss in left hand grip strength, reduced ambulation speed, and lowered systolic blood pressure when tested after a twelve minute walk. Thus, Tai Ji appears to favourably influence the two important physical fitness traits of balance and strength.

Physical training improves physiological capacities. While balance is affected by multiple factors its improvement is a more difficult task. Theoretically Tai Ji should be an appropriate exercise to increase both lower extremity strength and balance ability for all ages but particularly for the elderly. Liu, Lawson and Wrigley (1993) in their study of a 10 week physical training program of Tai Ji and other exercise found an

improvement in lower extremity strength and stability using a single legged stance after training an elderly group. In the training group, the strength improvement at the high angular velocity was 30% whereas at the low velocity it was 20%. The body sway forces declined 15% to 20% for the training group. No significant changes in strength and balance were found in the control group. They concluded that an appropriate 10 week Tai Ji course and some simple exercises improved both knee strength and balance in the elderly. Tai Ji training has confirmed that exercise can improve leg strength and static balance. Tai Ji involves a number of muscles and joints of the limbs and trunk and its movements emphasise balance as well as muscular strength.

Most older people are concerned about maintaining their capacity for independent living. Few older Australians are motivated to participate in healthy lifestyle behaviours such as physical exercise (Kendig, 1996). Tai Ji exercise has become increasingly popular in many countries as a method for older people to cope with stress and to maintain health. In future it is hoped that elderly Australians can be encouraged into accepting Tai Ji as a means of improving their mental outlook, fitness and their capacity for independent living. It should also be a useful modality for preventing or reducing the loss of bone structure and function.

2.4.2 Acupuncture

Acupuncture is the practice of puncturing the body with metal needles (steel, gold or silver) at specific points in order to regulate construction *qi*, defence *qi* and the *blood* (Wiseman and Ye, 1998).

According to Traditional Chinese Medicine (TCM) theory, the *kidney* system stores the *essence* and governs growth, development and reproduction (Zhang, 1992). Shen (1988) indicated that the functions of the *kidney*s are related to the functions of the adrenal gland, hypophysis and thalamus. Stimulating the acupuncture points on the *kidney* channel may increase oestrogen levels.

Helms (1987) suggested that acupuncture has a remarkable effect on the pituitary gland and adrenal cortex system, the sympathetic nervous system, the adrenal medulla system, the pituitary and thyroid gland system, the sexual glands and the posterior pituitary system and the actions at different sites of endocrine activity. More detail is available from Wyon, Lindgren, Hammar and Lundeberg (1994) who suggested that vasomotor symptoms are very common among peri menopausal women, the cause of the symptoms is not the low steroid concentration per se, but probably changes in central neuropeptide activity. Their study on acupuncture against climacteric disorders concluded that the frequency of flushes decreased significantly by more than 50% in both electrostimulated acupuncture and superficial needle position acupuncture.

As previously stated, in Traditional Chinese Medicine health is considered to be a function of the smooth flow of qi (qi translates as vital activity of life energy) through a series of pathways or meridians. Stimulating channel points can promote and regulate the energy (qi) and *blood* to activate bone formation and growth. TCM therapy aims not only to treat one disease but to regulate and balance the functions of the whole body (Zhang, 1992).

Acupuncture has been used to relieve the pain of osteoporosis for many years.

"Several types of pain relief do not involve taking pills. Most, including acupuncture, ultrasound, and trans-electrical-nervestimulation, are usually available in hospital physiotherapy departments or from independent practitioners." (Ellerington and Stevenson, 1993, p75).

"I became interested in acupuncture and was asked by a number of patients with osteoporosis if I could ease their pain with my needles. This continued when I became consultant acupuncturist at a public hospital where I treated a large number of women with pain resulting from compression fracture." (Rose, and Rose, 1994, p2). The following reports show the effects of acupuncture on bone mineral density (BMD); acupuncture can improve bone density by increasing the serum estradiol (E2). It must also be noted that acupuncture produces limited side effects from long-term use.

Wu, Wu, Qian, Li, Jue and Lin (2000) reported a pre and post 85 days' treatment comparison in 40 postmenopausal osteoporosis patients. Acupuncture was used on the main points of Da Zhu (BL 11), Da Zhui (DU 14), Ming Men (DU 4) and secondary points of Xuan Zhong (GB 39), Ge Shu (BL 17), Zu San Li (ST 36). A 1.28% increase in Lumbar BMD was found. Moxibustion with herbal moxa mainly included herbs Ai Ye, Yin Yang Huo, Bu Gu Zhi, Ci Wu Jia, Huang Qi, Dang Gui, Du Zhong, Gui Zhi and Huai Niu Xi. A 1.32% increase in Lumbar BMD was found. They concluded that acupuncture and moxibustion could increase BMD in osteoporosis patients after tonifying *kidney*, but no statistical significance was reported.

Liu, Wu and Wu (2001) utilising the above mentioned acupuncture and moxibustion points in rats found that acupuncture and moxibustion also promoted fracture healing in animal ovariectomized osteoporosis. 12 month old female rats were ovariectomized bilaterally to create osteoporosis, closed fractures were produced at the middle shaft of the right femur three months after bilateral ovariectomy. Five groups were randomly divided into control, ovariectomized, estradiol, acupuncture and moxibustion. The rats were dissected at 7, 14 and 28 days after fracture. Histological study, serum biochemical exam and bone morphogenetic protein (BMP) in callus were observed. Results showed that serum estradiol (S-E2), serum bone growth protein (S-BGP) and light density of bone morphogenetic protein (BMP) in the acupuncture group and the moxibustion group were significantly higher than those of the ovariectomized group on the 14th day after fracture. On the 28th day, S-E2, S-BGP and BMP in the acupuncture group and moxibustion group were close to those of the control group. On the 14th day, the amount of cartilage cells and osteoclasts in the ovariectomized group was a little more than that of the acupuncture group, moxibustion group and estradiol group. On the 28th day, calluses were all mature in each group, however only in the ovariectomized group were they porous.

Zhao, Yan, Shao, (1999) reported on rats where experimental osteoporosis was developed by ovariectomy on both sides. The effects of acupuncture and moxibustion on bone metabolism were investigated and a sham operation group and western drug group (intermascular injection of oestrogen – estradiol 2) were used as controls. The results showed a similar improvement in all treatment groups. Acupuncture and moxibustion on the points Ming Men (DU 4), Pi Shu (BL 20), Zu Shan Li (ST 36), Da Zhui (DU 14), appeared to be effective techniques for the prevention and treatment of osteoporosis. Acupuncture and moxibustion increased the level of oestrogen, inhibited bone resorption and promoted bone formation. This resulted in an improved bone metabolism as bone formation was promoted while resorption was inhibited. Acupuncture and moxibustion had a positive therapeutic effect on osteoporosis as oestrogen levels were increased.

A survey of the literature indicates that many acupoints can be used for the treatment of osteoporosis: nine of these acupoints were used more than 10 times. They were: Shen Shu (BL 23), Ming Men (DU 4), Guan Yuan (RN 4), Wei Zhong (BL 40), Tai Xi (KID 3), Pi Shu (BL 20), Yang Ling Quan (GB 34), Zu San Li (ST 36) and Xuan Zhong (GB 39). These points are located on the lower back or on the leg and are used to strengthen the back and legs. A number of them tonify *kidney* so strengthening sinews and bones. According to Zhou and Wang (2000), moxibustion on Shen Que (RN 8) and Zu San Li (ST 36) could significantly improve oestrogen levels in older adults. Liu (1998) reported that acupuncture treatment improved serum oestrogen levels, reduced the serum testosterone level, and reduced the ratio between calcium and creatinine in the urine.

Adequate clinical trials of acupuncture on bone related disease especially prevention or treatment of osteoporosis are scarce. A popular perception in the Western world is that acupuncture is mainly used for pain relief and the majority of the clinical trials have focused on pain management and musculoskeletal disorders (Tavola, Gala, Conte and

Invernissi, 1992; Takeda, and Wessel, 1994). Kang, Ansbacher and Hammoud (2002) indicated that there was insufficient data on alternative therapies for treating menopausal symptoms at this time, alternative and complementary medicine may play a role in the management of menopause, however well-designed large studies are still needed. Wang (1998) stated that most of these studies were conducted by researchers not sufficiently trained in acupuncture to provide quality TCM diagnosis and treatment.

2.4.3 Herbal Medicine

In Traditional Chinese Medicine (TCM), the kidney system is also said to control the bones and the production of marrow (Zhang, 1992). Shen (1988) indicated that many kidney tonifying herbs could accelerate bone repair thus indicating the relationship between the kidney and skeletal system. Avoiding vitamin D deficiency in the osteoporotic at risk groups is an important part of providing care for the elderly (Australian National Consensus Conference, 1996). Kidney tonifying herbs can improve the utilisation of Vitamin D3 thus improving calcium absorption. А preliminary clinical study on the prevention of bone loss in postmenopausal women with kidney invigorating herbs suggested that one of the therapeutic mechanisms of "Bushen Migu Ye" (a herbal formula) was the reduction of bone reabsorption without affecting bone formation in postmenopausal women (Shen, Du and Yang, 1994). According to Henderson (1999), Wang Y at the 21st Annual Meeting of the American Society for Bone and Mineral Research reported that a traditional Chinese medicine formula, which includes placenta powder, increases bone mineral density in osteoporosis patients. It was also considered superior to oestrogen at the dose of 1mg, four times daily. 85% of osteoporotic patients receiving a traditional Chinese medicine reported alleviated pain, while only 53% of those receiving oestrogen did. Additionally, BMD was significantly increased in patients receiving the Chinese medicine. Women given a low dose of oestrogen had no increase in BMD.

To avoid a lifelong increased risk of fractures due to low peak bone mass, oestrogen replacement is usually considered (Yang, Tsan, Chang, and Ng, 1995). However, due

to the side effects of long-term HRT use, alternative therapy has great value. Cui, Yu and Ding (1999) in their study compared the effects of hormone replacement therapy (HRT), calcium and a *kidney* and *spleen* strengthening formula - "Strong Bone Capsules" (SBC) on the treatment of the primary osteoporosis and relationship between the curative effect and bone metabolism. Seventy-four postmenopausal women with osteoporosis were treated with Chinese medicine capsules, compared with 31 type I primary osteoporosis postmenopausal women treated with calcium. The results showed that after three months the level of osteoporosis, serum ALP, CT and E2 had significantly increased when compared with the control group and no side effects were observed. They suggested that the effects of this *kidney* and *spleen* strengthening formula (SBC) are much better than calcium. "Strong Bone Capsules" had therapeutic effects in treating primary osteoporosis.

Kim, Lee, Choi and Lim (1998) discussed the clinical effect of Korean Red Ginseng on osteoporosis. The results showed that there were no statistically significant differences in clinical presentations, biochemical, and radiological assessments between the red ginseng and the control groups. No definite effectiveness of red ginseng on patients with osteoporosis was found. It was suggested that for effective treatment, more herbs and the selection of herbs according to the pattern of osteoporosis may be necessary especially for effective treatment in patients who have already suffered osteoporosis.

For relief of menopausal symptoms, black cohosh root extract and Dong Quai have good safety profiles but only black cohosh has demonstrated efficacy for this indication (Hardy, 2000). Kronenberg, and Fugh-Berman (2002) concluded that black cohosh and foods that contain phytoestrogens show promise for the treatment of menopausal symptoms. However long-term safety data on individual isoflavones or isoflavons concentrates is not available. In European phytotherapy, Pemifemin is commonly prescribed as an effective alternative to hormone replacement therapy for menopause (Mckenna, Jones, Humphrey and Hughes, 2001).

Chinese herbs have been used for many years to effectively treat menopausal and related syndromes. Ding, Soma, Takano-Yamamoto, Matsumoto and Sakuda, (1995) suggested that salvia miltiorrhiza bunge (SMB) (Dan Shen), a Chinese herb directly stimulates alkaline phosphatase activity of MC3T3-E1 cells in multilayer stage or calcification stage without any effect or proliferation. Locally administrated SMB may affect the differentiation of osteoclasts in vivo. These could result in less bone resorption and fewer fractures. Wu, Xu and Huang (1996) studied a mixture of extracts from eight traditional Chinese herbs in preventing and treating retinoic acid induced osteoporosis in rats. Results showed that the herbal formula displayed obvious action in preventing osteoporosis, the trabecular loss of tibiae and bone loss of compact bone were lowered markedly in herbal groups taking a high or middle dose when compared with control group. The trabecular area percentage and compact bone area percentage were increased significantly which approached the level of normal control groups. The formula could also improve pathological changes in microstructure of bone, increase the thickness of trabecula and cortex, reduce the trabecular gap and bone marrow cavity. They suggested that the mechanism might result in suppressing osteoclast activity and activating osteoblasts leading to a positive balance of bone metabolism, increasing the blood concentration of calcium and oestrogen as well as the antagonistic action against the injury of sex glands by retinoic acid. Song, Shen and Chen (2000) indicated that post-menopausal osteoporosis may be successfully treated with Chinese medicine as the herbs can be used to increase the level of estradiol (E2) and reduce the rate of bone turn-over.

Xue (1999, p500-501) in her book has outlined Feng's summary of the four different Chinese Medicine herbal treatment regimens for osteoporosis according to the symptoms displayed by the patient.

1. Kidney deficiency and cold pattern:

Symptoms and signs: Cold and sore back, soreness and weakness in the back and knees, tiredness and shortness of breath, difficulty sitting for an extended period, limited movement and hunched back, a high stepping gait, aversion to cold, preference for warmth, pain aggravated by cold, frequent

urination. Pale tongue, white greasy tongue coating, deep, thready or wiry pulse.

Treatment principle: Warm and tonify *kidney yang*, dispel cold and resolve *damp*.

Formula: You Gui Wan (Shu Di, Shan Yao, Shan Yu Rou, Gou Qi Zi, Du Zhong, Tu Si Zi, Fu Zi, Rou Gui, Dang Gui, Lu Jiao Jiao), a traditional formula from <Jin Yue Quan Shu>.

2. Yin deficiency and internal heat pattern

Symptoms and signs: Back pain, weak and tired knees, hunched back, heat in palms, feet and in the chest centre, dry mouth and tongue, red tongue with yellow and greasy coating, pulse deep, thready and rapid.

Treatment principle: Nourish *yin* and clear heat, dispel dampness and release Bi syndrome (back pain).

Formula: Zou Gui Wan (Shang Di, Shan Yao, Shan Yu Rou, Tu Si Zi, Gou Qi Zi, Niu Xi, Lu Jiao Jiao, Gui Pan Jiao), a traditional formula from <Jing Yue Quan Shu>.

3. Blood deficiency and water retention pattern

Symptoms and signs: Back pain, painful or swollen joints, tiredness with palpitations, pale and lifeless complexion, pale tongue, greasy white tongue coating, deep and thready pulse.

Treatment principle: Nourish blood and promote urination.

Formula: Dang Gui Shao Yao San (Dang Gui, Chuan Xiong, Bai Shao, Cang Zhu, Ze Xie and Fu Ling), a traditional formula from <Jin Gui Yao Lue>.

4. Qi deficiency and blood stagnation pattern

Symptoms and signs: Tiredness, spontaneous sweating, shortness of breath, taciturnity, dizziness or vertigo, back soreness, pain in the chest or

hypochondriac regions, sharp joint pain, tongue dark or with petechiae, pulse deep, thready and wiry.

Treatment principle: Tonify qi and nourish blood

Formula: Shi Quan Da Bu Tang (Dang Shen, Huang Qi, Fu Ling, Bai Zhu, Gan Cao, Rou Gui, Shu Di, Chuan Xiong and Bai Shao), a traditional formula from <Yi Xue Fa Ming>.

Some formulae and herbs associated with osteoporosis treatments are available in prepared form in China and are described in Table 2-2 according to Feng as outlined in Xue's book (1999, p501-504).

Table 2-2 Commonly Used Prepared Formulae for the Treatment of Osteoporosis

Herbs Application	Formula and Main Herbs	Action	Indications and Application	Caution
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Formula and Main Herbs	Action	Indications and Application	Caution
"Qing E Wan" a	Tonifying	Lower back pain due	Not for use in
traditional formula	kidney and	to kidney deficiency;	cases of yin
from book <jiu< td=""><td>strengthening</td><td>continuing lower back</td><td>deficiency</td></jiu<>	strengthening	continuing lower back	deficiency
Fang> (1102-1106):	back	soreness and	with internal
Bu Gu Zhi, Du		weakness as the chief	heat or yang
Zhong, Hu Tao Rou		symptom; sore and	excessive
Ċ,		weak knees	heat
		aggravated when over	
		tired, relieved after	
		rest in bed. For all	
		middle aged or older	
		people with kidney	
		deficiency, or for the	
		prevention of	
		osteoporosis	
"Jin Gui Shen Qi	Warm	Sore back and weak	Not for use in
Wan" a traditional	tonifying	knees due to kidney	cases with
formula from book	<i>kidney</i> yang	yang deficiency, cold	damp-heat
<jin gui="" lue="" yao=""></jin>		below the knees,	pattern
(AD25 – 225):		dysuria, or urinary	
Shu Di, Shan Yao,		frequency at night.	
Shan Yu Rou, Fu			
Ling, Ze Xie, Mu			
Dan Pi, Fu Zi, Rou			
Gui			

Formula and Main Herbs	Action	Indications and Application	Caution
"Gu Song Bao"	Tonifying	Osteoporosis, fracture	Use with
(modern* formula	kidney,	or arthritis caused by	caution in
produced by Gui	strengthening	osteoporosis and	cases of
Zou Fu Hua	sinew and	prevention of	spleen
Pharmaceutic	bones	osteoporosis	deficiency,
Company):			poor appetite
Qian Lin Hou,			and diarrhoea
Sheng Di, Mu Li			
"Gu Shu Kong" (a	Tonifying	Postmenopausal	Use with
modern* formula	kidney and	osteoporosis, mid and	caution if
produced by Liao	strengthening	old age osteoporosis,	abdominal
Ning Dong Gang	bones,	diabetes,	distension and
Pharmaceutic	benefiting	hyperthyroidism,	diarrhoea are
Company):	essence and	rheumatoid arthritis,	present
Huang Qi, Dan	tonifying	secondary	
Shen, Xian Ling Pi,	marrow,	osteoporosis	
Shu Di	invigorating		
	<i>blood</i> and		
	relieving pain		

Formula and Main Herbs	Action	Indications and Application	Caution
"Yi Shen Juan Bi	Warm,	Chronic Bi syndrome	Not for use in
Wan" (a modern*	tonifying	(rheumatic and	cases of
formula produced by	<i>kidney</i> yang,	rheumatoid arthritis,	stomach
Lian Yun Gang	searching out	aged joint pain,	excessive
Dong Feng	and	osteoporosis), with	<i>heat</i> , dry
Pharmaceutic	dispelling	symptoms such as	mouth,
Company):	wind, treating	joint pain, stretching	constipation,
Shu Di, Dang Gui,	Bi syndrome	difficulty, stiffness	and stomach
Xian Ling Pi, Bu Sui	and	and deformation	discomfort
Gu, Di Long, Di Bie	unblocking		
Chong	collaterals		
" Feng Shi Ye" (a	Dispelling	Wind cold damp Bi	Not for use
modern* formula	wind and	syndrome and	during
produced by Lu	dampness,	osteoporosis	pregnancy
Zhou Pharmaceutic	tonifying		
Company):	<i>liver</i> and		
Oiang Hou. Lu Jiao	kidney,		
Jiao. Bie Jia Jiao.	nourishing		
Hong Hua	<i>blood</i> and		
0	unblocking		
	collaterals		

Formula and Main Herbs	Action	Indications and Application	Caution
"Bi Chong Ji" (a	Tonifying	Chronic Bi syndrome	This is a
modern* Formula	<i>liver</i> and	and general	warm natured
produced by Da Lian	kidney,	deficiency; pain,	formula, for
Chang Bai Shan	strengthening	swollen, stiff and	preventing
Pharmaceutic	sinew and	deformed joints; and	osteoporosis,
Company):	bone,	stretching difficulty	1 bag each
Sheng Di, Fu Zi, Bu	dispelling		time, 2-3
Gu Zhi, Xian Ling	wind damp,		times a day.
Pi, Xu Duan, Hong	and		In cases of yin
Hua	unblocking		deficiency or
	meridians		excessive
			heat use it
			with caution
			or not at all
"Qi Li San" a	Invigorating	Trauma and injury,	Contraindica-
traditional formula	<i>blood</i> and	bone fractures, broken	ted for
from book <liang< td=""><td>reducing</td><td>sinew and pain caused</td><td>pregnant</td></liang<>	reducing	sinew and pain caused	pregnant
Fang Ji Ye>:	swelling,	by stagnation.	women
Xue Jie, Ru Xiang,	regulating qi	In cases of	
Mo Yao, She Xiang,	and relieving	osteoporosis with	
Bing Pian, Zhu Sha,	pain	fracture or broken	
Er Cha		sinew, internal and	
		external treatment can	
		be applied together	
Formula and Main Herbs	Action	Indications and Application	Caution
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"Liu Wei Di Huang	Nourishing	Kidney yin	Use with
Wan" a traditional	<i>yin</i> and	consumption,	caution in
formula from book	tonifying	deficient <i>fire</i> flaring	cases of
<xiao er="" td="" yao="" zheng<=""><td>kidney</td><td>up, sore back and</td><td>significant</td></xiao>	kidney	up, sore back and	significant
Zhi Jue> (960-		weak knee, loose	yang
1279):		teeth, dry mouth and	deficiency
Shu Di, Shan Yao, Shan Yu Rou, Fu Ling, Ze Xie, Mu		thirst, tinnitus, blurred vision, night sweating and sleeplessness	
Dan Pi		Osteoporosis sufferers with <i>yin</i> deficiency symptoms should use this formula	

*modern – post 1960

According to TCM theory the formulae mentioned above could be effective in relieving some of the symptoms of osteoporosis (Xue, 1999). Despite no available systematic research to examine the efficacy of these medications they are widely available and successfully self prescribed for bone loss prevention by the general Chinese population.

Chinese herbal formulae are able to increase body oestrogen levels through phytoestrogens that are a component of these natural herbs. They also provide a tonifyng effect on *kidney* as *kidney*'s function is stimulated and able to produce essential hormones thus reducing bone resorption leading to a reduction in bone loss.

The effects of tonifying herbs in preventing or reducing the loss of bone structure and function need to be further examined by both western and traditional Chinese medical science. A well-designed prescription according to "*Bian Zheng Lun Zhi*" (see Chapter 1) needs to be designed by a practitioner who has a good understanding of both western

and Traditional Chinese Medicine. The composition of the prescription needs to address the particular pattern of symptoms and signs of osteoporosis as evidenced by the patient. A well-designed formulation should also consider the acceptability of the taste, cost, safety issues, and popular application as a preventative.

2.5 Methodology Issues

2.5.1 Bone Density and Structure Tests

Low bone mineral density (BMD) is one of the strongest predictors of future osteoporotic fractures (Rosen, 2000). Clinically osteoporosis is defined as loss of bone density associated with fractures following minimal trauma or injury (Rose and Rose, 1994).

World Health Organization (WHO) criteria for the diagnosis of osteoporosis include:

- 1. Normal: BMD not more than 1 SD below the young adult mean;
- 2. Osteopenic: BMD between 1 and 2.5 SD below the young adult mean;
- 3. Osteoporosis: BMD more than 2.5 SD below the young adult mean;
- 4. Established (or severe) osteoporosis: BMD more than 2.5 SD below the young adult mean in the presence of one or more fragility fractures.

BMD is considered an important indicator which indicates the reduction of bone mineral contents, the degree of osteoporosis and the level of degeneration and hence seriousness of the condition.

Dual Energy X-ray Absorptionmetry (DEXA) gives 2-dimensional information on areal bone mineral density (BMD) (expressed as g/cm^2) throughout the whole body and has provided the most acceptable means to date of assessing osteoporosis in an individual.

However, bone density measurement is not the only method of diagnosing osteoporosis. Through comparison of reduction of bone mineral density in subjects of the same sex and age, predictions of the risk of osteoporosis can be made (Xue, 1998).

Over the past 15 years interest in the use of ultrasound for the assessment of osteoporosis has increased dramatically. Its use is now more acceptable in the collecting of extensive retrospective and prospective research data (according to CUBA clinical operating instructions). Ultrasound measurements have been proposed as a means of providing structural information on bone, but have also been shown to correlate with bone density (Kang and Speller, 1998).

Although measurements of BMD determined by DEXA have traditionally been the indications of bone function, in recent years it has been suggested that ultrasound measurements of the calcaneus may be more practical and may be used as a valid measurement parameter. Ultrasound measurements of bone include Broadband Ultrasound Attenuation (BUA) and Speed of Sound (SOS) through a skeletal segment. These techniques do not expose patients to ionizing radiations (Morbidelli, Spazzafumo, De Tommaso, 1998).

Roux, Fournier, Laugier, Chappard, Kolta, Dougados and Berger (1996) compared the ultrasound measurement of broadband ultrasound attenuation (BUA) with bone mineral density (BMD) at lumbar spine and found correlation coefficients of up to r = 0.56. In a similar evaluative study, Gonnelli, Cepollaro, Pondrelli, Martini, Rossi and Gennari (1996) determined correlations of r = 0.53 between BUA and BMD. Kang and Speller, 1998 reported that the BMD of the calcaneus, when closely matched to the site of ultrasound measurement showed a significant correlation. By excluding scans in which the ultrasound measurement appeared to include bone edges, correlations of approximately r = 0.86 were obtained. Suzuki, Kusumoto, Nagai, Yoshida, Watannabe, Kumagai, Amano, and Shibata (1996) state that DEXA and Ultrasound measure different bone properties so only modest direct correlations can be expected.

Much of the interest in ultrasound has resulted from its low cost, freedom from ionising radiation, portability, and ease of use. The promise of ultrasound providing new information about bone quality continues to motivate researchers and commercial developers. An increasing number of studies give mounting evidence that ultrasound devices for bone assessment can provide new and clinically useful information about bone quality which cannot be derived from bone densitometry alone (Brandenburger, 1993).

Quantitative Ultrasound (QUS) technique can be used for osteoporosis diagnosis. The WHO criteria cited previously for diagnosis of osteoporosis are also applicable for QUS. Xue (1999) indicated that women with low calcaneum BMD have an increased risk of hip fracture. Measuring calcaneum BUA, lumbar and hip BMD may be beneficial in diagnosing and predicting hip fracture in aged people. This is supported by a report from EPIDOS (an European organization) in Xue (1999) which evaluated 7575 women aged over 75. The ratio value of hip fracture (OR) to neck BMD was 1.9 (1.6 – 2.4); calcaneum BUA was 2.0 (1.6 – 2.4); calcaneum SOS was 1.7 (1.4 – 2.1). The correlation of the test results were positive in terms of spinal fracture and calcaneum BUA and SOS. This indicates that BUA and SOS could be used for fracture diagnosis. These measurements could be better indicators than DEXA measurements of the spine and hip. This is further evidence that QUS is a better measure of bone strength than BMD. QUS is potentially applicable for evaluating postmenopausal and age related bone loss.

2.5.2 Bone Formation and Resorption Tests

There is still a need for more specific methods of assessing disturbances in bone metabolism. Quantitative bone absorptiometry offers an accurate assessment of bone mass but it only measures structural changes that occur over several years in the individual patient. Direct serum measurements are useful because they allow for easy and frequent assessments without undue risk or discomfort (Calvo, Eyre, and Gundberg,

1996). Biochemical markers of bone turn-over provide a means of evaluating skeletal dynamics that complement static measurements of bone mineral density. Research applications of bone turn-over markers are of value in investigating the pathogenesis and treatment of bone diseases (Looker, Bauer, Chesnut, Gundberg, Hochberg, Klee, Kleerekoper, Watts, Bell, 2000).

Bone growth and modelling induce bone gain and bone resorption induces bone loss. The decrease in bone mass seen in osteoporosis is caused by an imbalance between bone resorption and bone formation during bone remodelling. Therefore, treatment can try to inhibit excessive bone resorption and/or increase bone formation. Disorders of bone remodelling are one of thee most common causes of osteoporosis especially in postmenopausal osteoporosis. Bone remodelling occurs in small packets of cells called basic muticellular units (BMUs). Bone remodelling is a complex process involving activation, resorption, and formation (A-R-F). It is a process of replacement of old bone with new bone. If the amount of newly formed bone during the formation period equals the amount of bone lost during the resorption period the bone balance is zero and bone is maintained. The bone balance is negative and bone loss occurs when the amount of bone during the formation period. In postmenopausal women bone resorption increases, with bone resorption greater than bone formation creating a negative bone balance, which accelerates bone loss and leads to osteoporosis (Ke, 1998).

The classic biochemical markers of bone disease, serum total alkaline phosphatase activity and urinary total hydroxyproline excretion, are strongly influenced by nonosseous metabolism and are subject to interference from systemic disorders. An ideal battery of tests would include indices of bone resorption and formation. The advances in research and development have provided assays with increased specificity, sensitivity, and availability (Lyritis, Magiasis, Tsakalakos, 1995). Dogan and Posaci (2002) indicated that biochemical markers reflect acute changes in bone metabolism and osteocalcin is one of the most promising markers. Osteocalcin is a relatively small protein that is rapidly filtered by the kidney and degraded (Xue, 1999; Power and

Fottrell, 1991). Serum osteocalcin levels are reportedly affected by changes in renal function. When renal glomerular function is impaired, circulating osteocalcin increases (Cheung, Manolagas, Catherwood, Mosely, Mitas II, Blantz, 1983).

There are some different opinions on the selection of bone remodelling indicators in climacteric women. Junqueira, da Fonseca, Bagnoli, Giannella-Netot, Mangueira, Coimbra, and Pinotti (2002) studied the biochemical markers of formation (osteocalcin) and bone reabsorption (cross-links of pyridinoline-CTx), bone mineral density and bone ultrasonometry compared to DEXA. 82 women, aged 45 to 60, menopausal from 1 to 10 years were included in the study. The results showed that the bone reabsorption marker (cross-links of pyridinoline-CTx) demonstrated statistically significant negative correlation with bone mineral density (lumbar and femoral neck), while the bone formation marker (osteocalcin) did not display a correlation with bone mineral density. Bone ultrasonometry yielded a statistically significant positive correlation with bone densitometry. They suggested that the bone reabsorption marker (cross-links of pyridinoline) and bone ultrasonometry and densitometry are measurements enabling evaluation of bone remodelling.

Bone densitometry as measured by Dual Energy X-ray absorptiometry is the key to diagnosis, but it has limitations. Ultrasound and peripheral densitometry may provide new, rapid screening tools. Biochemical markers may provide a method for the assessment of fracture risk as well as the response to therapy (Raisz, 1999). However, markers do not replace bone mineral density measurement (Dogan and Posaci, 2002). The bone reabsorption marker (cross-links of pyridinoline) and bone ultrasonometry and densitometry are measurements enabling evaluation of bone remodelling (Junqueira, et al., 2002).

2.5.3 Traditional Chinese Medical Assessments

TCM describes illness as "zeng" (a pattern of disharmony or a syndrome), a function of both internal and external phenomena adversely affecting the whole person. Illness is seldom thought of as being solely the result of a single causative agent (Watson, 1991). When making a diagnosis in TCM, the practitioner not only considers the generic signs and symptoms of a pathology, but also considers the individual's signs and symptoms, a consideration not given much significance within the Western medical framework (Watson, 1991). Diagnosis in TCM requires the application of various diagnostic procedures and the interpretation of that information in accordance with recognised patterns of disharmony. TCM diagnostic methods aim to collect signs, symptoms and other related diagnostic information from the client. These methods include interrogation, inspection, auscultation and olfaction, pulse feeling and palpation. All of these methods aim to provide a basis for differentiation in the patterns of disharmony. In this process, analysis and inferences are made on the basis of acquired clinical data (Yang, 1998).

The treatment principles and methods used in TCM are based on the patterns of disharmony of the disease. Each disease is differentiated into a number of patterns. The corresponding treatment is based on the underlying pathology of each pattern and not the disease per se. According to this unique principle, different treatments can be used to treat the same disease and the same treatment can be used to treat different illnesses. In the present study, the major patterns that have been found to reflect the condition of bone loss are *kidney qi* and *kidney yin* deficiency. The TCM treatments used during this study have a dual focus in correcting these patterns of disharmony as well as preventing the early onset of osteoporosis.

In summary Tai Ji exercise might provide a new and effective way of enhancing bone health. Tai Ji also improves balance, this is important as poor balance can lead to falls particularly in the elderly. Acupuncture is able to relieve pain, promote circulation and increase oestrogen levels. Chinese herbal medicine has the ability to tonify and nourish some deficiencies as well as increase oestrogen levels and strengthen bones. The current study was proposed to evaluate the three main modalities of TCM in terms of bone loss.

CHAPTER 3

METHODOLOGY

3.1 General Description

A two group pre- and post-treatment paired research design was used in this study. Fifty eight participants were recruited initially and divided into three groups. Forty of the initial 58 participants completed the treatments applicable to this study, underwent all assessment regimes and complied with subject requirements. Those eliminated did not meet all testing requirements or were affected by conditions not related to this study e.g. poor health. The overall research design consisted of three individual intervention modalities - Tai Ji exercise, Traditional Chinese Acupuncture Therapy and Traditional Chinese Herbal Therapy. Accordingly the 40 participants were divided into three groups: 12 in the Tai Ji group, 14 in the acupuncture group and 14 in the herbal group. Before and after each of the periods of treatment participants were tested to examine their bone structure and function by ultrasound as well as their bone turn over. They also received Traditional Chinese Medical assessment. Most of the subjects also completed a bone mineral density assessment by DEXA at the end of the study.

3.2 Subjects

The study was conducted using 40 women volunteers who generally met the menopausal profile of no period for three months, but having had one natural period in the last 12 months, or a prolonged irregular pattern (different to their previous menstrual pattern) and who completed all the requirements of the study. Although it was disappointing that 18 subjects of the original 58 participants did not complete the study, given the time required to comply with all the components of the project (eight months), and the demands on personal time the dropout / non-compliance rate of 31% is good. It should be noted that the majority of those who dropped out or who did not comply with

all requirements were classified as post-menopausal by the end of the treatment periods. Their data was excluded as they did not fit with the physiological profile (menopausal) of the major subject group. The characteristics of the subjects are described in Table 3-1.

	N	Minimum	Maximum	Mean	Std. Deviation (SD)
Age (yrs)	40	42.0	55.0	49.3	3.5
Height (m)	40	1.42	1.78	1.64	7.30
Weight (kg)	40	53.5	95.7	70.8	10.6

Table 3-1 Subject Characteristics

The 40 volunteer women meeting the menopausal profile were recruited from three areas:

- Staff of Victoria University (Melbourne, Australia)
- Staff of Department of Education, Employment and Training, Victoria (Melbourne, Australia)
- Volunteers from the local community (Melbourne, Australia)

All participants had lived in Melbourne for over 15 years. They became aware of this study through public e-mails within the university, posters at community health centres or leisure centres, local city councils, local newspapers and by word of mouth.

The volunteers were asked to state a preference for a treatment modality. They were then divided into three treatment groups; the Tai Ji group, the acupuncture treatment group and the herbal treatment group. Each participant's bone structure and function were tested using broadband ultrasound attenuation (BUA), and velocity of sound (VOS) alternatively referred to as speed of sound (SOS). Bone turn-over was tested using osteocalcin (OSTN), pyridinoline (PYR) and doxypyridinoline (D-PYR). These tests were carried out before the commencement of treatment. The treatment groups were then divided into subgroups A and B within each treatment modality based on their BUA. Their BUA results were listed in numerical order and volunteers were then paired based on the closeness of their BUA. One of each of these pairs was then placed into group A or B creating matched pairs. There was no significant difference between groups A and B at the outset of treatment. Details of the allocation of participants to groups are presented in Figure 3-1.



Figure 3-1 Diagram of Participation in the Study

3.3 Study Design

All methods of treatments were cross applied in the three subgroups. This meant that each group undertook the subgroup treatments for a period of four months before changing over from treatment to control or vice versa. In each treatment group A commenced treatment first. They were treated for four months then received no further treatment. Group B was not treated during the first four months. Relevant tests on both groups were taken after four months. Group B commenced treatment after the initial four months. They were then treated for the next four months. Group A was not treated during this period. Relevant tests on both groups were undertaken after eight months. As each group received four months of treatment and four months without treatment the duration of the study was set at eight months (see Figure 3-2).

Data from bone structure and bone function tests using a ultrasonic bone analyser (CUBA CLINICAL) and biomarkers of bone turn over using blood and urine tests were analysed by using SPSS 10.0 paired t-test. Data was also collected using Chinese medical assessments using the TCM four diagnostic techniques (see Section 3.4.4). This information was then analysed using Ridit analysis (as described in Section 3.5).

All participants were also given questionnaires relating to their diet and physical activity level for completion during the course of the study. The questionnaire allowed the researcher to monitor the volunteers' habits to determine that there were no significant changes to diet and physical activity as bone mass could have been affected. By filling in the questionnaire the volunteers were also made aware of their diet and physical activity habits thus encouraging them not to make any changes during the study. The methods of treatment conducted in this study were undertaken with the approval of the Ethics Committee of Victoria University.



Figure 3-2 Map of the Research Design

As previously discussed (Chapter 2) it has been determined that bone density and structure can change and fluctuate over time without treatment. By employing a paired design and comparing corresponding variables at each phase of the study it was possible to gain some critical data in relation to these natural changes. There was also an opportunity to observe any long-term treatment effects. Treatment effects have been considered within individual subgroups A and B and for the combination of subgroups A and B.

At both the beginning and the end of each treatment cycle (acupuncture, herbal medicine and Tai Ji exercise), all the participants underwent ultrasound bone structure and function tests, bone turn over assessments and Traditional Chinese Medical assessments (Appendix H). At the end of the study bone mineral density (BMD) results were assessed using DEXA measurement and compared with BUA results (see Section 3.4).

All participants in both the treatment group and control group were advised not to change their normal daily routines during the course of the study.

Additionally:

- Dietary information regarding calcium intake was recorded by questionnaire at the time of testing. This information was discussed at each of the interviews conducted as part of the testing. This was done to ensure that there was no significant change in the participants' nutritional practices (Appendix I).
- Information regarding the level of physical activity was recorded by questionnaire at the time of testing to establish whether subjects had been involved in any organised exercise program in the preceding four months. This baseline data was revisited at each of the three scheduled interviews

during the treatment to ensure that the participants had not changed their physical activity regimen during the study (Appendix J).

• Check lists for the administration of herbs were sent to the participants in the herbal group to record details of compliance in the administration of herbs (Appendix G).

The treatment procedures conducted in this study were undertaken with the approval of the Ethics Committee of Victoria University. Bone mineral density (BMD) assessment was measured using DEXA with the approval of both the Ethics Committee of Victoria University and the Department of Human Services, and the Radiation Safety committee of the Department of Human Services (see Section 3.4.2). A plain-language description of the study was provided to each applicant at the initial interview. The description paper included the following information:

- The background of the researcher.
- A brief explanation of the tests, Tai Ji exercise, acupuncture and Chinese herbal treatment.
- The epidemiology of osteoporosis.
- The aim of this study.
- The population and the treatment process of the study.
- The potential risks of the tests and therapies.
- The confidentiality and anonymity of the data collated. (see Appendix C)

The issues pertaining to the research were reinforced and explained by the researcher at each interview. The treatment and control cross over procedure were clearly described and explained to each participant. They were also told that they could withdraw from this study at any time. Each participant signed the informed consent statement (see Appendix D) before the exercise program and treatment started. All records were kept

secure and confidential and were only available to the researcher and relevant supervisors.

3.4 Specific Project Methodology

3.4.1 Project One – Effects of Tai Ji Exercise on Bone Structure and Function

Twelve volunteer menopausal women (aged 42-55 years, 50.0 ± 4.0 with similar social characteristics, 10 of them being administrative staff and two being teachers) were recruited to participate in this trial. The participants were divided into two groups (group A and group B, six participants respectively) matched according to their results using Broadband Ultrasonic Attenuation (BUA) testing as well as for age and menopausal status.

All participants were given information regarding the purpose of this study and the demands of this study design. Six participants (group A) practiced Tai Ji exercise (24 styles) for four months under the researcher's supervision. The exercise included about 10 minutes of introductory exercise and 50 minutes of Tai Ji exercise (see Appendix K for a description of introductory exercise and a description of the 24 Tai Ji movements), based on Crompton (1996) and the researcher's practical experience. The participants exercised for a period of one hour, twice weekly for four months. The other six served as a control group (group B) and did not exercise. The two groups were tested using BUA, VOS, OSTN, PYR and D-PYR as well as TCM assessment at the three test phases as indicated in Figure 3-2 (Map of the Research Design). After the initial phase of the four-month trial the groups exchanged places from control to treatment respectively for a further four-month period and then were tested again.

All participants were given a choice of three venues in which to practice Tai Ji. Those being the conference room at the Department of Education, Employment and Training,

Victoria (or the Fitzroy Gardens if the room was not available), the Dance Studio at Victoria University and a similar facility at the University of Melbourne.

3.4.2 Project Two – Effects of Acupuncture on Bone Structure and Function

Fourteen volunteer menopausal women (aged 42-55, 49.3 ± 3.6 years with similar social characteristics; ten of them being administrative staff, three being teachers and one a home duty mother) were recruited to participate in this trial. The participants were divided into two groups (group A and group B, seven participants respectively) and matched according to their results for Broadband Ultrasonic Attenuation (BUA) testing as well as for age and menopausal status.

The participants received traditional Chinese acupuncture therapy and were assessed according to the principles of Traditional Chinese Medicine. Three main acupuncture points in the lower legs were used in accordance with the common pattern of disharmony for each of the fourteen participants (see Chapter 5). See Table 3-2 for details of the procedures involved in acupuncture treatment.

Seven participants (group A) received acupuncture treatment (administered by the researcher) for four months. The other seven participants served as a control group (group B) and did not receive any acupuncture for the first four months. The two groups were evaluated using BUA, VOS, OSTN, PYR and D-PYR as well as TCM assessment at the three test phases as indicated in Figure 3-2 (Map of the Research Design). After the initial phase of the four-month trial the groups traded places from control to treatment respectively for a further four-month period and then were tested again.

All participants were given a choice of three venues from which to receive acupuncture treatment. Those being the Acupuncture laboratory at St. Albans Campus, the Exercise Physiological laboratory at Footscray Campus of Victoria University and the Harmony Chinese Medical Centre, Kew, all located in Melbourne.

TCM assessment results	Patterns of disharmonies mainly: <i>kidney qi</i> and <i>yin</i>	
	deficiency	
Main treatment principles applied	Tonify <i>qi</i> and <i>yin</i>	
Selection of acu-points	Tai Xi (<i>kidney</i> , KID 3) and San Yin Jiao (<i>spleen</i> , SP 6) –	
	nourish yin; Zu San Li (stomach, ST 36) – tonifies qi	
Locating the points	Use bone and muscle landmarks to locate all the points	
	which are all in the lower limbs (see Chapter 5)	
Sterilisation	Follow the standard procedure of acupuncture treatment	
	guidelines from Australian Acupuncture and Chinese	
	Medicine Association (AACMA) recommendation. Use	
	of medical alcohol swabs to sterilise the skin, TGA	
	approved one-time use acupuncture needles with tubes	
	were used.	
Needling Method	Insertion of the needles	
	The needle was held with the researchers' left hand, with	
	the thumb and index fingers holding the tube of the	
	needle. The needle was then separated from the tube, the	
	top of the right index finger was used to quickly tap the	
	top of the needle's handle to insert the needle into the	
	point, then the tube was taken off.	
	The angle formed by the needles and the skin surface:	
	According to the location of the points and the	

Table 3-2 Procedures Involved in Acupuncture Treatment

	therapeutic purpose of tonifying <i>qi</i> and <i>yin</i> , perpendicular
	insertions, in which the needles is inserted
	perpendicularly forming a 90 degree angle with the skin
	surface were applied.
	Depth of needles insertion
Needling Method,	It depended on the thickness of the tissue where the point
cont.	was located, pathological condition and the strength of
	sensation the subjects experienced.
	Zu San Li (ST 36) used to tonify <i>qi</i> , located below the
	knee (see Chapter 5 for detail). The depth of needling
	was about 0.5-1 cun (where 1 cun is equal to the width of
	the thumb at the second phalangeal joint).
	San Yin Jiao (SP 6) used to nourish yin, located 3 cun
	(the width of the person's four fingers at the second
	phalangeal joint) directly above the tip of the medial
	malleolus, on the posterior border of the tibia (see
	Chapter 5 for detail). The depth of needling was about
	0.5 <i>cun</i> .
	Tai Xi (KID 3) used to nourish yin, located in the
	depression between the medial malleolus and tendon
	calcaneus, level with the tip of the medial malleolus (see
	Chapter 5 for detail), The depth of needling was 0.3 cun.
	Reinforcing: reducing = 9:6 (see Chapter 5 for details),
	needles were inserted for 30 minutes, the subjects' tended
	to feel "Suan" (mild soreness), "Ma" (numbness),
	"Zhang" (distension) and "Tong" (pain). Due to the need
	to tonify and nourish the body, the needling techniques
	used in this study were gentle and adequate for the needs
	of the subject, this meant that there were no complaints

of pain.
Withdrawal of the needles
At the end of treatment the needles were taken out of the
skin, the acu-points were covered with cotton balls and
pressed for one minute on each point to prevent mild
bleeding and bruising.

3.4.3 Project Three – Effects of Chinese Herbal Medicine on Bone Structure and Function

Fourteen volunteer menopausal women (aged 42-53, 48.8 ± 3.0 years with similar social characteristics; nine of them being administrative staff, four being teachers and 1 home duties) were recruited to participate in this trial. The participants were divided into two groups (group A and group B, seven participants respectively) matched through Broadband Ultrasonic Attenuation (BUA) as well as age and menopausal status details.

The participants received traditional Chinese herbal therapy and were assessed according to the principles of Traditional Chinese Medicine. "Shu Di (prepared rhizome of rehmannia) Shan Zha (hawthorn fruit) formula" (see Chapter 6) was chosen as the treatment formula for this group in accordance with the common pattern of disharmony. The decoction (granules mixed with water) was taken twice per day, separate from food, over a period of four months (see Table 3-3). Seven participants (group A) received herbal treatment for four months while the other seven participants served as a control group (group B) as they did not receive any herbal treatment during the first four months. This meant that the two groups could be compared using BUA, VOS, OSTN, PYR and D-PYR as well as TCM assessment. After the initial phase of the four-month trial the groups traded places from control to treatment respectively for a further four-month period and then were tested again.

Table 3-3 Procedures of Herbal Treatment

Preparation of formula	The basic "Shu Di Shan Zha" formula was supplied by	
	and complied with Good Manufacturing Practice (GMP)	
	and complied with Good Manufacturing Fractice (GMF)	
	requirements. The formula was repackaged by the	
	researcher.	
Delivery	A week's supply of powder was sent to subjects with a	
	checklist (see Appendix G) to get detailed information of	
	adherence to the herbal regime.	
Method of taking	A dose of formula was mixed with warm water for	
formula	drinking separated by more than half an hour from food.	
	This was administered in the morning and evening.	
Checklist	The checklist was completed after taking the dose and	
	returned to the researcher when the next supply of formula	
	was picked up.	
Communications	Information about the subjects' state of health was	
	collected and the researcher answered any queries when	
	delivering the formula; subjects were also free to contact	
	the researcher at any time if they had questions.	

All participants were able to choose a convenient location from which to collect their herbs. Alternatively the herbs were delivered to the participants by the researcher. Details of herbal administration are outlined in Chapter 6.

3.5 Test Parameters

3.5.1 Ultrasound Tests

The test for bone material properties involved testing using an ultrasonic bone analyser (CUBA CLINICAL, McCue Ultrasonics, England). CUBA Clinical is a 'dry" Ultrasonic Bone Densitometry system. By placing the calcaneum between two directly contacting Ultrasonic Transducers, rapid measurements of Broadband Ultrasonic Attenuation (BUA) can show the structure and density of bone. Velocity of Sound (VOS/SOS) measures the elasticity and density of bone (CUBA CLINICAL manual p4, see Table 3-4 Specification of Measurement Methods). Blake, Herd, Miller and Fofelman (1994) have indicated that ultrasound transmission through the calcaneus is dependent on bone thickness as well as the density of scattering centres.

The calcaneum is a bone site of proven sensitivity to osteoporotic change (CUBA CLINICAL manual). These tests which determine BUA (dB/MHz), VOS (m/s); and BUA Normative Data Plots take approximately three minutes to conduct. Quality control (QA) checks with QA phantom were performed before each test (see Figure 3-3 and Figure 3-4).

The tests for bone material properties were performed pre-test, at the 4th month of the study and at the 8th month of the study. All tests were performed by a single investigator at the Exercise Physiology Laboratory, School of Human Movement, Performance and Recreation or the Nursing Laboratory, School of Health Sciences Victoria University or the Conference Room, Department of Education, Employment and Training, Victoria. The three venues have similar environments.

Measurements	Broadband Ultrasound Attenuation (BUA) and Velocity (VOS)
Display	BUA (dB/MHz) and BUA Normative Data Plots and VOS (m/s)
Measurement Time	Approximately 3 minutes
Operating Conditions	The CUBA Clinical can operate within the following environment: Ambient temperature range of + 10°C to + 40°C. Relative humidity range of 30% to 75%. An atmospheric pressure range of 700hPa to 1060hPa
QA test	The CUBA Clinical is a precision instrument but prior to each measurement session it is essential that the user checks its calibration against the BUA and Velocity Phantoms that are provided with the system
Measurement	Patient details data entry, making a measurement and results saving and printing (see figure 3-3 and 3-4 Printed Result)

Table 3-4 Specification of Measurement Method



Figure 3-3 Printed Result of a BUA Test

McCue CUBAclinical Osteoporosis Study Bone Densities Patient Details: Surname: Firstname: ID: DOB: Sex: Height (m): Weight (Kg): Notes: Patient Data: Scan Date Site **VOS** 1594 **%Exp** 99 **Zu** -0.13 **Ти** -0.96 Normative VOS VOS (m/s) 2000 1800 1600 1400 1200 0 10 20 30 40 50 60 70 80 90 100 Age (years) McCue CUBAclinical

Figure 3-4 Printed Result of a VOS Test

3.5.2 Dual Energy X-Ray Absorbtiometry Test

Dual energy x-ray absorbtiometry (DEXA) was used to measure bone density at the end of the study. This technique is a widely recognised method for diagnosing osteoporosis and evaluating treatment effects (Xue, 1998).

The instrument utilised was a Hologic QDR 4500W Bone Mineral Densitometer (DEXA) (see Figure 3-5). As outlined in Chapter 2 the accuracy of the Dual Energy X-ray Absorptiometry as a measure of change in bone status is well documented. The coefficient of variation has an excellent precision of <1.0% for total body scans by Hologic QDR 4500W Bone Mineral Densitometer. Despite the low radiation doses emitted from the DEXA device these emissions precluded it from being used as often as the other measures in this study. In this study the results from the DEXA tests were used to validate the findings of the previously described ultrasound analysis.

The Ethics Committee of the University, the Department of Human Services as well as the Radiation Safety Committee of the Department of Human Services approved the DEXA test. During this test participants were asked to lie on a bed for a lumbar spine (lumbar 1-4) scan that took approximately 30 seconds. The whole testing procedure took about 20 minutes. During the DEXA procedure the subjects were exposed to a very low level of ionizing radiation, scatter dose less than 1.0mR/hr = 0.01mSv/hr (NHMRC guidelines recommend the dose limits is less 1mSv in a year). The total radiation dose the subjects received was about 0.2% of the natural background radiation people receive every year. Information about the DEXA test was given to the subjects as described in attached Appendix E.

As described in the literature review although BMD measurement techniques have been recognised for diagnosis and treatment of osteoporosis a change in BMD represents only 70%-80% of changes in bone strength (Liu, 1998). Therefore, ultrasonic diagnosis should also be used in the determination of bone turn-over, structure and strength.

3.5.3 Bone Turn Over Tests

Osteoporosis is defined as a pathological condition in which no change occurs in the chemical composition of the bone but where bone resorption is abnormally increased. It results from a change in the balance between bone formation and bone resorption, i.e. more bone is lost than is formed. This compares with osteogenesis which leads to a decrease in the amount of bone (Liu, 1998).

Urinary pyridium crosslinks (pyridinoline/PYR and deoxypyridinoline/D-PYR) and serum osteocalcin are recommended as three of the most sensitive markers of bone loss in menopause and the response to some anti-resorptive therapies (Souberbielle, Cormier, Kindermans, 1999). The biomarkers, osteocalcin/BGP and urinary pyridium crosslinks: pyridinoline (PYR) / HP and deoxypyridinoline (DPD)/D-PYR/LP, used in this study indicated bone formation and bone resorption, respectively. The Royal Melbourne Hospital performed all laboratory tests.

The method for determination of urinary pyridium cross-links (bone resorption marker) is an in-house high pressure liquid chromatography (HPLC) method. The procedure involves: urinary hydrolysis, extraction and HPLC. The urine total pyridinium crosslinks, PYR and D-PYR were measured by monitoring fluorescence of elutes from HPLC. All crosslink values were corrected for the individual measured recovery of the internal standard, isodesmosine, and urine creatine concentration.

Victoria University

Phone: Fax:

Referring Physician:	Printed On:	
Patient Name: Social Security No: Patient ID: Postal Code:	Current Height: Current Weight: DOB:	
Sex: Ethnicity:	Age: Menopause Age:	Sec.



Image not for diagnostic use Total BMD CV 1.0%



Scan Inform	ation:		
Scan:			
Scan Mode:	Fast		
Analysis:			· ·
Operator:	1.1.1		
Model:	Hologic Q	DR-4500W (S/I	N 48771)
Comment:			
Region	Area	BMC	BMD
	[cm ²]	[g]	[g/cm ²]
L1	12.60	11.31	0.898
L2	14.12	16.13	1.142
L3	15.26	18.02	1.181
L4	17.72	19.99	1.128
Total	59.70	65.46	1.096

Results Summary:

Total BMD:	1.096 g/cm ²		
Peak reference:	105%	T score:	0.4
Age matched:	114%	Z score:	1.2

Physician Comments:



Figure 3-5 Printed Result of a DEXA Test

The procedure of the quantitative measurement of osteocalcin (Bone formation marker) in serum employs a two-site immunoradiometric assay (IRMA). Reagents: DSL-7600 ACTIVETM Human Osteocalcin Coated-Tube IRMA kit, kit insert included.

For osteocalcin assessment 5ml of full blood was obtained by venipuncture. The serum was then separated before storage. A serum sample of each participant was taken at the test 1 (pre-test), test 2 (cross-over, 4^{th} month) and test 3 (post-test, 8^{th} month) stages. All samples were stored at -70° C until analysis.

For pyridium crosslinks assessment the participants were asked to bring their urine sample according to the requirements outlined "2 hour urine collection-early morning sample" prior to the test being conducted (see Table 3-5 and Appendix F), all samples were stored at -70° C until analysis.

3.6 Traditional Chinese Medical Assessment

Traditional Chinese diagnostic patterns are differentiated based on symptoms and signs. The occurrence of certain symptoms and signs indicate certain patterns of disharmony. In TCM, when positive symptoms and signs are evident, this also reflects the positive changes of the internal organs' functioning and health status. During menopause only a few main patterns of disharmony predominate, these include *kidney yin* deficiency, *liver yin* deficiency and *liver qi* stagnation, *kidney* and *spleen* deficiency, discord between *heart* and *kidney* and body fluid/liquid deficiency (see Table 3-6). Disharmonies in women's bodies tend to arise in specific ways at specific times in their lives depending upon their constitutional make-up.

Table 3-5 Steps for Urination Collection

Steps	Requirements	Examples
1	The specimen needs to be collected	
	fasting. Fasting begins from 12 midnight	
	the night before. Do not eat until after the	
	collection has been completed.	
2	Start the collection by emptying your	Start the collection at
	bladder and discard this specimen (into the	7:00 am by emptying
	toilet).	bladder into toilet.
3	Record time and date on small bottle.	From 7:00am collect all
	From this time until completion (2 hours	urine into small
	later) all urine is collected into the small	container.
	bottle provided.	
4	Exactly 2 hours from the start of the	Empty bladder for the
	collection empty the bladder for the last	last time into small
	time into the small bottle. Collection is	container at 9:00am.
	now complete and you are free to eat.	
5	Urine specimen must be kept as cold as	
	possible during transportation. It is best	
	kept in the refrigerator or cooler until	
	delivery.	

Forty women who met the general criteria of the menopausal profile were recruited for this study. In order to prescribe the common treatment plan according to TCM pattern analysis all of the participants underwent a thorough TCM diagnostic assessment. The assessment included the four TCM classical diagnostic techniques to detect the common pattern and determine the appropriate Tai Ji exercises, common acupuncture points and common herbal formula. The four diagnostic techniques are outlined below:

- 1. Looking: to observe the systemic and regional changes through the person's appearance, manner, emotions, spirit, facial colour, skin, tongue and secretions;
- 2. Listening and smelling: voice, respiration, body odour.
- 3. Asking: to gain information about the onset and progress of the chief complaint, present symptoms, associated symptoms with the chief complaint and other relevant conditions. Ten TCM classical questions were asked (chills and fever, abnormal sweating, appetite, taste and thirst, urination and bowels, body pain, sleep and menstruation history).
- 4. Palpation: *CunKou* pulse (radical artery behind wrist) were taken (Yang, 1998).

A TCM diagnostic sheet was designed by the researcher (see Appendix H) and used to record the above symptoms and signs to determine each participant's pattern of disharmony. The common patterns of disharmony and clinical manifestations are listed in Table 3-6. For this study five patterns of disharmony were selected.

The Five Patterns of Disharmony can be described as:

1. *Kidney Yin* Deficiency: is the syndrome of lack of *kidney yin*. A congenital deficiency, over indulgence in sexual activities or emotional stress can transform into fire, febrile diseases, chronic disease leading to *kidney yin* deficiency. Disease mistreatment can also cause this syndrome.

Table 3-6 TCM Patterns of Disharmony and Clinical Manifestations of the Forty
(40) Participants

Patterns	Main Clinical Manifestations
1. Kidney Yin Deficiency	Feeling of heat, insomnia, sleeplessness,
(Shen Yin Xu)	tiredness, night sweating, lower back pain,
	thirst, headache, knee/leg pain, dark/smelly
	urine, irritability, anxiety.
2. Liver Yin deficiency and	Hot flushes and sweating, night sweating,
Liver Qi Stagnation (Gan	thirst, headache, stress, depression,
Yin Xu and Gan Qi Yu Jie)	irritability, anxiety, abdominal distension.
3. Kidney and Spleen	Tiredness, abdominal distension, diarrhoea,
Deficiency (Pi Shen Lian	swollen ankles/fingers.
Xu)	
4. Discord between the <i>Heart</i>	Insomnia, sleeplessness, palpitations, lower
and Kidney (Xin Shen Bu	back pain, knee pain, thirst, feeling hot, night
Jiao)	sweating.
5. Body fluid/liquid	Constipation, thirst, dry skin, dark urine.
deficiency (Yin and blood	
deficiency/Yin Xue Bu Zu)	

2. *Liver Yin* Deficiency and *Liver Qi* Stagnation: *Liver qi* stagnation refers to the syndrome that occurs when the *liver* fails to conduct and disperse *qi* appropriately resulting in the *qi* not flowing smoothly. Any factors, such as depression can cause *liver qi* stagnation and can contribute to these syndromes. *Liver yin* deficiency is characterised by a shortage of *yin* and

body fluids in the *liver*. Most cases are caused by emotional disorders that cause stagnated *qi* to transform into *fire* which affects body *fluids* and *yin*. *Liver yin* is taken away by the *fire* and becomes deficient. Some chronic diseases or warm diseases can also consume *liver yin* and lead to this syndrome.

- 3. Kidney and Spleen Deficiency: This syndrome appears when the qi and/or yang are insufficient in both the spleen and the kidney. The prolonged effects of diarrhoea or oedema can lead to deficiency involving both spleen and kidney. Diarrhoea or oedema are the most common conditions leading to this syndrome.
- 4. Discord between *Heart* and *Kidney*: According to TCM theory of the five elements (Wu Xing), the *Xin* (heart meridian system) is seen as analogous to *fire* because the *heart* is like an energy station which brings warmth to the body. The *kidney* is analogous to water because it mainly initiates the water metabolism. The *fire* (*heart*) is prevented from becoming over active by *water* (*kidney*). The *heart* and *kidney* balance each other and assist and check the action of the other. The disruption of this relationship is often referred to as "discord between the *heart* and *kidney*".
- 5. Body *fluid/liquid* deficiency: Sweating, vomiting, diarrhoea, haemorrhage, loss of *essence*, *yin* deficiency and excessive *yang* can all lead to deficiency of body *fluid* which fails to moisten and nourish the body. All of these dry symptoms come from excessive *yang* and insufficient *yin* (Yang, 1998).

All of the TCM symptoms and signs used in this study are well recognised and documented in TCM theory. The symptoms and signs were compiled during the three interviews at the pre, 4th month and 8th month tests. The subjects expressed and described their feelings and symptoms to the researcher who recorded and checked all

their symptoms according to the four TCM diagnostic methods as outlined above. The following subjective symptoms were described by the subjects and noted: lower back pain, knee/leg/foot pain, aching bones, poor appetite, abdominal distension, tiredness, palpitations, insomnia, irritability/anxiety/stress, headache, thirst and itchy skin. The researcher then asked about the severity of the particular symptoms i.e. mild or medium or severe. The subjects were also asked to evaluate their current symptoms compared to the times of the previous interviews i.e. pre-test and 4th month, 4th month and 8th month - did they feel better?

The researcher also adopted standard objective TCM diagnostic methodologies to examine each individual subject to verify their feelings. These methods involved noting colour / shape changes to certain points on the ear and a comparison of colour change to certain musculo - skeletal points (see Figure 3-6 from Cheng and Cheng, 2000). These diagnostic procedures are aimed at observing pathological changes that indicate pain. In this way subjective symptoms were compared to objective methods. Shan (1996) explained that,

"Auricular points are the sites where the auricle links with the *zang* and fu organs, channels and collaterals, tissues and organs, four limbs and all bones. They are also the points through which the channel qi (*jing* qi) is transported to the auricle. Therefore, the spots on the auricle where physiological functions and pathological changes can be reflected are called auricular points, which are the specific spots used for diagnosis and treatment of disease. When the internal organs or parts of the body are in an abnormal condition, various positive reactions will appear in the corresponding area of the auricle" (p16).

Therefore, by analysis of changes of these positive reaction points, the location and nature of a disease can be deduced and furthermore, applying stimulation to these auricular points can treat the disease. Auricular points are often called reaction points, sensitive points, positive points, tender points, lower resistance points, high conductivity points or treatment points (Shan, 1996).



Figure 3-6 Ear Diagnosis and Acupressure Points

For the symptoms of diarrhoea, swollen ankles/fingers, hot flushes, hot feet, night sweats, constipation and dark/malodorous urine information was obtained by questioning. Swollen ankles/fingers were also observed or palpitated. The confirmed findings were then used as evidence of the efficacy of TCM modalities in relieving the symptoms listed in Tables 4-7, 5-7 and 6-7. The scores given in these tables are the combined scores for both groups A and B (pre and post treatment results).

According to traditional Chinse medicinal theory and practical experience lower back pain, especially chronic lower back pain, is the chief symptom of *kidney* deficiency. Referring to Deng (1987), the lower back is the house of the *kidney* and its appearance reflects the *kidney's* condition. The root of the entire *kidney* related meridian concentrates at the lower back, therefore when the *kidney* is deficient lower back pain will occur. *Kidney* deficiency by degree is inevitable with aging due to a decline in *kidney* function. Combined with other symptoms and signs patterns of disharmony can be determined based on whether the weakness is due to *kidney yin* or *kidney yang* or *kidney qi* deficiency. As outlined in Chapter 2, the *kidneys* govern the bone, the *liver* governs the sinews, so a deficiency of *kidney yin* and *liver yin* results in the bones and sinews receiving insufficient nourishment. If there is *kidney yang qi* deficiency lower parts of the body are not warmed so the subjects complained of knee and/or leg and/or foot are pain and aching bones.

According to TCM theory the water metabolism relies on the promoting function of *qi*. Therefore water or fluid retention is a pathological result of *qi* deficiency (Deng, 1987). Deng describes the digestive system's function in Western medicine as equal to the *spleen*'s function in TCM. One of the *spleen*'s main functions is to transport and transform the nutrients and spread them to the whole body. *Spleen* deficiency affects the digestive function of the *stomach*, causing difficulty in the digestion of food, poor appetite, and abdominal distension. *Spleen* deficiency also causes an inability to effectively transform and transport water/fluid. As a result it remains in the intestines and causes diarrhoea. It also remains in certain parts of the body causing local or
generalised oedema. *Spleen* deficiency results in the *spleen* not being able to produce enough nutrients, there is insufficient postnatal *essence* to assist in the functioning of the internal organs. Tiredness is a common *spleen* deficiency symptom as there is not enough *qi* to nourish the body. *Kidney* is also involved in the *water/fluid* metabolism, *kidney* deficiency cannot steam the *water/fluid* upward and disperse it to the body, swollen ankles are a common symptom as a result. *Kidney* deficiency results in a failure of *kidney* to balance *heart* as *water* fails to balance *fire* this results in *heart heat/fire* hyperactivity which can result in palpitations. This is another common symptom in menopausal women.

Yin deficiency symptoms especially general and *kidney* and *liver yin* deficiency symptoms often match common menopausal symptoms. According to *yin-yang* theory, as outlined in Chapter 1, due to *yin* deficiency, *yang* is relatively hyperactive as a result heat symptoms often appear together with *yin* deficiency symptoms, such as hot flushes, hot feet/palms, night sweats and insomnia. Each organ has its own associated *yin* and *yang*, if due to *yin* deficiency the *liver* lacks nourishment its function is affected. *Liver* function disorders often result in *liver qi* stagnation causing emotional symptoms such as stress, this is a common symptom in menopause due to *liver qi* stagnation. *Liver* heat hyperactivity due to an imbalance of *yin* and *yang* results in irritability, anxiety and headache, these are common in menopause. General *yin* deficiency can also cause dryness symptoms common to menopause such as thirst, itchy skin, constipation and dark/malodorous urine.

Looking at these symptoms as groups common patterns of disharmony can be derived. Tables 4-8 and 4-9 in Chapter 4 list the groups of symptoms of Tai Ji participants; Tables 5-8 and 5-9 in Chapter 5 list the groups of symptoms of acupuncture participants and Tables 6-8 and 6-9 in Chapter 6 list the groups of symptoms of herbal treatment participants.

3.7 Statistical Analysis

The following data was collected and then analysed through the application of paired ttest using SPSS 10.0. The data was used to determine the following:

- The differences between group A and group B before treatment commenced.
- The differences between pre- and post-treatment results for all the participants in all modality groups (group A and group B) in the first four months with group A as the treatment group and group B as the control group. The difference between the pre- and post-training of the Tai Ji group and its control group; pre- and post-treatment of the acupuncture group and its control group; and pre- and post-treatment of herbal medicine group and its control group. Pre and post treatment effects were also considered for the combination of group A and B. P < 0.05 was accepted as significant.</p>
- The differences between fourth month and eighth month testing in all the participants in all modality groups in group B and group A (commencing after the fourth month to the eighth month) with group B as the treatment group and group A as the comparison group. The difference between the pre- and post-training of the Tai Ji group and its comparison group; pre- and post-treatment of the acupuncture group and its comparison group; and pre- and post-treatment of herbal medicine group and its comparison group. P < 0.05 was accepted as significant.
- The differences between post-treatment (4th month) results in group A and long-term effects after treatment cessation as visible through testing four months after treatment (8th month) for all three modalities. The differences between pre-test and 4th month in group B as the control in all three modalities.

The correlation between BMD and BUA was determined with the use of SPSS 10.0 - regression (statistical software package).

The collected data in relation to Chinese medical symptoms was analysed with the application of Ridit analysis (Jin, 1993) to determine the effects of the three modalities on traditional Chinese medical symptoms.

CHAPTER 4

EFFECTS OF TAI JI EXERCISE ON BONE STRUCTURE AND FUNCTION

4.1 Introduction

Tai Ji is a physical activity involving exercise that has long been practiced by many people in Eastern cultures. Its movements are slow, graceful and flowing and are linked to rhythmic breathing and passive concentration. This combination is claimed to be beneficial for physical health and psychological well-being. Specific Tai Ji movements are related to health benefits for particular organs of the body such as the liver, the lungs and the kidneys as defined in the tradition of Chinese medicine (Williams, 1996). The relaxation, health maintenance and healing benefits of Tai Ji have been known and enjoyed by Chinese people for more than 700 years (Khor, 1993).

Tai Ji is one of the masterful Eastern techniques and has centuries of development behind it. Khor (1993) indicated that Tai Ji's secrets' have begun to filter into the West bringing a new approach to health, well-being and even happiness. He also believed that Tai Ji combines both a physical and a mental means of 'escape' that helps to restore order and 'control' to a hectic life. As such it represents one of the most effective ways of dealing with stress and building a positive foundation for health-related behavior.

Exercise is generally accepted as being of value in the condition of osteoporosis. Moderate exercise protects against osteoporosis. Too little or excessive exercise may cause osteoporosis (O'Brien, 2001). In fact, prolonged physical activity can lead to a negative calcium balance, whereas moderate physical activity maintains bone mass (Isaia, Ferrario, Salamano, Mussetta, Campagnoli, Fabris, and Molinatti, 1990). Sixty per cent of bone growth occurs during adolescence suggesting that once bone mass is lost it cannot be fully regenerated. In order to maintain bone mass appropriate exercise should be undertaken at an early age as a preventative strategy. Reid (1996) stated that in the elderly, exercise can be used to reduce the occurrence of fractures by 10%. This could be of more value than increasing BMD by a few percent. Women over 65 can benefit from exercise as it results in an increase in their BMD, an effect according to Tanaka, Nishi, Haiji, Imamura and Nawata (1992) not due to increasing calcium intake.

Appropriate forms of exercise could reduce the risk of falls in the elderly leading to a reduction in the number of fractures in this group. Progressive strength training has been demonstrated to be a safe and effective form of exercise that reduces the risk of falling and may also elevate BMD (Henderson, White and Eisman, 1998). Henderson et al. (1998) also suggested that in the frail elderly, activities to improve balance and confidence are also of value. Group activities, such as Tai Ji, may be a cost-effective way of providing an appropriate form of exercise.

A comprehensive exercise program coupled with drug therapy would be of benefit as falls and fractures could be prevented. This program should include stretching, strengthening, impact and balance exercises. In terms of balance, Tai Ji has been proven to be successful in decreasing falls (Lane and Nydick, 1999). Tai Ji exercise also stretches and strengthens the body. This study examined the effect of a four-month program of Tai Ji exercise on bone structure and function in menopausal women. This type of program had not been evaluated in the past for its effect on bone health.

To date there has been no specific research on the benefits of Tai Ji exercise in the prevention of osteoporosis. This study has significance for the community and for an increased understanding of the relationship between Tai Ji, exercise and bone health. There is little research on the potential benefits of low intensity physical activity in terms of health and well-being in the community. Preliminary evidence (Han and Morris, 1991) suggests that gentle exercise is of benefit to people who are normally

sedentary. They may be more willing to undertake this type of gentle exercise while not being prepared to undertake a more active type of exercise.

4.2 Research Design and Methodology

To evaluate the effects of Tai Ji exercise on bone turn-over in menopausal women, a paired design over an eight months period was utilised (see Figure 4-1). Participants practised 24 movements Tai Ji exercise twice per week.

Twelve of the 40 menopausal women who completed the study (aged 42-55 years) were involved in this trial (see Table 4-1 Subject Characteristics). The participants were divided into two groups (Group A and Group B, six participants respectively) matched according to their Broadband Ultrasonic Attenuation (BUA) scores as well as some consideration of their menopausal status and other related criteria as outlined in Chapter 3. All participants were given information regarding the purpose of this study and the demands of this study design. They were assigned to a group and their relevant treatment regime – Tai Ji exercise was outlined. They were told which group they belonged to, and as a result whether they were initially in a treatment or control group. The subjects were asked to maintain their existing level of physical activity form so that the researcher could confirm that there were no significant changes in the level of physical activity (see Chapter 3 and Appendix J).



Figure 4-1 The Research Design

	N	Minimum	Maximum	Mean	St. Deviation
Age (yrs)	12	42	55	50.0	4.0
Height (m)	12	1.52	1.78	1.67	6.84
Weight (kg)	12	54.9	91.8	70.1	10.2
BUA (dB/MHz)	12	61.7	98.4	75.6	12.2

Table 4-1 Subject Characteristics

	Group A	Group B
BUA (mean±SD)	74.9±13.2	76.3±12.4

Effectively six participants (Group A) practiced Tai Ji exercise (24 movements) for four months under the researcher's supervision. During the second four months this group did not exercise. This second four months or control period gave some indication of the residual or long-term effect of Tai Ji exercise on the various parameters considered in this study. Conversely, the other group of six participants served as a control group (Group B) as they did not exercise in the first four months but practised Tai Ji in the second four months. Group B was not studied for residual effect of exercise, as there was no follow up study after they completed their exercise period. During the first four "control months" this group was used to provide some indication of the effects of the passage of time (without treatment) on the parameters considered in this study. This meant that the two groups could be compared using BUA, VOS, OSTN, PYR and D-PYR as well as TCM assessment. After the initial phase of the four month trial the groups traded places from control to treatment respectively for a further four-month period and then were tested again.

Subjects in the Tai Ji group completed 32 one hour sessions of Beijing 24-movements Tai Ji over sixteen weeks. The twice a week sessions were undertaken with at least two days between sessions. Each session involved the same sequence of movements, the introductory exercise and the Tai Ji exercise, which were based on the 24 movements. Consecutive movements were chosen to facilitate the smooth flow of *qi* in the body. This harmonizes the body which leads to fewer menopausal and osteoporosis symptoms. Basic instruction was provided in terms of movements, transitions and the breathing techniques for each movement within the sequence. The instructor corrected movements that were not performed correctly and encouraged subjects to learn the sequence so that rhythm and smoothness could be developed with practice.

While performing Tai Ji the participants' attention must be focused exclusively on the exercises being performed. The muscles must be relaxed and movements must be made slowly and smoothly. All movements should be practiced with the minds attention being totally focussed on the movement being performed. Concentration on, and positioning of different parts of the body were examined by the researcher and adjusted to suit individual needs as required to gain maximum benefit from the exercises.

The Beijing 24-movements Tai Ji (simplified 24-posture Tai Chi Chuan) was employed in this study. It involves twenty-four different kinds of movements (see Appendix K for full details of each movement). These movements are designed to gather *qi*, focus the mind, relax the body, move *qi* and *blood*, exercise the muscles, joints and lumbar region. The set of movements helps the balance function of the body and strengthens the muscles and sinews. According to TCM theory these movements are able to improve the functioning of the five internal organ systems, this is particularly useful for this study as *kidney*, *spleen* and *liver* are particularly relevant to bone loss.

The Beijing 24 movements are:

- 1. Commencement
- 2. Part wild horse's mane on both sides -3 times
- 3. White crane flashes it wings
- 4. Brush knees on both side -3 times
- 5. Strum the lute
- 6. Curve back arms on both sides 4 times
- 7. Grasp the bird's tail left style
- 8. Grasp the bird's tail right style
- 9. Single whip
- 10. Wave hands like clouds left style
- 11. Single whip
- 12. High pat on horse
- 13. Kick with right heel
- 14. Strike opponent's ears with both fists
- 15. Turn and kick with left heel
- 16. Push down and stand on left leg
- 17. Push down and stand on right leg
- 18. Work at shuttles on both sides R. L.
- 19. Needle at sea bottom
- 20. Flash arm
- 21. Turn to deflect downward, parry and punch
- 22. Apparent close-up
- 23. Cross hands
- 24. Closing form

4.3 Statistical Analysis

All of the collected data (BUA, VOS, OSTN, PYR, D-PYR and TCM symptoms) for each participant were recorded at the beginning, the mid-point and the end of the study. Differences were calculated from the results of pre-test, fourth month and eighth month within the groups and between groups. The results were analysed by paired t-tests using the SPSS 10.0 and Ridit analysis with results of p<0.05 being accepted as statistically significant.

4.4 Results

This study examined the effects of four-months of Tai Ji exercise on bone health. Twelve women participated in this study and completed the exercise phase with a 90% attendance rate and with no change to their other physical activities. All of the mentioned data (BUA, VOS, OSTN, PYR, D-PYR and TCM symptoms) were used for statistical analysis. It is also possible to consider the effects of the Tai Ji exercise according to the four TCM groupings i.e. *kidney* deficiency symptoms, *qi* deficiency / water retention symptoms, *yin* deficiency / deficient heat / *qi* stasis symptoms and *yin* deficiency / deficient heat symptoms.

4.4.1 Bone Structure Results

Effects of Tai Ji exercise on Broadband Ultrasound Attenuation (BUA)

BUA is an indicator of the trabecular orientation and pattern in bone that can show the structure and density of bone as explained in Chapters 1 and 3. Table 4-2 and Figure 4-2 show the results of Tai Ji exercise on BUA. The results indicate that before Tai Ji exercise there was no significant difference in BUA between the two groups (p=0.698). After four months of Tai Ji exercise the BUA in Group A showed a significant increase (p=0.016). After a further four months without exercise, the BUA levels in Group A (8^{th} month) were significantly lower than those recorded at the 4^{th} month (p=0.012). During the first four-month period without exercise the BUA in Group B showed a significant decrease (p=0.004). After four months of Tai Ji exercise the BUA levels showed a marked increasing trend (p=0.055), although this was not statistically significant. Groups A+B combined results (pre and post treatment comparison) showed a significant increase in BUA (p=0.001).

Group (n=6)	Pre-test	4 th Month	8 th Month
Α	74.9±13.2	80.2±15.6*	72.2±11.5#
В	76.3±12.4	70.1±14.4	75.4±10.2
$C_{\text{roup}}(n-12)$	Dra treatment	Post treatment	n
Group (n-12)	r re-treatment	r ost treatment	þ
A + B	72.5±13.4	77.8±12.8	0.001

Table 4-2 Effects of Tai Ji Exercise on Broadband Ultrasound Attenuation (BUA) (dB/MHz) (M±SD)

*Significantly different from the data of pre-test, p=0.016. #Significantly different from the data of 4th month, p=0.012.



Figure 4-2 Effects of Tai Ji Exercise on Broadband Ultrasound Attenuation (BUA) (dB/MHz) (M±SD)

Effects of Tai Ji Exercise on Velocity of Sound (VOS)

Velocity of Sound (VOS) is an indication of elastic modulus and breaking force of the bone as explained in Chapter 1 and 3. Table 4-3 and Figure 4-3 show the results of four months of Tai Ji exercise on VOS. The results indicate that there was no significant difference between the pre-test, 4th month and 8th month results in either Group A or Group B. Groups A+B combined results (pre and post treatment comparison) were not statistically significant (p=0.684). This indicates that there was no significant change either over the passage of time or with Tai Ji exercise. It is possible that VOS, which measures bone elasticity, was not a sensitive indicator of bone structure change in this four-month period.

4.4.2 Bone Formation and Resorption Results

While the ultrasound tests provided equivocal evidence of bone structure change, the bone turn-over markers OSTN showed a significant increase in both Group A and Group B, while D-PYR also showed some positive treatment effects.

Effects of Tai Ji Exercise on Bone Formation

Osteocalcin (OSTN) is regarded as a bio-marker of bone formation as explained in Chapter 1 and 3. Table 4-4 and Figure 4-4 show the results of four months of Tai Ji exercise on OSTN. There was no significant difference in the osteocalcin level between the groups before exercise. After four months of Tai Ji exercise the osteocalcin level in Group A increased significantly (p=0.016). Four months after ceasing Tai Ji exercise the level of osteocalcin in Group A remained at a relatively high level compared to that of the pre-test (P=0.052). During the first four-month period without exercise there was no significant difference in the osteocalcin level in Group B. After four months of Tai Ji exercise the osteocalcin level of those in Group B was significantly increased (p=0.039). Groups A+B combined results (pre and post treatment comparison) showed a significant increase in OSTN (p=0.001).

Group (n=6)	Pre-test	4 th Month	8 th Month
Α	1631.7±62.9	1631.0±26.2	1616.5.1±54.8
В	1591.2±55.2	1581.7±71.0	1595.8±32.2
Group (n=12)	Pre-treatment	Post treatment	р
A + B	1606.4±69.2	1613.4±33.5	0.684
2000 1950 1950 1850 1800 1550 1650 1650 1650 1650 1550	4th r	• • • •	

Table 4-3 Effects of Tai Ji Exercise on Velocity of Sound (VOS) (m/s) (M±SD)

Figure 4-3 Effects of Tai Ji Exercise on Velocity of Sound (VOS) (m/s) (M±SD)

Group (n=6)	Pre-test	4 th Month	8 th Month
A	14.8±10.6	21.2±13.2*	20.2±14.3
В	14.0±5.3	14.5±4.4	19.3±6.3#&
Group (n=12)	Pre-treatment	Post treatment	р
A + B	14.6±7.8	20.3±9.9	0.001

Table 4-4 Effects of Tai Ji Exercise on Osteocalcin (OSTN) (ng/ml) (M±SD)

*Significantly different from the data of pre-test, p=0.016. #Significantly different from the data of pre-test p=0.039. &Significantly different from the data of 4th month test, p=0.035.



Figure 4-4 Effects of Tai Ji Exercise on Osteocalcin (OSTN) (ng/ml) (M±SD)

Effects of Tai Ji Exercise on Bone Resorption

Pyridinoline (PYR) and deoxypyridinoline (D-PYR) are urinary pyridum crosslinks which are regarded as bio-markers of bone resorption as explained in Chapter 1 and 3. Table 4-5 and Figure 4-5 show the results of four months of exercise treatment on PYR; Table 4-6 and Figure 4-6 show the results of four months of exercise treatment on D-PYR.

Before Tai Ji exercise, there was no significant difference in urinary pyridinoline (PYR) between Groups A and B (p=0.924). After four months of Tai Ji exercise the level of urinary pyridinoline in Group A was lower than that of the pre-test but there was no significant difference between pre-test and the 4th month test results (p=0.607). Four months after ceasing Tai Ji exercise the level of urinary pyridinoline in Group A was higher (no statistical significance) than that of the 4th month test but no significant difference was found between the 4th month test and the 8th month test results (p=0.363).

During the first four month period without exercise there was no significant difference in the urinary pyridinoline level in Group B (p=0.316). After a further four months of Tai Ji exercise the urinary pyridinoline level was lower than that of the 4th month but there was no significant difference between the 4th month test and the 8th month test results (p=0.363). Groups A+B combined results (pre and post treatment comparison) did not show a significant change (p=0.272).

There was a difference (which was not statistically significant) in deoxypyridinoline (D-PYR) between the groups before exercise started (p=0.162). Comparing the pre and post exercise results there was a decreasing trend in D-PYR in both groups and the A+B combined result but the results were not statistically significant (p=0.079). There were variations in the test results for D-PYR over the control and treatment periods for both Group A and Group B. These changes were not statistically significant. D-PYR in

Group A showed a decreasing tendency (p=0.136) after exercise, an increasing trend appeared after exercise ceased (p=0.091). D-PYR in Group B increased significantly without exercise (p=0.024) and decreased after exercise even though there was no statistical significance (p=0.408).

Group (n=6)	Pre-test	4 th Month	8 th Month
Α	55.8±12.3	52.4±22.1	57.8±14.7
В	55.1±22.6	68.1±20.4	61.2±23.3
Group (n=12)	Pre-treatment	Post treatment	р
A + B	61.9±17.3	56.8±22.1	0.272

Table 4-5 Effects of Tai Ji Exercise on Urinary Pyridinoline (PYR) (nmol/mmol Cr) (M±SD)



Figure 4-5 Effects of Tai Ji Exercise on Urinary Pyridinoline (PYR) (nmol/mmol Cr)

Table 4-6 Effects of Tai Ji Exercise on Urin	ary Deoxypyridinoline (D-PYD)
(nmol/mmol Cr) (I	M±SD)

Group (n=6)	Pre-test	4 th Month	8 th Month
Α	11.8±3.5	9.7±5.1	12.4±4.4*
В	9.0±4.1	13.6±5.1#	12.50±5.0
Group (n=12)	Pre-treatment	Post treatment	р
A + B	12.7±4.3	11.1±5.0	0.079

*Higher than the data of 4th month test, p=0.09. #Significantly different from the data of pre-test, p=0.024



Figure 4-6 Effects of Tai Ji Exercise on Urinary Deoxypyridinoline (D-PYR) (nmol/mmol Cr) (M±SD)

4.4.3 Traditional Chinese Medical Assessment

Traditional Chinese diagnostic patterns are differentiated based on symptoms and signs as explained in Chapter 3 (see Chapter 3, Table 3-6). The occurrence of certain symptoms and signs indicate certain patterns of disharmony. These symptoms and signs reflect changes in the internal organs' function and health. In TCM, menopause is considered a natural progression in life and patterns of disharmony in women's bodies tend to arise in specific ways depending upon their constitutional make-up. TCM treatments aim to balance yin and yang to alleviate these symptoms. Table 4-7 shows the results of four months of Tai Ji exercise treatment on the main TCM symptoms related to bone loss and menopause. Some of the major symptoms were relieved (statistically significantly) by Tai Ji exercise; i.e. abdominal distension, tiredness, hot flushes and night sweats. In other symptoms results were not significant. Tongue and pulse analysis have been omitted from this table as their interpretation is more subjective and dependent upon the observers' knowledge and experience of TCM skills. The effects on menopausal symptoms as a result of Tai Ji exercise are seen in Tables 4-8 - 4-9. The symptoms studied reflect TCM patterns of disharmony. The tables show that Tai Ji, exercises (used to harmonize the body) were based on balancing *yin*, *yang*, *qi* and *blood*. This balancing had the effect of alleviating some of the bone loss and menopausal symptoms.

All of the TCM symptoms and signs outlined in this section (Table 4-7, 4-8, and 4-9) are well recognised within TCM theory as indicated in Chapter 3. The symptoms and signs were recorded during the three interviews at the pre, 4th month and 8th month tests. The results were then used as evidence of the efficacy of Tai Ji in relieving the symptoms listed in Table 4-7. The results given in this table are the combined results for both Group A and B (pre and post treatment results).

The group of tables in 4-8 demonstrate the changes in the groups of symptoms outlined as well as the changes in individual cases in Group A. These results were grouped on the basis of the patterns outlined in Chapter 3. The group of tables in 4-9 demonstrate the symptoms and their changes for individual cases in Group B. By grouping these symptoms the tables directly show relevant changes to symptoms.

Tables 4-8-1 and 4-9-1 indicate *kidney* deficiency symptoms. As outlined in Chapter 3, the lower back houses the *kidney* and its symptoms reflect the *kidney's* condition. Lower back pain was shown to be relieved and knee/leg/feet pain (which also reflect the state of *kidney*) was also relieved by Tai Ji treatment. The long-term effect also appeared positive.

Symptom /Number of Subjects	Pre-treatment Degree of Symptom*				Post Degr Sym	-treat ree of ptom	Ridit p **		
	0	1	2	3	0	1	2	3	
Lower back pain	5	3	3	1	9	2	1	0	>0.05
Knees/Leg/Feet pain	8	1	3	0	11	1	0	0	>0.05
Aching bones	12	0	0	0	12	0	0	0	>0.05
Poor appetite	12	0	0	0	12	0	0	0	>0.05
Abdominal distension	5	5	2	0	10	2	0	0	< 0.05#
Diarrhoea	11	1	0	0	12	0	0	0	>0.05
Swollen ankles/fingers	8	2	2	0	10	2	0	0	>0.05
Tiredness	7	3	2	0	11	1	0	0	< 0.05#
Palpitations	9	2	1	0	12	0	0	0	>0.05
Hot flushes	3	5	4	0	9	3	0	0	< 0.01#
Feet hot and/or pain	12	0	0	0	12	0	0	0	>0.05
Night sweating	4	4	4	0	9	3	0	0	< 0.05#
Insomnia	9	1	2	0	10	2	0	0	>0.05
Irritability/Anxiety/Stress	8	0	3	1	8	2	2	0	>0.05
Headaches	8	0	2	2	10	2	0	0	>0.05
Thirst	7	5	0	0	10	2	0	0	>0.05
Itchy skin	9	2	1	0	10	2	0	0	>0.05
Constipation	9	1	1	1	9	1	2	0	>0.05
Dark/smelly urine	8	1	3	0	9	3	0	0	>0.05

Table 4-7 Effects of Tai Ji Exercise on Traditional Chinese Medical Symptoms for Group A+B (n=12)

*0=no symptom; 1=mild symptom; 2=medium symptom; 3=severe symptoms ** Ridit analysis was used to test for statistical significance.

p<0.05 indicates that the symptoms were relieved with Tai Ji exercise to a statistically significant level.

Tables 4-8-2 and 4-9-2 indicate symptoms of *qi* deficiency and its related symptoms of oedema. As outlined in Chapter 3, *spleen* and *kidney qi* deficiency are very common in menopausal women.

Tables 4-8-3 and 4-9-3, 4-8-4 and 4-9-4 indicate *yin* deficiency symptoms especially general *yin*, *kidney* and *liver yin* deficiency symptoms that match common menopausal symptoms as outlined in Chapter 3.

Considering the groups of symptoms together the common patterns of disharmony can be considered *yin* and *qi* deficiency especially in the *kidney, spleen* and *liver*.

Degree of	Low	ver back	pain	Knee	/Leg/Feet	t pain	Aching Bones				
symptom	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month		
0*	2	4	4	5	6	6	6	6	6		
1	1	1	1								
2	2	1	1	1							
3	1										

Table 4-8-1 Observation of *Kidney* Deficiency Symptoms' Change in Tai Ji Group A (n=6)

*0: no symptoms; 1: mild; 2: medium; 3: severe

Lower back pain, knee/leg/feet pain and aching bone are common *kidney* deficiency symptoms. Table 4-8-1 indicates that in Group A four subjects suffered from lower back pain, after four months of Tai Ji exercise two of them still suffered mild/medium pain, but the others had recovered. After four months without treatment no recurrence occurred. One subject had medium knee/leg/foot pain, after four months of Tai Ji exercise the subject recovered. No one complained about bone ache in this group.

Degree of Symptom	Poo app	or oetite		Abo dist	domi censio	nal)n	Diarrhoea		Diarrhoea		Diarrhoea		rhoea		Diarrhoea		Diarrhoea		Diarrhoea		Diarrhoea		Diarrhoea		ollen des/ gers		Tiredness		Palpitations		
	P*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th													
0**	6	6	6	3	4	4	6	6	6	3	4	4	3	5	4	3	6	6													
1				1	2	2				1	2	2	1	1	2	2															
2				2						2			2			1															
3																															

Table 4-8-2 Observation of *Qi* Deficiency/Water Retention Symptoms' Change in
Tai Ji Group A (n=6)

*P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

Table 4-8-2 indicates that one of the three subjects suffering abdominal distension recovered with Tai Ji exercise, the other two did not recover completely. Three subjects suffered swollen ankles/fingers; they partially recovered with Tai Ji exercise. No recurrences were reported after the exercise ceased. Three subjects suffered from tiredness, they partially recovered with Tai Ji exercise and only one had mild symptoms recur after treatment ceased. Abdominal distension, tiredness and palpitations are major *qi* deficiency symptoms, swollen ankles/fingers are typical *qi* deficiency and water retention symptoms. Tai Ji exercise was effective in relieving some of these symptoms.

Table 4-8-3 indicates that the symptoms of hot flushes were relieved from medium to a mild level for two subjects, four subjects recovered completely, the long-term effect was maintained for four months for all subjects. Other symptoms showed partial recovery with Tai Ji exercise. Hot flushes, night sweats, insomnia and headache are typical menopausal symptoms caused by yin deficiency and deficient heat, these were partially relieved with Tai Ji exercise.

Table 4-8-3 Observation of Yin Deficiency/Deficient Heat/Qi Stasis Symptoms
Change in Tai Ji Group A (n=6)

Degree of Symptom	Hot flushes		Hot feet and/or palms		Night sweating		Insomnia		Irritability /Anxiety/ Stress		lity y/	He	Headaches					
	P*	4th	8th	Р	4th	8th	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0*	0	4	4	6	6	6	1	5	6	5	6	6	4	4	4	2	4	4
1	2	2	2				3	1		1							2	2
2	4						2						1	2	2	2		
3													1			2		

*P = pre-test, 4th = 4th Month, 8th = 8th Month **0: no symptoms; 1: mild; 2: medium; 3: severe

Table 4-8-4 Observation of *Yin* Deficiency/Deficient Heat Symptoms' Change in Tai Ji Group A (n=6)

Degree of Symptom	Thirst			Itchy Skin			Constipation			Dark/smelly urine		
	P*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	3	5	5	4	5	5	4	4	4	3	4	4
1	3	1	1	2	1	1	1			1	2	2
2							1	2	2	2		
3												

*P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

Table 4-8-4 indicates that the symptom of thirst was totally relieved from a mild level for two subjects, one subject did not improve, the long-term effect was maintained for four months for most of the subjects. Other symptoms showed partial recovery with Tai Ji exercise, however constipation was not relieved by Tai Ji exercise. Thirst, itchy skin, constipation and dark/malodorous urine are symptoms of body fluid deficiency in TCM. Tai Ji exercise had some effect in balancing the body but results were not significant in nourishing yin / body fluid in this group.

Degree of	Lower	back pain		Knee/L	.eg/Feet pa	in	Aching Bones			
symptom	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month	
0*	3	3	5	3	3	5	6	6	6	
1	2	2	1	1	1	1				
2	1	1		2	2					
3										

Table 4-9-1 Observation of *Kidney* Deficiency Symptoms' Change in Tai Ji Group B (n=6)

*0: no symptoms; 1: mild; 2: medium; 3: severe

Table 4-9-1 indicates that in Group B three subjects suffered from lower back pain; after four months of Tai Ji exercise one of them still suffered mild pain but the others had recovered. Three subjects had medium knee/leg/foot pain; four months of Tai Ji exercise relieved the pain for two subjects. No one complained about bone ache.

Table 4-9-2 indicates that four subjects suffering abdominal distension recovered with Tai Ji exercise. One subject suffering from diarrhoea recovered with treatment. One subject suffered swollen ankles/fingers recovered with Tai Ji exercise. Two subjects suffered from tiredness, both recovered with treatment. Abdominal distension, tiredness and palpitations are major qi deficiency symptoms, swollen ankles/fingers are typical qi

deficiency and water retention symptoms. Tai Ji exercise was effective in relieving these symptoms.

Degree of Symptom	Poor appetite		Abdominal distension		Diarrhoea		Swollen ankles/ fingers		Tiredness		s	Palpitations						
	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	6	6	6	2	2	6	5	5	6	5	5	6	4	4	6	6	6	6
1				4	4		1	1		1	1		2	2				
2																		
3																		

Table 4-9-2 Observation of *Qi* Deficiency/Water Retention Symptoms' Change in
Tai Ji Group B (n=6)

*P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

Table 4-9-3 Observation of Yin Deficiency/Deficient Heat/Qi Stasis Symptoms'Change in Tai Ji Group B (n=6)

Degree of Symptom	Hot flushes		Hot feet and/or palm		Night sweating		Insomnia		Irritability/ Anxiety/ Stress		Headaches							
	P*	4th	8th	Р	4th	8th	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	3	3	5	6	6	6	3	3	4	4	4	4	4	4	4	6	6	6
1	3	3	1				1	1	2			2			2			
2							2	2		2	2		2	2				
3																		

*P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

Table 4-9-3 indicates that the symptoms of hot flushes were relieved from a mild level for two subjects, one subject did not recover. The symptoms of night sweats were relieved from medium to a mild level for two subjects, two subjects recovered completely. Insomnia was relieved from medium to a mild level for two subjects. Hot flushes, night sweats, insomnia and headache are typical menopausal symptoms caused by yin deficiency and deficient heat, these were partially relieved with Tai Ji exercise.

Table 4-9-4 Observation of *Yin* Deficiency/Deficient Heat Symptoms' Change in
Tai Ji Group B (n=6)

Degree of Symptom	Thirst			Itchy Skin			Constipation			Dark/smelly urine		
	P*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	4	4	5	5	5	5	5	5	5	5	5	5
1	2	2	1			1			1			1
2				1	1		1			1	1	
3								1				

*P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

The symptom of thirst was relieved from a mild level for one subject, one subject recovered completely. Other symptoms showed partial recovery with Tai Ji exercise. Thirst, itchy skin, constipation and dark/malodorous urine are symptoms of body fluid deficiency in TCM. Tai Ji exercise has the effect of balancing yin and yang therefore it relieved some symptoms of body fluid deficiency.

4.5 Discussion

The effects of Tai Ji on the parameters used in this study to describe bone health are equivocal. Table 4-10 indicates considerable variation in results.

Parameter	Group A	Group B	Groups A+B
BUA	1	\rightarrow	\uparrow
VOS	\rightarrow	\rightarrow	\rightarrow
OSTN	1	\uparrow	\uparrow
PYR	\rightarrow	\rightarrow	\rightarrow
D-PYR	\rightarrow	\rightarrow	\rightarrow

Table 4-10 Summary of the Significance of the Tai Ji Exercise Results

Note: \uparrow = Significant increase

 \rightarrow = No significant change

 \downarrow = Significant decrease

BUA increased significantly as a result of four months of Tai Ji exercise. In Group A and Groups A+B combined there was an increase, Group B showed an increasing trend which was not statistically significant (p=0.055). Four months after ceasing exercise the BUA decreased significantly in Group A. This indicated that Tai Ji exercise should be performed continually if a higher level of BUA is to be maintained. In Group B during the first four months where there was no exercise, BUA decreased significantly. After a subsequent four months of Tai Ji exercise for Group B there was a trend toward an increase in BUA although the figure was not statistically significant. This comparison suggests that the natural loss of BUA can be prevented with Tai Ji exercise. As Henderson et al. (1998) suggested, physical exercise may assist in strengthening balance thereby reducing the risk of injury from falls and may also enhance bone mass

density in the elderly. It is important to note that due to the dearth of research on the effects of Tai Ji exercise on bone mass and density the long-term effect of Tai Ji exercise on BUA indicates a need for further study.

In this study, there was no significant change in VOS in either Group A or Group B or Groups A+B combined pre and post treatment results. The lack of any appreciable changes in VOS as compared with the positive results evident in BUA leads to speculation that VOS is an insensitive indicator of changes in bone structure. Liu (1998) stated an increase in BUA might be associated with a change in bone structure and function. The results of this study confirm the positive effect of Tai Ji exercise on BUA in one group but not in VOS in any group. The mechanism for improving bone structure and density may be explained by bone formation (OSTN) results.

It has been reported that exercise may improve bone formation to some extent (Bemben, Fetters, Bemben, Nabavi, and Koh, 2000). Osteocalcin (OSTN) is an effective biomarker, which reflects the level of bone formation. This study shows that four months of treatment using Tai Ji exercise significantly increased the level of OSTN in both Group A and Group B. For Group A there was an increase in the level of OSTN after four months of Tai Ji exercise. Although there was a reduction in the level of OSTN in the post treatment period the decrease was not statistically significant and the level of OSTN indicates bone formation the results confirmed that Tai Ji exercise has positive effects on bone structure and density. For Group B, although there was a significant increase in OSTN after the four months of Tai Ji exercise. These results also suggest that Tai Ji exercise could well contribute to an improvement in bone formation.

It has been reported that aerobic training leads to changes compatible with reduced bone resorption (Woitge, 1998). Tai Ji exercise is considered to have an aerobic effect so it is likely that it may reduce bone resorption. In the present study, pyridinoline (PYR) and

deoxypyridinoline (D-PYR) were used as indices of bone resorption. The values of PYR and D-PYR after treatment with Tai Ji exercise were lower than those of sedentary control groups in this study, although there were no significant differences between the control and exercise groups. However, the level of D-PYR increased significantly in Group A after cessation of Tai Ji exercise. In Group B, the level of D-PYR increased significantly before the exercise, but decreased after exercise. If a longer Tai Ji exercise period was available in a further study it is possible that a statistically significant result in D-PYR may be achieved. The results of pyridum crosslinks demonstrate that D-PYR is relatively more sensitive than PYR which match the results outlined in Chapter 5 (see 5.4 for detailed information).

The results of this study indicate that Tai Ji exercise can not only prevent the natural loss of bone by tending to decrease the bone resorption but may also increase bone structure (BUA) by increasing bone formation (OSTN) thus balancing the bone turnover (between OSTN and D-PYR). As Kirsteins, Dietz and Hwang (1991) indicated Tai Ji is a form of weight-bearing exercise that has the potential advantage of stimulating bone growth and strengthening connective tissue. Further long-term examination of this effect is required.

Table 4-11 provides a comparison of the results from this study with other similar studies. Welsh and Rutherford (1996) suggested that high-impact aerobic exercise in postmenopausal women and men over 50 years old is feasible and effective at maintaining muscle strength and increasing proximal femur BMD but not spine or total body BMD. In Welsh and Rutherford's study low impact exercise was used and subjects were menopausal not postmenopausal. PYR and D-PYR crosslinks' results from Welsh and Rutherford were statistically significant with prolonged high-impact aerobic exercise.

Table 4-11 Comparisons Between the Results of This Study and Others

	This Study	Welsh and R	Rutherford (1996)	Brooke-Wavell, et al. (2001)
Subject	Menopausal	Postmenopa	usal women and	Postmenopausal
	women (42-	men over 50) years (50-73 yrs)	women (60-70
	55 yrs)			yrs)
Number of subjects	Treatment	Treatment g	group (N=15);	#Group 1 (N=20);
	group (N=6);	Control grou	up (N=15)	Group 2 (N=17);
	Control			Group 3 (N=15);
	group (N=6)			Group 4 (N=16)
Intervention	Tai Ji	High-impac	t aerobic exercise	Brisk walking
Duration	4 months	6 months	12 months	12 months
BUA treatment group	Increased by			Increased by
(G)	7.1%			3.3%, (P=0.02) in
	(P<0.05)			Group 2
BUA Control G	Decreased by			No significant
	8.1%			change
	(P<0.05)			
VOS Treatment G	No change			
VOS control G	No change			
BMD treatment G			Total body / spine	No significant
			BMD no change;	change
			Proximal femur	
			BMD increased	
			(P=0.009)	

	This Study	Welsh and F	Rutherford (1996)	Brooke-Wavell, et al. (2001)
BMD control G			Total body BMD	No significant
			decreased by	change except
			0.3% (P=0.02);	Group 3
			Proximal femur	decreased by
			BMD decreased	1.4%, (P=0.01)
			by 0.8%	
			(P=0.049)	
OSTN treatment G	Increased by			
	43.2%			
	(P<0.05)			
OSTN control G	No change			
PYR treatment G	Decreased by	Significant	No change	
	6.1%	-ly		
	(P>0.05)	reduced		
		by 7.2%;		
		P=0.0019		
PYR control G	Increased by	No change	No change	
	23.6%			
	(P>0.05)			
D-PYR treatment G	Decreased by	Decreased	No significant	No significant
	17.8%	by 7.7%;	change	change
	(P>0.05)	(P=0.021)		
D-PYR control G	Increased by	No change	No change	Increased in
	51.1%			Group 1 but
	(P<0.05)			P>0.05

#Group 1 = 20 previously sedentary women remained sedentary (Sed/Sed); Group 2 = 17 took up brisk walking (Sed/Walk); Group 3 = 15 who had been walking regularly for 1 year returned to their former sedentary lifestyle (Walk/Sed); Group 4 = 16 continued brisk walking over a second year (Walk/Walk).

In this study Tai Ji as a form of gentle aerobic exercise affected D-PYR but results were not statistically significant after four months of exercise. If the duration of the Tai Ji exercise period was increased a more pronounced effect may have been observed. As a gentle form of exercise Tai Ji practise can be performed more frequently and in such a case the effects may be more positive. As Bennell, Hart, Nattrass and Wark, (1998) indicated the amount of exercise necessary to cause bone structural change in humans is unknown. They found that acute and subacute changes in the ultrasound measurements of the calcaneus followed intense exercise, BUA values in marathon runners were significantly elevated by 5.0% immediately after the marathon but returned to baseline levels 5-6 days following the marathon. Changes in BUA values in the controls were not significant. VOS measurements were not significantly different across the three testing sessions in both the runners and controls. As was found in this current study these results suggest that BUA was more likely to change than VOS. The current study resulted in a higher percentage result in increased BUA than the other studies listed in Table 4-11 but the time period for exercise that results in lasting structural change in the calcaneus needs to be studied further.

Brooke-Wavell et al. (2001) indicated that women taking up brisk walking for exercise showed no change in BMD but a significant increase in calcaneal BUA. There was no significant effect on BMD or BUA of continuing brisk walking but calcaneal BMD declined on ceasing brisk walking. Bone resorption increased in sedentary women but not exercisers suggesting the effect of exercise on bone in postmenopausal women could be through amelioration of this increased turn-over. Even though there was no significant decrease in D-PYR, BUA increased significantly. This mechanism might be explained better from the results of this current study on balancing bone formation and resorption although the subjects' number are too limited to have full confidence in the results. The changes in BUA, PYR and D-PYR are not as low as those outlined in the above two studies. The results in this study are not statistically significant but percentage changes in a number of areas are higher than other studies.

The impact of physical activity on bone turn-over may depend on the kind of exercise and intensity of exercise (Woitge 1998). Tai Ji exercise might contribute to bone formation rather than bone resorption. Furthermore, the increased BUA in Group A and Groups A+B combined in this current study might be associated with the increased bone formation (as indicated by OSTN) induced by the Tai Ji exercise. This proposition is supported by Qin, Au, Choy, Leung, Neff, Lee, Lau, Woo and Chan (2002), they reported that a Tai Ji exercise group of menopausal women had significantly higher BMD than a control group in the lumbar spine, proximal femur and the ultradistal tibia. They suggested that Tai Ji exercise may help retard bone loss in the weight-bearing bones of postmenopausal women.

Table 4-12 shows the small percentage differences in the means of BUA, VOS and OSTN between Group B without exercise and Group A after ceasing exercise. This indicates that there are no long-term or residual effects from Tai Ji in these various indices of bone health. The small increase in PYR and D-PYR between the 4th and 8th months in Group A (after the cessation of exercise) compared with Group B without exercise indicates that Tai Ji has a long-term effect in reducing the rate of increase of bone resorption. However the long-term effects of Tai Ji exercise on bone health are not clear (see Table 4-12) further study is required to determine the relationship between duration and parameter changes.

The tables of symptoms listed (Tables 4.7 - 4.9) show that some of the fatigue symptoms were relieved after Tai Ji exercise. This was particularly obvious in the areas of body aches, lower back pain and tiredness. Tai Ji exercise can improve the general *qi* and blood circulation, tonify *qi* and unblock meridians. These improvements result in the relief of the symptoms of menopause. The movements are balanced and use the lumbar region as an axle to stretch and relax the back muscles. According to TCM patterns of disharmony, hot flushes, insomnia or sleeplessness, tiredness, pain in the lower back and legs are all associated with *kidney* deficiency. As the *kidneys* are located in the lower back this exercise particularly benefits *kidneys*' function.

Table 4-7 outlines the major effects of this study on the most common menopausal symptoms, however a number of participants reported improvements in areas that have not been included in this table. These are outlined in the following paragraphs.

Table 4-12 Summary of Changes in Group B in the First Four Months without
Treatment and the Long-Term Treatment Effect in Group A in the Second Four
Months after Treatment Ceased

Parameter	Group B	% Change 1*	Group A	% Change 2**
BUA	\rightarrow	- 8.1%	\downarrow	- 10.0%
VOS	\rightarrow	- 0.6%	\rightarrow	- 0.9%
OSTN	\rightarrow	+3.6%	\rightarrow	- 4.7%
PYR	\rightarrow	+ 23.6%	\rightarrow	+ 10.3%
D-PYR	1	+ 51.1%	\rightarrow	+ 27.8%

Note: \uparrow = Significant increase

 \rightarrow = No significant change

 \downarrow = Significant decrease

* % Change 1 = (test 2 - test 1) / test 1 - where test 1 is initial testing, test 2 is testing at 4^{th} month

** % Change 2 = (test 3 - test 2) / test 2 - where test 2 is 4^{th} month testing, test 3 is testing at 8^{th} month

One participant who suffered from hypertension reported her high blood pressure was reduced from a level where Western medication was considered to a more acceptable level. She also suffered from elevated cholesterol levels and found that Tai Ji exercise reduced her cholesterol to the degree that she could stop taking Western medication. High blood pressure in TCM is considered to be a pattern of *kidney yin* deficiency and *liver yang* hyperactivity, Tai Ji exercise harmonised *yin* and *yang* and reduced high blood pressure. It is possible that Tai Ji, by promoting *qi* and *blood* circulation in the

channels, resulted in the clearing of accumulations (such as cholesterol) in these channels. In TCM terms the arteries are considered to be a type of channel so by promoting *qi* and *blood* circulation accumulations within these channels can be cleared (Deng 1999).

Frequent night urination is another symptom of *kidney* deficiency. In total five participants in Group A and Group B complained about this symptom. They suffered interrupted sleep causing loss of energy in the daytime. Reduced sleep negatively affects the restoration of *yin* or may even consume *yin*. The promotion of yang *qi* and strengthening of the *kidney* with Tai Ji was able to alleviate this symptom thus balancing *yin* and *yang*.

Three participants mentioned that they felt more flexible after practicing Tai Ji. One stated that: "After Tai Ji exercise, my left side feels easier to move", this indicates that Tai Ji exercise can improve body balance limiting the risk of falls, balance *yin* and *yang* to improve flexibility, unblock channels to supply *qi* and *blood* to improve the nourishing of muscles and bones. Lan, Lai, Wong and Yu (1996) found in their study that Tai Ji practitioners achieved greater flexibility and a lower percentage of body fat compared with their sedentary counterparts. They also found that Tai Ji training benefits health-related fitness and may be prescribed as a suitable conditioning exercise for the elderly.

Another analysis from Crompton (1996, p8) explained Tai Ji's effect in another way:

"When an animal moves one part of its body – for instance, its head, the whole body follows this movement or adjusts to it. Civilized people for the most part do not achieve this: their movements are usually disjointed and exaggerated. This is because people have lost contact with their innate capacity to move naturally. It is as though each set of muscles has a mind of its own, controlled by humans' emotional states, sudden thoughts and reactions built up over decades of misuse."

"In Tai Chi efforts are made to correct this and to return to the softness and pliability of childhood. A major element of this is
to learn how to move the whole body as one unit. When you turn your body in the Tai Chi Form, the whole body turns. This produces smoothness and harmony, and this materially affects the flow of *blood*, energy and breathing. Instead of each muscle group having a 'mind of its own', there is one 'mind' or one thought permeating the movement and this thought is one of unity of action."

Six months after ceasing Tai Ji exercises one participant sought further treatment for hot flushes that had recently, partially returned. The study design meant that participants in Group A who were treated for the first four months had to stop Tai Ji for the following four months. To gain long-term benefits from Tai Ji exercise many participants continued (if in Group B) or restarted (if in Group A) their Tai Ji practice after the study was completed. Their common experience was expressed in the following words: "We all got benefit from Tai Ji exercises. We feel very relaxed and can concentrate by ourselves when practising outside. We all enjoy practising Tai Ji".

Tai Ji practitioners have summarized the following 13 "important points" in Khor's book (1994, p156).

- 1. The philosophies and principles of Tai Chi can be applied to all aspects of your life.
- 2. Your Tai Chi practice should last as long as you enjoy it. At a minimum, twenty minutes, five times a week.
- 3. The saying "no pain, no gain' has no place in Tai Chi.
- 4. Tai Chi can be safety practiced by the elderly. It can also improve your performance in sport and children's health, fitness and ability at school. It can help ease pregnancy and labour and bring joy to the mentally handicapped.
- 5. Tai Chi exercises the mind, body and spirit, and brings out the natural abilities of the whole person.
- 6. Tai Chi can help you to balance your thoughts and emotions and be calm.

- 7. Life is constantly changing, but Tai Chi can help you find stability.
- 8. The calmness, relaxation and stability you acquire in Tai Chi will help you to open your mind to the life within and around you.
- 9. Apply the concept of moderation in all you do.
- 10. Give your attention to the present.
- 11. Tai Chi will help you to learn to let go.
- 12. Be calm, be yourself. Don't strain to be someone else.
- 13. Tai Chi helps you return to the state of the "Uncarved Block". This state of freedom and emptiness makes all things possible.

As indicated by Crompton (1996), the specific postures and movements of Tai Ji can increase the flow of qi, the essential body energy to heal and strengthen both body and mind. The form is a rhythmic series of flowing movements that tone muscles, loosen joints, increase circulation, improve digestion and reduce stress.

It is anticipated that the results of this study will have a direct impact on health promotion and health related physical activity in the community. The study will help to promote Tai Ji as an exercise activity for the community and particularly for people who have not found other forms of sport and exercise appealing. This has the potential to raise community involvement in physical activity for those individuals and, as a consequence, to lower the health care needs of these people and cut the costs of health care in the community.

It is widely accepted that weight-bearing exercise offers protection against osteoporosis. The optimum benefits can be obtained from moderate levels of exercise as excessive levels can in fact have deleterious effects. Tai Ji exercise is a moderate form of weight bearing exercise. Its positive effects on bone formation are supported by the statistically significant increases in BUA and OSTN. Along with the tangible improvements some subjects also reported subjective benefits and some incidental health improvements. The most readily measurable effects were positive changes to the symptoms as identified in Section 4.4.3. The less quantifiable results included an improved sense of general well reported by the subjects. One subject with a history of hypertension reported a decrease in blood pressure after taking up Tai Ji exercises and another reported a marked reduction in her nocturia.

Melton, Khosla, Atkinson, O'Fallon and Riggs (1997) claimed that reduced bone formation as assessed by OSTN was associated with prior osteoporotic fractures. Tai Ji exercise might be effective in reducing bone fractures in a number of ways. Tai Ji improves balance, this means that practitioners are less likely to fall thus reducing the risk of bone fractures (Liu, Lawson and Wrigley, 1993). Tai Ji improves bone formation (according to this study) thus preventing osteoporosis, which contributes to bone fractures. Further studies are required to elucidate the mechanism of Tai Ji exercise on the improvement of bone formation.

4.6 Conclusion

In summary, this study evaluated the effects of the 24 movements Tai Ji exercise on bone structure and function. To observe bone structure and function BUA and VOS, bone formation marker (OSTN) and bone resorption markers (PYR and D-PYR) were studied before and after four months of Tai Ji exercise. Improved bone structure and increased bone density in menopausal women were reflected by BUA results. The increased BUA appears to be associated with increased bone formation rather than decreased bone resorption. Tai Ji exercises also relieved symptoms related to bone loss. It appears that Tai Ji exercise may not only improve balance and confidence in the elderly but also could contribute to improved bone function and structure.

CHAPTER 5

EFFECTS OF ACUPUNCTURE ON BONE STRUCTURE AND FUNCTION

5.1 Introduction

Acupuncture is the insertion of metal needles into specific points, known as acupoints, on the human body. *Qi* and *blood* in the meridians are adjusted using various manipulation techniques, this balances *yin* and *yang* in the body to prevent and treat diseases (Yao, 1993).

A fundamental concept of Traditional Chinese Medicine (TCM) is qi. This is translated as "intrinsic energy". TCM theory holds that there are invisible channels of energy (*Jing Luo*) all over the body. These channels conduct the qi to all parts of the body and are connected to vital organs. *Qi* assists the various organs and fluids of the body to function correctly (Crompton, 1996). Acupuncture treatment regulates qi that further regulates *blood* to prevent and treat qi and *blood* problems and maintain a healthy body.

According to the TCM classic "Nei Jing", the *kidney* system comprises the *kidney*, marrow, bone and brain. In this holistic theory, the *kidney* controls bones in the body. The relationship between the physiology and pathology of the *kidney*, marrow and brain is associated with pathways made up of channels and collaterals. According to the *Jing Luo* theory (the theory of Channels and Collaterals) and differential diagnosis, *Foot Shao Yin Kidney* channel, *Foot Tai Yang Bladder* channel, *Foot Tai Yin Spleen* channel and *Foot Jue Yin Liver* channel are all related. A close relationship exists between the *Foot Shao Yin Kidney* and *Foot Tai Yang Bladder* channels. This relationship, in combination with the role of the *kidney*, as governing bone and marrow and the path of the *Bladder* channel through the back and hip areas associate weakness in the back and hips with a *kidney* problem. This supports the TCM view that the occurrence of bone loss and osteoporosis in the region of the lower back and hips (and a high rate of fractures as outlined in Chapters 1 and 2) are associated with TCM *kidney*.

Kidney controls bones and also affects hormone levels in the body as discussed in Chapter 2. If acupuncture can improve *kidney* function then bone density may be improved. The research reports outlined in Chapter 2 showed that acupuncture can improve bone density by increasing serum estradiol (E2). According to Wolfe (1998), there are three forms of estrogen that are active in the female body: estrone, estradiol and estriol. Estradiol is the primary estrogen produced by the ovaries and estrone is formed by conversion of estradiol. Western medicine essentially defines menopausal problems as a lack of estrogen production, Western therapy prescribes estrogen replacement therapy for menopausal women. Under the TCM paradigm acupuncture improves estradiol levels (see Chapter 2) so it could be considered a replacement or partial replacement therapy.

It must also be noted that acupuncture produces no side effects with long-term application. Scientific research suggests that acupuncture is a simple technique that provides stable therapeutic results with few side effects (Li and Chen, 1998). The effects of acupuncture on bone structure and function are not yet clear as there have been few studies in this area. Past studies on treating osteoporosis with acupuncture have been limited to clinical observation because modern diagnostic methods, such as specific bone turn-over markers; osteocalcin (OSTN), pyridinoline (PYR) and deoxypyridinoline (D-PYR) were not available. Very little research is available to date into the effects of acupuncture on bone structure and function using western biochemical laboratory techniques and objective methods.

5.2 Research Design and Methodology

To evaluate the effects of traditional Chinese acupuncture therapy strategies on bone turn-over in menopausal women, this study used a paired design for eight months (see Figure 5-1). Participants received acupuncture treatment using acupoints San Yin Jiao (SP6), Zu San Li (ST36) and Tai Xi (KID3) (see Figure 5-2).

Fourteen of the 40 menopausal women who completed the study (aged 42-55 years) were involved in the acupuncture group (see Table 5-1). This group was then divided into sub groups A and B based on their bone structure and function test results (BUA) with further reference to their menopausal status and other related criteria (as mentioned in Chapter 3, also see Figure 5-1). All participants were given information regarding the purpose of this study and the demands of this study design. They were told which group they belonged to and as a result whether they were initially in a treatment or control group.

	Ν	Minimum	Maximum	Mean	St. Deviation
Age (yrs)	14	42	55	49.3	3.6
Height (m)	14	1.52	1.73	1.65	5.65
Weight (kg)	14	53.5	95.7	74.6	11.4
BUA (dB/MHz)	14	57.0	108.7	78.6	15.7

Table 5-1 Subject Characteristics

	Group A	Group B
BUA (mean±SD)	76.0±17.9	81.1±14.6



Figure 5-1 The Research Design

The participants were given acupuncture therapy in accordance with TCM principles and differential diagnosis. Effectively the study for Group A involved treatment for the first four months and non-treatment for the second four months. The second four months or control period gave some indication of the residual or long-term effect of acupuncture on the various parameters considered in this study. Conversely, Group B did not show any residual effect of treatment, as there was no testing after the 8th month for this group. However the first four "control months" with this group do provide some indication of the effects of the passage of time on the parameters considered in this study.

The two groups were compared using BUA, VOS, OSTN, PYR and D-PYR as well as TCM assessment (see Chapter 3). The treatment principles of tonifying and nourishing *kidney* and *yin* were based on the common pattern of disharmony exhibited by these women as outlined in Chapter 3.3.2.

Treatment involved the use of the points on meridians that tonify and nourish the body. By using specific acupuncture points, certain organs may be tonified, nourished and regulated. Figure 5-2 shows the locations of the treatment points used in this study.

Spleen 6 (San Yin Jiao) – the meeting point of three meridians (*spleen, liver* and *kidney*), which has the effect of "killing three birds with one stone". This point affects the three *yin* organs, so by tonifying this point *yin* is nourished. *Spleen* 6 is often used to strengthen the transporting and transforming function of the *spleen*. It also enhances the production of qi and *blood* to nourish the body, especially *heart, liver* and *kidney* (Tang, Dang and Geng, 1999).

Figure 5-2 Diagram of the Point Locations

Kidney 3 (Tai Xi) – the *yuan* (source) point of the *kidney* meridian has a strong tonifying effect as well as a nourishing yin effect. It is also the *shu* (transport) point of the meridian so it transports the *kidney yin* (water) to the upper body. Consequently, *kidney 3* as a water point balances fire to eliminate heat symptoms and prevent cold symptoms. The element of the *heart* is fire, so this point harmonises *heart* and *kidney*. *Kidney 3* has been used classically to regulate the *chong* and *ren* meridians. These two meridians are closely related to the reproductive system of women (Tang, Dang and Geng, 1999).

Stomach 36 (Zu San Li) – the earth point of the earth meridian. It has a very strong effect in strengthening the *spleen* and *stomach*, (the earth organs). Stomach 36 is used as it harmonises the digestive system, relieving digestive symptoms. It also supports *spleen* 6 by enhancing the production of *qi* and *blood* (Tang, Dang and Geng, 1999). As indicated in Chapter 3, at around the age of 35-40 years, the digestion (*spleen* and *stomach*) becomes less efficient, therefore producing less *qi* and *blood*. This is relevant to menopause for two interrelated reasons. Firstly, it means that over time, there is not the production of the super-abundance of blood required for menstruation. And second, it means that less postnatal or acquired *essence* (the *spleen* derives this *essence* from ingested nutrients) is available to supplement *prenatal* (*kidney*) *essence*. This leads to the consumption of *prenatal essence*, lending credence to the decreasing of oestrogen levels and the aging process. Thus *Stomach* 36 could assist in tonifying *kidney* to prevent bone loss. In TCM theory the organs relate to nature and interact accordingly.

Spleen 6 (SP 6) is located on the posterior border of the medial aspect of the tibia and is a distance of 3 *cun* above the tip of the medial malleolus. ("*Cun*" is a TCM linear measure, one *cun* equals one TCM body inch. Three *cun* is equal to the width of the patient's four fingers at the second phalangeal joint).

Kidney 3 (KID 3) is in the depression between the tip of the medial malleolus and the achilles tendon.

Stomach 36 (ST 36) is located 3 *cun* below the lower edge of the patella, one cun (a thumb width at the second phalangeal joint) lateral to the anterior crest of the tibia.

Each of the participants was treated thirty-two times by the researcher. Treatments were given twice a week. Each session lasted 45 minutes; comprising 10 minutes consulting, checking and recording, 5 minutes preparation and skin sterilising and 30 minutes of acupuncture treatment. Before each treatment, symptoms and signs were recorded according to TCM diagnostic methods. During each treatment, participants were asked to lie down and expose the areas, (i.e. lower legs) to be treated.

Needles and Needling Methods:

The same style, brand and size of needles were used for all treatments during the study. The same needling techniques, (skin preparation, needle manipulation) were used on all subjects:

Brand:	Hwato
Size:	0.22 (Diameter) X 30mm (Long)
Style:	Chinese disposable with tube
Needling angle:	Perpendicularly
Needling depth:	0.3 <i>cun</i> to 0.7 <i>cun</i> (9mm-20mm)
Form of manipulation:	Uniform reinforcing-reducing method (reinforcing: reducing = 9:6)
Retaining time:	30 minutes

The uniform reinforcing-reducing method involves twirling supplementation and drainage. This is a method of achieving supplementation or draining by rotating the needle between the thumb and index finger of the right hand. Forward movement of the thumb and backward movement of the index finger making the needle rotate clockwise produces supplementing stimulus. Forward movement of the index finger and

backward movement of the thumb, making the needle rotate anti-clockwise produces a draining needle stimulus according to Wiseman and Ye (1998).

The ratio of reinforcing: reducing = 9:6 refers to rotating the needle nine times for supplementing and six times for draining. According to the TCM patterns of disharmony, for these participants' deficiency, they required supplementation while draining was needed to treat symptoms.

5.3 Statistical Analysis

Test results were recorded for subjects at the commencement of the study, at the midpoint and at the end of treatment. Differences between the treatment and control groups were calculated for pre-test, 4th month and 8th month test results as well as within groups and between groups, i.e. Group A and Group B. After the crossover (when the treatment and control groups swapped roles) the same style of observations and calculations were made. Data was analysed using paired t-tests in SPSS 10.0 and Ridit analysis with results of p<0.05 being accepted as statistically significant.

5.4 Results

This study examined the effects of four months of treatment using acupuncture points SP6, ST36 and KID3 on bone health. Fourteen menopausal women participated and completed this study. The average attendance rate was 91%. The results of tests for BUA, VOS, OSTN, PYR and D-PYR as well as TCM symptoms were used for statistical analysis. It is also possible to consider the effects of the acupuncture treatment according to the four TCM groupings i.e. *kidney* deficiency symptoms, *qi* deficiency / water retention symptoms, *yin* deficiency / deficient heat / *qi* stasis symptoms and *yin* deficiency / deficient heat symptoms.

5.4.1 Bone Structure Results

Effects of Acupuncture Treatment on Broadband Ultrasound Attenuation

As indicated in Chapters 1 and 3, Broadband Ultrasound Attenuation (BUA) is an indication of the trabecular orientation and pattern in bone, which can show the structure and density of bone. Table 5-2 and Figure 5-3 show the results of the acupuncture treatment on BUA. The results indicated that the BUA showed an increasing trend with acupuncture treatment. After four months of acupuncture treatment, the BUA in Group A increased by 8.2% but this increase was non-significant (P=0.124). It decreased after treatment stopped but again there was no statistical significance (p=0.692). In Group B, BUA was significantly decreased after four months without treatment (p=0.004), but it was significantly increased with treatment (p=0.010). There was no significant difference of BUA between A and B group at pretesting. The general treatment effect in both Group A and Group B combined, (comparison between pre-treatment and post-treatment of Group A results + Group B results) was significant (p=0.005).

Effects of Acupuncture Treatment on Velocity of Sound

As discussed in Chapters 1 and 3, Velocity of Sound (VOS) is an indication of elastic modulus and breaking force of the bone. Table 5-3 and Figure 5-4 show the results of four months of acupuncture treatment on VOS. The results show while VOS tended to increase in both Group A and B after treatment, the result was not statistically significant (p>0.05). VOS showed a decreasing trend in Group B without treatment, but again the decrease was not statistically significant. The results indicated that there was no significant effect of acupuncture on VOS.

Group (n=7)	Pre-test	4 th month	8 th month
Α	76.0±17.9	82.2±21.3	78.7±22.3
В	81.1±14.6	69.9±11.4*	76.5±14.7 [#]
Group (n=14)	Pre-treatment	Post treatment	р
A+B	73.0±14.8	79.4±17.9	0.005

Table 5-2 Effects of Acupuncture Treatment on Broadband Ultrasound Attenuation (BUA) (dB/MHz) (X±SD)

* Significantly different from the data of pre-test, P=0.004.

Significantly different from the data of 4th month, p=0.01.



Figure 5-3 Effects of Acupuncture Treatment on Broadband Ultrasound Attenuation (BUA) (dB/MHz) (X±SD)

Group (n=7)	Pre-test	4 th month	8 th month
Α	1501.0±219.4	1607.4±31.9	1600.4±22.8
В	1596.1±33.2	1578.4±50.6	1589.4±66.0
Group (n=14)	Pre-treatment	Post treatment	р
A + B	1539.7±158.1	1598.4±50.6	0.210

Table 5-3 Effects of Acupuncture Treatment on Velocity of Sound (VOS) (m/s)



Figure 5-4 Effects of Acupuncture Treatment on Velocity of Sound (VOS) (m/s)

5.4.2 Bone Formation and Resorption Results

While the tests for BUA and VOS were equivocal in their provision of evidence of enhanced bone structure, the bone turn-over markers OSTN, PYR and D-PYR showed some positive treatment results.

Effects of Acupuncture on bone formation

As indicated in Chapters 1 and 3, osteocalcin (OSTN) is regarded as a biomarker of bone formation. Table 5-4 and Figure 5-5 show the results of four months of acupuncture treatment on OSTN, and it is apparent that at the end of treatment the OSTN level of Group A had risen significantly (p=0.020). Four months after treatment ceased, the OSTN level still remained high, compared with the pre-test result (p=0.679). The OSTN level of Group B showed a moderate decrease during its control period, but this was not statistically significant. No significant change occurred without treatment (p=0.089). After four months of treatment, it rose to a higher level compared with pre-treatment, but the result was not statistically significant (p=0.183). The general treatment effect in both Group A and B combined (comparison between pre-treatment and post-treatment of Group A results + Group B results) showed a significant increase (p=0.006).

Bone Resorption Results

As indicated in Chapters 1 and 3, pyridinoline (PYR) and deoxypyridinoline (D-PYR) are urinary pyridum cross links which are regarded as bio-markers of bone resorption. Table 5-5 and Figure 5-6 show the results of four months of acupuncture treatment on PYR while Table 5-6 and Figure 5-7 show the effects on D-PYR. It is apparent that four-months of acupuncture treatment reduced the level of the bone resorption marker D-PYR. The reduction of PYR, the cross-link marker, was not statistically significant.

Group (n=7)	Pre-test	4 th month	8 th month
Α	16.4±8.4	24.1±6.9*	23.4±9.6 [#]
В	24.1±10.2	21.3±8.3	25.1±7.9

Table 5-4 Effects of Acupuncture Treatment on Osteocalcin (OSTN) (ng/ml)

Group (n=14)	Pre-treatment	Post treatment	р
A + B	18.8±8.4	24.6±7.2	0.006

*# Significantly increased levels compared with pre-test measure, *p=0.020, #p=0.032



Figure 5-5 Effects of Acupuncture Treatment on Osteocalcin (OSTN) (ng/ml)

PYR test results showed that at the end of treatment the PYR level of Group A had a tendency to decrease (-4.3%), but the result was not statistically significant, p=0.691. Four months after treatment ceased the PYR level increased (11.6%), but again there was no statistical significance, p=0.383. The PYR level of Group B increased without treatment (6.4%, p=0.522) but after four months of treatment, it decreased (-6.6%, p=0.612). Again these results indicated that there was no statistical significance in these change. The combined effects of both Group A and B also showed no statistical significance, p=0.493.

D-PYR test results showed that at the end of treatment, the D-PYR level of Group A had decreased significantly (p=0.001). Four months after treatment ceased, the D-PYR level increased significantly, to about the same level as pre-treatment (p=0.038). The D-PYR level of Group B increased without treatment (p=0.056) while after four months of treatment it decreased (p=0.188). While there was no significant difference between Group A and B at pre-test, a significant difference between them existed at the 4th month (p<0.000). The effect in both Group A and B combined showed statistical significance (P=0.002), indicating that in these subjects acupuncture treatment reduced the level of D-PYR and thus bone resorption.

Group (n=7)	Pre-test	4 th month	8 th month
А	62.6±16.6	59.9±20.0	67.0±22.7
В	66.0±19.3	70.2±12.3	65.6±18.6

 Table 5-5 Effects of Acupuncture Treatment on Urinary Pyridinoline (PYR) (nmol/mmol Cr)

Group (n=14)	Pre-treatment	Post treatment	р
A + B	66.4±14.6	62.8±18.9	0.493



Figure 5-6 Effects of Acupuncture Treatment on Urinary Pyridinoline (PYR) (nmol/mmol Cr)

Table 5-6 Effects of Acupuncture Treatment on Urinary Deoxypyr	idinoline (D-
PYR) (nmol/mmol Cr)	

Group (n=7)	Pre-test	4 th month	8 th month
Α	13.4±2.8	9.8±2.8*	13.6±3.4 [#]
В	12.2±5.6	15.8±4.9	14.0±4.0

Group (n=14)	Pre-treatment	Post treatment	р
A + B	14.6±4.0	11.9±4.0	0.002

* Significantly different from pre-test data, p=0.001.
 # Significantly different from the data of 4th month, p=0.038



Figure 5-7 Effects of Acupuncture Treatment on Urinary Deoxypyridinoline (D-PYR) (nmol/mmol Cr)

5.4.3 Traditional Chinese Medical Assessment

Traditional Chinese diagnostic patterns are differentiated, based on symptoms and signs (see Chapter 3, Table 3-6) as explained in Chapter 3.

The occurrence of certain symptoms and signs indicate certain patterns of disharmony. Table 5-7 shows the results of four months of acupuncture treatment on the main TCM symptoms related to bone loss and menopause. Most of the major symptoms i.e. lower back pain, knee/leg/foot pain, abdominal distension, swollen ankles/fingers, tiredness, palpitations, hot flushes, night sweats, insomnia, headache and thirst were relieved to a statistically significant level by acupuncture treatment. These symptoms are mainly bone loss and menopause related symptoms. Tongue and pulse analysis has not been detailed here due to the need for advanced TCM knowledge required for correct interpretation.

Grouped according to the patterns of disharmony, Tables 5-7 - 5-8 show the groups of symptom changes which indicate the acupuncture effects on different TCM internal organ systems and *yin*, *yang*, *qi*, *blood* in detail.

Traditional Chinese diagnostic patterns are differentiated, based on symptoms and signs as explained in Chapter 3 (see Chapter 3, Table 3-6). The following symptoms and signs were compiled during the three interviews at the pre, 4th month and 8th month tests. The findings were then used as evidence of the efficacy of acupuncture in relieving the symptoms listed in Table 5-7. The scores given in this table are the combined scores for both Group A and B (pre and post treatment results).

Table 5-8 demonstrates the groups of symptoms and the changes for individual cases in Group A that matched the closely related patterns outlined in Chapter 3. Table 5-9 demonstrates the symptoms and changes for individual cases in Group B.

Symptom /	Pre-t	reatme	ent		Post-	treatm		Ridit	
Number of subjects	0*	1	2	3	0	1	2	3	p**
Lower back pain	2	5	4	3	8	5	1		<0.01#
Knee/Leg/Foot pain	5	2	4	3	10	4			<0.01#
Aching Bones	13		1		14				>0.05
Poor appetite	13		1		14				>0.05
Abdominal distension	8	3	2	1	13	1			<0.05#
Diarrhoea	9	5			13	1			>0.05
Swollen ankles/fingers	8	2	2	2	14				<0.01#
Tiredness	2	7	2	3	13		1		<0.01#
Palpitations	7	6	1		12	2			<0.05#
Hot flushes	0	5	8	1	5	9			<0.01#
Hot feet/pain	12	2			13	1			>0.05
Night sweats	1	7	5	1	11	3			<0.01#
Insomnia	3	6	3	2	8	5	1		<0.05#
Irritability/Anxiety/Stress	9	2	2	1	12	1	1		>0.05
Headache	4	1	7	2	7	7			<0.01#
Thirst	4	3	5	2	9	3	2		<0.05#
Skin itch	13		1		14				>0.05
Constipation	8	5	3		9	6	1		>0.05
Dark/malodorous urine	7	3	3	1	11	2	1		>0.05

Table 5-7 Effects of Acupuncture Treatment on Traditional Chinese Medical Symptoms of Groups A+B (n = 14)

* 0=no symptom; 1=mild symptom; 2=medium symptom; 3=severe

** Ridit analysis was used to test for statistical significance. # p < 0.05 indicates that the symptoms were relieved with treatment to a statistically significant level.

Tables 5-7-1 and 5-8-1 indicate *kidney* deficiency symptoms. As indicated in Chapter 3, the lower back is the house of the *kidney* and its symptoms reflects the *kidney's* condition. Lower back pain was shown to be relieved and knee/leg/feet pain was also relieved by acupuncture treatment. The long-term effect also appeared positive.

Tables 5-7-2 and 5-8-2 indicate symptoms of *qi* deficiency and its related symptom oedema. As outlined in Chapter 3, *spleen* and *kidney qi* deficiency are common in menopausal women.

Tables 5-7-3 and 5-8-3, 5-7-4 and 5-8-4 indicate *yin* deficiency symptoms especially general *yin*, *kidney* and *liver yin* deficiency symptoms that match common menopausal symptoms as outlined in Chapter 3.

Considering the groups of symptoms together, the common patterns of disharmony can be determined as *yin* and *qi* deficiency especially in *kidney, spleen* and *liver*.

Table 5-8-1 Observation of Kidney Deficiency Symptoms' Change in Acupunctur	re
Group A (n=7)	

Degree of	Lower	back pai	n	Knee/I	Leg/Foot	pain	Aching bones				
symptom*	Pre-test	4 th Month	8 th Month	Pre-test	test 4 th 8 th Month Month		Pre-test	4 th Month	8 th Month		
0	2	4	3	4	6	4	6	7	7		
1	1	3	3		1	3					
2	2		1	1			1				
3	2			2							

* 0: no symptoms; 1: mild; 2: medium; 3: severe

Lower back pain, knee/leg/feet pain and aching bones are common *kidney* deficiency symptoms. In Group A five subjects suffered from lower back pain, after four months of acupuncture treatment three of them still suffered mild pain but the others had recovered. After four months without treatment only one subject had a recurrence of medium level pain. Three subjects had medium to severe knee/leg/foot pain, four months of acupuncture treatment reduced the pain to a mild level.

Degree of Symptom**	Poor appetite		Abdominal distension			Diarrhoea			Swollen ankles/ fingers			Tiredness			Palpitations			
	Р*	4 th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8 th	Р	4th	8th
0	6	6	6	4	6	5	3	6	5	3	7	5		7	6	4	6	5
1		1		1	1	1	4	1	2	1		2	3		1	2	1	2
2	1		1	1						1			1			1		
3				1		1				2			3					

 Table 5-8-2 Observation of *Qi* Deficiency/Water Retention Symptoms' Change in Acupuncture Group A (n=7)

* P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

** 0: no symptoms; 1: mild; 2: medium; 3: severe

Two of the three subjects suffering abdominal distension recovered with acupuncture treatment but one had a recurrence of symptoms four months after treatment. Three of the four subjects suffering from diarrhoea recovered with treatment, only one suffered recurrence after the treatment ceased. Four subjects suffered swollen ankles/fingers, all recovered with acupuncture but two suffered recurrences after the treatment ceased. Seven subjects suffered from tiredness, all recovered with treatment and only one had mild symptom recurrence after treatment ceased. Abdominal distension, tiredness and palpitations are major qi deficiency symptoms, swollen ankles/fingers are typical qi deficiency and water retention symptoms. Acupuncture treatment was effective in relieving these symptoms.

Degree of symptom **	Ho flus	t shes	nes p		Hot feet/ palms		Night sweats		Insomnia			Irr /Ar Str	itabi ixiety ess	lity y/	Headache			
	P*	4th	8th	Р	4th	8th	P*	4th	8th	Р	4th	8th	Р	4th	8 th	Р	4th	8th
0	0	2	2	6	7	7	1	5	3	2	5	4	4	5	5	3	5	4
1		5	5				3	2	3	2	1	2	1	2	1		2	2
2	6			1			2		1	1	1	1	1		1	2		1
3	1						1			2			1			2		

 Table 5-8-3 Observation of Yin Deficiency/Deficient Heat/Qi Stasis Symptoms'

 Change in Acupuncture Group A (n=7)

* P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

** 0: no symptoms; 1: mild; 2: medium; 3: severe

The symptoms of hot flushes were relieved from medium to a mild level for five subjects, two subjects recovered completely, the long-term effect was maintained for four months for all subjects. Other symptoms showed partial recovery with acupuncture treatment. Hot flushes, night sweats, insomnia and headache are typical menopausal symptoms caused by *yin* deficiency and deficient heat, these were partially relieved with acupuncture treatment.

				_		_							
Degree of Symptom	Thirs	t		Itchy	skin		Const	tipatio	1	Dark/Malodorous urine			
**	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	
0	2	5	4	6	7	6	4	4	3	2	4	4	

 Table 5-8-4 Observation of Yin Deficiency/Deficient Heat Symptoms' Change in Acupuncture Group A (n=7)

* P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

** 0: no symptoms; 1: mild; 2: medium; 3: severe

The symptoms of thirst were relieved from severe to a mild level for two subjects, three subjects recovered completely, the long-term effect was maintained for four months for most of the subjects. Other symptoms showed partial recovery with acupuncture treatment. Thirst, itchy skin, constipation and dark/malodorous urine are symptoms of body fluid deficiency in TCM. Acupuncture administered at the *yin* nourishing points increased body fluids.

Table 5-9-1 Observation of Kidney Deficiency Symptoms' Change in AcupunctureGroup B (n=7)

Degree of	Lower	back pai	n (n)	Knee/I	Leg/Foot	pain (n)	Aching bones (n)				
symptom*	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month		
0			5	1	1	6	7	7	7		
1	4	4	2	2	2	1					
2	2	2		3	3						
3	1	1		1	1						

* 0: no symptoms; 1: mild; 2: medium; 3: severe

In Group B seven subjects suffered from lower back pain, after four months of acupuncture treatment two of them still suffered mild pain but the others had recovered. Six subjects had medium to severe knee/leg/foot pain, four months of acupuncture treatment relieved the pain.

Degree of Symptom **	Poor appetite		e	Abdominal Distension			Diarrhoea			Swollen Ankles/ Fingers			Tired			Palpita- tion		
	Р*	4th	8 th	Р	4th	8th	Р	4th	8th	Р	4^{th}	8th	Р	4th	8 th	Р	4th	8th
0	7	7	7	4	4	7	6	6	7	5	5	7	3	2	6	3	3	6
1				2	2		1	1		1	1		4	4		4	4	1
2				1	1					1	1		1	1	1			
3																		

 Table 5-9-2 Observation of *Qi* Deficiency/Water Retention Symptoms' Change in Acupuncture Group B (n=7)

* P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

** 0: no symptoms; 1: mild; 2: medium; 3: severe

Three subjects suffering abdominal distension recovered with acupuncture treatment. One subject suffering from diarrhoea recovered with treatment. Two subjects suffered swollen ankles/fingers, all recovered with acupuncture. Five subjects suffered from tiredness, all recovered with treatment. Abdominal distension, tiredness and palpitations are major qi deficiency symptoms, swollen ankles/fingers are typical qi deficiency and water retention symptoms. Acupuncture treatment was effective in relieving these symptoms.

 Table 5-9-3 Observation of *Yin* Deficiency/Deficient Heat/*Qi* Stasis's Change in Acupuncture Group B (n=7)

Degree of Symptom **	Ho flus	t shes		Ho pal	t feet ms	t/	Night sweats			Ins	omn	ia	Irri Anz Stro	itabil kiety/ ess	ity/	Headache			
	P*	4th	8th	Р	4th	8th	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	
0			3	6	6	6			6	1	1	3	5	5	7	1	1	2	
1	5	5	4			1	4	4	1	4	4	4	1	1		1	1	5	
2	2	2		1	1		3	3		2	2		1	1		5	5		
3																			

* P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

** 0: no symptoms; 1: mild; 2: medium; 3: severe

The symptoms of hot flushes were relieved from medium to a mild level for four subjects, three subjects recovered completely. The symptoms of night sweats were relieved from medium to a mild level for one subject, six subjects recovered completely. Insomnia was relieved from medium to a mild level for four subjects, two subjects recovered completely. Headache was relieved from medium to a mild level for four subjects, one subject recovered completely. Other symptoms showed partial recovery with acupuncture treatment. Hot flushes, night sweats, insomnia and headache are typical menopausal symptoms caused by *yin* deficiency and deficient heat, these were partially relieved with acupuncture treatment.

Table 5-9-4 Observation of <i>Yin</i> Deficiency/Deficient Heat Symptoms'	Change in
Acupuncture Group B (n=7)	

Degree of Symptom	Thirsty			Skin	itch		Cons	tipatio	n	Dark/Malodorous urine			
**	Р*	4th	8th	P 4th 8th		8th	Р	4th	8th	Р	4th	8th	
0	2	2	4	7	7	7	4	4	6	5	5	7	
1	1	1	2				3	3	1	1	1		
2	4	4	1				1	1		1	1		
3													

* P = pre-test, $4^{th} = 4^{th}$ Month, $8^{th} = 8^{th}$ Month

** 0: no symptoms; 1: mild; 2: medium; 3: severe

The symptom of thirst was relieved from medium to a mild level for two subjects, one subject recovered completely. Constipation was relieved from medium to a mild level for one subject, three subjects recovered completely. Other symptoms showed partial recovery with acupuncture treatment. Thirst, itchy skin, constipation and dark/malodorous urine are symptoms of body fluid deficiency in TCM. Acupuncture administered at the *yin* nourishing points increased body fluids.

5.5 Discussion

The results of the effects of acupuncture on the parameters used in this study to describe bone health are equivocal. As Table 5-10 indicates the results varied between groups and were not constant even for the combined data of Group A and Group B.

Parameter	Group A	Group B	Groups A+B
BUA	\rightarrow	1	1
VOS	\rightarrow	\rightarrow	\rightarrow
OSTN	1	\rightarrow	1
PYR	\rightarrow	\rightarrow	\rightarrow
D-PYR	\downarrow	\rightarrow	\downarrow

Table 5-10 Summary of the Significance of the Acupuncture Treatment Results

Note: \uparrow = Significant increase

 \rightarrow = No significant change

 \downarrow = Significant decrease

The results indicated that the BUA, which reflects bone structure and density, increased with acupuncture treatment in Group A and Groups A+B combined. The increased BUA of Groups A+B combined appears to be associated with the increased bone formation marker OSTN of Groups A+B combined, and decreased bone resorption marker D-PYR of Groups A+B combined.

It is interesting to note that unlike BUA which increased significantly in two of the acupuncture treatment groups (B and A+B) VOS did not change. Howard, Nguyen, Pocock, Kelly and Eisman (1997) suggested that in a small number of studies examining VOS and fracture risk, VOS appears to have a weaker predictive power than BUA. This concurs with the results of this study where the small change in VOS indicates that this parameter is either a less sensitive indicator of bone health or that changes in VOS lag behind changes in BUA. Langton, Ballard, Langton and Purdie (1997) in their study demonstrated that BUA provides an improved referral procedure to that currently achieved with clinical referral criteria and supports the concept of BUA being used as a selective pre-screen for DXA in 7th decade subjects. Kutilek and Bayer (2001) reported that girls with anorexia nervosa have low BUA and high VOS values, compared with reference data. In their study BUA was significantly lower (p<0.004) and VOS significantly higher (p<0.0001), neither of which correlated with the duration of anorexia nervosa or the number of missed cycles.

Zhou and Wang (2000) stated that acupuncture is an effective therapy for treating osteoporosis based on clinical practise, however this therapy for treating osteoporosis is in the initial stage of development, only clinical observation is currently available. They further explained that there has not yet been a proper scientific study using accurate measurements of bone density. Some commonly used biomarkers eg. Estradiol II are used but they do not accurately indicate bone remodelling. Specific markers like. OSTN, PYR are not currently being used. They also indicated that a further problem in considering acupuncture treatment in this case is that there is no particular consideration of a common pattern of disharmony and therefore there are variations in point selection. This current study emphasises the common pattern of disharmony and selects only three points according to this common pattern. This method can easily be followed and allows for future experiments. Table 5-12 compares the acupuncture results of this study on bone structure and density with another two available studies, which followed a_similar approach. Even though the studies can not be compared directly due to different forms of measurement, the effects of acupuncture appear positive in all cases.

	This Study	Liu and Zhang (2000)	Wu, et al. (2000)	
Subjects	Menopausal women (42-55 yrs)	Osteoporosis patients (52-74 yrs)	Osteoporosis patients (55-65 yrs)	
Number of subjects	Groups A+B, N=14, pre and post treatment comparison	N=25, pre and post treatment comparison	N=18, pre and post treatment comparison	
Intervention	Acupuncture on Tai Xi (KID 3), San Yin Jiao (SP 6) and Zu San Li (ST 36)	Acupuncture on main points: Bai Hui (DU 20), Da Zhui (DU 14), Zhi Yang (DU 9), Yao Yang Guan (DU 3), Ming Men (DU 4); secondary points (choose 4-6 in each treatment): Guan Yuan (RN 4), Qi Hai (RN 6), Shen Shu (BL 23), Pi Shu (BL 20), Xuan Zhong (GB 39), Tai Xi (KID 3), Zu San Li (ST 36), San Yin Jiao (SP 6)	Acupuncture on the main points: Da Shu (BL 11), Da Zhui (DU 14), Ming Men (DU 4); secondary points: Xuan Zhong (GB 39), Ge Shu (BL 17), Zu San Li (ST 36)	
Duration	Twice per week in 4 months	30 - 60 treatments in 3 months	60 treatments in 85 days	
BUA Pre and post- treatment comparison	Groups A+B Increased by 8.8% (P=0.005)			
VOS Pre and Post- Treatment comparison	Groups A+B Increased by 3.8% (P>0.05)			
BMD		BMD increased 0.3 – 0.8.		
Pre and post- treatment (single x-ray absorption- metry)		8 subjects' BMD increased by 19.4%, 11 subjects' BMD increased by 10.9%, 4 subjects' BMD increased by 3.2%, no report on significance.		

Table 5-11 Comparisons Between the Results of This Study and Others

	This Study	Liu and Zhang (2000)	Wu, et al. (2000)
BMD Pre and post- treatment (dual x-ray absorption- metry)			Lumbar 1-4 BMD increased by 1.28%; neck of femur BMD increased by 0.43%, no report on significance.

Studies related to the effects of acupuncture on BUA in menopausal women are not readily available for comparison. This paired study has been performed primarily to evaluate the effects of acupuncture on BUA in menopausal women. Looking at the combined results from Groups A+B there appears to be a significant increase in BUA as a result of acupuncture therapy. Individual differences in the subjects might explain why no significant difference was observed with acupuncture treatment in Group A. The aggregated numbers of Groups A+B (where a significant result was found) also indicate that the subject numbers in Group A and B were insufficient to generate consistent statistically significant responses.

Acupuncture treatment results were positive on the bone formation marker OSTN, as seen through its effects on Groups A+B combined. These results suggest that increased bone formation in Groups A+B combined might be responsible for the increased BUA of Groups A+B combined in menopausal women. The increased OSTN and decreased D-PYR also indicate that acupuncture has a positive effect in balancing bone formation and bone resorption and hence in improving bone health.

Acupuncture treatment significantly reduced D-PYR in Group A and made a significant difference at the 4th month between Group A with treatment and Group B without treatment. This infers that acupuncture treatment can be used to reduce bone loss and improve bone function. The mechanism for this result may be explained by the clinical case report by Kuno and Cerqueira (1995); they indicated that acupuncture can cause enhanced bone metabolism demonstrated by increased activity on bone scans.

Yilmaz, Bayram, Erbagci and Kilincer (1999) suggested that D-PYR might be more efficient in evaluating bone resorption than PYR. This study supports this view as in two of the three groupings significant decreases occurred in D-PYR but there was no change in PYR. A review of Table 5-5 and Figure 5-6 indicates that although the changes in the means of the PYR in both groups were consistent they were small and statistically insignificant.

The results between the 4th and 8th months in Group A (after the cessation of treatment) indicate that there are few long-term or residual effects of acupuncture on the various indices of bone health. The small percentage changes in the means for BUA, VOS and OSTN suggest that the acupuncture treatment may have had some effect on the detrimental changes over time which were experienced by Group B.

It should also be noted that in Group B during the first four months, where there was no acupuncture treatment, the means for BUA, VOS, OSTN, PYR and D-PYR all showed a negative movement, although this was not significant. According to a one year study conducted by Seifert-Klauss, Mueller, Luppa, Probst, Wilker, Hoss, Treumann, Kastner and Ulm (2002), changes in bone turn-over begin in late pre-menopause, when decreased bone formation may precede increased bone resorption. In the Seifert-Klauss et al study PYR and D-PYR changed significantly with time during peri-menopause (n=24). This current four-month study indicated a similar trend in bone turn-over. The value of acupuncture in preventing or reducing bone loss over time should be given further consideration. The results between the 4th month and 8th month in Group A (after the cessation of treatment) indicate that the long-term effects of acupuncture treatment on BUA, VOS, OSTN may be positive (see Table 5-12) even though the results of this study are not statistically significant.

Table 5-12 Summary of the Changes in Group B in the First Four Months without Treatment and the Long-Term Treatment Effect in Group A in the Second Four Months after Treatment Cease

Parameter	Group B	% Change 1*	Group A	% Change 2**	
BUA	\rightarrow	- 13.8%	\rightarrow	- 4.3%	
VOS	\rightarrow	- 1.1%	\rightarrow	- 0.4%	
OSTN	\rightarrow	- 11.6%	\rightarrow	- 2.9%	
PYR	\rightarrow	+ 6.4%	\rightarrow	+ 11.9%	
D-PYR	\rightarrow	+ 29.5%	1	+ 38.8%	

Note: \uparrow = Significant increase

 \rightarrow = No significant change

 \downarrow = Significant decrease

* % Change 1 = (test 2 - test 1) / test 1 - where test 1 is initial testing, test 2 is testing at 4^{th} month

** % Change 2 = (test 3 - test 2) / test 2 - where test 2 is 4^{th} month testing, test 3 is testing at 8^{th} month

In a study of the correlation between calcaneus BUA and age, Xue (1998) found that BUA has a high negative correlation with age. From 20 to 50 years of age BUA was relatively stable but when menopause commenced BUA continually decreased, 0.4 - 0.8 dB/MHZ (0.4 % - 1%), per year. During the 0 - 5 postmenopausal years, the average reduction was 2.5% per year then the reduction reduced to 0.5% per year. The current study shows a higher reduction in BUA (see Table 5-12) in Group B without treatment.

Xue (1998) also indicated that these results indicate that women over 51 years of age showed a reduction in BUA of 11.5% per year and this became worse with age. Any change in SOS was not significant. Xue also argued that BUA and SOS can also be used to distinguish premenopausal from postmenopausal women. Premenopausal women (before 50 years of age) had a BUA of 65.8 ± 1.9 (n=131), while scores of postmenopausal women 56.7 ± 3.6 (n=122), p<0.05 were observed indicating a clear

BUA threshold in menopausal status. To distinguish people who are not at risk of fracture Xue suggested a BUA score of 79.0 ± 2.8 , those at risk of fracture had a BUA score of 65.7 ± 4.0 , p<0.01.

Beijing Ji Shui Tang Hospital (Xue, 1990) has also reported calcaneum BUA and SOS (VOS) reference data (X \pm S) as follows, which also showed a rapid decrease in BUA and VOS from the age range 41 – 50 to 51 – 60 years of age but a stabilisation in the later post menopausal period.

Age	Ν	BUA (dB/MHz)	SOS (m/s)
41 - 50	47	70.2 ± 13.7	1517.9 ± 18.5
51 - 60	75	58.7 ± 13.9	1500.7 ± 26.0
61 - 70	41	57.6 ± 14.7	1493.1 ± 0.5

Note: UBIS-3000 model QUS instrument, BUA CV: 1.34% (n=6), SOS CV: 0.59% (n=6). SOS is the equivalent to VOS.

Table 5-13 Comparisons between the Test Results (OSTN, PYR and D-PYR) and
Medical Ranges

Reference ranges provided by the	Pre-test of this study		4 th month test of this study		8 th month test of this study	
Royal Melbourne Hospital	Group A	Group B	Group A	Group B	Group A	Group B
Osteocalcin (ng/ml):	16.4±8.4	24.1±10.2	24.1±6.9	21.3±8.3	23.4±9.6	25. 1±7. 9
Pre–menopausal women: 6.2 – 19.0						
Post-menopausal women: 5.4 – 24.0						
Pyridinoline (nmol/mmol Cr):	62.6±16.6	66.0±19.3	59.9±20.0	70.2±12.3	67. 0±22. 7	65.6±18.6
Pre–menopausal women: 21 – 90						
Post-menopausal						

Reference ranges provided by the Royal Melbourne Hospital	Pre-test of this study		4 th month test of this study		8 th month test of this study	
	Group A	Group B	Group A	Group B	Group A	Group B
women: 33 – 110						
Deoxypyridinoline (nmol/mmol Cr):	13.4±2.8	12.2±5.6	9.8±2.8	15.8±4.9	13.6±3.4	14.0 ± 4.0
Pre–menopausal women: 4.6 – 17						
Post-menopausal women: 3.0 – 26						

On the basis of the above table the results from this study show that findings for OSTN, PYR and D-PYR are within the normal range.

In this current study acupuncture therapy relieved symptoms associated with menopause including hot flushes and night sweats. This supports the TCM theories relating to *kidney*, *qi* and *blood* as well as providing practical symptomatic relief for participants. Acupuncture was found to be effective, providing substantial relief to women experiencing menopausal and bone loss symptoms. These symptoms included hot flushes, night sweats, stress, headache, insomnia, oedema, lower leg and lower back pain, and tiredness (see Table 5-8). According to TCM theory *kidney* is involved and consequently acupuncture treatment was given to tonify and nourish *kidney qi* and *yin*.

The treatment of *kidney* with acupuncture (according to TCM theory) can be used to alleviate menopausal symptoms. A similar effect in relieving menopausal syndrome was investigated by Wyon et al. (1994). The details in Section 2.4.2, indicate that acupuncture against climacteric disorders concluded that the frequency of flushes decreased significantly by more than 50% in both electrostimulated acupuncture and superficial needle position acupuncture. Another study conducted by Dong, Ludicke, Comte, Campanna, Graff and Bischof (2001) reported that acupuncture was effective in relieving vasomotor and physical disturbances in menopausal women with effects
lasting a minimum of three months after termination of treatment. However it did not change psychosocial or sexual symptoms, nor did it change the measured reproductive hormones.

Traditional Chinese Medicine considers that the *kidney* system plays an important role in menopausal syndromes. When *kidney*'s function decreases bone mass decreases as there is less *essence/yin/blood* to nourish the brain to control the resulting central neuropeptide activity. The current study provides promising results in relation to relieving hot flushes using the *kidney* tonifying and nourishing method possibly by affecting central neuropeptide activity. It should be noted that in Western medical theory menopause is considered to be related to central neuropeptide activity.

In addition to the observations outlined above the subjects in this study provided other valuable information. Three subjects reported that they had lost weight, especially after the first and second week of treatment. Follow up evaluation showed that the lowered weight was maintained but no further weight reduction was evident. TCM views fluid or water retention as resulting from *kidney* deficiency leading to a failure to promote the water metabolism. *Kidney* deficiency is associated with the *kidney* meridian system. *Spleen* deficiency reduces the body's capability of transforming or transporting water. Accumulation of body fat and weight gain is often a result of this type of deficiency. The *Kidney* and *Spleen* deficiency pattern is associated with various symptoms in menopausal women that western medicine explains as disorders or changes in hormonal function (Xu, 1995). This additional treatment effect indicated that acupuncture can harmonise the body and improve body balance in terms of *yin* and *yang*.

All subjects reported feeling "better". One reported that after treatment, she did not need to take anti-depressants, even during times of stress. After treatment, another subject reported symptomatic relief from day and night sweats, which sometimes only manifested on the right side of the body (indicating a possible imbalance between *yin* and *yang*). Two subjects reported improvement in their shoulder pain.

Menopause and its associated syndromes as outlined by some of the subjects (see Table 5-7 and as described in individual reports as outlined above) particularly fluid retention in TCM can be mainly attributed to *kidney* and *spleen*. TCM attributes fluid or water retention to a *kidney* deficiency. *Spleen* deficiency on the other hand results in the failure of water transference and transportation within the body. This manifests as body fat and consequently causes weight gain (Xu, 1995). The "*Kidney* and *Spleen* deficiency" pattern matches many endocrinal problems which Western medicine commonly diagnoses as menopausal or post-menopausal related syndrome and treats with hormone replacement therapy.

According to TCM theory, the "*lungs, spleen* and *kidneys*" regulate the water metabolism. Oedema may be attributed to a functional disturbance of any of these visceral organs. In chronic cases, oedema is always due to "*spleen* and *kidney* deficiency" (Yang, 1998).

The transportation function of the "*spleen*' includes control of the water metabolism. If the *spleen* function is impaired, oedema is often more marked in the limbs than in other parts of the body. This may occur concurrently with anorexia, abdominal distension, oliguria, loose stools, cold limbs, sallow complexion and a white, slippery tongue coating (Yang, 1998).

Among the visceral organs, the *kidney* is the chief regulator of the water metabolism. Deficiency of "*kidney yang*" may cause oedema which is more marked in the lower part of the body and is accompanied by lumbago, oliguria, aversion to cold, cold limbs, pallor and a whitish, moist tongue coating (Yang, 1998).

In summary, tonifying *kidney* and *spleen* with acupuncture therapy can relieve symptoms that commonly occur in menopausal women. BUA showed an increasing

trend with acupuncture treatment of SP 6, ST 36 and KID 3. The increased BUA might be associated with increased bone formation and decreased bone resorption.

The acupuncture points chosen for this study are safe needling points located on the lower leg. This raises the interesting possibility that self-applied acupressure might be useful in preventing or treating osteoporosis. Ulett, Han and Han (1998) suggested that needles are not necessary because healing is not by manipulating qi but rather by neuroelectric stimulation for the gene expression of neuropeptides. Further study is required to determine whether the effects of self-applied acupressure are as effective as acupuncture treatment.

5.6 Conclusion

Acupuncture is a non-drug therapy that has a homeostatic function. Traditionally, in TCM, acupuncture has not been used in the treatment of osteoporosis. Recently there has been some use of acupuncture in this area but studies are limited.

This study has a theoretical and practical basis as it examines the effects of acupuncture on BUA, VOS, OSTN and PYR, D-PYR. Acupuncture on Tai Xi (KID 3), San Yin Jiao (SP 6) and Zu San Li (ST 36) tended to increase BUA, balance bone formation and resorption and strengthen *kidney* as evidenced by the relief of symptoms reported in this study.

CHAPTER 6

EFFECTS OF CHINESE HERBAL MEDICINE ON BONE STRUCTURE AND FUNCTION

6.1 Introduction

As human beings in the Western world grow older the problems of osteoporosis will become more prominent. The literature review outlined in Chapter 2 suggests that there is no effective treatment currently available for osteoporosis once it has developed. Prevention therefore, appears to be the most realistic approach. In Traditional Chinese Medicine (TCM) treatment is aimed at disease prevention. The principles of Chinese medicine emphasize the treatment of disease as early as possible, even before it occurs. Diagnosis techniques in TCM provide information of potential disease before signs and symptoms appear. Balancing yin and yang and regulating *qi* and *blood* at this time often prevents the occurrence of disease. As early as the *Internal Classic - Nei Jing*, disease prevention and measures to prevent a disease from taking a turn for the worse were discussed.

According to TCM the occurrence of disease involves two factors. The pathogenic factor is, according to Wiseman and Ye (1998, p180), any entity from outside or from within that threatens health and therefore is an important cause of disease. The second factor is the body's anti-pathogenic factor (immune system) which if weakened in any way allows the disease to affect the body. The two factors must be considered in disease prevention. Treating a disease involves treating the pathogenic factor first and also strengthening the anti-pathogenic factor. TCM diagnosis is used to determine how the disease is treated. This is a basic principle of Bian Zheng and Lun Zhi (ie. Planning the treatment according to the diagnosis) (Yin, 1992).

In treating deficiency syndromes (as is the case with menopause and bone loss), doctors of TCM must pay particular attention to tonifying and nourishing the *spleen* and *kidney*. According to TCM theory as outlined in Chapter 1, *kidney* declines with age as is typical in menopausal disorders resulting in menopausal symptoms and osteoporosis. *Kidney* can be adversely affected as a result of prolonged illness or disorders. In TCM great importance is attached to tonifying the *kidney* throughout rehabilitation from chronic diseases (Zhang, 1992).

Menopausal problems and osteoporosis relate to *kidney* decline and can be tonified with natural substances. In recent years, phytoestrogens (such as flavones, isoflavones and coumestans) have been given a lot of attention in terms of treating bone loss and post-menopausal osteoporosis (Miksikek, 1994). Chen (2002) in her book states that there have been many studies to test the positive effects of phytoestrogen in reducing bone loss or even increasing bone structure and density. Phytoestrogens, such as some isoflavones are produced from soy bean flour. Many traditional Chinese herbs and foods contain phytoestrogens so theoretically they could be used to treat osteoporosis and menopausal syndromes.

In this study a herbal formula which is composed of natural plants was used to prevent or reduce bone loss. The use of natural remedies in the treatment of disease has become common in the world today. This type of treatment is a part of TCM as most herbal remedies are natural. Other studies (Shen, et al., 1994; Wu, et al., 1996; Henderson, 1999; Cui, et al., 1999; Horiuchi, et al., 2000; Brynin, 2002) that have been undertaken support the use of natural plants in the treatment of bone loss and menopausal symptoms (details in Chapter 2, Section 2.4.3). The results in these studies which have considered parameters such as BMD and bone markers have been relatively positive. However the effects of herbs on bone structure and function requires more extensive examination and this study attempts to ameliorate this deficiency. As Chinese traditional herbs have been used in the treatment of menopausal symptoms for a long time their effects have been studied extensively but are re-examined in this study. The following section examines the effects of Shu Di Shan Zha formula and explains the link between menopausal and bone loss symptoms that have been treated with Shu Di Shan Zha formula.

6.2 Research Design and Methodology

To evaluate the effects of traditional herbal medicine on bone turn-over in menopausal women, this study used a paired design for eight months (see Figure 6-1). Participants received herbal treatment using Shu Di Shan Zha formula.

Fourteen of the 40 menopausal women who completed the study (aged 42-55 years) were involved in this trial (see Table 6-1). The participants were divided into two groups (Group A and B, seven participants respectively) matched through Broadband Ultrasonic Attenuation (BUA) as well as age and menopause status details. All participants were given information regarding the purpose of this study and the demands of this study design. They were told which group they belonged to and as a result whether they were initially in a treatment or control group. This meant that the two groups could be compared using BUA, VOS, OSTN, PYR and D-PYR as well as TCM assessment.

	Ν	Minimum	Maximum	Mean	St. Deviation
Age (yrs)	14	42	53	48.8	3.0
Height (m)	14	1.42	1.75	1.61	8.32
Weight (kg)	14	55.8	85.7	67.5	9.5
BUA (dB/MHz)	14	43.2	90.3	65.5	13.7

Table 6-1 Subject Characteristics

	Group A (n=7)	Group B (n=7)				
BUA (mean±SD)	63.7±13.4	67.3±14.8				



Figure 6-1 The Research Design

Study participants underwent TCM diagnosis with the aim of working out treatment strategies. Diagnosis confirmed *kidney* deficiency to be the chief pattern of disharmony in these subjects. Some subjects exhibited symptoms of deficiencies of *yin*, *qi* and *blood*, which are often a result of *kidney* deficiencies. Even though some subjects did not show these deficiencies at the time of examination TCM theory suggests that they will occur in the future and require preventive treatment. This supports the evidence as outlined in Chapter 2. Thus the thrust of this study involved tonifying principles. In choosing a treatment formula for this study *kidney yin* nourishing, *qi* and *blood* regulating and tonifying herbs were chosen. The effects of this formula in preventing and treating bone loss were the focus of this study.

After the initial phase of the four month trial the groups traded places from control to treatment respectively for a further four-month period and then were tested again. The seven subjects (Group A) who were treated with Traditional Chinese Herbal Therapy were assessed according to TCM principles. The decoctions (granules mixed with water) were taken every morning and evening over a period of four months. During this period another seven subjects (Group B) served as a control group.

At completion of the first four month period the first group (Group A) stopped their treatment and changed to serve as a "control". In this way pre treatment and post treatment results could be compared with results obtained four months after treatment. This design enabled an evaluation of the long-term effect of the herbal medicine intervention on the various parameters considered in this study. The second group (Group B) received herbal treatment for the following four months. In this way the first four months allowed Group B to be used as a "control" to provide some indication of the effects of the passage of time (without treatment) on the parameters considered in this study.

To meet the objectives of this study, to prevent and reduce bone loss, a Shu Di (Prepared Rehmannia Root, *Radix Rehmanniae Praeparata*) Shan Zha (Hawthorn Fruit, *Fructus Crataegi*) formula was selected. The basic functions of this formula are to nourish *yin*, tonify *qi* and *invigorate blood*. It mainly contained polysaccharides, multiple kinds of organic acids, phytoestrogen - isoflavones and adequate amounts of strontium and zinc. The chosen herbs for this study were pleasant in taste, food based and inexpensive. The basic formula was supplied by Hong En Science and Technology Development Co. Ltd. and complied with Good Manufacturing Practice (GMP) requirements. The formula was imported in bulk from China, where the patent is available and it was repackaged for participants by the researcher. Dosage, which can be varied, of this extract powder is based on TCM analysis of the patients condition. The recommended formula dosage range is 10-30g a day for menopausal women.

The subjects were asked to record the time at which they took their herbs on the check list as attached in Appendix G. They were also advised to keep the herbs in a dry and cool place and note any missed doses. Completed checklists were returned to the researcher when subjects picked up new supplies of herbs.

6.3 Statistical Analysis

Test results were recorded for subjects at the commencement of the study, at the midpoint and at the end of treatment. Differences between the treatment and control groups were calculated for pre-test, 4^{th} month and 8^{th} month test results as well as within groups and between groups, i.e. Group A and Group B. After the crossover (when the treatment and control groups swapped roles) the same observations and calculations were made. Data was analysed using paired t-tests in SPSS 10.0 and Ridit analysis with results of p<0.05 being accepted as statistically significant.

6.4 Results

This study examined the effects of four-months of treatment using Chinese herbal "Shan Zha Shu Di" formula on bone health. Fourteen menopausal women participated in this study and completed all the tests. Data from bone structure and function tests, biomarkers of bone turn over and Chinese medical assessments were collected from each subject. The adherence rate in terms of taking the herbs was 95%. All of the above mentioned data (BUA, VOS, OSTN, PYR, D-PYR and TCM symptoms) were used for statistical analysis. It is also possible to consider the effects of the herbal treatment according to the four TCM groupings i.e. *kidney* deficiency symptoms, *qi* deficiency / water retention symptoms, *yin* deficiency / deficient heat / *qi* stagnation symptoms and *yin* deficiency / deficient heat symptoms.

6.4.1 Bone Structure Results

Effect of Herbal Treatment on Broadband Ultrasound Attenuation

BUA is an indicator of the trabecular orientation and pattern in bone that can show the structure and density of bone as explained in Chapters 1 and 3. Table 6-2 and Figure 6-2 show the results of herbal treatment on BUA. There was no significant difference between Group A and B at the pre-test (p=0.698). Groups A+B combined results were statistically significant (p=0.030) indicating that herbal treatment had a positive effect on BUA. The post-treatment BUA level for Group A showed a marked increase (p=0.007). Group B showed an increasing tendency after treatment but this was not statistically significance (p=0.767). Without treatment the BUA level of Group B showed a decreasing tendency but this was not of statistical significance (p=0.113). After stopping treatment the BUA of Group A decreased significantly (p=0.015) although it was still higher than the pre-treatment level. Group B BUA pre-treatment results indicate that decreasing BUA levels is a trend in the natural menopausal process. In this study herbal treatment appeared to alleviate the decline of BUA and even bring it to a higher level.

Group (n=7)	Pre-test	4 th month	8 th month		
Α	63.7±13.4	71.8±16.0*	66.8±14.3 [#]		
В	67.3±14.8	63.4±15.0	64.2±14.2		
Group (n=14)	Pre-treatment	Post treatment	р		
A + B	63.6±13.7	68.0±15.1	0.03		

Table 6-2 Effect of Herbal Treatment on Broadband Ultrasound Attenuation (BUA) (dB/MHz)

*Significantly different from the data of pre-test, p=0.007. #Significantly lower than the data of 4th month, p=0.015.



Figure 6-2 Effect of Herbal Treatment on Broadband Ultrasound Attenuation (BUA) (dB/MHz)

Effect of Herbal Treatment on Velocity of Sound

There was no significant difference in VOS between the pre-test, 4th month and 8th month results in both Groups A and B. VOS, which measures bone elasticity, did not change significantly as a result of these treatments. There was no significant decrease in VOS in Group B before treatment intervention and a natural fall in VOS in this situation would be expected. Further research is required in this area to explain this result as the changes in VOS did not match the changes of BUA. It is also possible that VOS is not a sufficiently sensitive measurement for the evaluation of the effects of herbal treatment on bone structure and function change.

Group (n=7)	Pre-test	4 th month	8 th month
Α	1588.9±32.5	1594.4±47.5	1587.1±28.8
В	1620.0±23.2	1611.4±15.8	1605.1±19.0
Group (n=14)	Pre-treatment	Post treatment	р
A + B	1600.1±27.2	1600.0±35.2	0.963

Table 6-3 Effect of Herbal Treatment on Velocity of Sound (VOS) (m/s)



Figure 6-3 Effect of Herbal Treatment on Velocity of Sound (VOS) (m/s)

6.4.2 Bone Formation and Resorption Results

While the tests for BUA and VOS were equivocal in their provision of evidence of bone turn-over, the bone turn-over markers OSTN, PYR and D-PYR showed some positive treatment results.

Effects of Herbal Treatment on Bone Formation

Osteocalcin (OSTN) is regarded as a bio-marker of bone formation as explained in Chapters 1 and 3. Table 6-4 and Figure 6-4 show the results of four months of herbal treatment on OSTN. There was no significant difference between Group A and B at the pre-test (p=0.666). Comparing the combined data collected from pre and post treatment of Groups A+B, OSTN increased significantly (p=0.029). After taking herbs for four months Group A and Group B showed an increasing tendency in OSTN but this was not statistically significant within each individual group (p=0.084 for Group A; p=0.232 for Group B). Four months after ceasing treatment the OSTN level of Group A showed an increasing tendency that was not statistically significant (p=0.478).

Group (n=7)	Pre-test	4 th month	8 th month		
Α	17.9±5.1	22.7±6.7	24.7±8.3		
В	20.6±14.3	21.0±15.2	24.5±13.8		
Group (n=14)	Pre-treatment	Post treatment	р		
A + B	19.4±11.0	23.6±10.5	0.029		

Table 6-4 Effect of Herbal Treatment on Osteocalcin (OSTN) (ng/ml)



Figure 6-4 Effect of Herbal Treatment on Osteocalcin (OSTN) (ng/ml)

Bone Resorption Results

Pyridinoline (PYR) and deoxypyridinoline (D-PYR) are urinary pyridum cross links which are regarded as two bio-markers of bone resorption as explained in Chapters 1 and 3. Table 6-5 and Figure 6-5 show the results of four months of herbal treatment on PYR; Table 6-6 and Figure 6-6 show that effect on D-PYR.

There is a marked tendency toward a decrease in PYR in Group A after treatment (p=0.057), and an increasing tendency in Group B without treatment but both effects are not statistically significant (p=0.125). The combined data from pre and post treatment testing of Groups A+B combined also indicates a decreasing trend in PYR but the result was non significant (p=0.071).

In Group A, D-PYR significantly decreased after treatment (p=0.018) but significantly increased after treatment ceased (p=0.015). In Group B, D-PYR showed an increasing tendency without treatment (p=0.089), decreasing after treatment, but these results were not statistically significant (p=0.248). The combined data of pre and post treatment results in Groups A+B showed that herbal treatment could reduce the level of D-PYR significantly thus reducing bone resorption (p=0.011).

Group (n=7)	Pre-test	4 th months	8 th months
Α	71.9±23.3	60.7±16.2	66.7±17.1
В	66.6±15.7	74.0±12.5	68.3±18.2
Group (n=14)	Pre-treatment	Post treatment	р
A + B	73.0±18.0	64.5±17.0	0.071

Table 6-5 Effect of Herbal Treatment on Urinary Pyridinoline (PYR) (nmol/mmol Cr)



Figure 6-5 Effect of Herbal Treatment on Urinary Pyridinoline (PYR)

(nmol/mmol Cr)

Group (n=7)	Pre-test	4 th month	8 th month
Α	16.6±5.5	13.0±4.7*	16.8±6.3 [#]
В	13.7±4.0	17.3±4.0	15.5±3.5
Group (n=14)	Pre-treatment	Post treatment	р
A + B	17.0±4.6	14.2±4.2	0.011

Table 6-6 Effect of Herbal Treatment on Urinary Deoxypyridinoline (D-PYR) (nmol/mmol Cr)

*Significantly different from the data of pre-test, p<0.01. #Significantly different from the data of 4th month, p<0.05.



Figure 6-6 Effect of Herbal Treatment on Urinary Deoxypyridinoline (D-PYR) (nmol/mmol Cr)

6.4.3 Traditional Chinese Medical Assessment

Traditional Chinese diagnostic patterns have been differentiated on the basis of symptoms and signs as explained in Chapter 3. The occurrence of certain symptoms and signs in TCM indicate certain patterns of disharmony. These symptoms and signs reflect changes in the internal organs' function and health. In TCM menopause is considered a natural progression in life and patterns of disharmony that result in women's bodies tend to arise in specific ways depending upon their constitutional make-up. TCM treatments aim to balance yin and yang to alleviate these symptoms. Table 6-7 shows the results of four months of herbal treatment on the main TCM symptoms related to bone loss and menopause. Some of the major symptoms were relieved (statistically significantly) by herbal treatment; i.e. lower back pain, tiredness, hot flushes, night sweats, insomnia, headache and thirst. Tongue and pulse analysis has not been detailed here due to the need of advanced TCM knowledge required for correct interpretation.

The effects on menopausal and bone loss symptoms as a result of herbal treatment are seen in Tables 6-8 - 6-9. The symptoms studied reflect TCM patterns of disharmony. The tables show that herbal treatment (used to nourish and harmonize the body) was based on nourishing *yin* to balance *yin and yang*, tonifying *kidney qi* and *yin* and regulating *blood*. This balancing had the effect of alleviating some of the bone loss and menopausal symptoms.

All of the TCM symptoms and signs outlined in this section (Tables 6-7, 6-8, and 6-9) are accepted within TCM theory as indicated in Chapter 3. The following symptoms and signs were collected during the three interviews at the pre, 4th month and 8th month tests. The results were then used as evidence of the efficacy of herbal treatment in relieving the symptoms listed in Table 6-7. The results given in this table are the combined results for both Groups A and B (pre and post treatment results).

Symptom / Number of subjects	Pre- Degi	e-treatment gree of Symptom			Post-treatment Degree of Symptom				Ridit
	0*	1	2	3	0	1	2	3	p^^
Lower back pain	7	4	2	1	12	2	0	0	<0.05#
Knees/Leg/Feet pain	10	4	0	1	13	0	1	0	>0.05
Aching bones	14	0	0	0	14	0	0	0	>0.05
Poor appetite	14	0	0	0	14	0	0	0	>0.05
Abdominal distension	7	4	3	0	10	3	1	0	>0.05
Diarrhoea	13	1	0	0	14	0	0	0	>0.05
Swollen ankles/fingers	13	0	1	1	13	0	1	0	>0.05
Tiredness	4	4	6	0	13	1	0	0	<0.01#
Palpitations	9	3	2	0	12	1	0	0	>0.05
Hot flushes	1	8	5	0	9	5	0	0	<0.01#
Hot feet/pain	13	1	0	0	13	1	0	0	>0.05
Night sweats	4	4	6	0	7	7	0	0	<0.05#
Insomnia	1	8	5	0	11	3	0	0	<0.01#
Irritability/Anxiety/Stress	8	1	2	3	11	3	0	0	>0.05
Headaches	4	5	5	0	7	7	0	0	<0.05#
Thirst	4	6	2	2	12	2	0	0	<0.01#
Itchy skin	12	1	1	0	14	0	0	0	>0.05
Constipation	8	3	2	1	12	1	1	0	>0.05
Dark/smelly urine	12	0	2	0	12	2	0	0	>0.05

Table 6-7 Effect of Herbal Treatment on Traditional Chinese Medical Symptoms of Groups A+B (n=14)

*0=no symptom; 1=mild symptom; 2=medium symptom; 3=severe

**Ridit analysis was used to test the statistical significance.

#Symptoms were significantly released statistically with treatment, p<0.05 Some of the major symptoms were significantly relieved: lower back pain, tiredness, hot flushes, night sweats, insomnia, headache and thirst. The group of tables in 6-8 demonstrate the changes in the groups of symptoms outlined as well as the changes in individual cases in Group A. These results were grouped on the basis of the patterns outlined in Chapter 3. The group of tables in 6-9 demonstrate the symptoms and their changes for individual cases in Group B. By grouping these symptoms the tables show relevant changes to symptoms (particularly changes in the symptoms for individual subjects).

Tables 6-8-1 and 6-9-1 indicate *kidney* deficiency symptoms. The lower back houses the *kidney* and its symptoms reflect the *kidney's* condition as outlined in Chapter 3. Lower back pain was shown to be relieved and knee/leg/feet pain (which also reflect the state of *kidney*) was also relieved by herbal treatment. The long-term effect also appeared positive.

Tables 6-8-2 and 6-9-2 indicate symptoms of *qi* deficiency and its related symptom of oedema. *Spleen* and *kidney qi* deficiency are very common in menopausal women as outlined in Chapter 3.

Tables 6-8-3 and 6-9-3, 6-8-4 and 6-9-4 have been grouped to indicate general *yin* deficiency symptoms that match common menopausal symptoms as outlined in Chapter 3.

When the groups of symptoms are examined together the common patterns of disharmony can be considered as belonging to *yin* and *qi* deficiency especially in the *kidney*, *spleen* and *liver* systems.

Table 6-8-1 Observation of Kidney Defici	iency Symptoms' Change in Herbal Group
А ((n=7)

Degree of	Lower	back pai	n	Knee/L	.eg/Feet p	oain	Aching bones			
Symptoms	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month	
0	5	6	6	5	6	6	7	7 7		
1		1	1	1	1					
2	2					1				
3				1						

*0: no symptoms; 1: mild; 2: medium; 3: severe

Lower back pain, knee/leg/feet pain and aching bones are common *kidney* deficiency symptoms. In Group A two subjects suffered from lower back pain, after four months of herbal treatment one of them still suffered mild pain, but the other one had recovered. After four months without treatment no recurrence occurred. Two subjects had knee/leg/foot pain, after four months of herbal treatment, partial recovery was observed. No one complained about aching bones in this group.

Table 6-8-2 Observation of *Qi* Deficiency/Water Retention Symptoms' Change in
Herbal Group A (n=7)

Degree of Symptom	Poor appetite		f Poor Abdominal Diarrhoea appetite distension		Swollen ankles/ fingers			Tiredness			Palpitations							
	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	7	7	7	5	5	5	6	7	6	5	6	6	1	6	4	4	7	5
1				1	2	1	1		1				2	1	2	2		2
2				1		1				1	1		4		1	1		
3										1		1						

*P= pre-test, 4th=4th Month, 8th= 8th Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

Two subjects suffered abdominal distension, one suffered from diarrhoea, one suffered swollen ankles/fingers; all partially recovered with herbal treatment and also maintained

some long-term effect after treatment ceased. Six subjects suffered from tiredness, five of them recovered with herbal treatment, three of them suffered a recurrence of symptoms after treatment ceased. Three subjects suffering from palpitations recovered after herbal treatment but two had symptoms recur after treatment ceased. Abdominal distension, tiredness and palpitations are major qi deficiency symptoms, swollen ankles/fingers are typical qi deficiency and water retention symptoms. Herbal treatment was effective in relieving some of these symptoms.

Degree of Hot Hot Night Insomnia Irritability Headaches Symptom flushes feet/palm sweats /Anxiety/ Stress P* 4th 8th Р 4th 8th P* 4th 8th Р 4th 8th Р 4th 8th Р 4th 8th 0** 7 7 3 5 5 3 6 4 7 6 1 6 6 4 2 6 6 3 2 2 2 2 2 3 4 1 1 1 1 1 1 1 4 2 2 2 2 1 1 3 2 1 1

 Table 6-8-3 Observation of *Yin* Deficiency/Deficient Heat/*Qi* Stasis Symptoms'

 Change in Herbal Group A (n=7)

*P= pre-test, 4th=4th Month, 8th= 8th Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

The symptoms of hot flushes were relieved from medium to a mild level for one subject, six subjects recovered completely, the long-term effect was maintained for four months for four subjects. The symptoms of insomnia were relieved from a medium to a mild level for one subject, five subjects recovered completely, the long-term effect was maintained for four months for four subjects. Other symptoms showed partial recovery with herbal treatment. Hot flushes, night sweats, insomnia and headache are typical menopausal symptoms caused by yin deficiency and deficient heat, these were partially relieved with herbal treatment.

Degree of Symptom	Thirs	t		Itchy skin			Constipation			Dark/smelly urine		
Symptom	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	1	6	5	6	7	7	4	7	7	6	6	6
1	3	1	2				3				1	1
2	1			1						1		
3	2											

Table 6-8-4 Observation of Yin Deficiency/Deficient Heat Symptoms' Change in
Herbal Group A (n=7)

*P= pre-test, 4th=4th Month, 8th= 8th Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

The symptom of thirst was relieved from a severe level to a mild level for one subject, five subjects recovered completely, the long-term effect was maintained for four months for most of the subjects. Three subjects suffering from constipation recovered completely with herbal treatment, the long-term effect was maintained for four months for all the subjects. Other symptoms showed partial recovery with herbal treatment. Thirst, itchy skin, constipation and dark/malodorous urine are symptoms of body *fluid* deficiency in TCM. Herbal treatment showed marked effects on nourishing *yin* / body *fluid* in this group.

Table 6-9-1 Observation of Kidney Deficiency Symptoms' Change in Herbal GroupB (n=7)

Degree of Symptom	Lower	back pai	n	Knee/I	Leg/Feet p	pain	Aching bones			
	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month	Pre-test	4 th Month	8 th Month	
0*	2	2	6	4	4	7	7	7	7	
1	4	4	1	3	3					
2										
3	1	1								

*0: no symptoms; 1: mild; 2: medium; 3: severe

In Group B five subjects suffered from lower back pain, after four months of herbal treatment one of them still suffered mild pain but the others had recovered. Three subjects had mild knee/leg/foot pain, four months of herbal treatment relieved the pain for all three subjects. No one complained about aching bones in this group.

Degree of Symptom	Poc app	or petite	e	Abo dist	domi ensio	nal on	Diarrhoea		Swollen ankles/ fingers		Tiredness		ess	Palpitations				
	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	7	7	7	2	2	5	7	7	7	7	7	7	3	3	7	6	5	6
1				3	3	2							2	2			1	1
2				2	2								2	2		1	1	
3																		

 Table 6-9-2 Observation of *Qi* Deficiency/Water Retention Symptoms' Change in Herbal Group B (n=7)

*P= pre-test, $4^{th}=4^{th}$ Month, $8^{th}=8^{th}$ Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

Five subjects suffered from abdominal distension, three completely recovered, two subjects' symptoms were improved from a medium to mild level with herbal treatment. One subject suffering from diarrhoea recovered with treatment. Four subjects suffered from tiredness, all recovered with treatment. Only one subject suffered from palpitations, this symptom was relieved with herbal treatment from a medium to a mild level. Abdominal distension, tiredness and palpitations are major qi deficiency symptoms, swollen ankles/fingers are typical qi deficiency and water retention symptoms. Herbal treatment was effective in relieving these symptoms.

Degree of Symptom	Hot flushes		es f		t t/pal	/palm Night Insomnia		ia	Irr /Ar Str	itabi ixiety ess	lity y/	He	adac	hes				
	Р*	4th	8th	Р	4th	8th	P*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	1	1	3	6	6	6	1	1	2			5	5	5	5	1	1	1
1	5	5	4	1	1	1	2	2	5	4	4	2				3	3	6
2	1	1					4	4		3	3		2	1	2	3	3	
3														1				

Table 6-9-3 Observation of Yin Deficiency/Deficient Heat/Qi Stasis Symptoms'Change in Herbal Group B (n=7)

*P= pre-test, 4th=4th Month, 8th= 8th Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

The symptoms of hot flushes were relieved from a mild level for two subjects, one subjects' symptoms were improved from a medium to a mild level, three subjects did not improve with treatment. The symptom of night sweats was relieved from a medium to a mild level for four subjects, one subject recovered completely. Insomnia was relieved from a medium to a mild level for two subjects, five subjects completely recovered with herbal treatment. Hot flushes, night sweats, insomnia and headache are typical menopausal symptoms caused by yin deficiency and deficient heat, these were partially relieved with herbal treatment.

Table 6-9-4 Observation of *Yin* Deficiency/Deficient Heat Symptoms' Change in Herbal Group B (n=7)

Degree of Symptom	Thirst			Itchy skin			Constipation			Dark/smelly urine		
	Р*	4th	8th	Р	4th	8th	Р	4th	8th	Р	4th	8th
0**	3	3	6	6	6	7	4	4	5	6	6	6
1	3	3	1	1	1				1			1
2	1	1					2	2	1	1	1	
3							1	1				

*P= pre-test, 4th=4th Month, 8th= 8th Month

**0: no symptoms; 1: mild; 2: medium; 3: severe

The symptom of thirst was relieved from a mild level for one subject while three subjects recovered completely. Other symptoms showed partial recovery with herbal treatment. Thirst, itchy skin, constipation and dark/malodorous urine are symptoms of body *fluid* deficiency in TCM. Herbal treatment had the effect of nourishing *yin* which affects body *fluids* thus it relieved some symptoms of body *fluid* deficiency.

6.5 Discussion

The effects of traditional Chinese herbal medicine on bone structure and function in a high-risk population for osteoporosis (menopausal women) using Shu Di Shan Zha formula as the intervention was studied in this paired design cross-over study of 8 months. The results of the effects of this herbal medicine on the parameters used in this study to describe bone health are equivocal. As Table 6-10 indicates the results varied between groups and were not constant even for the combined data of Group A and Group B.

Parameter	Group A	Group B	Groups A+B
BUA	1	\rightarrow	↑
VOS	\rightarrow	\rightarrow	\rightarrow
OSTN	\rightarrow	\rightarrow	1
PYR	\rightarrow	\rightarrow	\rightarrow
D-PYR	\downarrow	\rightarrow	\downarrow

Table 6-10 Summary of the Significance of the Herbal Treatment Results

Note: \uparrow = Significant increase

 \rightarrow = No significant change

 \downarrow = Significant decrease

The results of this study showed that four-months of Chinese herbal treatment improved the level of BUA in menopausal women and ameliorated menopausal symptoms in some subjects. The Shu Di Shan Zha formula improved BUA, OSTN and D-PYR in some groups. This could be due to its *kidney* tonifying effects which result in the promotion of calcium absorption. Previous studies (Shen, et al., 1994; Wu, et al., 1996 as outlined in Chapter 2, Section 2.4.3) support the theory that there is a relationship between *kidney*, vitamin D₃ and calcium which could explain the effects of the formula.

All ingredients in Shu Di Shan Zha formula are natural plants, the results of this study on bone turn over can therefore be compared with other studies involving natural The effects of natural treatment on bone turn-over have also been treatments. considered in other studies. Bellati and Liberati (1994) indicated that the administration of the arginine-lysine-glycerophyosphorphoric-acid-lactose association led to an increase in bone density and plasma osteocalcin, a reduction in painful symptoms and analgesic intake and a reduction in the serum levels of parathromone and hydroxyproline in menopausal osteoporosis. The results obtained were believed to be the consequence of improved intestinal absorption of calcium. Chow, Yeung, Law, Chan and Lau (1982) in their study on the effect of Davallina Orientalis on bone healing in mice suggested that this herb could increase the breaking strength of a fracture site. Another single herb study of Guizhou epimedium conducted by Yu, Chen, Li and Zhang (1999) through their in vitro study showed that the epimedium inhibited the osteoclastic resorption of bones. The in vivo investigation demonstrated that both the epimedium and estradiol levels were able to increase mineral content and promote bone formation. The results from these studies show that natural treatments affect bone turnover in different ways.

However the effects of herbal therapy on bone turn-over need further study as no statistically significant result occurred in this study. VOS did not change significantly and this warrants further study as based on BUA results a change was expected.

However it is noted that in all projects in this thesis VOS appeared to lag other dependent variables. It is also possible that the lack of significant results can be explained by Vedi and Compston's comments (1996) on their HRT research. They found that there was no evidence that conventional hormone replacement therapy had anabolic effects at the level of bone remodelling and indicated that its beneficial skeletal effects were a result of the suppression of bone turn-over and the reduction in the size of resorption cavities.

The "Shu Di Shan Zha" formula used in this study is based on foods and this provided a better taste than traditional formulae. It is a natural recipe that can safely be used by any individual in the population even though their syndromes may be a result of different patterns of disharmony. Some women have problems eating certain foods e.g. those who do not eat diary products. These women can still use this formula and it will provide them with certain essential phytoestrogens and other essential nutrients. In TCM there is a basic belief that the *kidneys* rule the bones. The design and efficacy for treatment in this study are based on this statement. Shu Di Shan Zha formula can tonify the *kidneys* resulting in the successful prevention and treatment of bone loss. The formula is able to provide a treatment that is capable of improving kidney qi and yin vacuity weakness and as a result strengthening the sinews and bones. In addition, Shu Di nourishes *yin, blood* and bone marrow (according to TCM theory), the herb Shan Zha invigorates *blood* thus eliminating lower back and knee pain (according to TCM) theory). This formula is appropriate for the prevention and treatment of bone loss and menopausal symptoms due to *qi and yin* deficiency as well as deficient heat according to Chinese medicine.

This study suggests that "Shu Di Shan Zha formula" has a positive effect on bone structure and function. The treatment might be more effective if the herbal formula is administered for a longer period than utilised in this study. According to Table 6-11, in Group B during the first four months, where there was no herbal treatment, the means for BUA, VOS, OSTN, PYR and D-PYR all showed no significant change. The results between the 4th and 8th months in Group A (after the cessation of treatment) indicate

that there are no long-term or residual effects of herbs on the various indices of bone health. However there are_significant changes in BUA and D-PYR but these changes are minor when compared with Group B. The value of herbal treatment in preventing or reducing bone loss over time should be given further consideration. As reported by Wang and Miao (1999) one of the significant characteristics of Chinese herbs in treating osteoporosis is that many patients' clinical symptoms and signs were alleviated or had disappeared before bone turn-over markers showed any significant change. Thus longer term studies involving the administration of herbal formulae are needed to confirm the effects of herbal treatment. Long-term administration of herbs may be able to maintain the higher level of BUA thus preventing bone loss.

Table 6-11 Summary of Changes in Group B in the First Four Months without Treatment and the Long-term Treatment Effect in Group A in the Second Four Months after Treatment Cease

Parameter	Group B	% Change 1*	Group A	% Change 2**
BUA	\rightarrow	- 5.8%	\downarrow	- 7.0%
VOS	\rightarrow	- 0.5%	\rightarrow	- 0.5%
OSTN	\rightarrow	+ 1.9%	\rightarrow	+ 8.8%
PYR	\rightarrow	+ 11.1%	\rightarrow	+ 9.9%
D-PYR	\rightarrow	+ 26.3%	1	+ 29.2%

Note: \uparrow = Significant increase

 \rightarrow = No significant change

 \downarrow = Significant decrease

* % Change 1 = (test 2 - test 1) / test 1 - where test 1 is initial testing, test 2 is testing at 4^{th} month

** % Change 2 = (test 3 - test 2) / test 2 - where test 2 is 4^{th} month testing, test 3 is testing at 8^{th} month

The adverse behavioural symptoms associated with menopause were also considered one of the main reasons for disruption in the lives of the women who participated in this study. Some of the subjects reported that in recent years other family members had complained about the behavioural aspects of their menopausal problems. Three subjects in this study emphasized that after receiving herbal treatment they felt much happier and could cope better with their stressful work and living environments. Their children said that their "yelling mother" had been replaced with a new mother.

Symptoms such as hot flushes, sweats, headaches, lower back pain, swollen extremities, abdominal bloating and shoulder pain responded very well to herbs. A few chronic symptoms like constipation showed slight improvement in one group. The treatment principle was chosen based on a holistic approach. This meant that a holistic recovery was gained as a result.

One subject mentioned that she lost 12 kg during the treatment. A few complained of significant weight increase before treatment, which was controlled with treatment. After the treatment had stopped all subjects showed a tendency toward weight increase. One subject noted that her high cholesterol level changed from abnormal to normal during treatment without taking other medicine. TCM views fluid or water retention as resulting from *kidney* deficiency leading to a failure to promote the water metabolism. *Kidney* deficiency is associated with the *kidney* meridian system. *Spleen* deficiency reduces the body's capability of transferring or transporting water. Accumulation of body fat and weight gain is often a result of this type of deficiency. The *Kidney* and *Spleen* deficiency pattern is associated with various symptoms in menopausal women that western medicine explains as disorders or changes in hormonal secretary function (Xu, 1995).

Irritability and quick temper are very commonly reported symptoms among menopausal women and some postmenopausal women. Four subjects reported that these symptoms increased before their herbal treatment but improved or disappeared entirely after one and half weeks of treatment. None had recurrences during the treatment. When the treatment group crossed over to be the "control" group they reported the return of mild symptoms. One and half to two months after the completion of treatment these subjects reported "on and off" recurrences of these symptomatic emotions. At their own request three of the four subjects suffering symptoms continued taking the prescribed herbs for an extra period. One woman took the herbs for a further two weeks. Another two continued treatment for an additional month. On questioning six months later they all claimed to be free of these symptoms.

Irritability and quick temper are caused by "gan" (liver meridian system) qi stagnation and heat in the liver. More severe gan qi stagnation leads to the generation of more heat. The yin (body fluid, blood as outlined in Chapter 1) deficiency, which cannot balance with yang can also give rise to heat hyperactivity (Yang, 1998). A more likely causal factor for such symptoms as irritability, restlessness, palpitation and insomnia especially in menopausal and postmenopausal women is discord between the "xin" (heart meridian system) and the shen (kidney meridian system). A kidney yin/water deficiency may lead to an imbalance of heart heat/fire and to heart heat hyperactivity (Yang, 1998). The TCM treatment principle applied for harmonizing these symptoms in this study is to nourish the shen (kidney) yin to balance the heat.

A number of participants contacted the researcher in the six months following the completion of the study to report their status. One subject reported: "I have found no better medicine than this one". An increase in energy was generally reported during treatment, the energy levels were maintained for six months after treatment was completed. None of the subjects suffered from common cold or flu during the treatment period. Self-assessment of general outlook and well-being were reported as "feeling good". Four months after stopping all treatment there was one report of headaches returning but not to the same degree as before the treatments.

The general TCM principles utilised in this study as a guide to the selection of herbs were: nourish *kidney*, tonify *spleen* and *stomach*, nourish *yin* and *blood*, clear *heat* and invigorate *blood*. This study proved the effectiveness of the herbal formula used in alleviating subjects' symptoms, partially proved by BUA and D-PYR results. In the female population common symptoms of menopause include irregular periods, hot flushes and night sweats (Stoppard, 1994). Lack of oestrogen also leads to the risk of developing osteoporosis and cardiovascular disease. Clinical data is available on the effects of calcium supplementation with and without HRT, exercise, exercise plus calcium and exercise with HRT on bone loss.

One means of effectively preventing post-menopausal bone loss is hormonal replacement therapy. Christiansen, Hassager and Riis, (1990) indicated that large controlled studies have shown that bone loss can be stopped or decelerated. Evidence (mostly indirect) points to a reduction in fractures in subjects treated with oestrogen. However hormonal substitution therapy has some disadvantages so it is not offered to all postmenopausal women. If Chinese herbal treatment is able to provide results comparable to HRT this type of treatment would be considered by practitioners and the population in general.

Other studies have used similar parameters to this study in evaluating the effects of HRT. Ulla, Araujo, Giglione, Fajreldine, Domingo, Noriega and Rivoira (1997) reported that after 12 months of treatment using HRT + alendronate 10 mg/day, 15 postmenopausal women with osteopenia had their lumber BMD increased by 6.5%. The current study also showed a positive trend in bone structure and density with herbal treatment.

Delmas and Gimona (1996) suggested that oestrogens are widely believed to be effective against postmenopausal osteoporosis. However there are some outstanding questions which still need an answer. The minimal effective dose regimen of oestradiol needs to be established and the relationship between oestradiol levels and efficacy on bone turn-over and bone mass need to be further clarified. The formula used in this study was only one of a large number of TCM formulae that are available for the treatment of bone loss. The selection of the appropriate herbal formula and the dose required to affect bone turn-over from a large range of herbs and/or formulae as indicated in Chapter 2 also awaits further study.

This study has theoretical and practical value as it examines the effects of herbal treatment on BUA, OSTN, PYR and D-PYR. Shu Di Shan Zha formula balanced bone metabolism, relieved common menopausal and bone loss symptoms. This shows that the *kidney* strengthening and *yin* nourishing effects of the formula were achieved. Subjects recruited were Australian menopausal women. This is significant as most previous available studies involved Asian not Western subjects who tend to suffer more from menopausal and bone loss symptoms according to current literature. The herbs were carefully chosen so that they tasted "good". They were derived from natural plants according to the classic Materia Media. The formula is neutral in nature so it can be applied to most groups within the population. This formula is especially valuable as a preventative treatment.

6.6 Conclusion

Chinese medical herbal therapy – Shu Di Shan Zha formula was able to affect the level of BUA and reduce the level of D-PYR in menopausal women as well as ameliorating menopausal symptoms in most of the subjects. However the mechanism of herbal therapy on bone turn-over warrants further study.

CHAPTER 7

GENERAL DISCUSSION

7.1 Introduction

Traditional Chinese Medicine has a long history of clinical success. The literature recording and verifying this history extends back over 2000 years or more and includes over 30,000 volumes (Liu, 1998). By comparison, modern Western medicine as it has been practiced over the last 50-100 years is a very young system (Wolfe, 1998). Therefore many of the newest Western medical treatments for a given ailment have yet to be tried over even one generation thus allowing for the development and measurement of long-term side effects. On the other hand, many Western medical treatments are quite efficacious. Wolfe suggested that modern Western medicine might be best seen as part of a large system of medicine, which allows people more options and stronger responses. At times the swift and effective treatments of Western medicine are useful and necessary in serious, acute, or life-threatening situations. "For chronic or functional disorders, however, Chinese medicine offers a viable alternative, indeed an effective and humane alternative in areas which Western medicine offers few options or only treatments with many uncomfortable and possible dangerous side effects" (Wolfe, 1998, p14).

The results of this study indicate that Tai Ji exercise, acupuncture and herbal medicine have a benefical effect on bone structure and density, bone formation and resorption and menopausal and bone loss symptoms. The following discussion outlines the effects of the three modalities in relieving common symptoms. This discussion also provides additional information in terms of TCM diagnosis relating to bone loss, the correlation between BMD and BUA measurements and the possibility of using new bio-markers to effectively and accurately measure the effects of treatment using Chinese medical modalities.

The design of this study, which utilised a cross-over approach of two four month periods, enabled an evaluation to be undertaken of not only the effects of the treatment but also the influence of time on the chosen parameters and the residual effects of the three intervention. These three experimental effects can be summarised as:

	Group A	Group B
Period 1 (1 st 4 months)	Effect of treatment*	Effect of time
Period 2 (2 nd 4 months)	Residual effect of treatment	Effect of treatment*

* data aggregated for some statistical purposes.

Tables 7.1 - 7.5 summarise the effects of time, the interventions and the residual effect of the treatment on the three subject groups.

7.2 Comparison of the Effects of Treatment Using the Three TCM Modalities on BUA, VOS, OSTN, PYR and D-PYR in This Study

7.2.1 Comparison of the Effects of the Three Modalities on BUA

Table 7-1 and the accompanying graph indicate that both Group A and Group B had increases in their BUA readings for all three modalities (see Chapters 4, 5 and 6 for statistical analysis of these results). It is also apparent from Table 7-1 that there was a natural decline in BUA readings over the four month period that Group B maintained its control status (ie a pre-treatment period). These natural declines from each of the three treatment groups are relatively consistent and can be compared to the post treatment period results of Group A. This comparison does indicate that there was a residual effect of treatment in both the Tai Ji and acupuncture groups but not of the herbal group. Conversely the herbal group (both Groups A and B) showed improvements in BUA readings during the treatment period. Improvements in Group A were far greater than those in Group B. After the cessation of the treatment for four months the decline in

BUA for Group A was high but it must be remembered that the increase in Group A during the treatment period was very high. These results suggest that further study is required in all modalities but particularly for the herbal modality.

Table 7-1 Changes in BUA between Pre-Test and 4th Month for Group A, 4th Month and 8th Month for Group B, Pre-Test and 4th Month for Group B and 4th Month and 8th Month for Group A

	BUA change after 4 months treatment in Group A	BUA change after 4 months treatment in Group B	BUA change after 4 months (no treatment) in Group B	BUA change after ceasing treatment for 4 months in Group A
Tai Ji Exercise	+7.1%	+7.6%	-8.1%	-1.0%
Acupuncture	+8.2%	+9.4%	-13.8%	-4.3%
Herbal medicine	+12.7%	+1.3%	-5.8%	-7.0%



(1): BUA change after 4 months treatment in Group A

(2): BUA change after 4 months treatment in Group B

(3): BUA change after 4 months (no treatment) in Group B

(4): BUA change after ceasing treatment for 4 months in Group A

Figure 7-1 Changes in BUA between Pre-Test and 4th Month for Group A, 4th Month and 8th Month for Group B, Pre-Test and 4th Month for Group B and 4th Month and 8th Month for Group A
BUA was used as the main parameter to measure the effects of treatment in this study. It is apparent that there were positive changes as a result of treatment using all three Chinese medicine modalities. According to Damilakis, Dretakis and Gourtsoyiannis (1992), changes in BUA may reflect bone structure and density change rather than natural change of bone. Dretakis et al. considered 98 female subjects in the age range 25-87 years. Multiple regression analysis, with independent variables of age and osteoporosis status, showed that the difference in the pooled mean BUA values was more disease related and less age related. They noted that the correlation between BUA and age was not significant in pre-menopausal women.

7.2.2 Comparison of the Effects of the Three Modalities on VOS

Table 7-2 and the accompanying graph show the changes in VOS for Group A and B after four months of treatment, four months of natural change in Group B without treatment and four months after ceasing treatment in Group A. Only acupuncture treatment produced an increase in VOS in Group A but the result was not statistically significant (see Chapter 4, 5 and 6). As was discussed earlier in Chapters 4, 5 and 6, it is likely that VOS measures a different component of bone structure than BUA. It either does not respond to the modalities utilised or responds slowly to these treatments. Given the changes observed in the other dependent variables it is a reasonable conclusion that VOS is an insensitive indicator of changes in bone status.

The tables (Table 7-1, 7-2) which outline the effects of TCM treatment on BUA and VOS can be compared with findings in other studies. Palacios, Menendes, Calderon, Rubio and Spine (1993) studied 111 Spanish women aged 30-70 years not taking medication or suffering from disease affecting bone metabolism. In the study BUA decreased by 32% between 30-70 years. In this present study BUA increased with treatment but decreased without treatment.

Table 7-2 Changes in VOS between Pre-Test and 4th Month for Group A, 4th Month and 8th Month for Group B, Pre-Test and 4th Month for Group B and 4th Month and 8th Month for Group A

	VOS change after 4 months treatment in Group A	VOS change after 4 months treatment in Group B	VOS natural change (without treatment) for 4 months before treatment	VOS change after ceasing treatment for 4 months in Group A
Tai Ji Exercise	-0.0%	+0.9%	-0.6%	-0.9%
Acupuncture	+7.1%	+0.7%	-1.1%	-0.4%
Herbal medicine	+0.3%	+0.4%	-0.5%	-0.5%



(1): VOS change after 4 months treatment in Group A

(2): VOS change after 4 months treatment in Group B

(3): VOS change after 4 months (no treatment) in Group B

(4): VOS change after ceasing treatment for 4 months in Group A

Figure 7-2 Changes in VOS between Pre-Test and 4th Month for Group A, 4th Month and 8th Month for Group B, Pre-Test and 4th Month for Group B and 4th Month and 8th Month for Group A

Schott, Hans, Sornay-Rendu and Delmas (1993) using the Lunar Achilles system studied 512 health women aged 20-50 year, 244 women aged 31-79 years and 201 women aged 74-91 years. BUA had an average 20% decrease and VOS a 5% decrease between the ages of 20 and 90 years. BUA significantly decreased between 41 and 50

years (p=0.029) and between 50-60 years (p=0.036). VOS showed no significant decrease within the 10 year age groups except between 51 and 60 years. This finding is similar to this present study in that VOS changes did not match BUA changes.

Yamazaki, Kushida, Ohmura and Sano (1994) studied 842 female volunteers in the age range 21-79 years. The declines in BUA were 8.9% per year and VOS 3.8% per year. Compared with the above described data, BUA changes were still more sensitive than VOS changes in the women in this study but the changes in BUA were lesser than the other studies described including apparent changes.

Cepollaro, Agnusdei, Gonnelli and Matrini (1995) considered 134 women aged 10-90 years and 100 males aged 10-93 years. The average yearly decrease was 12.9% in BUA and 4.9% in VOS for men and 17.2% in BUA and 4.2% in VOS for women, both aged 30-90 years. Again, BUA changes were more significant than VOS changes with these changes matching the results of this current study.

7.2.3 Comparison of the Effects of the Three Modalities on OSTN

Table 7-3 and the accompanying graph show the changes in OSTN for Groups A and B after four months of treatment. Comparing these results with the four months of natural change in Group B without treatment and in Group A after ceasing treatment, all three modalities appear to improve OSTN (see Chapter 4, 5 and 6 for statistical significance). Without treatment OSTN varied in all three modality groups. With treatment OSTN increased at an average of 30.77%.

Table 7-3 Changes in OSTN between Pre-Test and 4th Month of Group A, 4th Month and 8th Month of Group B, Pre-Test and 4th month of Group B and 4th Month and 8th Month of Group A

	OSTN change after 4 months treatment in Group A	OSTN change after 4 months treatment in Group B	OSTN natural change during 4 months without treatment in Group B	OSTN change after ceasing treatment for 4 months
Tai Ji Exercise	+43.2%	+33.1%	+3.6%	+4.7%
Acupuncture	+47.0%	+17.8%	-11.6%	-2.9%
Herbal medicine	+26.8%	+16.7%	-1.9%	+8.8%



(1): OSTN change after 4 months treatment in Group A

(2): OSTN change after 4 months treatment in Group B

(3): OSTN change after 4 months (no treatment) in Group B

(4): OSTN change after ceasing treatment for 4 months in Group A

Figure 7-3 Changes in OSTN between Pre-Test and 4th Month of Group A, 4th Month and 8th Month of Group B, Pre-Test and 4th month of Group B and 4th Month and 8th Month of Group A

7.2.4 Comparison of the Effects of the Three Modalities on PYR and D-PYR

Table 7- 4 and the accompanying graph show the changes in PYR for Group A and B four months and eight months into the study. Comparing these results with the four months natural change in Group B without treatment, treatment in all three modalities appear to decrease PYR (see Chapter 4, 5 and 6 for statistical significance). Comparing

the natural reduction in PYR in Group B with Group A four months after ceasing treatment, it does not appear that there was a significant residual effect from the treatment.

Table 7-4 Changes in PYR between Pre-Test and 4 th Month in Group A, 4 th Month
and 8 th Month in Group B, Pre-Test and 4 th Month in Group B and 4 th Month and
8 th Month in Group A

	PYR changes after 4 months treatment in Group A	PYR changes after 4 months treatment in Group B	PYR natural changes during 4 months without treatment	PYR changes after ceasing treatment for 4 months in Group A
Tai Ji Exercise	-6.1%	-10.1%	+23.6%	+10.3%
Acupuncture	-4.3%	-6.6%	+6.4%	+11.9%
Herbal medicine	-15.6%	-7.7%	+11.1%	+9.9%



(1): PYR change after 4 months treatment in Group A

(2): PYR change after 4 months treatment in Group B

(3): PYR change after 4 months (no treatment) in Group B

(4): PYR change after ceasing treatment for 4 months in Group A

Figure 7-4 Changes in PYR between Pre-Test and 4th Month in Group A, 4th Month and 8th Month in Group B, Pre-Test and 4th Month in Group B and 4th Month and 8th Month in Group A

Table 7-5 and the accompanying graph which show the changes in D-PYR for Groups A and B after four months treatment indicates that all modalities had an effect on this parameter (see Chapter 4, 5 and 6 for statistical significance). As with OSTN there

does not appear to be a long-term residual effect on this variable as a result of the treatment modalities.

	D-PYR changes after 4 months treatment in Group A	D-PYR changes after 4 months treatment in Group B	D-PYR natural changes during 4 months without treatment	D-PYR changes after ceasing treatment for 4 months in Group A
Tai Ji Exercise	-17.8%	-8.1%	+51.1%	+27.8%
Acupuncture	-26.9%	-11.4%	+29.5%	+38.8%
Herbal medicine	-21.7%	-10.4%	+26.3%	+29.2%

Table 7-5 Changes in D-PYR between Pre-Test and 4th Month in Group A, 4thMonth and 8th Month in Group B, Pre-Test and 4th Month in Group B and 4thMonth and 8th Month in Group A



(1): D-PYR change after 4 months treatment in Group A

(2): D-PYR change after 4 months treatment in Group B

(3): D-PYR change after 4 months (no treatment) in Group B

(4): D-PYR change after ceasing treatment for 4 months in Group A



D-PYR results in this study showed a clear positive (decreasing) change after all three types of TCM treatment and negative (increasing) change without treatments or after treatments ceased. Again this indicates a lack of a residual effect from treatments. Compared with the other bio-markers, PYR and OSTN, the changes in D-PYR are more

significant. D-PYR is considered a relatively more sensitive bio-marker as explained in Chapter 4.

In considering the correlations between biochemical markers and ultrasound indices, Hoshino, Kushida, Takahashi, Yamazaki, Denda and Atsumi (2000) indicated that an increase in bone turn-over occurs four years before menopause, however the correlations between biochemical markers (OSTN, PYR and D-PYR) and ultrasound indices (BUA and VOS) were too low to allow prediction of bone change in the individual patient. The above tables indicate that percentage changes in biomarkers and ultrasound indices were different between groups in this study, it should be noted that the results can be affected by individual differences.

Table 7-6 considers the effects of the three modalities on the five parameters (BUA, VOS, OSTN, PYR and D-PYR) in Groups A+B between pre and post treatment in this study. There are indications that BUA and OSTN have the same trend of significance in all groups in the three modalities. BUA and D-PYR have the same trend of significance in the herbal and acupuncture treatment groups. VOS and PYR do not have the same significant response as BUA, OSTN and D-PYR. Although PYR and D-PYR are the pyridium cross links, it seems that D-PYR is more sensitive than PYR according to this study.

	1		
Parameter	Tai Ji Exercise Groups A+B	Acupuncture Groups A+B	Herbal treatment Groups A+B
BUA	\uparrow	$\boldsymbol{\uparrow}$	$\boldsymbol{\uparrow}$
VOS	\rightarrow	\rightarrow	\rightarrow
OSTN	\uparrow	$\boldsymbol{\boldsymbol{\uparrow}}$	${\leftarrow}$
PYR	\rightarrow	\rightarrow	\rightarrow
D-PYR	\rightarrow	\downarrow	\downarrow

Table 7-6 Summary of the Significance of the three modalities in Groups A+BResults between pre and post treatment

Note: \uparrow = Significant increase; \rightarrow = No significant change; \downarrow = Significant decrease

7.3 Comparison of the Three Modalities on Relieving Common Symptoms

Three of the major modalities of TCM were used in this study to examine their effect on bone loss in menopausal women. Tai Ji is an exercise that may affect bone formation; acupuncture may suppress bone resorption and activate bone formation; herbal medicine may improve phytoestrogen levels thus improving the balance of bone turnover in menopausal women.

Results of this study indicate a trend toward the three TCM treatments, based on the principals of TCM, increasing bone structure and function in different ways. The results of this study are not statistically significant in some areas and further study is required to elucidate the effectiveness of these treatments.

To compare the effects of Tai Ji, acupuncture and Chinese herbal treatment on relieving common symptoms according to TCM theory a Ridit Analysis was conducted. The results of the Ridit Analysis (Table 7-7) indicated that there is no significant difference (p>0.05) between groups where in Table 7-7 the letter (**a**) appears in the same row. There is no significant difference between the three modalities in relieving some menopausal and bone loss related major symptoms; such as hot flushes, night sweating; lower back pain and bone ache. All modalities provided positive results in some areas but an interpretation based on individual modalities was not possible. This may primarily be due to the limited number of participants exhibiting similar symptoms.

Significant differences (p<0.05) are apparent between groups where in Table 7-7 the letter (**b**) appears in the same row. Herbal treatment showed less effect in treating swollen ankles/fingers than Tai Ji and acupuncture treatment due to the limited number of subjects with these symptoms. Acupuncture proved more effective in treating palpitations. Acupuncture and herbal treatment were more effective in treating

irritability/anxiety/stress. Herbal treatment was more effective in treating constipation. This indicates the effectiveness of the herbs in nourishing *yin* (*body fluid*); in this respect herbal treatment was the strongest, then acupuncture, then Tai Ji treatment.

Symptom*/		r	Fai J	i		1	Acupuncture			Herb					
Number of subjects	0	1	2	3		0	1	2	3		0	1	2	3	
Lower back pain	4	2	1	0	a	6	5	1	0	a	5	2	0	0	a
Knees/Leg/Feet pain	3	1	0	0	a	5	4	0	0	a	3	1	1	0	a
Aching bones	0	0	0	0	a	1	0	0	0	a	0	0	0	0	a
Poor appetite	0	0	0	0	a	1	0	0	0	a	0	0	0	0	a
Abdominal distension	5	2	0	0	a	5	1	0	0	a	3	3	1	0	a
Diarrhoea	1	0	0	0	a	4	1	0	0	a	1	0	0	0	a
Swollen ankles/fingers	2	2	0	0	a	6	0	0	0	a	0	0	1	0	b
Tiredness	4	1	0	0	a	11	0	1	0	a	9	0	1	0	a
Palpitations	3	0	0	0	a	5	2	0	0	b	3	2	0	0	a
Hot flushes	6	3	0	0	a	5	9	0	0	a	8	5	0	0	a
Hot feet/pain	0	0	0	0	a	1	1	0	0	a	0	0	0	1	a
Night sweats	5	3	0	0	a	9	3	0	1	a	3	7	0	0	a
Insomnia	1	2	0	0	a	5	5	1	0	a	10	3	0	0	a
Irritability/Anxiety/Stress	0	2	2	0	a	3	1	1	0	b	3	3	0	0	b
Headache	2	2	0	0	a	3	7	0	0	a	3	7	0	0	a
Thirst	3	2	0	0	a	5	3	2	0	a	8	2	0	0	a
Itchy skin	1	2	0	0	a	1	0	0	0	a	2	0	0	0	a
Constipation	0	1	1	1	a	1	6	1	0	a	8	1	1	0	b
Dark/smelly urine	1	3	0	0	a	4	2	1	0	a	0	2	0	0	a

Table 7-7 Comparisons between the Effects of Tai Ji, Acupuncture and HerbalTreatment on Common Symptoms

*0=Completely recovered; 1=Released; 2=Mild effect; 3=No effect

The results of Ridit Analysis indicated that there is no significant difference (p>0.05)between groups where the letter (a) appears in the same row. There are significant difference (p<0.05) between groups where the letter (**b**) appears in the same row. The above table shows that Tai Ji and acupuncture treatment are more effective in treating swollen ankles/fingers; acupuncture is more effective in treating palpitations; acupuncture and herbal medicine effective are more in treating irritability/anxiety/stress; herbal medicine is more effective for the treatment of constipation.

As this study only used single treatment modalities the effects of using more than one treatment modality at the same time is unknown. In TCM clinical practice more effective treatment often involves the use of more than one modality, this suggests that further study is required.

TCM acknowledges that illness is a part of life that will always be faced by humanity. Health and disease are like yin and yang (see Chapter 1), one cannot exist without the other; the two form a continuum. There will always be people with painful chronic illness and disease who require adequate care since a cure is not always available. This is why the TCM paradigm stresses prevention over cure, as there are often no efficacious treatments for disease once it has progressed to a certain condition. Where a treatment does not exist all that can be provided is adequate palliative care. This requires that the practitioner treat the patient as a person rather than a body with a disease (Nester, 1999).

According to TCM principles the causes and patterns of osteoporosis and menopause are clear. Rather than provide symptomatic treatment TCM focuses on the underlying cause and provides a comprehensive therapy to treat the root of the disease as well as the symptoms to achieve a holistic result. TCM views osteoporosis as primary deficiency and secondary excess. The pattern differentiation in TCM considers osteoporosis to be *liver* and *kidney* deficiency combined with *qi* and *blood* deficiency as the primary disharmony, cold *damp*, *phlegm* and *blood* stasis are the secondary disharmony.

The symptoms of the various patterns include back pain, weak knees and tiredness. Back pain is a common symptom of bone loss resulting from *kidney* deficiency. It appears initially as a sore ache in the body with weak knees and tiredness, this develops into significant pain when affected by external or internal factors (as outlined in Chapter 2). TCM offers preventive treatment prior to the development of these syndromes in such interventions as Tai Ji, acupuncture and herbal medicine. If prevention or treatment (once the disease exists) is not applied in time the development of osteoporosis leads to lumbar vertebra and hip fracture, hunchback, limited movement in the lumbar region, hips and knee joints.

All three traditional Chinese medical modalities, Tai Ji exercise, herbal medicine and acupuncture utilised in this study provided relief to patients suffering from menopausal related syndromes (in some cases the relief was statistically significant). The results also indicated that these modalities could be used as a basic treatment and preventative therapy for menopausal syndromes and osteoporosis.

7.4 Discussion of Assessment Methods

7.4.1 Correlation between BUA and BMD

Thirty-four subjects received their final BMD test assessed by DEXA as described in Chapter 3. The DEXA results were compared with the BUA readings of the same subjects. The BUA and DEXA tests were assessed at the end of the 8^{th} month. This study gave a correlation result of r=0.496 between BMD and BUA. Figure 7-1 'Correlations between BUA and BMD' indicates that there is a low but significant positive correlation between BMD and BUA (p=0.003). This correlation does indicate

that there was a relationship between BMD and BUA, two different measures of bone density. As BMD was only measured at the end of the project further research using both BUA and BMD should be undertaken.

Based on the figure 'curve fit' the following equation BMD=0.7272+0.0035BUA was derived. As R²=0.246 only 24.6% of all data information is included in the equation. These findings can be compared with other studies (see Table 7-8 and Chapter 2) where results showed this study's finding to be at the low end of a fairly tight range of correlations.



Figure 7-6 Correlations between BUA and BMD

Table 7-8 Comparisons between	Correlations of St	tudies Using BUA	and BMD
	Results		

	This study	Roux, et al (1996)	Connelli, et al (1996)	Kang and Speller (1998)
Subjects	Menopausal women	Osteoporosis patients	Osteoporotic women	Postmenopausal and young normal women
No of subjects	34	236	104	75
Correlation (r)	0.50	0.56	0.53	0.63

Table 7-8 shows the correlation coefficients between BMD at lumbar spine as measured by DEXA and BUA at calcaneus by ultrasonic bone analyser according to the four studies. The results are similar, the slightly lower r score from this study as compared to the others may be due to the smaller population or its different composition. Further study is required.

As outlined in Chapter 2, BMD is generally considered to be the most accurate measurement for bone density but it does not provide all the required information in relation to bone structure and function. While in this study BUA only had a moderate correlation with BMD it must be noted that BUA provides additional and different information to BMD.

7.4.2 Bone Turn-over Markers

The reason for choosing OSTN, PYR and D-PYR as the bone turn-over markers used in this study was based on other research results. Serum osteocalcin for bone formation and pyridium cross links for bone resorption have been mentioned as the two most valuable current bone markers (Souberbielle, Cormiere and Kindermans, 1999 and Garnero and Delmas, 1997). These two bone markers are in common use today.

Women with osteoporosis are more likely to have a high bone turn-over. Reduced bone formation as assessed by OSTN is also associated with prior osteoporotic fractures. Melton, Khosla, Atkinson, O'Fallon and Riggs, (1997) indicate that a substantial subset of elderly women have an elevated bone turn-over and this appears to adversely influence BMD and fracture risk. Combined biochemical and BMD screening may provide a better prediction of future fracture risk than BMD alone. The measurement of biochemical bone markers will therefore be very useful in evaluating bone status and could be used for screening postmenopausal osteopenia (Miura, Yamamoto, Yuu,

Kigami, Ohta, Yamamura, Ohnaka and Morita, 1995). However bone resorption markers are more efficient than bone formation markers in the diagnosis of postmenopausal osteoporosis. Urinary Dpd (D-PYR)/creatinine ratio has the highest osteoporosis diagnostic value (Yilmaz, Bayram, Erbagci and Kilincer, 1999).

An evaluating review by Looker, et al. (2000), stated that elevated bone resorption markers appear to be associated with increased fracture risk in elderly women but there is less evidence of a relationship between bone formation markers and fracture risk. The critical question of predicting fracture efficacy with treatment remains unanswered. Changes in bone markers as currently determined do not predict BMD response to either bisphosphonates or hormone replacement therapy. Single measurements of markers do not predict BMD cross-sectionally (except possibly in the very elderly), whether treated or untreated. Markers can potentially be used in the clinical management of osteoporosis but their use has not been established. Additional studies with information on negative and fracture endpoints as well as positive predictive values are needed to evaluate fully the utility of bone turn-over markers in individual patients.

It must be noted as Watts, Nolan, Brennan and Yang (2000) indicated that data variability minimizes the predictive value of bone marker changes in monitoring individual therapy.

7.4.3 The Use of TCM Assessment as a Diagnostic Tool to Predict Bone Loss

The key to effective management of osteoporosis is early diagnosis (Cavalieri, 2000). In this respect TCM provides its own methodology for evaluating potential bone loss.

The association between postmenopausal osteoporosis and *kidney* deficiency syndrome in TCM was evaluated by Chen, Hsue, Chang and Gee, (1999). The results showed that

patients with *kidney qi* deficiency and *kidney yin* deficiency were more likely to be suffering osteoporosis than those who were not. The *kidney qi/ yin* deficiency group had a higher probability of developing osteoporosis than the *kidney qi* deficiency or *kidney yin* deficiency group. In conclusion, a marked association between *kidney* deficiency syndrome and postmenopausal osteoporosis was observed.

Liu, Liu and Li (2000) reported on the BMD of 36879 people measured by a research group in 13 provinces in China. Results showed that all people with *kidney* deficiency had lower BMD than those without *kidney* deficiency. In this study there was a strong relationship between TCM diagnosis and the parameters of BUA, bone formation and bone resorption markers. This study supports these findings (see Table 7-9). Most of the subjects with a *kidney* deficiency pattern have relatively low BUA, OSTN and relatively high D-PYR. Utilizing TCM diagnostic methods to evaluate bone turn-over is a valuable resource as it may be possible to determine which women are at risk of bone loss and thus preventative strategies could be implemented. However before this approach is adopted further detailed studies should be undertaken to evaluate the relationship between *kidney qi/yin* deficiency and bone structure and function.

Table 7-9 Comparisons between BUA, OSTN, PYR and D-PYR Results for Kidne	ey
<i>Qi/Yin</i> Deficiency Patterns	

	<i>Kidney</i> <i>qi/yin</i> deficiency pattern	BUA below average	VOS below average	OSTN below average	PYR above average	D-PYR above average
Number of subjects	25	16	9	16	10	13

Of the 25 subjects who exhibited *kidney qi/yin* deficiency patterns, 16 subjects had below average BUA, 9 had below average VOS, 16 had below average OSTN, 10 had above average PYR, 13 above average D-PYR.

7.4.4 Use of New Biomarkers to Assess Endocrine Function

New biomarkers to assess endocrine function are required to determine the effectiveness of the TCM treatments used in this study. The study shows that symptoms were relieved but the available biomarkers did not provide validating data.

Some new biomarkers have been used as an indicator of disease risk. Davis and Bradlow (1995) and Bradlow, Davis, Lin, Sepkovic and Tiwari (1995) used the ratio of $16\alpha/2$ -Hydroxyestrone as a biomarker of breast cancer risk. This system is based on the oestrogen (estradiol) metabolism pathway and shows that some environmental estrogens can increase the level of "bad" metabolite 16α -Hydroxyestrone, and some phytoestrogens (soy constituents) can increase the level of "good" metabolite 2-Hydroxyestrone. According to Xu (2002) Hong En health drink contains some isoflavones (genistein and diadzein) which can increase the level of 2-Hydroxyestrone. Traditional Chinese herbs containing phyto-estrogens for osteoporosis therapy could be used as a protective measure against osteoporosis.

7.5 Recommendations and further applications

In this study more attention was paid to the prevention rather than the treatment of osteoporosis. Scientific methods were used to measure the effects of treatment on bone loss. The subjects recruited for this study were not typical osteoporosis sufferers as they were women of menopausal age not diagnosed as suffering from osteoporosis. These women were in a high-risk category in terms of osteoporosis because of changing hormone levels. TCM diagnosis methods placed some of these women as being at risk in terms of osteoporosis while others did not appear to be at risk. The herbs and acupuncture points used in the treatments are commonly used as they are neutral in nature and will suit most of the population. For patients who are suffering from

osteoporosis long-term use of these therapies is recommended, this could be combined with other stronger treatments based on the above mentioned principles.

This was an investigative study of the impact of these modalities on osteoporosis. The treatments used in this study provided some relief in a relatively short time however four months is a limited period and longer time studies are needed to examine the significance of TCM treatments on bone structure and function. The results tend to support the objective of this study which was to examine the effects of Ti Ji exercise, acupuncture and herbal medicine treatments on bone structure and function, as outlined in Chapter 1, in relation to bone structure and function. This study establishes that TCM has value as a viable alternative preventative treatment method. The use of only one TCM modality at a time means that the effects of each modality as a discrete treatment were studied. In practice it is probable that the use of two or three modalities together would provide a better treatment. Further study in this area is required. Apart from the three modalities, in practice TCM dietary therapy using specific foods in the diet is usually incorporated in treatment. Traditional Chinese dietary therapy (limitations of this study precluded its use) should also be considered to enhance the treatment effects of the modalities used in this study.

The equivocal results of this study support the need for further study to determine the effectiveness of the three interventions utilized in this study; traditional Chinese herbal medicine, acupuncture and Tai Ji exercise in the prevention or treatment of problems associated with bone structure and function in this population group. TCM could be particularly valuable for people who are disabled or recovering from osteoporotic fractures and even those who are currently receiving other therapies. The results support the establishment of similar programs for health promotion and increased life satisfaction among other groups of people susceptible to osteoporosis.

Public health programs need to be supported by government and corporate changes in policies that provide time, facilities and incentives for maintaining an appropriately

active life-style (Haskell, 2000). The modalities utilised in this study could be effective health treatments. Tai Ji exercise does not require any major facilities, acupuncture and herbal medicine are relatively inexpensive and safe and available in most of the major cities in Australia.

The table below (Table 7-10) outlines the recommendations of the researcher.

Recommendations
• TCM diagnostic methods should be used in diagnosing bone loss
• TCM modalities should be used in the treatment of bone loss
• TCM should be used as an alternative treatment method for the prevention of osteoporosis
• Further study is needed to determine the effectiveness of the TCM modalities
• Longer time studies are required on the effectiveness of TCM treatment on bone structure and function
• The use of two or three TCM modalities together should be studied
• Long-term use of Tai Ji, acupuncture and herbal medicine for osteoporosis patients should be applied
• Programs of health promotion and increasing life satisfaction among other groups of people who may be susceptible to osteoporosis should be established

Table 7-10 Summary of Recommendations

7.6 Conclusion

All three modalities positively affected bone turn-over to some extent. In this study they improved the bone turn-over in different ways.

- Tai Ji (24 movements) is an exercise which affected bone turn-over through the improvement of bone formation.
- Acupuncture (points of SP 6, ST 36 and KID 3) affected bone turn-over through both bone formation and resorption by increasing oestrogen levels.
- Herbal medicine (Shu Di Shan Zha formula) appeared to be associated with improved hormone levels and contributed to decreasing of bone resorption but further study is required.

All of these treatments were considered useful in alleviating the symptom of osteoporosis according to the theories of traditional medicine.

In TCM it is considered very important that the balance between bone formation and resorption be maintained. If this balance is not maintained bone loss will occur. The present study focused on TCM treatment principles:

- *Kidney* tonifying and nourishing treatment were administered.
- *spleen* tonifying treatment was administered.
- *blood* invigorating treatment was administered.

These treatments were used to balance bone formation and resorption. The results showed that all three modalities; Tai Ji exercise, acupuncture and Chinese herbal medicine contributed to improved bone structure and function by balancing bone formation and bone resorption. These treatments are useful in relieving the symptoms of menopause and reducing bone loss. The three modalities utilised in this study to prevent or reduce bone loss in menopausal women have the potential to result in considerable savings in terms of government spending on public health. This is particularly significant in Australia today as it has an aging population and many people are at risk of suffering bone loss. Traditional Chinese medical modalities can be particularly effective as they provide both prevention and treatment cheaply. This type of treatment may provide a new model of health care in this field.

The combined use of the three types of TCM treatment in osteoporosis therapy is recommended as they all affect bone turn-over in slightly different ways and could be more effective when used together. Preventive treatment is more effective than therapeutic treatment for bone loss in menopausal women. In TCM prevention has been more acceptable than treatment for thousands of years. The results of this study could also support the establishment of similar programs for health promotion and improved life quality for other groups in the population who may be susceptible to osteoporosis.

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Effects of Exercise and Traditional Chinese Medical Modalities on Bone Structure and Function

VOLUNTEERS NEEDED 60 menopausal women aged 45-65

Subjects can choose from three methods of treatment:Acupuncture- Twice a weekChinese Herbal Drink- Twice a dayTaiji (TaiChi) Exercise- 2 to 3 times a week (1 hour)

Venues:

Victoria University, Footscray Park Campus, Building L, Level 4, Dance Studio Victoria University, St Albans Campus, Building 3, Nursing Lab Additional venue - may be arranged according to location of participants

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Appendix B OSTEOPOROSIS RISK QUIZ

Name	Date of birth:	Occupa	tion:					
Postal	address:	Tel	:					
1. Ai	e you an Australian citizen?		Yes	_No				
(If not	(If not, please indicate where you were born?							
How l	ong have you lived in Australia? (ye	ears)						
2. (a)	Does or did your mother have osteoporosis (eg: fra	icture, h	unchb	ack)?				
	YesNo							
(b) Do you have any sisters with osteoporosis?		Yes	_No				
3. (a)	Have you had your ovaries surgically removed?		Yes	_No				
(b) At any time in your adult life was there a time you	did not	mens	truate (have a period) for				
	more than three consecutive months?	les]	No	-				
	(If 'yes', for how long did this occur?)						
4. (a)	What year did you begin menopause?							
(b) What do you think are your main symptoms?							
(c)	How many years did you have relatively regular m	enstrua	l cycle	es?				
5. (a)) If you are post menopausal, are you being treated v	with oes	trogen	or HRT after				
	menopause?		Yes	_No				
	(b) If yes, for how many months?							
(c) What dosage per day?							
6. Do	you diet frequently?		Yes	_No				
7. Do	you smoke? (if yes, for how long?)		Yes	_No				
8. (a)	How much alcohol do you drink per week?			-				
(b) What do you usually drink? (eg. beer, wine, spirit)							
9. (a)	How many cups of coffee do you drink per day?							
(b) How many cups of cola do you drink per day?							
10. (a)	Have you ever taken medication for longer than two	o montł	ns that	may causes bone loss?				

[such as: corticosteroids used for arthritis, inflammatory bowel disease, asthma; aspirin;

antacids; isoniazid (used for tuberculosis), heparin, anticonvulsants, or diuretics]

Yes___(circle one) No____

(b) Is there any medication not described in the previous question, that you have taken for a prolonged period of time (more than 3 months)? If so, what's the name of the medication,

(c) Have you suffered from any of the following illnesses. [eg. hyperthyroidism (including over-replacement with thyroxine medicine), hyperparathyroidism, liver and kidney Yes (circle one) No disease, malabsorption or cancer]? 11. Do you have scoliosis? Yes No 12. Were you ever confined to bed for longer than 2 weeks in two years? Yes No (If yest, please indicate the duration .) 13. Were you sedentary (less physically activity) as a child? Yes No Were you sedentary (less physically activity) as a young adult? Yes___No___ Were you sedentary (less physically activity) as an adult? Yes No (a) How many hours of exercise did you do as a child or young adult per week? (b) Have you ever played sport as an adult? Yes No (c) How many hours a week (training plus competition) Yes___No___ 14. Do you get regular exposure to sunlight? Yes___No___ Does your diet intake content of cod-liver oil?

Appendix C PLAIN-LANGUAGE DESCRIPTION OF THE STUDY

EFFECTS OF EXERCISE AND TRADITIONAL CHINESE MEDICAL MODALITIES ON BONE STRUCTURE AND FUNCTION

I (Hong Xu) am a Ph.D. student, and lecturer at Victoria University. I have completed a five year program at the Beijing University of Traditional Chinese Medicine in China and worked as a traditional Chinese medical doctor and lecturer both in Beijing, Hong Kong and I have now been in Melbourne for the past eight years. I would appreciate your participation in my project. Please read the following information about the study and feel free to ask any questions or discuss any concerns that you may have.

INTRODUCTION:

Taiji (Tai Chi) exercise, Acupuncture and Herbal Medicine are natural therapies that have long been prescribed for pre-menstrual and menstrual problems. They are amongst the oldest and most widespread healing methods in the world. Although they have been used for thousands of years, they have only recently gained credibility in the western world.

"The view of the World Health Organisation (WHO) is that the sheer volume of evidence in favour of the ancient practice of acupuncture, demands that the therapy be given major consideration by those in primary health care" (Boylston, 1987, p115).

Osteoporosis is rapidly becoming one of the most important public health problems in the world. It is widely believed that fractures occurring as a result of osteoporosis, particularly among post-menopausal women, has reached almost epidemic proportions (Ellerington, 1993).

This study will evaluate the effectiveness of Taiji (Tai Chi) exercise, acupuncture and herbal medicine in preventing or reducing the loss of bone structure and function in menopausal and post-menopausal women.

POPULATION AND TREATMENT:

Sixty volunteers (subjects) will participate in this study. Subjects will be assessed on the basis of an interview with the researcher and on meeting the requirements of healthy menopausal or post-menopausal woman by the osteoporosis risk quiz and diagnostic therapy of traditional Chinese medicine. If the volunteer meets the criteria, she will be asked to participate in this study.

Depending on the group that subjects are in, experiential treatment will occur either twice or six days a week. Subjects meeting the criteria will be randomly assigned to either a control or a treatment group according to their bone structure and function, age, bio-markers tests results

and menopause period. The treatment groups will be given exercise, acupuncture or herbal therapy in accordance with traditional Chinese medical principles and differential diagnosis, the control group will be asked to maintain their normal activities. At the completion of the first stage, subjects who are in the control group will cross over with the treatment groups and receive Taiji exercise, acupuncture or herbal therapy. Subjects in any of the treatment groups could become a control group member after the cross over.

All subjects participating in this study will be required to document their calcium intake, as well as complete a checklist and normal physical activity form.

There are no risks or side-effects with Taiji exercise, acupuncture and herbal therapies. Sometimes however a mild soreness may be felt and slight bruising could occur around the acupuncture points during or after treatment. The blood sampling (10mls) that occurs at the start, crossover, and end of the project could also cause minor discomfort and some people may also have some a small amount of bruising around the needle site.

The confidentiality and anonymity of the research files will be respected and only the researchers will have access to the subject's data. Participation in this study is voluntary. Informed consent will be obtained from all subjects.

At any time during the study a subject may withdraw without any prejudice. The subject may at any time contact the researcher (Hong Xu) to discuss concerns or questions.

Appendix D INFORMED CONSENT FORM

Victoria University of Technology

PROJECT:	Effects of exercise and traditional Chinese modalities on bone
	structure and function
INVESTIGATOR:	Dr. Hong Xu
SUPERVISORS:	Prof. David Lawson, Dr. Vanda Fortunato

I, ______ acknowledge that the nature of the project has been described to me and I understand the stated information with regards to the program of study and the involvement that I will have in the study as a participant. I have been made aware of the risk involved.

I have had an adequate chance to ask questions at this time, and understand that should questions arise at any time during my involvement in the study I may ask them.

I understand that the study will last approximately eight months and I am aware that I am free to withdraw from the study at any time.

I have been informed that the information I provide will be kept confidential.

Signed:

Witness other than the experimenter:

Date:

Thank you for participating in this study. Your participation will add to our knowledge of effective therapies to assist people in preventing or reducing the loss of bone structure and function.

Any queries about your participation in this project may be directed to the researcher (Name: Hong Xu ph. 93652765). If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University of Technology, PO Box 14428 MCMC, Melbourne, 8001 (telephone no: 03-9688 4710).

[*please note: where the subject/s is aged under 18, separate parental consent is required; where the subject is unable to answer for themselves due to mental illness or disability, parental or guardian consent may be required.]

Appendix E ADDITIONAL INFORMATION SHEET

Effects of Exercise and Traditional Chinese Medical Modalities on Bone Structure and Function - Hong Xu's Research Project

Dear Participants,

As we mentioned during the previous tests, there is an additional test - DEXA will be introduced in our nearly completed project, please read the following information for the DEXA test, and advise your option according to the above time table if you agree to do this test.

What is DEXA measurement?

Dual energy X-ray absorption measurement

Why did we add this measurement in this research?

The accuracy of the Dual Energy X-ray Absorptiometry as a measure of change in bone status is well documented. The relative minimal radiation doses emitted with the DEXA device however preclude it from being able to be used as often as the other measures in this study.

The results of DEXA measurement will be used to compare with the other results we got from this research.

Who's eligible to take part?

You are eligible if you :

- 1. are over 18 years of age,
- 2. are not pregnant,

What testing is involved?

Testing at the City Campus of Victoria University

Within the above listed time, you will be asked to visit the City Campus of Victoria University (base ment, CRESS unit) to have your bone density measured simultaneously using the Dual Energy X-ray Absorptiometry. During this test, you will be asked to lie on a bed for a lumbar spine (lumber 1-4) scan that takes approximately 0.5 minutes, whole procedure takes about 20mins. A researcher who is licensed to use the device will conduct this test.

What are the risks?

During the DEXA procedure you will be exposed to a very low level of ionizing radiation. The total radiation dose you will receive is about 0.2% of the natural background radiation you receive every year. The risk from this exposure is less than 1 in 1,000,000 or about the same as smoking 2 cigarettes or being struck by lightening.

You should also note that if you agree to participate you can withdraw from this measurement at any time and that this withdrawal will not jeopardize you in any way.

If you have any questions regarding the measurement please contact Hong XU at Victoria University on 9 365 2765 or via email – <u>Hong.Xu@vu.edu.au</u>.

Appendix F STEPS FOR URINATION COLLECTION!

PLEASE FOLLOW THE FOLLOWING STEPS FOR URINATION COLLECTION!

2hr Urine Collection-Early morning sample

This specimen needs to be collected fasting. Fasting begins from 12 midnight the night before. Do not eat until after the collection has been completed.

1. Start the collection by emptying your bladder and discard this specimen (into the toilet).

2. Record time and date on small bottle. From this time until completion (2 hours later) all urine is collected into the small bottle provided.

3. Exactly 2 hours from the start of the collection empty the bladder for the last time into the small bottle. Collection is now complete and you are free to eat.

For example:

- Start the collection at 7:00 am by emptying bladder into toilet.
- From 7:00am collect all urine into small container.
- Empty bladder for the last time into small container at 9:00am.

*Please note urine specimen must be kept as cold as possible during transportation. It is best kept in the refrigerator or cooler until delivery.

Appendix G Check List for TCM Herb Daily Intake

Name: ______

	Mor	nday	Tue	sday	Wedn	esday	Thu	rsday	Fri	day	Satu	rday	Sun	day	
Week	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	am	pm	Notes
1															
2															
3															
4															

Please write the time you take the herbs in the appropriate box above. This form must be returned to Dr. Hong Xu at the time when you pick up the new herbs. Please note the herbs must be kept in a dry and cool place at all times. If you miss a dose please note in the appropriate box above.

Instruction for taking herbs:

1. Herbs presented in bags should be taken 1 hour before or after breakfast. Dose half bag every morning.

2. Herbs presented in bottle should be taken every evening 1 hour after dinner. Dose five grams (five spoonsful) wash down with warm water.

Duration:

Appendix H Traditional Chinese Medicine Assessment Form

			IN	0.		
D/O/B:						
Occupation:			Te	l:		
		Inquiring/As	king:			
Presenting Complain	t:					
Current Medication:						
current wieureation.						
Major Past Illnesses:						
Chills/Fever:						
Abnormal Sweating:						
Appetite, taste & thir	st:					
Bowels:						
Urination:						
Sleep:						
Pain:						
Menstruation:						
Tongue	L	eft Ear		Right	Ear	
Tongue		eft Ear		Right	Ear	
Tongue	Pulse	eft Ear	ght	Right	Ear	
Tongue	Pulse	eft Ear	ght Rear	Right	Ear Control Control Co	
Tongue	Pulse	eft Ear	ght Rear	Right	Ear Description	
Tongue	Pulse	Rig Front Middle	ght Rear	Rate Q	Ear Description	
Tongue	La Pulse Superficial Middle Deep	Riquest Ear	ght Rear	Right	Ear Description	
Tongue	Pulse Superficial Middle Deep	eft Ear Rig Front Middle	ght Rear	Rate Q	Ear Description hualities	
Tongue	Pulse Superficial Middle Deep	Riq	ght Rear		Ear Description	
Tongue	Pulse Superficial Middle Deep	Rig	ght Rear		Ear Description rualities	

Traditional Chinese Medical Assessment

Appendix I Dietary Information

Appendix J Physical Activity Information

Appendix K Description of Tai Ji Exercise

Description of introductory exercise

Walking	Place and face the palms together on the "Dan Tian" point (the width of the
	person's four fingers at the second phalangeal joint under the navel that is
	the root of qi). Place the left heel down in front of the body, keep the sole
	raised. Keep the knee straight, not bent.
	Bend the right knee and at the same time lower the sole of the left foot to the
	floor. As you do so, relax the left leg as much as possible.
	Shift the full weight on to the left leg, bending the knee. Raise the heel of
	the right foot. Repeat steps 1-3 on the other side. Walk forwards with these
	postures for about 10 steps.
	Then place the two palms on the 2 parallel "Kidney Shu" points [the width
	of the person's two fingers at the second phalangeal joint (1.5 cun) lateral to
	the lower border of the spinous process of the 2^{nd} lumbar vertebra which is a
	kidney tonifying and lower back strengthening point], place the toes down
	then walk backwards.
Horse Stance	Stand with the feet slightly wider apart than the hips, similar to shoulder
and Holding	width, assume a horse-riding stance. Feel really solid.
A Ball	Relax and wait for a minute until you feel "settled". Bring the arms in a
	wide circle out to the sides. Then bring the arms in front as if holding a big
	ball. The palms face the chest, thumbs up, fingertips about 5cm apart, hold
	for about three minutes.
	Gaze horizontally into the middle distance for three minutes. Slowly bring
	the palms closer to the body to the "Dan Tian" point and without touching it
	"brush" down too the lower abdomen. Bring the arms to the sides.

Description of Tai Ji exercise

Name of 24 Tai Ji	Descriptions
1. Commencing	Stand in a relaxed posture, feet close together, arms hanging naturally, eyes level with the horizon looking into the middle distance.
	Step the left foot out, the feet should be shoulder width apart, keeping the feet parallel. Raise the arms in front of you to shoulder level, elbows slightly bent outwards, palms down. Bring the elbows down, closer to the body and lower the palm to hip level.
	Raise the left hand a few centimetres and lower the right hand a few centimetres, turning the waist a little to the left. Raise the right hand a few centimetres and lower the left hand a few centimetres, turning the waist a little to the right.
2. Part wild horse's mane on both sides –3	1 st time - Bring the left foot, heel raised, closer to the right foot and "hold a ball" on the right side, right hand on top. Turn right on the ball of the left foot and look to the left. Step left into the Bow Stance,
times	pressing down with the right palm and raising the left palm in front of you.
	2 nd time – Shift the weight back on to the right leg and raise the left toes, turning the waist right; "hold a ball" on the right side, right hand on top. Turn left, keeping the left toes raised and "hold a ball" on the left side, left hand on top. Shift the weight on to the left foot and bring the right foot close to it, heel raised.
	3^{rd} time – postures opposite to 2^{nd} time.
3. White crane flashes it wings	Slide the right foot forward a few centimetres, heel raised, weight mainly on left foot and make as if to "hold a ball", left hand on top.
	Settle the weight back on to the right foot, turn the waist to the right, raising the right hand and lowering the left.
	Turn the waist left to face forwards, lift the right hand diagonally, forward opposite the right temple and lower the left palm alongside the left thigh.

4. Brush knees on	1 st time - Turn the left foot inward. Lower the right palm down and
both sides – 3	raise the left palm up. Look back over the right shoulder. Turn the right
times	foot out. Continue to lower the right palm, then raise it, facing upwards;
	at the same time the left palm should circle down across the chest. The
	weight then shifts to the right leg: swivel to face forwards, left heel
	raised. The right hand should be raised till it is level with the ear. Take
	one step directly forward turning the whole body 90 degrees. The left
	palm "brushes" above the left knee and the right hand pushes forward.
	2 nd time - Shift the weight and raise the left toes. Turn the waist left.
	Raise the left palm, facing up, level with the chin. "Point" the right
	fingers at the left elbow joint. Step up with the right foot, close to the
	left, heel raised. Begin to "brush" across the waist with the right hand,
	palm down and push forward with the left palm. Step directly to the
	front with the right foot into a Bow Stance and complete the "brush"
	and push.
	3^{rd} time – forward postures on the opposite side a 2^{nd} time.
5. Strum the	Sometimes known as "Jade Girl Strums The Lute". Draw the right foot
lute	closer to the left, heel raised and lower both hands, palms down. Shift
	the weight on to the right foot and raise the left heel. Bend both wrists
	and "point" the fingers downward a little. Raise the left leg about 30cm
	from the floor, knee bent, then place the heel down, at the same time
	lifting the hands into a rough lute holding position.
6. Curve back	1 st time - Lower the right hand past the thighs and raise it, palm up,
arms on both	level with the shoulder. Stretch the left hand forward, palm down. Look
sides – 4 times	at the right palm. Bring right palm close to the ear and pull left hand
	back towards the thigh, palm up. Draw the left foot close to the right,
	heel raised. Move backward, facing forward. Step directly backwards
	with the left foot and shift the weight on to it, pushing forward with the
	right hand and pulling the left hand beside the left thigh.
	2 nd time – Raise the left hand, palm upwards, level with the shoulder.
	Turn the right palm upwards. Turn the waist to look at the left hand.
	Draw back the right foot to the left, heel raised. Bring the left hand
	beside the left ear and draw the right hand, palm up, towards the right

	thigh. Step directly backwards with the right foot, shifting the weight
	on to it. Push forward with the left hand and bring the right hand, palm
	up, beside the right thigh.
	3^{rd} time – Turn the waist to the right. Backward postures opposite side to 2^{nd} time.
	4 th time – Backward postures the same as 2 nd time
7. Grasp the	Turn the waist to the right, bringing the left foot close to the right foot,
bird's tail – left	heel raised. "Hold a ball" on the right side, the right hand on top. Step
style	forward, into a Bow Stance with the left foot. Raise the left arm in a
	curve across the body. Press down with the right hand till it is beside the right thigh.
	Turn the waist left, raising the left palm to point upwards and bringing
	the right palm, facing upwards, below and to the side of the left
	forearm. Roll back by shifting the weight on to the right leg, lowering
	the right arm and bringing the left arm over towards the chest.
	Place the right fingers on the left pulse point, turning the waist to face
	east once more. Shift the weight forward into a Bow Stance and extend
	the arms ahead of the body, keeping the elbows slightly bent.
	Slide the right palm, facing downward, over the left palm and begin to
	shift the weight back on to the right leg. Shift the weight back on to the
	right leg and draw the elbows down to the sides of the chest, palms
	pointing up and facing away from the body. Shift the weight on to the
	left leg in a Bow Stance, extend the arms into a Push and keep the
	elbows slightly bent.
8. Grasp the	Shift the weight back on to the right foot and turn inwards on the left
bird's tail – right	heel into an inward turned stance. Wipe the hands horizontally to the
style	right. The posture is opposite to 7 (grasp the bird's tail – left style).
9. Single whip	Move the weight on to the left leg, as the waist turns left the right foot
	swivels inwards on the heel. Wipe the hands horizontally to the right.
	Shift the weight on to the right leg and raise the left heel as you swivel
	on to the ball of the foot. Push the right hand ahead as the left palm
	descends. Draw the right hand close to the right side of the chest and

	make a "beak", fingers and thumb tips touching. Lower the left hand
	under the "beak". Step directly forward with the left heel, pushing the
	"beak" out to the side and back. Begin to shift the weight on to the right
	foot, raising the left palm diagonally upwards across the abdomen and
	chest until it faces the head. Shift the weight into a Bow Stance,
	pushing directly forward with the left palm. Swivel the right foot
	inwards slightly on the heel.
10. Wave hands	Swivel right on the left heel as you shift the weight on to the right foot.
like clouds –	Open the right palm and bring the left palm down beside the left thigh.
left style	Swivel right on the left heel as you shift the weight on to the right foot.
	Open the right palm and bring the left palm down beside the left thigh.
	Shift the weight on to the left foot, drawing the right foot alongside it.
	Turn and look right as you pull the right arm.
	Raise the left palm facing the body and lower the right palm. Complete
	bringing the right foot parallel to the left. Turn the waist and trunk to
	the left and in doing so take the arms to the left side of the body. There
	should be no independent arm movement. At the moment you complete
	this turn slide the right foot inwards closer to the left foot. Begin to
	raise the right hand and lower the left, turning the waist right, to the
	front.
	Continue to turn to the right with the right hand at neck height and the
	left in front of the lower abdomen. Complete the right wards turn and
	look to the right foot. Step away to the left with the left foot. The feet
	are always parallel throughout this movement. Begin to raise the left
	hand and lower the right, shifting the weight on to the left foot.
	Complete the raising of the left hand and lowering of the right.
	beginning to turn to face forward. Complete the turn to the left.
11 Single whin	Step diagonally forward to the right a few centimetres with the right
TT: Single winp	foot Make a "beak" with the right hand and cup the left palm under it
	Step a little to the left with the left heel touching the ground and draw
	the left nalm facing the neck in front of you. Turn to the left and bring
	the left hand in front of the face, beginning to shift the weight on to the
	richt foot. Shift the weight into a Dow Stance weight on the left foot.
	ingit toot. Shift the weight into a Bow Stance, weight on the left foot

	and push the left hand ahead of the face, facing directly forward.
12. High pat on horse	Begin to draw the left foot back towards the right, heel raised, opening put the right palm, turning the left palm up and looking at the right hand. Draw the left foot back, heel raised and push the right hand forward, palm down. At the same time bring the left hand down. Weight is on the right foot. Continue to push the right hand forward and pull the left back into the positions shown.
13. Kick with right heel	Step on to the left heel and lower the hands, palms down, beside the thighs. Shift the weight on to the left leg and raise the right heel. Cross the hands over at the lower forearms and raise then in front of the chest. Raise the arms in front of the neck and lift the right knee. Toes point down. Turn the trunk to face 45 degrees between front and right hand side (right diagonal), palms face outwards. Kick out with the right foot slowly and spread the arms at shoulder height. Point the toes.
14. Strike opponent's ears with both fists	Swivel on the left foot so that the whole body faces 45 degrees between the front and the right hand side. Bring both palms to face downwards, in front of the body at shoulder height. Raise the right knee a little higher and clench both fists lightly, palms facing the body, held vertically. Step forward with the right foot on to the heel and slowly swing the arms down and out to the sides. Shift the weight forward into a Bow Stance, weight on the right foot and "strike" to the temples of an imaginary opponent. Move slowly as always.
15. Turn and kick with left heel	Shift the weight on to the left leg as you turn left, turning the right foot inwards on the heel and lowering the hands, palms facing inwards. Continue to turn left. Shift the weight back on to right foot and swivel further round on the right heel and then on the left. Cross the hands in front of the waist. Raise the hands to neck height, turning them away from the body and raise the left knee, toes pointing down. Kick out to 45 degrees between the front and the left hand side with the left foot, separating the hands at shoulder height.
16. Push down and stand on left leg	Make a "beak" with the right hand and point the left fingers at it, palm down. Bend the left knee. Step directly left with the left foot and begin to sweep the left palm down in front of the body. Shift the weight on to

	the left leg and push the left palm forwards. Move into a completed
	Bow Stance, raising the left palm vertically upwards in front of the face
	and hook behind you with the "beak" of the right hand.
17. Push down	Raise the right knee so that the thigh is parallel with the floor. Press
and stand on right	down to thigh level with the left hand and thrust upwards with a
leg	vertical right palm, facing inwards.
18. Work at	Begin to lower the right leg, swivel a little to the left, making a "beak"
shuttles on both	with the left hand, at shoulder height and "point" the right fingers
sides – R. L.	towards it. Place the right foot on the floor and thrust downwards with
	the right hand along the side of the thigh. Shift the weight on to the
	right leg to make a Bow Stance, thrusting upwards vertically with the
	right palm and hooking back with the "beak" of the left palm.
	Raise the left knee so that the thigh is parallel with the floor, thrusting
	up with the left palm, vertically and bringing the right palm down.
	Step down to the left front with the left heel and bring the right palm in
	front of the abdomen, facing inwards. The left palm is raised beside the
	left side of the head. Shift the weight fully on to the left leg and raise
	the right heel, while both palms "hold a ball" on the left side of the
	body, left palm on top. Step to 45 degrees between the front and the
	right hand side with the right foot, raise the right arm, palm facing the
	body, pushing forward across the chest with the vertical left palm. Shift
	the weight fully into a Bow Stance, 45 degrees between the front and
	the right hand side, raising the right hand above the head and pushing
	forward at chin height with the vertical left palm. Ease the weight back
	on to the left leg. The left palm faces upward, cupped below the right
	elbow as you lower it in front of the chest. Lower the arms a little
	further as you shift the weight on to the right leg and draw the left foot
	up behind it. Step towards the 45 degrees between the front and the left
	hand side with the left heel, bring the left hand in front of the chest and
	push across the chest with the vertical right palm. Shift the weight into
	a Bow Stance, raising the left hand in front of and above the head. Push
	forward with the vertical right palm.
19. Needle at sea	Draw the right leg in closer to the left, with the heel raised. Begin to

bottom	press down equally with both palms. Shift weight back on to right leg,
	turning to the right. Lower the left palm down across the chest and raise
	the right palm. The left heel is slightly raised. Turn the waist back to
	the left, raising the right palm up beside the head and lowering the left
	palm down towards the outside of the left thigh. Look down. Thrust
	down with the right palm, facing inwards. Pull the left palm beside the
	left thigh and "sit down" on the rear leg, bending forward.
20. Flash arm	Rise up with weight mainly on the right leg. Step directly left. Raise the
	right hand, palm facing out and the left hand in front of the face. Shift
	the weight into a Bow Stance, directly left hand side and push ahead
	with the left palm.
21. Turn to	Shift the weight on to the right foot and turn the left foot inwards,
deflect	swiveling on the heel. Circle both of the hands over the head. Shift the
downward, parry	weight back on to the left foot and turn out the right foot, swiveling on
and punch	the heel, toes raised. Press down with both palms. Face right. Draw the
	right foot back to the left, heel raised. Take the left arm up to the left
	side to just below shoulder height. Make a light fist with the right hand.
	Draw it in front of the abdomen. Raise the right knee, thigh parallel
	with the floor, toes down. Raise the right fist up to the chest as you
	press down with the left palm. Step forward with the right foot, on to
	the heel and strike (slowly) with the back of the right fist at an
	imaginary opponent's face.
	Turn out the right foot and shift the weight on to it. Push forward with
	the vertical left palm and draw the right fist back to the hip, lightly
	clenched. Step forward with the left foot, on to the heel. Begin to bring
	the right fist forward and to bend the left arm. Shift the weight on to the
	left foot to make a Bow Stance and punch slowly horizontally forward,
	bring the vertical left palm beside the right forearm.
22. Apparent	Slide the left hand, palm down, under the right upper arm as you turn
close-up	the right palm upwards and open. Begin to move weight back slowly on
	to the right foot. Turn the left palm upwards and separate both hands so
	that the fingers point directly in front of you. The weight continues to
	move back on to the right leg. With the weight mainly on the right leg,

	lower the elbows to the sides of the chest. Shift the weight into a left Bow Stance and push horizontally forward with both vertical palms.
23. Cross hands	Shift the weight to the right leg. Turn right and turn the left foot inwards, swiveling on the heel. Push the right hand out to the front at face level. Begin to shift the weight back on to the left leg, swiveling the right foot right on the heel. Push the right palm out far right. Move the weight on to the left leg and sweep the right palm inwards towards the centre of the body as the left palm does the same. Draw the right leg back, parallel with the left (face the direction as at the very beginning). Cross both hands in front of the upper chest, right furthest from the body.
24. Closing form	Draw both hands apart to the sides of the upper chest. Lower the palms to the sides of the thighs and look at the horizon, middle distance. Bring the left foot back to the right, heels close together and lower the palms to a natural position beside the thighs.