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ABSTRACT

Introduction Chronic disease self-management (CDSM) is a vital component of congestive heart failure (CHF) programmes. Recent CHF guidelines have downgraded CDSM programmes citing a lack of gold-standard evidence. This protocol describes the aims and methods of a systematic review to collate and synthesise the published research evidence to determine the effectiveness of CDSM programmes and interventions for patients treated for CHF.

Methods Medline, PubMed, Embase, CENTRAL, CINAHL, Cochrane Central Register of Controlled Trials, PsycINFO, SCOPUS, Web of Science, the Science Citation Index and registers of clinical trials will be searched from 1966 to 2024. In addition, the reference lists of shortlisted articles will be reviewed. Randomised controlled trials, with case management interventions of CDSM and CHF with reported major adverse cardiovascular events (MACEs), will be extracted and analysed. There is no restriction on language. Study protocol template developed from Cochrane Collaboration and Reporting adheres to Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol guidelines for systematic review and meta-analyses 2020. Two independent authors will apply inclusions and exclusion criteria to limit article search and assess bias and certainty of evidence rating. Data extraction and study description of included studies will include quality appraisal of studies and quantitative synthesis of data will then be undertaken to ascertain evidence for the study aims. Subgroup analyses will be conducted for different CDSM programmes. The primary outcome will be a significant change in MACE parameters between intervention and control arms. Meta-analysis will be conducted using statistical software, if feasible.

Ethics and dissemination Ethics approval is not sought as the study is not collecting primary patient data. The results of this study will be disseminated through peer-reviewed scientific journals and also presented to audiences through meetings and scientific conferences.

PROSPERO registration number CRD42023431539.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Extracts data on the effectiveness of major cardiovascular events from studies across several decades.
⇒ Only data from high-quality randomised controlled trials are extracted.
⇒ Impactful qualitative and observational studies are not included in the synthesis of evidence.
⇒ Publication bias, studies with positive or statistically significant results are more likely to be published than those with negative or non-significant findings.

BACKGROUND

Chronic disease self-management (CDSM) programmes are initiated with multiple goals. Among these are achieving four goals (performance mastery, modelling, interpretation of symptoms and social persuasion), three tasks (medical management, role management and emotional management) and five skills (problem-solving, decision-making, resource utilisation, forming a patient/healthcare provider partnership and taking action). When patients achieve higher grades of these skills (described as self-efficacy or self-tailoring) they can better use medical resources to stabilise their medical conditions, prevent hospital readmissions or new admissions, and reduce the burden on health system from higher level health seeking.[1] CDSM programmes are established for many chronic diseases, however, when the lens is turned toward congestive heart failure (CHF), the early momentum of evidence supporting improved self-efficacy,[2–4] and reducing readmissions[5] is not sustained particularly when accounting for major adverse cardiovascular events (MACEs).[6] Thus, th momentum this decade, began with a downgrade for CDSM from a key disease-specific performance measure to a quality measure in CHF, from this lacking of MACE evidence.[6–9]

The importance of this, with perspective, to the disease burden and cost for CHF management that are escalating,

is noteworthy. Globally the prevalence exceeds 30 million persons. There remains a gradient for delivering guideline care domain from developed to developing nations and within all nations. Hospitalisations and preventable readmissions remain a leading health economic burden with 20%–50% of patients seeking readmission at 1, 3 and 6 months.[10] These figures relate to HF with reduced ejection fraction (HFrEF). The focus of this paper does not include HF with preserved ejection fraction (HFpEF), that accounts for the other 50% of CHF patients, due to different pathophysiology and treatment strategies.[10 11]

Chronic disease and CHF management programmes, share similar care domains, an aspect being CDSM. It is imperative that CDSM provides a valued contribution to CHF programmes. From a health services perspective the aims of CDSM programmes would primarily be to contain economic resource utilisation and healthcare costs.[12–18] Patient health-seeking interactions, wholistically, are binary and are contained to community health networks or via acute services (ambulance, emergency, hospital admission). When these cases transition back to ambulatory care new information and healthcare team members require integration into existing care plans. These and other chronic and subacute patients that spill over to acute pathways are potentially preventable using CDSM programmes to achieve self-efficacy in patients. It is imperative that CDSM provides a valued contribution to CHF programmes. On these facts, this systematic review (SR) on CDSM in CHF identifies two important gaps:

1. What is the effectiveness of CDSM in CHF in reducing MACE, primarily, as measured by established performance measures?
2. What is the magnitude of the effectiveness of CDSM in CHF, secondarily, in improving MACE?

The study goal, for this SR, to address the above gaps, will be to pool the published evidence for studies that used CDSM tools and programmes, in the management of participants with CHF which reported quantitative MACE evidence. In this context, the studies will provide assessments of the efficacy of CDSM for improving MACE in CHF. Second report trends for the positive and negative determinants for attaining self-efficacy and objective improvements in CHF outcome will be recorded. This study aims, primarily, to determine the current status among CHF patients of the efficacy of CDSM programmes compared with routine care in improving MACE (and quality-adjusted life-years (QALY)). Secondarily, to quantify the size of the effect wherever possible among CHF patients prescribed CDSM programmes.

METHODS

This study has been registered under the International Prospective Register of Systematic Reviews (PROSPERO) under the registration number: CRD42023431539. This systemic review protocol was performed based on the standards derived from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement.[19] The process undertaken for the protocol will involve defining (1) eligibility criteria, (2) search strategy, (3) data extraction, (4) risk of bias assessment and (5) data analysis.

Review question: What is the current grade of evidence[20] for self-management in CHF and its impact on improving MACE?

Eligibility criteria

Types of studies

The study will include randomised controlled trials (RCTs) that have studied and reported MACE outcomes on CDSM programmes in patients with HFrEF. To reduce the effect of bias in interpreting reported outcomes, we will limit observational trials.[21] Studies found in the search databases will be accepted without restrictions on language and publication date. Study protocols will be limited to search, description of programmes and description of data analysis with respect to relevant outcomes.

Types of participants

We will include adult participants (18 years and above), diagnosed with systolic HF or HFrEF, with ejection fraction <45% (grade 2 or higher), who have been enrolled in a study exploring CDSM programmes in those patients with documented HFrEF during one or more visits within a 12-month period of diagnosis or referred during an admission with acute decompensated HF. CHF classification, decompensation and terminology are referenced in section 2 American Heart Association and American College of Cardiology (ACC/AHA) HF guidelines.[10] We will enrol all aetiologies of CHF including, ischaemic, viral, idiopathic, drugs and alcohol, metabolic and others. Decompensation is defined as worsening symptoms and signs of CHF.[10 11] Population excluded—HFpEF and HFrEF diagnosed with left ventricular ejection fraction >50% (or grade 1) are excluded. Also excluded are trials that do not provide detailed description of the CDSM programme used in the CHF patients. No other groups or demographics, for for example, age, gender or ethnicity, will be excluded.

Types of interventions

Studies that use a CDSM programme, delivered through standardised disease management pathway,[22] that primarily aim to improve outcomes including MACE will be included. Terminology of interventions

include disease management—an established pathway to organise and deliver care[23]; gold standard—accepted as published within consensus guidelines and often with class 1a evidence[10 11]; health provider—person delivering CDSM intervention are either medical staff (primary care or specialists) or allied health pharmacists, nurse, physiotherapist, occupational therapists; case manager—primary person involved in communicating with client and other relevant health services staff, who may or may not be primary intervention provider; monitoring—ongoing periodic assessment after initial intervention for at least 8–12 weeks. Within each trial, during the period of care, management changes may occur. These changes may be routine or usual care, and when documented will be recorded as a comparison to the study intervention. If there is ambiguity our team will contact the trial authors to clarify areas of ambiguity, however, it is acknowledged the length of time from these studies may make this difficult.

Experimental interventions

The gold-standard comparators for CDSM and CHF are standardised quality measures for CHF[6] and European Heart Association and ACC/AHA HF guidelines.[10 11] We acknowledge use of the Flinders Programme of Chronic Condition Self-management (CFPI)[12 18] and validated tools (SCHFI V.6.2, SCHFI V.7.2 and EHFScBS V.9).[9 19] The core principles of the CFPI are disease management, self-management, care coordination and coaching. Self-management domains include self-monitoring, self-maintenance and self-tailoring. Within each programme, additional disease-specific domains, for for example, CHF (which is largely guideline standardised),[10 11] comorbidities such as diabetes mellitus (DM), chronic renal impairment, hypertension and others may be included. Patients will be enrolled into these programmes and trials are randomised to the placebo arm or equivalent, which will be described. Trial programmes disease management will be standardised against domains described in Krumholtz *et al*[24] ; these will be of varying: 'intensity'—the frequency of interval visits; 'duration'—the time between the first and last session; 'delivery'—the method of communication and personnel used; 'location'—the site clients and staff are receiving and delivering the programmes; 'cost'—the funding and cost of delivering the programmes; 'transition, follow-up and discharge'—the support structure provided after programme ends for continued behavioural conditioning, readmission prevention and programme related supports and refreshers.

Table 1 Screening protocol

Title and abstract screening		
Is the study published in English?	If 'yes', go to B	If 'no', document abstract and extractable data. Include with team consensus.
► Does the study involve one of the following designs or analyses: ► Randomised controlled trials and non-randomised trials	If the answer is 'yes', go to C OR if it is not clearly stated in the abstract, go to C	If the publication is a commentary, perspective, editorial, review, or conference abstract, exclude the study
Does the study explain HF diagnosis and ejection fraction cut-off; methodology of CDSM intervention	If the answer is 'yes' OR if it is not clearly stated and you are in doubt, then include the study for a full-text screening and move to 'D'	If 'no', exclude the study
Full-text screening		
Does the study involve adults aged >18 years	If 'yes', go to E	If 'no', exclude the study
Does the study involve one of the following designs or analyses: randomised controlled trials and non-randomised trials	If the answer is 'yes', go to F	If no, exclude the study
Does the study explain CDSM Programme Any activity aimed at improving a component of patient's illness behaviour either self-monitoring, self-management or attainment of self-efficacy	If the answer is 'yes', then move to G OR if it is not clearly stated and in doubt: flag for discussion	If 'no', exclude the study
Does the study include outcomes of our interest? Such as (a) major adverse cardiovascular event such as mortality, morbidity, readmission or procedure; Secondary outcomes (a) healthcare cost (b) quality of life measures	If the answer is 'yes', then include it for data analysis	If 'no', exclude the study

Adapted from Hartling *et al*.[26]
CDSM, chronic disease self-management; HF, heart failure.

Table 2 Proposed search terms developed on MEDLINE

What is the effectiveness of CDSM in CHF in primarily reducing MACE as measured by established performance measures?			
Population	Intervention	Comparison	Outcome
Heart failure	Chronic Disease Self-Management Programme	Routine Heart Failure Care studies	MACE
Search terms			
heart failure: CHF [All Fields] OR "CCF"(All Fields] OR "congestive cardiac failure" (MeSH Terms)OR "congestive heart failure"(All Fields] OR "chronic heart failure"(All Fields] OR "heart failure"(MeSH Terms) OR "HFrEF"(MeSH Terms)	**self-management:** "self-management"(MeSH Terms] OR "self management"(MeSH Terms] OR ("self"(All Fields) AND "management"(All Fields)) **self-care:** "self-care"(MeSH Terms] OR "self care"(MeSH Terms) OR ("self"(All Fields) AND "management"(All Fields))	**Trial:** randomised controlled trial [All Fields] or RCT [All Fields] or randomised controlled trial [MESH Terms]	**performance:** "MACE" [MeSH Terms] OR "Major Adverse Cardiovascular Outcomes" [All Terms] OR Readmision [MeSH Terms] OR "Readmission" [All Terms] or "Death" [All Terms] or "Death" [MESH)

*Results of the three tables will be combined with 'AND'.

Comparator interventions

The study will compare baseline CDSM programme intervention in conjunction with CHF programs[10 11] vs only generic CHF programmes as routine baseline care. The intervention arm can be controlled or quasi-experimental (multiarm design) or non-controlled. No exclusion is made to disease management domains[23] in location (home versus (centre based, eg, primary health, cardiology clinic or hospital, method delivery (in person, technology, written, audio, etc), duration or intensity. These will, however, be graded and described.

Objectives, scientific hypotheses

CHF disease management programmes are comprehensive and revolve around published guidelines.[10 11 16 24] Process of care measures[23] (or key performance measures) used in an organised fashion factoring the relevant standardised disease management domains[23 24] have successfully translated CHF trial level outcomes, for hospitalised and hospital-based outpatient patients, to the general population attending these services. However, it is of interest that studies evaluating CDSM programmes[4 9 12] in CHF, have yet to provide gold-standard evidence.[6] Does this imply CDSM programmes do not work in CHF while they have been robust in other chronic disease such as asthma, DM and hypertension?.[1 12] Thus, based on the current ACC guidelines for CDSM in CHF[6 10 11] and other chronic diseases, we hypothesise:

1. Pooled data on the effectiveness as evidenced in MACE (and QALY) improvement will help inform the foundations for future studies.
2. Meta-analysis of quantitative data will point to strength of a CDSM intervention and this could help design definitive RCT's in this area.

Types of outcome measures

Primary outcomes

We anticipate this study to deliver several findings. First, the primary outcomes will conclude on the level and quality of quantitative evidence for CDSM in CHF in reducing MACE. Overall, any shortfalls extracted in deriving the conclusion will be sufficient information to inform a trial to test CDSM programmes in CHF, that could inform CHF guidelines.

Secondary outcomes

We anticipate this study will provide, data on health economics and quality of life. In addition, it may also provide an idea of trends in barriers and facilitators for CDSM in CHF. This may help steer a focused pooled study on this topic, in the future.

Search strategy

Study characteristics

RCTs will be sought after in this systematic search. Nevertheless, we opted to exclude observational studies in order to mitigate bias and ensure the robustness of the evidence (table 1 and Research Checklist PRISMA 2020 checklist).

Electronic search

Comprehensive search will be conducted, between July and August 2024, in Medline via EBSCOhost (1950–2024), the Cochrane Central Register of Controlled Trials (2024), Embase (1980–2024), CINAHL (1982–2024), PsycINFO (1887–2024), Science Citation Index (1987–2024) and Registers for clinical trials. Searches will be designed and conducted by PI and assisted by librarians. Experts in the area will also be contacted to provide feedback on gaps in the literature review. The following MeSH terms will be used to shortlist studies: "self-management", or self management" or "self-care" or "self care" or "chronic disease self-management" or chronic disease self-management"; and "heart failure" or "cardiac failure" or "congestive heart failure" or congestive cardiac failure" or "chronic heart failure" or "chronic cardiac failure" or "cardiomyopathy" or heart failure with reduced ejection fraction (HFrEF) or systolic heart failure (SHF); AND ["effectiveness" or "efficacy" or "MACE" or "major adverse cardiovascular events" or "readmission" or "death"]. In addition, a 'snowball' search of relevant selected reviews,

previously published reviews and reference lists of shortlisted studies on the to extract additional relevant studies. The search is not limited to language or publication date (table 2).

Searching other resources and information sources

It will be conducted as the study evolves and as required. All new changes will be documented as an amendment to the protocol.

Data collection and analysis

Study selection

An initial assessment of title and abstract for eligibility will be performed independently by (PI and MB). Further evaluation in full text of potentially eligible studies will be selected unblinded according to a standardised procedure by (PI and MB) for definite eligibility. Disagreements during the full text-based study selection process will be discussed and resolved by consensus. A third reviewer (FH) will review all steps, details and resolve disagreement, discrepancies or uncertainties and act as arbiter. Study protocol authors will be contacted to provide further details on results or studies will be excluded from the main analysis. More information about the process of selection of studies is given in (table 3).

Data extraction and management (data collection)

Each study will undergo data extraction by two investigators independently. Phase 1 will involve a pilot and targeted extraction (approximately five studies) using a standardised protocol and case/study report form or instrument/tool (table 3).[6] The areas of interest are study quality, trial characteristics, patient data and outcomes. PI and MB will extract data from each study independently. Phase 2 will involve the refinement of the instrument. Data will be extracted from reports of studies according to the following algorithm '((1) review of the study protocol, (2) review of the major publication ie, published in a 'high-impact' journal, report of major outcome, (3) review of all other publications with quantitative data and (4) contact to authors in the case of inconsistencies within reports). All data of a single study will be displayed comprehensively in the review even if reported in different publications' (table 2).

Data items

To tabulate findings from included articles, a data extraction template will be designed (table 3), factoring CHF specific measures,[6] to include the following domains: (1) study source information (first author, year of publication and country); (2) characteristics of the study population (age, sex, race, comorbid conditions, CHF severity, stage, aetiology, etc), study enrolment criteria (sample size and mean age), details of interventions (content, number, length, frequency of session, format, delivery mode, setting, duration, follow-up and attrition rate), outcomes, measures and findings; (3) Nature of intervention (programme domains, case assessment, delivery, monitoring, reassessment and outcomes) and usual care and (4) types of primary and secondary quantitative outcomes chosen include MACE, clinical parameters, surrogate biomarkers, health resource utilisation, length of follow-up and QALY.

Assessment of risk of bias in included studies (quality assessment and certainty of evidence)

In order to assess the validity and quality of included studies, two reviewers will appraise each study and rate risk of bias according to predefined standards using the revised Cochrane Collaboration's tool in RCT (RoB 2.0) for assessing risk of bias.[25] While this tool has been validated, a detailed checklist is needed to use it appropriately.[25] Using the risk of bias tool adopted by the EPOC Group,[26] we adapted a previously published checklist which we would like to publish a priori as recently suggested.[27 28] The certainty of the evidence for selected outcomes was rated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach. Five aspects (risk of bias, inconsistency, indirectness, imprecision and publication bias) of the GRADE will classify the evidence into four grades (very low, low, moderate and high). The GRADE profiler Guideline Development Tool (GRADEpro GDT) will be used to summarise findings.

Data analysis, assessment of heterogeneity and publication bias

Planned methods for studies analysis and statistical methodology

The searching process and data extraction will be guided by Cochrane Handbook for Systematic Reviews of Interventions.[25] The initial step will be a summary of the included findings in a table and qualitative analysis. Table descriptors and subgroups will include intervention strategies, intensity and training standardisations used to deliver CDSM programmes, as well as usual care. Subgroup analyses will be performed on key domains likely various comorbid conditions, training of intervention arms, treatment intensity and other unanticipated factors to be described after all included articles are finalised. Study heterogeneity can be common in CDSM and other complex interventions, and heterogeneity tests will be performed on subgroups.[26–30] Quantitative synthesis will be conducted should relevant data be extracted; this includes meta-analysis using random effects model. Meta-analysis will be conducted using statistical software R, if feasible. To compare different outcome measures with single effect sizes (standardised mean differences) quantitative synthesis may be more appropriate.

Risk of bias in individual studies

The Cochrane Risk of Bias tool will be used to assess the risk of bias, and the Metafor package will be used to perform the data analysis. To assess the validity of studies that are included two reviewers, in pairs, will assess and rate risk of rate risk of bias from standards defined in the Cochrane Collaboration's tool.[24–26] This validated tool requires a checklist that details how to appropriately

Table 3 Data extraction format

Characteristics	Details to be extracted*
Publication details	Title
	First author's last name
	Journal
	Year of publication
	Publication type: Funding source
Population characteristics	Age
	Gender
	Religion/race/ethnicity
	Enrolled participants
Location	Language and Country of origin where study conducted (recorded but not excluded)
	Setting; ambulatory or admitted (home/ community clinic/ tertiary hospital)
Study methodology/ design	Study design: analytical cross-sectional studies, case–control studies, longitudinal studies, RCTs, non-RCTs
	Aim of the study
	Method of data collection
	Recruitment and sampling methods
	Eligibility (inclusion and exclusion criteria)
	Type of analysis
Intervention details	CDSM programme domains
	CDSM programme dimension
	CHF programme and guidelines domains
	CHF programme and guideline dimensions
	Frequency
	Intensity
	Time after illness detected
	Type of delivery
	Duration in weeks
	Method of psychometric scoring measurement (subjective or objective)
Outcome details	List down outcome, variable type: continuous or categorical, type of analysis, effect measures with 95% CI (such as OR, risk ratio, HR) No of participants analysed, number list to follow-up
Limitations	
Others	

Congestive heart failure-specific measures are obtained from ACC/AHA published standards: (1) Measure description: Percentage of patients age ≥18 years with a diagnosis of heart failure who were provided with self-care education during ≥1 visits within a 12-month period; (2) Numerator—Patients who were provided with self-care education during ≥1 visits within a 12-month period. *Self-care education may include the following: Definition of heart failure (linking disease, symptoms and treatment) and cause of patient's heart failure; recognition of escalating symptoms and concrete plan for response to particular symptoms; indications and use of each medication; recommendations for modification of risks for heart failure progression; specific diet recommendations; individualised low-sodium diet; recommendation for alcohol intake; specific activity/exercise recommendations; importance of treatment adherence and behavioural strategies to promote treatment adherence; importance of monitoring weight daily at home; (3) Denominator: All patients age ≥18 years with a diagnosis of heart failure who were seen at least once for any visit within a 12-month period; (4) Denominator Exclusions: Heart transplant LVAD; (5) Denominator exceptions. Documentation of medical reason(s) for not providing self-care education (eg, comfort care only, dementia or cognitive impairment) Documentation of patient reason(s) for not providing self-care education (eg, patient refusal); (6) Measurement period: 12 months; (7) Sources of data her data administrative data/claims (inpatient or outpatient claims); Administrative data/claims expanded (multiple sources) paper medical record; (8) Attribution: Individual practitioner facility; (9) Care setting: Outpatient, selected inpatient programmes (adapted from reference 6 26).
ACC/AHA, American Heart Association and American College of Cardiology; CDSM, chronic disease self-management; CHF, congestive heart failure; LVAD, Left Ventricular Assist Device; RCT, randomised controlled trial.

assess risk of bias.[28] Using the risk of bias tool adapted by the EPOC Group and published by Freund.[26–30]

Measures of treatment effect

The results will be presented using a risk ratio with a 95% CI to express estimates of effects for dichotomous variables and outcomes. For continuous variables and outcomes, the results will be expressed as the mean difference with 95% CI. For outcomes measured using a variety of methods, the size of the intervention effect will be presented as standardised mean difference with 95% CI.

Dealing with missing data

In cases where trials have missing data, attempts will be made to contact the authors of individual trials for clarification or to source any missing data. Should missing data be unavailable, the following strategy that evaluates any likely influence of missing data on the overall pooled analysis will be used[25]:

1. Worst-case scenario: all participants are counted as failures.
2. Extreme worst case: experimental group participants are counted as failures and control group participants are counted as successes.
3. Extreme best case: experimental group participants counted as successes and control group participants counted as failures.

Assessment of heterogeneity

For statistical heterogeneity, we will use a χ^2 test. In addition, heterogeneity will be quantified using the I^2 statistic value ranging from 0% to 100%; $p<0.1$ of χ^2 test or $I^2>50\%$ indicates statistically significant heterogeneity. Subgroup analysis will subsequently be used to assess potential clinical heterogeneity.[25–30]

Assessment of reporting biases

Should meta-analyses include 10 or more RCTs, asymmetry will be assessed visually using funnel plots. Asymmetry will also be tested using the Harbord modified test for dichotomous outcomes and the Egger test for continuous outcomes.[25–30]

Data synthesis

If there are sufficient trials to examine the same intervention with comparable methods, in comparable populations, the trials will be combined and an estimated pooled intervention effect using meta-analysis be undertaken. Continuous data will be pooled using inverse variance method, and dichotomous data using the Mantel-Haenszel method. The fixed-effect model will be used to combine data when there is low statistical heterogeneity. However, when $p<0.1$ or $I^2>50\%$, the random-effect model will be used to provide a more conservative estimate of effect. All analyses will be performed using a specialised meta-analysis software. In the unlikely scenario of a meta-analysis not being possible, narrative summaries of individual trials will be detailed in a table format.[25–30]

Subgroup analysis and investigation of heterogeneity

The subgroup analysis is required in order to understand the heterogeneity effects if there is sufficient data. A range of variables will be explored, these include age, sex, type of HF, aetiology of HF and nature of control group (placebo, self-management intervention). The intervention effects will then be analysed using χ^2 test, with $p<0.05$, demonstrating statistically significant differences between subgroups.

Summary of findings

The 'summary of findings' will be detailed in a table format. The GRADEpro GDT will be used to grade the quality of included trials against the outcomes outlined. Two coauthors will assess the included trials against the criteria within five grades, independently. These criteria include study limitations, imprecision, inconsistency, indirectness and publication bias. In addition, trials will be rated along four categories, which include (high, moderate, low and very low). Any differences or discrepancies in grade and rating will be resolved through consensus of the authors and/or if required a third author.

Amendments

Any amendments will be documented in chronology, with changes and rationale described in detail and published for awareness of readers, in the methods section of the final output manuscript.

Patient and public involvement

No patient is involved.

Ethics and dissemination

Ethical approval is not required for the study, as no primary patient data are collected. This review will extract current and comprehensive research publications on CDSM and CHF. At this juncture it is vital to inform the literature on the efficacy of CDSM within the CHF context. It is important to plan studies to counter the downgrade of evidence and inform future guidelines. Our team will present the findings from this review at scientific conferences and also publish the findings in peer-reviewed scientific journals using the PRIMSA 2020 guidelines.[19 31]

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