




# Self-care interventions for adults with heart failure: A systematic review and meta-analysis protocol

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## Abstract

**Aim:** To synthesize and compare outcomes from controlled trials of interventions to improve heart failure self-care among adults.

**Background:** Heart failure self-care interventions are recommended for preventing and detecting exacerbations, improving symptom management and preventing hospitalizations. Little is known about the overall effectiveness of heart failure self-care programmes and which types of interventions show the greatest improvement in outcomes.

**Design:** Systematic review and meta-analysis, including moderator analyses.

**Methods:** Multiple databases (including MEDLINE/PubMed, CINAHL, PsycINFO, Scopus and Cochrane Central Register of Controlled Trials) will be searched from inception through 2018 along with grey literature searches to identify trials testing interventions to improve self-care outcomes of adults with heart failure. Data will be extracted from eligible studies on sample, methodological and intervention characteristics and data to calculate effect sizes. Data will be analysed using random-effects models. Moderator variables will be analysed with meta-regression and subgroup analyses. Risk for bias will be assessed using the Cochrane Risk for Bias tool and by examining potential sources of bias as moderator variables. Funding for this project began in July 2017.

**Discussion:** We will analyse self-care behaviour outcomes and clinical outcomes including hospitalizations, mortality, disease severity and quality of life. This will be the most extensive meta-analysis of heart failure self-care interventions to date.

## Impact:

- Comparative effectiveness of existing self-care interventions is not yet known.
- This research will identify the most promising self-care intervention components for designing better interventions and guide targeting of interventions to specific sub-populations.

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## KEYWORDS

comparative effectiveness, heart failure, intervention, meta-analysis, nursing, protocol, self-care, systematic review

## 1 | INTRODUCTION

Heart failure (HF) afflicts over 5.7 million persons in the United States and at least 23 million people worldwide (Heidenreich et al., 2013; Mozaffarian et al., 2015). HF risks are well documented and include high morbidity and mortality, frequent hospitalization, high healthcare costs, impaired functional status and poor quality of life (Gheorghide, Vaduganathan, Fonarow, & Bonow, 2013; Jaarsma, Johansson, Agren, & Stromberg, 2010; Kochanek, Murphy, Xu, & Arias, 2014; Mozaffarian et al., 2015; Riegel, Moser, et al., 2009; Roger et al., 2012; Zambroski, Moser, Bhat, & Ziegler, 2005). Although HF mortality rates have improved somewhat over the past 20 years, the improvement is small and overall deaths due to HF continue to rise (Benjamin et al., 2017). Despite many advances in HF treatment, key clinical and patient-reported outcomes such as hospitalization rates and health-related quality of life have not improved since 2000 (Mozaffarian et al., 2015).

### 1.1 | Background

HF self-care is a concept that encompasses a set of health behaviours associated with improved patient outcomes (Riegel et al., 2017). HF self-care behaviours include—but are not limited to—medication taking, exercise, diet, weight measurement, symptom recognition and response and fluid management (Riegel, Moser, et al., 2009; Yancy et al., 2013). HF treatment guidelines emphasize the need for patients to implement HF self-care strategies to achieve the best possible outcomes (Lindenfeld et al., 2010; Riegel, Moser, et al., 2009; Yancy et al., 2013). However, many patients do not successfully or reliably implement these behaviours, leading to poorer outcomes than could be attained if they were to engage in self-care.

Numerous studies have tested interventions to improve HF self-care behaviours and associated outcomes. A lack of adequate research synthesis has prevented conclusions about the comparative effectiveness of HF self-care interventions, leading to a lack of clarity in practice guideline recommendations for HF self-care (Lindenfeld et al., 2010; Yancy et al., 2013). Comparative effectiveness analyses are necessary to facilitate improved patient, provider and health system outcomes for HF.

## 2 | THE REVIEW

### 2.1 | Aims

The purpose of this systematic review and meta-analysis is to integrate scientific knowledge about interventions to enhance self-care for adult HF patients, including an understanding of which factors influence the success of interventions on self-care behavioural outcomes and on important clinical outcomes. We seek to answer the following research questions: (a) What are the overall effects of HF self-care interventions on self-care behavioural outcomes (medication adherence, exercise/physical activity, adherence to a low-sodium diet, daily weight measurement, symptom recognition, fluid

management, annual influenza vaccination and keeping appointments)? (b) What are the overall effects of HF self-care interventions on clinical outcomes (mortality, readmissions, disease severity, healthcare use and quality of life)? (c) How do intervention effects on self-care behaviour and health outcomes vary based on study design characteristics and risks of bias? (d) Are HF self-care interventions more effective for certain patient populations, based on factors such as disease severity, gender, ethnicity/race, age or prescribed drugs? (e) How do effects of interventions on self-care behaviour and health outcomes vary depending on intervention characteristics (e.g., intervention content, combination of intervention components, intervention dose and type of interventionists)?

### 2.2 | Methodology

This project will follow standard systematic review methods and use a random-effects meta-analytic approach to synthesize the review findings. Exploratory moderator analyses will be used to explain heterogeneity and generate hypotheses for further research.

#### 2.2.1 | Criteria for study selection

This project will identify studies published through 2018 of adult HF patients (aged 18 years and older) where an intervention was tested to improve a component of HF self-care. The most recent state of the science papers on HF self-care list the following health behaviours as components of HF self-care: (a) taking medication; (b) monitoring symptoms (daily body weight, dyspnoea, oedema, etc.); (c) eating a low-salt diet; (d) restricting fluids; (e) performing regular physical activity; (f) restricting alcohol intake; (g) managing body mass/weight; (h) stopping smoking or other tobacco use; (i) obtaining regular preventive care (e.g., influenza and pneumonia vaccinations, dental care and avoiding infection); (j) addressing changes in mood, depression or anxiety; (k) keeping appointments with healthcare providers and (l) recognizing and addressing changes in symptoms such as taking an additional diuretic in response to increased oedema (Riegel, Moser, et al., 2009; Riegel et al., 2017; Yancy et al., 2013). Studies we review may offer additional self-care behaviours, which we will add to the codebook and include in the data set.

Studies of cognitively impaired and/or institutionalized individuals will be excluded due to many of their HF self-care behaviours being managed or controlled by others. Only two-group (controlled) trials will be included in the meta-analysis. We will only include studies published in English; however, we will also include non-English studies if they have an English-language version of the abstract containing sufficient data for effect size (ES) calculation.

#### 2.2.2 | Search strategy for identification of studies

Initial searches will be designed by an expert health sciences librarian to search computerized databases (including MEDLINE/PubMed, CINAHL, PsycINFO, Scopus and Cochrane Central Register of Controlled Trials) from inception through 2018. A draft search strategy is

**TABLE 1** MEDLINE search strategy

1	exp heart failure/
2	((heart or cardiac) adj failure) or Congestive heart).mp.
3	self care/or self administration/or self examination/
4	(self care or selfcare or Self monitoring or Self management or Self administration).mp.
5	(1 or 2) and (3 or 4)
6	limit 5 to systematic reviews
7	(randomized controlled trial or clinical study or clinical trial or clinical trial phase i or clinical trial phase ii or clinical trial phase iii or clinical trial phase iv or comparative study or controlled clinical trial or evaluation studies or meta analysis or multicenter study or observational study or pragmatic clinical trial).pt.
8	5 and 7
9	((systematic or integrative or umbrella) adj3 review).mp.
10	(metaanaly\$ or meta analy\$).mp.
11	(evidence adj3 synthesis).mp.
12	pooling project.mp.
13	(rapid adj1 review).mp.
14	best practice\$.ti. or evidence synthesis.mp. or best evidence.mp.
15	(medline or pubmed or cinahl or embase or psycinfo or scopus or cochrane).ab.
16	((review\$ or search\$) adj10 (literature or database\$ or systematic\$)).mp.
17	or/9-16
18	5 and 17
19	self care/or self administration/or self examination/
20	(self care or selfcare or Self monitoring or Self management or Self administration).mp.
21	medication adherence/or patient compliance/or treatment refusal/or patient dropouts/
22	((treatment\$ or regimen or medication\$ or patient\$) adj3 (complan\$ or adher\$ or noncomplan\$ or nonadher\$)).mp.
23	(taking adj1 (medication\$ or medicine\$)).mp.
24	((fill\$ or unfill\$) adj prescription\$).mp.
25	Health Knowledge, Attitudes, Practice/
26	exercise/or exertion/or muscle stretching exercises/
27	physical conditioning, human/
28	plyometric exercise/or running/or jogging/or swimming/or walking/or stair climbing/or warm-up exercise/
29	physical fitness/
30	exp sports/or "Physical Education and Training"/
31	exercise therapy/
32	healthy lifestyle/or life style/or drinking behavior/
33	diet, sodium-restricted/or caloric restriction/or diet, reducing/
34	healthy diet/or energy intake/or exp diet/or feeding behavior/
35	Weight Reduction Programs/
36	oral hygiene/or toothbrushing/
37	patient participation/or refusal to participate/or patient acceptance of health care/

(Continues)

**TABLE 1** (Continued)

38	primary prevention/or secondary prevention/or immunization/or vaccination/or pneumococcal vaccines.mp.
39	vaccination refusal/
40	(37 and 38) or 39
41	affect/or irritable mood/or depression/or anxiety/
42	alcohol drinking/or alcohol abstinence/or temperance/
43	smoking cessation/or smoking/pc
44	"Tobacco Use Cessation"/or Tobacco/or "Tobacco Use"/
45	smoking/
46	health behavior/
47	((low adj (salt or sodium) adj diet\$) or dash diet\$).mp.
48	((salt or sodium) adj free adj diet\$).mp.
49	((fluid\$ or sodium or salt) adj3 (intak\$ or restrict\$)).mp.
50	diet.hw. or (diets or dieting).mp.
51	((daily adj weigh\$) or (weight adj1 monitor\$)).mp.
52	((symptom or side effect\$) adj (manag\$ or monitor\$)).mp.
53	(annual adj3 (vaccination\$ or immunization\$ or immunisation\$ or shot or shots)).mp.
54	((annual or regular) adj3 (dental or dentist)).mp.
55	((keep\$ or kept or miss or missed or missing or cancel\$) adj3 appointment\$).mp.
56	(Dnka\$ or noshow\$ or no show\$1).mp.
57	((alcohol\$ adj3 (intak\$ or restrict\$ or abstain\$ or abstin\$)) or drinking behavior\$).mp.
58	((quit\$ or stop\$ or abstain\$ or abstinen\$) adj3 (smoking or tobacco)).mp.
59	(Healthy adj (eat\$3 or diet\$ or habit\$ or behav\$)).mp.
60	"TREATMENT ADHERENCE AND COMPLIANCE"/
61	smoking reduction/
62	vaccination coverage/
63	tobacco smoking/or cigar smoking/or water pipe smoking/or cigarette smoking/or smoking, non-tobacco products/
64	or/19-63
65	intervention\$.mp.
66	(motivational adj (interview\$ or counsel\$)).mp.
67	motivational interviewing/
68	nondirective therapy/
69	action plan\$.mp.
70	(barrier\$ adj2 manag\$).mp.
71	biofeedback, psychology/
72	biofeedback.mp.
73	feedback, psychological/
74	feedback.mp.
75	behavior therapy/
76	applied behavior analysis/
77	cognitive remediation/
78	exp cognitive therapy/
79	mindfulness/

(Continues)

**TABLE 1** (Continued)

80	relaxation therapy/
81	meditation/
82	exp psychotherapy/
83	(substitut\$ adj behavio\$).mp.
84	contingenc\$.mp.
85	"Reinforcement (Psychology)"/
86	patient education as topic/
87	incentiv\$.mp.
88	goals/
89	(goal\$1 adj3 setting).mp.
90	reward/
91	thought restructuring.mp.
92	cues/
93	house calls/
94	(home adj2 (tele\$ or visit\$ or monitoring)).mp.
95	education.mp. or ed.fs.
96	telehealth.mp.
97	calendars as topic/
98	product packaging/
99	product labeling/
100	drug packaging/or drug labeling/
101	habit formation.mp.
102	exp social support/
103	self-help groups/
104	exp peer group/
105	support group\$.mp.
106	mentoring/or mentors/
107	(mentoring or coaching).mp.
108	teach-back communication/
109	psychotherapy, group/
110	group therap\$.mp.
111	Directive Counseling/or Counseling/or Distance Counseling/
112	(counseling or counselling).mp.
113	((phone adj call\$) or phonenumber\$).mp.
114	(Telephone adj (support or call\$)).mp.
115	negotiating/or persuasive communication/or reminder systems/or social networking/
116	correspondence as topic/or electronic mail/or postcards as topic/ or text messaging/
117	program\$.mp.
118	disease management.mp.
119	case manage\$.mp.
120	navigator\$.mp.
121	((pharmac\$ or nurs\$) adj led).mp.
122	contracts/
123	training.mp.
124	(ehealth or e health).mp.

(Continues)

**TABLE 1** (Continued)

125	home care.mp.
126	Dietary Approaches To Stop Hypertension/
127	obesity management/
128	wearable electronic devices/or fitness trackers/
129	Stakeholder Participation/
130	or/65-129
131	(1 or 2) and 64 and 130
132	6 or 8 or 18 or 131

reported in Table 1. We will then conduct ancestry searches using the reference lists of eligible studies and review articles and search the tables of contents for the past 10 years in journals that published eligible studies. We will use Scopus to search for additional publications by the first and senior authors of eligible studies. Including these additional search strategies yields more eligible studies than relying solely on computerized database searching (Morrisey & DeBourgh, 2001).

We will also search for unpublished studies, as the primary difference between published and unpublished studies is not their methodological quality, but rather the significance of the results. These searches will include searches of research registries (e.g., clinicaltrials.gov) and conference abstracts to identify unpublished studies. Using multiple and diverse search strategies helps to avoid bias in meta-analysis results (Helmer, Savoie, Green, & Kazanjian, 2001; McAuley, Pham, Tugwell, & Moher, 2000; Sindhu & Dickson, 1997a, b). All citations from searches will be managed using an EndNote database to facilitate screening of titles and abstracts.

### 2.2.3 | Trial eligibility and methodological quality assessment

Initial search results will be screened by two members of the research team. In this screening, titles and abstracts will be read to evaluate whether the study includes an intervention to improve an aspect of HF self-care. Any possibly eligible citations will be marked for full-text retrieval. The full text of possibly eligible studies will then be reviewed and for non-eligible studies, the reasons for ineligibility will be noted in the study tracking database. A study will not be excluded until it is clear that it does not fulfil inclusion criteria. Likewise, any study that appears to lack sufficient data to calculate an effect size will not be excluded until completing all searches for other publications on the same study and contacting the study authors to request additional data.

Study quality will be addressed in two ways. First, two members of the research team will independently evaluate eligible studies using the Cochrane Collaboration's Risk for Bias tool, which permits grading each domain of potential bias as "low risk," "high risk" or "unclear risk" (Higgins et al., 2011). Second, we will consider methodological quality as an empirical question, coding data about aspects of study quality and potential risks for bias, and then analysing that data in moderator analyses to see whether potential risks for bias are significantly related to study effect size.

## 2.2.4 | Data collection and validation

Data will be independently extracted by two coders, who will then make data comparisons until 100% agreement is reached on every coding item. Electronic coding forms and databases will be used to reduce errors and facilitate data comparison to check for accuracy. The data extraction codebook is based on a structure used in prior meta-analyses and has been pilot tested. Intervention components will be coded using the Behavior Change Technique Taxonomy (Michie et al., 2013) to facilitate interpretation across other studies and reviews.

## 2.2.5 | Outcome measures

We will conduct a series of meta-analyses on multiple behavioural outcomes: medication adherence, exercise/physical activity, adherence to a low-sodium diet, daily weight measurement, symptom recognition, fluid management, annual influenza vaccination and adherence to clinic appointments. Some of these behavioural outcomes will be more frequently reported than others across studies and some may only be captured in more global HF self-care measures, such as the Self-Care of Heart Failure Index (Riegel, Lee, Dickson, & Carlson, 2009).

We will also extract data on the following clinical outcomes: mortality, readmissions, disease severity, healthcare use and quality of life. Similar to the behavioural outcomes, not all clinical outcomes will necessarily be reported across all studies, so the final list of outcomes to be analysed will be determined by the extent of the reported and usable data.

## 2.2.6 | Data analysis

Descriptive statistics will be calculated using SPSS to report characteristics of the studies, samples and interventions. We will then use Comprehensive Meta-Analysis software (Biostat, Inc., Englewood, NJ, USA) to calculate an ES for each codable outcome from each study, using standardized mean difference for continuous variables and relative risk for dichotomous events. When results from the same study are reported across multiple papers, we will group them as companion papers and report the results as a single study. When studies report multiple intervention groups, we will code the intervention groups as separate comparisons. If needed and appropriate, data from multiple intervention groups in the same study may be combined into a single pair-wise comparison for analysis (Higgins & Green, 2011).

Mean ES across studies will then be calculated, including heterogeneity statistics ( $Q$  and  $I^2$ ), using a random-effects model. The random-effects model is appropriate for these analyses due to the expected variation in interventions and samples found across HF self-care intervention studies. Separate meta-analyses will be conducted for each type of outcome. Potential outliers will be identified graphically using forest plots and statistically by checking for large standardized residuals. We will then conduct meta-regression and

sub-group analyses to investigate the impact of differences in intervention types, patient demographics and study designs on ES.

## 2.2.7 | Analysing and mitigating risks for bias

Whether publication bias is present will be assessed visually by examining funnel plots and statistically using Egger's test (Egger, Davey Smith, Schneider, & Minder, 1997; Higgins & Green, 2011). Each ES will be weighted by the reciprocal of its sampling variance to give larger sample sizes more influence in the meta-analyses.

Studies will be carefully evaluated to avoid including the same study more than once in any meta-analysis. For instance, when the same author is included on multiple publications, the study characteristics (methods, sample sizes) will be compared to determine whether the publications are reporting separate studies or are companion papers reporting different analyses (i.e., time points, sub-groups) of the same sample of patients.

## 2.3 | Ethical considerations

This research is being conducted using meta-analysis methods with existing trial data. The analyses will not include any identifiable patient data. Ethical committee approval was not required for this research.

## 2.4 | Validity, reliability and rigour

The project will be implemented using best practices in systematic review and meta-analysis methods (Borenstein, Hedges, Higgins, & Rothstein, 2009; Cooper, 2010). Results will be reported according to the PRISMA guidelines for reporting the results of systematic reviews and meta-analyses (Moher, Liberati, Tetzlaff, & Altman, 2009).

## 3 | DISCUSSION

This comparative effectiveness study will allow us to identify the most promising targets for intervention development to improve HF self-care and related outcomes. Not only will the planned moderator analyses identify the most effective intervention components, but we will also be able to explore how intervention efficacy may vary for different patient populations. While this project will use aggregated retrospective data, large meta-analyses can compare the effectiveness of different approaches at far less cost than a prospective trial designed to compare multiple interventions.

### 3.1 | Limitations

Any systematic review and meta-analysis is limited by the number of available studies on the topic, the level of detail about interventions in the study reports and the types of data reported for calculating effect sizes. We will make every effort to include all eligible studies

and will contact the authors of primary studies that do not report sufficient data for effect size calculation.

## 4 | CONCLUSION

This meta-analysis will compare the efficacy of HF self-care interventions, providing data on which intervention components are associated with the greatest improvement in outcomes and which patient populations are more likely to respond to certain types of interventions. Results from this project will contribute to the development of targeted interventions for specific patient groups. Furthermore, the findings may shed light on the relative usefulness of different intervention components for assisting patients with self-care behaviour change and achieving desired clinical outcomes.

## CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

## AUTHOR CONTRIBUTIONS

TR, PC, EJ and BR made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data. TR, PC, EJ and BR were involved in drafting the manuscript or revising it critically for important intellectual content and gave final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. TR, PC, EJ and BR agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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