

Effectiveness of patient-centered self-care education for adults with heart failure on knowledge, self-care behaviors, quality of life, and readmissions: a systematic review protocol

Yves E Casimir, MSN, RN, NP-C¹

Marvelin M Williams, MSN, RN, FNP¹

Mei Y Liang, MSN, RN, FNP¹

Supawadee Pitakmongkolkul, MSN, RN, NP-C¹

Jason T Slyer, DNP, RN, FNP-BC, CHFNP²

1.College of Health Professions, Pace University, New York, NY

2.College of Health Professions, Pace University, New York, NY; The Northeast Institute for Evidence Synthesis and Translation (NEST) at Pace University – Lienhard School of Nursing

Corresponding author:

Yves Casimir,

email: yc98460n@pace.edu

Review objectives

The objective of this review is to synthesize the best available evidence regarding the effectiveness of patient centered self-care education for adult patients with heart failure relating to heart failure knowledge, self-care behaviors centered on heart failure, heart failure-related quality of life, and heart failure readmissions within one year of an index hospitalization.

A secondary objective of this review is to determine the most effective education approach for interventions included in the review to deliver patient-centered self-care education to adult patients with heart failure.

Background

Over the last decade, heart failure (HF) has become a growing epidemic.¹ Currently, HF impacts over 5.7 million people in the United States;¹ more than 15 million people in Europe,² approximately 500,000 people in Canada,³ and 277,800 people in Australia.⁴ Despite evidence-based therapies in HF, the prevalence, incidence, and mortality have progressively increased

over the past 25 years.⁵ The projected HF prevalence in 2030 is expected to further increase by 25 %.⁶

HF is a complex clinical syndrome that is caused by cardiac dysfunction either in systole, diastole, or both, resulting in impairment of the left ventricle causing dilatation, hypertrophy, or both.⁷ The symptoms of HF are characterized by dyspnea, fluid retention, edema and fatigue.⁷ HF is associated with adverse outcomes, including high rates of hospitalization, readmission, and mortality, in addition to poor quality of life. Noncompliance with a complex medical regimen, sodium and fluid restriction, lifestyle recommendations, a lack of understanding of the HF disease process, and a lack of knowledge about signs and symptoms related to decompensation can lead to recurrent worsening of HF symptoms, hospital readmission, and impaired quality of life.^{8,9}

HF is the most common disease resulting in hospital admission for patients who are 65 years and older.⁹ Hospital readmission is the consecutive admission to the same hospital, a different hospital, or another acute care facility related to a specific condition for which treatment was rendered on a previous hospitalization.¹⁰ Approximately 25% of patients with HF are readmitted within 30 days following hospital discharge, and 50% are readmitted within 6 months of discharge.^{9,11} The 30-day hospital readmission rate for patients with HF in the United States is currently reported to be 24.7%.¹⁰ These high rates of readmission are capturing attention as subsequent hospitalizations lead to worsening morbidity and mortality, decreased quality of life, and increase costs of care. Readmissions may be secondary to improper or ineffective treatments, the education strategy used, a lack of patient participation in the medical regimen, the lack of knowledge related to or the inability to perform self-care behavior, or the failure on the part of the patient to take action in order to prevent further decompensation.¹²

Patient education is necessary for the effective management of HF symptoms.¹³ The evidence-based practice guidelines from the American College of Cardiology/American Heart Association (ACC/AHA),¹⁴ the Heart Failure Society of America (HFSA),⁷ and the European Society of Cardiology (ESC)² recommend that patients with HF receive individualized education and counseling, placing emphasis on self-care. It has been shown that hospitalized patients with HF who received HF education had a 20% improvement in medication compliance after one year.¹⁵ Intensive, systematic, tailored, and planned education and support has been shown to be effective in improving self-care behaviors in patients with HF.¹⁶

The aim of HF patient education is to provide information that assists in acquiring the knowledge and skills necessary to understand and manage their condition. The components of HF patient education as outlined by current practice guidelines from ACC/AHA, HFSA, and ESC include the following: (a) an understanding of the causes of their HF; (b) medication indications; (c) the important of medication adherence; (d) potential causes of HF decompensation; (e) recognition of escalating symptoms; (f) HF disease management strategies; (g) low sodium diet; (h) restriction of alcohol intake; (i) restriction of fluid intake; (j) smoking cessation; (k) physical activity; (l) behavioral strategies to promote treatment adherence; and (m) the need for ongoing follow-up with a health care provider.^{2,7,14} HF education has been demonstrated to empower patients to

take care of themselves, prevent and manage symptoms, prevent hospital readmission, reduce morbidity and mortality, reduce cost, and improve quality of life.^{17,18}

HF education focused around symptom management is an essential component to improve patient outcomes. It includes the need for patients to understand the signs and symptoms to HF; recognize a new onset of symptoms or change in symptoms (such as weight gain greater than two pounds within two days or five pounds within one week, worsening shortness of breath, chest pain, edema, abdominal bloating, or fatigue); understand the importance of daily weights; and associate weight gain with volume overload and worsening HF. Patients need to understand how to respond to a change in symptoms, which at a minimum should include contacting their health care provider. HF patient education should also include information about the importance of medication adherence (consistently taking medication as prescribed), adjusting diuretics based on weight, maintaining a balanced exercise regime, sleep and rest cycles, and adhering to smoking cessation.¹⁹ Providing individualized education to patients with HF may aid in their understanding of the treatment plan and incorporation of self-care behaviors into daily routines.

The Institute of Medicine defines patient-centered care as the provision of care that is respectful and responsive to a patient's preferences, needs, values, and perceives patients as leaders of their clinical care.²⁰ It is important to understand how patients view their health and what outcomes they deem to be important. A core tenet of patient-centered care is that patients manage their own care, while collaborating with the health care team in making treatment decisions.²¹ Patient-centered care is the right care, the highest quality care, and the most cost effective care for a patient; provided through a team approach.²² Patient-centered care depends upon effective communication, empathy, and the development of a partnership between providers and the patient to improve patient care outcomes.²³ The Institute of Medicine recommends the inclusion of a patient's cultural traditions, preference, values, social circumstances, and lifestyle into the patient-centered approach to care.²⁰ Patient-centered care represents a care approach strategy geared towards meeting individual patient's needs and preferences as part of the treatment plan to achieve desired outcomes.²⁴ Patient-centered care focuses on the patient, not the disease, while empowering individual patients to become knowledgeable and more informed about their diagnosis, successfully manage their symptoms, and engage in self care behaviors.

Self-care is the process in which individuals perform daily activities to maintain health.²⁵ Self-care includes the activities that individuals, families, and communities undertake with the intention of enhancing health, preventing disease, limiting illness, and restoring health.²⁶ Appropriate self-care can minimize potential health problems, improve quality of life, and decrease costs in patients with HF.²⁷ Self-care includes the principles of self-maintenance and self-management.²⁵ HF self-maintenance is the ability of the individual patient to adhere to prescribed treatments while monitoring and recognizing symptoms of decompensation.²⁸ HF self-management involves patients who are active in the management of their condition and make appropriate adjustments to their self-care behaviors or treatment plan based on self-assessment.²⁸ Self-management is the process by which a patient utilizes obtained knowledge and skills to maintain a sense of wellness.²⁸ These skills include coping with lifestyle changes necessary to be successful at living with a chronic condition, as well as having the ability to adjust and work through physical and

emotional challenges while engaging in a daily routine to manage care needs at an optimal level.²⁹

The goal of patient-centered self-care education is to inform and increase a patient's knowledge and self-care capabilities using an individualized approach in an effort to achieve desired outcomes: improved HF knowledge, improved self-care behaviors, improved quality of life, and reduced readmissions. HF education is the provision of information on HF to improve knowledge, clinical outcomes, patient's overall cardiac status, functional capacity, and quality of life, as well as to reduce mortality.⁷ A patient's HF knowledge can be measured by valid and reliable instruments such as the Atlanta Heart Failure Knowledge Test (A-HFKT).³⁰

Self-care behaviors include medication adherence, symptom monitoring, dietary adherence, fluid restriction, weight monitoring, smoking cessation and management of symptoms.¹⁸ Self-care behavior can be measured by valid and reliable instruments such as the Self-Care Heart Failure Index (SCHFI),³¹ or the European Heart Failure Self-Care Behavior Scale (EHFScBS).³²

Quality of life represents the interpretation of the ease with which patients are able to cope with the impact of a disease on a daily basis and maintain a normal lifestyle. Quality of life refers to a patient's perception of health and the impact of treatment on health status.³³ Quality of life can be measured by valid and reliable instruments such as the generic Short Form 36 (SF-36),³⁴ or HF specific instruments such as the Minnesota Living with Heart Failure Questionnaire (MLHFQ),³⁵ or the Kansas City Cardiomyopathy Questionnaire (KCCQ).³⁶

Hospital readmission is defined as the consecutive unplanned or planned admission to the same hospital or another acute care hospital related to a previous hospitalization regarding a specified condition.¹⁰ Patients are typically tracked at discharge, and each readmission for any cause within a prescribed time period is tallied.

A search of Joanna Briggs Institute Library (the Database of Systematic Reviews and Implementation Reports), the Cochrane Library of Systematic Reviews, MEDLINE, and CINAHL for previously conducted systematic reviews identified six prior systematic reviews related to education for patients with HF.^{12,17,18,37-39} These reviews look at HF education interventions in general; none looked specifically at patient-centered, self-care education interventions. See Appendix I for details on the objectives, methods, results and conclusion of the identified systematic reviews. The identified systematic reviews contained studies published through 2010. None of the prior systematic reviews used a comprehensive search strategy; they included a search of grey literature to uncover all evidence related to the question asked and reduce the risk of publication bias. The current review will seek to identify all studies that evaluate the effectiveness of patient-centered, self-care education compared with general, non-individualized education strategies for adult patients with HF, while identifying any additional evidence created since the prior systematic reviews were conducted. This review will look specifically at the effects of patient-centered, self-care education on HF knowledge, self-care behaviors, quality of life, and readmissions. In addition, this review will seek to determine the most effective approach at delivering patient-centered, self-care education to adult patients with HF.

Keywords

heart failure, patient education, patient-centered care, readmission, self-care, heart failure knowledge, quality of life

Inclusion criteria***Types of participants***

This review will consider studies that include all adult patients, 18 years and older, of any race, ethnicity, or gender with a diagnosis of HF regardless of etiology, severity, duration of HF, or presence of comorbid conditions.

Type of intervention

This review will consider all types of patient-centered, self-care education interventions for adult patients with HF provided by any health care provider, regardless of frequency, duration and intensity. For this review, patient-centered, self-care education interventions are defined as interventions designed towards the patient as a unique individual, taking into consideration a patient's individual needs, preferences and values. The patient is the central focus of the planned intervention with a goal of meeting patient specific self-care educational goals and desired outcomes.

Comparator intervention

This review will consider as comparators standard care or non-patient-centered education programs such as written or video taped education materials that have not been individualized to a patient's specific needs, preferences or values.

Types of outcomes

This review will consider studies that include the following outcomes as measured by valid and reliable instruments within one year post-intervention:

- Heart failure knowledge such as knowledge related to the general pathophysiology of HF, treatment strategies, and signs/symptoms of HF as measured by valid and reliable instruments such as the Atlanta Heart Failure Knowledge Test (A-HFKT).
- Heart failure self-care behaviors including, but not limited to, HF management, symptom monitoring, and implementation of treatment strategies as measured by valid and reliable instruments such as the Self-Care Heart Failure Index (SCHFI) or the European Heart Failure Self-Care Behavior Scale (EHFScBS).
- Heart failure-related quality of life related to areas such as maintaining physical activity and exercise, symptom burden, self-efficacy, and maintaining social interaction and support, as measured by valid and reliable instruments such as the generic Short Form

36 (SF-36), or HF specific instruments such as the Minnesota Living with Heart Failure Questionnaire (MLHFQ) or the Kansas City Cardiomyopathy Questionnaire (KCCQ).

- Heart failure admissions or readmissions within 1 year post intervention. For this review, hospital readmission is the consecutive admission to the same hospital, a different hospital, or another acute care facility related to a specific condition for which treatment was rendered on a previous hospitalization.

Types of studies

The review will consider randomized controlled trials (RCTs); in the absence of RCTs other research designs, such as non-randomized controlled trials, observational studies, or descriptive and case studies will be considered for inclusion to enable the identification of current best evidence regarding the effectiveness of patient-centered self-care education for adult patients with HF.

For this review, non-randomized controlled trials refer to a study design where participants have been allocated to intervention and control groups by a method that is not random, and therefore, does not meet the criteria for a true experimental design. Non-randomized controlled trials are used when random allocation may reduce the effectiveness of the intervention, and when the intervention depends on the participant's active participation which is influenced by the participant's beliefs and preferences.⁴⁰

Search strategy

The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe an article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in the English language will be considered for inclusion in this review.

The concept of patient-centered care was highlighted by the 2001 Institute of Medicine report, *Crossing the Quality Chasm*.⁴¹ This reports calls for the delivery of care that is not only safe and effective but is guided by patient's preferences, needs, and values. Since its publication, hospitals have incorporated patient-centered care into their healthcare delivery systems.⁴² In addition, the prior systematic reviews outlined above on general HF patient education interventions identified studies published beginning in the 1990s. Therefore, this review will consider studies published

from 1990 through to the current date of the review for inclusion to identify the best evidence regarding the effectiveness of patient-centered self-care interventions for patients with HF.

The databases to be searched include:

PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Excerpta Medica Database (EMBASE), PsycINFO, Cochrane Central Register of Controlled Trials (CENTRAL), Education Resources Information Center (ERIC), Health Source: Nursing/Academic Edition, Scopus, DynaMed

The search for unpublished studies will include:

New York Academy of Medicine, ProQuest Dissertations & Theses, ClinicalTrials.gov, Google Scholar, Virginia Henderson International Nursing Library, World-Cat, and websites for:

Heart Failure Society of America and American Association of Heart Failure Nurses

Initial keywords to be used:

heart failure, patient education, patient-centered care, readmission, self-care, heart failure knowledge, quality of life

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix II). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data collection

Data will be extracted from papers included in the review by two independent reviewers using the standardized data extraction tool from JBI-MAStARI (Appendix III). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

Data synthesis

Quantitative data will, where possible be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratios (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and also explored using subgroup analyses based on the different study designs included in this review. Where statistical pooling is not possible the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

Conflicts of interest

None to disclose.

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Appendix I: Characteristics of prior systematic reviews examining heart failure patient education

Author (Year)	Barnason, Zimmerman, and Young, 2011³⁸
Review objective	To determine the effectiveness of interventions to improve heart failure self-care and patient related factors; such as knowledge about heart failure, self-efficacy for heart failure self-care, and beliefs regarding heart failure self-care.
Methods	Database searched: MEDLINE, PsycINFO, Cochrane database of clinical trials, and CINAHL. Years searched: 2000-2010. Critical appraisal of included studies not performed.
Inclusion criteria	Non-pharmacological interventions to improve self-care in patients with heart failure. Both treatment and control groups received standard heart failure education. Measured self-care or other patient-related factors associated with self-care. Studies written in the English language and published between 2000-2010.
Number of included studies	19 randomized controlled trials.
Author's conclusions	Cognitive-behavioral interventions were the most frequently used method to improve self-care behaviors. Findings demonstrated increased knowledge among intervention group participants, supporting the efficacy of augmenting standard heart failure patient education.
Difference between review and current protocol	The review focused on any interventions to improve self-care of patients with heart failure including self-maintenance, self-management behaviors, self-monitoring of patients, and patient-related factors. The proposed review will focus specifically on heart failure education interventions that are patient-centered.

Author (year)	Boren, Wakefield, Gunlock, and Wakefield, 2009³⁹
Review objective	To identify educational content and techniques that led to successful patient self-management and improved outcomes in heart failure education programs. To determine what outcome measures are used to evaluate the effectiveness of education.
Methods	Databases and years searched: MEDLINE (1966-2007), CINAHL (1982-2007) and the Cochrane Central Register of Controlled Trials (last quarter

	2007). The Jadad Scale was used to assess the quality of included papers.
Inclusion criteria	Self-management education program with patient specific outcome measures. The study authors identified no specific outcomes measures, as one purpose was to determine what outcomes measures were in use to evaluate education programs. Studies written in the English language.
Number of included studies	35 randomized controlled trials.
Author's conclusions	This systematic review supports the benefits of education interventions in heart failure management. Verbal teaching supplemented with written materials was the method used in 34 of the included studies. The most common topics reviewed were medications and side effects, as well as symptom monitoring and management. Knowledge and behavior improved in most studies.
Difference between review and current protocol	This review focused on knowledge and disease management interventions in general. While this review looked at patient-specific outcome measures, the interventions included were not specifically patient-centered. The proposed review will focus on patient-centered interventions aimed to provide the necessary knowledge and skills that would meet specific patient needs related to heart failure care management as opposed to provider decisions tailored towards meeting heart failure educational needs for individual patients.

Author (year)	Boyde, Turner, Thompson, and Stewart, 2011¹⁷
Review objective	To systematically review educational interventions that have been implemented for heart failure patients and assess their effectiveness.
Methods	Database searched: CINAHL, MEDLINE, PsycINFO, EMBASE, and the Cochrane Library. Years searched: 1998-2008. Authors did not specify any language restrictions. Critical appraisal of included studies not performed.
Inclusion criteria	Heart failure educational interventions defined as pre-specified learning activities where the educational interventions were evaluated either directly by knowledge or self-care abilities, or indirectly by readmission rates, mortality, or quality of life.
Number of included studies	19 randomized controlled trials.

<p>Authors' conclusions</p>	<p>15 of the included studies demonstrated an improvement in the outcome measured after implementation of the heart failure education strategy. Educational interventions varied considerably in delivery methods and duration, as well as the outcome measures that were used for the evaluation. One-on-one education interventions were most common. Verbal teaching was the most common but least effective method. Verbal teaching should be combined with another method to provide reinforcement. Four studies included a patient assessment prior to employing the education strategy. A patient-centered approach to education based on educational theory and evaluated appropriately may assist to develop an evidence base for patient education.</p>
<p>Difference between review and current protocol</p>	<p>This review focused on general educational intervention approaches such as written materials, a multi-disciplinary team approach, and group sessions. The proposed review will focus on patient-centered educational interventions in the promotion of heart failure self-care as priority over provider determined interventions in meeting specific patient's educational needs.</p>

<p>Author (year)</p>	<p>Ditewig, Blok, and van Veenendaal, 2010³⁷</p>
<p>Review objective</p>	<p>To examine the effectiveness of self-management interventions compared to usual care on mortality, all-cause hospital readmissions, heart failure hospitalization rate, and quality of life in patients with heart failure.</p>
<p>Methods</p>	<p>Databases searched: MEDLINE, CINAHL, EMBASE and the Cochrane Library. Years searched: 1996-2009. The Delphi list of randomized controlled trials was used to assess the quality of included papers.</p>
<p>Inclusion criteria</p>	<p>Studies evaluating heart failure self-management interventions compared to usual care. Outcome measures: mortality, all-cause hospital readmission, heart failure hospitalization rate, and quality of life. Language restriction did not apply.</p>
<p>Number of included studies</p>	<p>19 randomized controlled trials.</p>
<p>Author's conclusions</p>	<p>Heart failure self-management programs, as part of a multifaceted heart failure program, demonstrated a positive effect on readmissions, mortality, and quality of life. Ten of the included studies contained interventions that empowered patients to perform self-monitoring; however, outcomes directly related to this component were not reported. Included studies demonstrate methodological shortcomings impairing validation of the effectiveness of one specific self-management intervention on outcomes for patients with heart failure.</p>

Difference between review and current protocol	This review looked at the effectiveness of self-management interventions as part of multifaceted heart failure programs in patients with heart failure, The effectiveness of the comprehensive programs on outcome measures were assessed. The proposed review will focus specifically on the effectiveness of patient-centered self-care education for adults with heart failure on knowledge, self-care behaviors, quality of life, and readmissions.
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Author (year)	Fredericks, Beanlands, Spalding, and Da Silva, 2010¹⁸
Review objective	To determine what approach, mode, and dose is most effective in producing changes in heart failure patient education.
Methods	Databases searched: CINAHL, MEDLINE, the Cochrane Library, EMBASE, HEALTHSTAR. Years searched: 1986-2008. Critical appraisal of included studies not performed.
Inclusion criteria	Educational Intervention involving the provision of self-care information to adult patients with heart failure. The outcomes assessed were related to self-care knowledge, self-care behaviors, and experience of symptoms. Studies published in the English language from 1986-2008.
Number of included studies	47 randomized controlled trials and 22 quasi-experimental studies.
Authors' conclusions	The most effective means of delivery of heart failure patient education is through individualized education using a combination of media on a one-to-one basis over multiple sessions.
Difference between review and current protocol	This review focused on the most effective teaching method of heart failure patient education such as individualized education, combined teaching methods, one-to-one teaching method, and in multiple sessions of patient education. The proposed review will look specifically at patient-centered interventions focusing on heart failure education to improve knowledge, quality of life, self-care behaviors, and readmission.

Authors (year)	Yehle and Plake, 2010¹²
Review objective	To better understand how to structure educational interventions for heart failure patients to improve self-efficacy for self-care behaviors.

Methods	Databases searched: PUBMED, MEDLINE, CINAHL, the Cochrane Library, ERIC, Academic Search Premier, Health Sources: Nursing/Academic Edition. Years searched: 1996- 2009. Studies written in the English language. Critical appraisal of included studies not performed.
Inclusion criteria	Educational interventions for patients with heart failure that assessed self-efficacy as an outcome. Studies published in English language. Dissertations and non peer-reviewed studies were excluded.
Number of included studies	Nine randomized controlled trials, two treatment only studies, one cross-sectional study.
Authors' conclusions	The included studies confirmed that self-efficacy is an important component of interventions to improve self-care. No one approach to enhance self-efficacy was identified. One on one interventions reported improved self-efficacy in nine of the included studies. None of the included studies described specific components of the intervention that could impact self-efficacy.
Difference between review and current protocol	This review focused on standard heart failure education including information about heart failure, symptoms, medication, exercise, diet, fluid restriction, and activities. This review concluded that it is not the amount of education that improves self-efficacy but some other factors that may include ones unknown at the present time. The proposed review will evaluate patient-centered approaches to self-care education for patients with heart failure.

Appendix II: Appraisal instruments
MAStARI appraisal instrument

JBIR Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer ----- Date -----

Author ----- Year ----- Record Number -----

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were participants blinded to treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Was allocation to treatment groups concealed from the allocator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Were those assessing outcomes blind to the treatment allocation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Were the control and treatment groups comparable at entry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were groups treated identically other than for the named interventions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in the same way for all groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include Exclude Seek further info.

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer Date

Author Year Record Number

	Yes	No	Unclear	Not Applicable
1. Was study based on a random or pseudo-random sample?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Were the criteria for inclusion in the sample clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Were confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Were outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If comparisons are being made, was there sufficient descriptions of the groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include Exclude Seek further info

Comments (Including reason for exclusion)

JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

Reviewer Date

Author Year Record Number

	Yes	No	Unclear	Not Applicable
1. Is sample representative of patients in the population as a whole?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are the patients at a similar point in the course of their condition/illness?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has bias been minimised in relation to selection of cases and of controls?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are confounding factors identified and strategies to deal with them stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Are outcomes assessed using objective criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Was follow up carried out over a sufficient time period?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Were the outcomes of people who withdrew described and included in the analysis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Were outcomes measured in a reliable way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Was appropriate statistical analysis used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall appraisal: Include Exclude Seek further info.

Comments (Including reason for exclusion)

Appendix III: Data extraction instruments
MAStARI data extraction instrument

**JBI Data Extraction Form for
 Experimental / Observational Studies**

Reviewer Date

Author Year

Journal Record Number

Study Method

RCT Quasi-RCT Longitudinal

Retrospective Observational Other

Participants

Setting _____

Population _____

Sample size

Group A _____ Group B _____

Interventions

Intervention A _____

Intervention B _____

Authors Conclusions: _____

Reviewers Conclusions: _____

Study results

Dichotomous data

Outcome	Intervention () number / total number	Intervention () number / total number

Continuous data

Outcome	Intervention () number / total number	Intervention () number / total number