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HOME-BASED REHABILITATION OF PATIENTS WITH HEART FAILURE: EVIDENCE, SELF-CARE AND HEALTH STATUS

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Home-based rehabilitation of patients with heart failure: Evidence, Self-care and Health Status

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“Nursing and rehabilitation in relation to patients with Heart Failure”./ Larsen P, Pedersen PU. 2010. Poster session presented at Nordic College of Caring Science conference Vasa Finland

“Protocol for a quasi-experimental study on Rehabilitative nursing for patients with Heart Failure”./ Larsen P, Hørdam B, Boesby S and Pedersen PU. 2011. Poster session presented at International Council of Nurses conference, Valetta, Malta

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“What is the effectiveness of dietary salt reduction for patients with Heart Failure: a systematic review protocol”/ Larsen P, Pedersen PU and Tsiami A. 2013. Oral presentation at 2th European Joanna Briggs Institute regional symposium, Coimbra, Portugal:

ENGLISH SUMMARY

Background

Patients with heart failure are living with a serious progressive disease and need long-term rehabilitation and care in hospital as well as in primary and community care settings. The elements of the non-pharmacological rehabilitation are based on recommendations from the European Society of Cardiology and focus on self-care and compliance with the recommendations in general. There are no specific guidelines for rehabilitation in primary care where maintaining rehabilitation takes place. The purpose of this study was to develop and test a protocol for rehabilitation of patients after completing rehabilitation in an outpatient clinic. The protocol is based on the principle of EBHC and tests the effect of systematic involvement of patients in their rehabilitation in their own home by stimulating an increase in self-care. Outcomes of the interventions are health status and self-care ability (Paper 1, 2, 3 and 6). In order to contribute to the pool of evidence when updating CPGs with recommendations for patients with HF an systematic review has been carried out. The review focused on effectiveness of reducing dietary sodium intake versus normal dietary sodium intake in patients with heart failure on reducing readmission rate (Paper 4 and 5.)

Methods

The study design is quasi-experimental. Patients in the control group followed the conventional rehabilitation. For patients in the intervention group an individual rehabilitation plan was drawn up which was supplemented with telephone follow-up after 4 and 12 weeks. For all patients self-care behaviour and health status were measured at inclusion in the study (baseline), after 4 and after 12 weeks. Self-care behaviour was measured with the European Heart Failure Self-care Behaviour Scale and health status was measured with the Short Form 36 and EuroQol EQ5D. Furthermore, a systematic review on effectiveness of reducing dietary sodium intake versus normal dietary sodium intake in patients with heart failure on

reducing readmission rate was carried out in order to add to the pool of existing evidence.

Results

A total of 162 patients were included in the study of whom 137 (84.6%) completed it. The groups were equivalent with regard to gender, age, NYHA class, body mass index, living alone and dependence on help. Drop out analysis shows no differences between the groups in relation to demographic variables (p =0.106 – 0.907). There were no differences in total self-care behaviour between the groups at baseline. Within the control group no changes in the self-care score were observed. Within the intervention group a significant change was observed indicating a higher degree of self-care. Total EQ5D scores showed no significant differences between the groups at baseline. Subgroup analyses showed a significant difference in usual activities with an increase from 34.4 % at baseline to 51.4 % after 12 weeks (p=.0002). There are a significantly reduced number of patients reporting anxiety/depression in the intervention group. SF 36 scores showed no changes between or within the groups from baseline to twelve weeks.

A reduction in dietary sodium intake in patients with HF in high dose diuretic treatment increased the risk for readmission with OR 2.53 (2.12-3.03) and for mortality with OR 2.24 (1.81 – 2.79)

Conclusion

A systematic prepared intervention lead by a CNS based on the patient's self-care behaviour scores and telephone follow up 4 and 12 weeks after primary contact leads to a significant increase in the total self-care behaviour score in patients with HF. It is necessary to further develop and test the telephone follow up for patients in the primary care after discharge from the outpatient clinic. SF 36 and EQ5D measures showed no significant increase in Health Status between the groups. Subgroup analysis showed a significant within-group increase in the intervention group in EQ5D scores related to the anxiety level (p=0.034) from baseline to 12 weeks. There may be a correlation between the increase in self-care behaviour in

patients in the intervention group after 12 weeks and a reduction in anxiety measured with EQ5D. It seems that patients with Heart Failure in high dose diuretic treatment are at risk of being harmed, in terms of readmission rates as well as to have a higher risk of mortality if they reduce their daily sodium intake as prescribed.

DANSK RESUME

Baggrund

Patienter med hjertesvigt lever med en alvorlig fremadskridende sygdom der kræver en langsigtet rehabilitering og pleje såvel på hospital som i primær sektor. Den ikke farmakologiske rehabilitering er baseret på anbefalinger fra European Society of Cardiology og fokuserer på egenomsorg og overholdelsen af de givne anbefalinger i almindelighed. Der er ingen specifikke retningslinjer for rehabiliteringen i primær sektor, hvor vedligeholdelsesrehabiliteringen finder sted. Formålet med denne undersøgelse var at udvikle og afprøve en protokol for rehabilitering af patienter efter endt rehabilitering i hjertesvigtsambulatoriet. Protokollen er baseret på principperne i Evidence Based Health Care og tester effekten af systematisk inddragelse af patienterne i deres rehabilitering i eget hjem gennem stimulation til øget egenomsorg. Der måles på sundhedstilstand og egenomsorgsadfærd. (Artikel 1, 2, 3 og 6.) Endvidere er der udarbejdet en metaanalyse med det formål at øge den der danner grundlaget for udarbejdelsen af anbefalinger for klinisk praksis. Der er derfor foretaget en systematisk gennemgang af litteraturen på området relateret til daglig reduktion i saltindtag hos patienter med hjertesvigt. Gennemgangen fokuserede på effektiviteten i reduktionen af dagligt saltindtag sammenlignet med en normal daglig saltindtagelsen hos patienter med hjertesvigt (Paper 4 og 5.).

Metoder

Der er gennemført et kvass-eksperimentelt studie. Patienterne der deltog i kontrolgruppen fulgte den konventionelle rehabilitering. For patienterne der deltog i interventionsgruppen blev udarbejdet en individuel rehabiliteringsplan, som blev suppleret med telefonisk opfølgning efter 4 og 12 uger. For alle patienter blev egenomsorgsadfærd og sundhedsstatus målt ved inklusion i studiet (baseline) samt efter 4 og 12 uger. Egenomsorgsadfærden blev målt med European Heart Failure Self-Care Behaviour Scale og sundhedstilstanden blev målt med Short Form 36 og EuroQol EQ5D.

Desuden er der udarbejdet en metaanalyse til dokumentation af effekten af en reduktion i dagligt saltindtag hos patienter med hjertesvigt.

Resultater

I alt 162 patienter blev inkluderet i undersøgelsen, hvoraf 137 (84,6 %) gennemførte undersøgelsen. Grupperne var ækvivalente med hensyn til demografiske data. Drop out analyse viserat der ingen forskelle er mellem grupperne i forhold til demografiske variabler (p = 0,106 til 0,907). Der var ingen forskel i den samlede egenomsorgsadfærd mellem grupperne ved baseline. I kontrolgruppen skete der ingen ændringer i den totale egenomsorg score. I interventionsgruppen ses højere grad af egenomsorg. Samlet EQ5D scoringer viste ingen signifikante forskelle mellem grupperne ved baseline. Analyser af undergrupper viste en signifikant forskel relateret til "sædvanlige aktiviteter" med en stigning fra 34,4 procent ved baseline til 51,4 procent efter 12 uger (p = 0,0002). Relateret til angst / depression ses der en signifikant reduktion i antal patienter, der rapporterede angst / depression i interventionsgruppen. SF 36 scoringer viste ingen ændringer mellem eller inden for grupperne fra baseline til tolv uger.

En reduktion i saltindtag i kosten hos patienter med hjertesvigt i højdosis diuretisk behandling ser ud til at kunne øge risikoen for genindlæggelse (OR 2,53 (2,12-3,03)) og for dødelighed (OR 2,24 (1,81-2,79))

Konklusion

En systematisk forberedt intervention udført af en klinisk sygeplejespecialist baseret på patientens egenomsorgsadfærd og telefon opfølgning 4 og 12 uger efter første kontakt fører til en betydelig stigning i det samlede egenomsorgsadfærd hos patienter med HF. Det er nødvendigt at videreudvikle og teste telefonen opfølgning for patienter i den primære sundhedssektor efter udskrivning fra ambulatoriet. SF 36 og EQ5D målinger viste ingen signifikant stigning i sundhedstilstanden mellem grupperne. Undergruppe analyse viste en signifikant stigning i interventionsgruppen i EQ5D scoringer relateret til angstniveauet (p = 0,034) fra baseline til 12 uger. Der

kan være en sammenhæng mellem stigningen i egenomsorgsadfærd hos patienter i interventionsgruppen målt efter 12 uger, og en reduktion i angst målt med EQ5D.

Det ser ud til, at patienter med hjertesvigt i højdosis diuretisk behandling, har en højere risiko for at blive genindlagt samt at have en højere risiko for dødelighed, hvis de reducerer deres daglige saltindtag

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1.0 **Introduction**

Prevalence of Heart Failure (HF) is estimated to be 2-3 % of the European population and over the next decade the number of people suffering from HF is expected to increase. [1] HF is a progressive disease leading to physical disability, frequent hospital admissions and general decline in Health Status (HS) and quality of life [2, 3] and in the end stage it is characterized by high morbidity and mortality [4, 5]. It is estimated that the five-year mortality rate is nearly 70%. [3] If individual patients adhere to pharmacological and non-pharmacological therapy, they can reduce the progression of the disease and the decline in their HS in everyday life. In order to postpone the progression of the disease and to minimise the general cardiovascular risk factors patients need to have insight into the expected consequences of the disease and the management of symptoms and their impact on daily life.[6] Studies have shown that it is possible to increase patients' self-care ability and improve their adherence to treatment, improve outcomes of rehabilitation and reduce costs for the health care sector.[6-11]

Evidence was introduced as the basis for health care in 1978 by the World Health Organization in the Alma Ata Declaration and endorsed in 1979.[12] In the declaration it is stated that *"We recommit ourselves to strengthening, adapting and reforming, as appropriate, our health systems, including essential public health functions and services, in order to ensure universal access to health services that are based on scientific evidence, of good quality and within affordable limits, and that are sustainable for the future."*[12]

Cardiac rehabilitation is primary offered by hospitals and outpatient clinics. The main purpose of rehabilitation is to increase physical function, decrease recurrence of the diseases, morbidity and mortality.[13] Furthermore, studies have shown that only between 10 to 50 % of all patients eligible for cardiac rehabilitation actually participate in a rehabilitation programme.[14-16] This means that the health care sector needs to reform the ways of delivering rehabilitation and make rehabilitation accessible for more patients, within a framework of sustainable resources.

Living with HF is difficult; it is associated with high impact on everyday life, morbidity, mortality and high costs for the health care sector. Therefore attention paid to developing evidence based treatment and rehabilitation after being diagnosed with HF is important.[6, 7] This thesis is focused on how to provide rehabilitation that respects the preferences of the individual while integrating findings from existing research in the context of primary and community care settings

2.0 Background

2.1 Evidence Based Health Care

Evidence Based Health Care (EBHC) is a term that endeavours to encompass Evidence Based Medicine (EBM), Evidence Based Health Care Practice (EBHCP), and Evidence Based Clinical Practice (EBCP). The basis for these concepts was introduced by Archie Cochrane [17]and is described in*: "Effectiveness and efficiency: Random Reflections on Health Services."*[17, 18] Sackett defined Evidence Based Practice (EBP) as the best treatment patients can get based on the best available and systematic collected evidence based research [19]. In agreement with this Guyatt framed his view thus, *"Evidence-based clinical practice requires integration of individual clinical expertise and patient preferences with the best available external clinical evidence from systematic research and consideration of available resources."*[20]

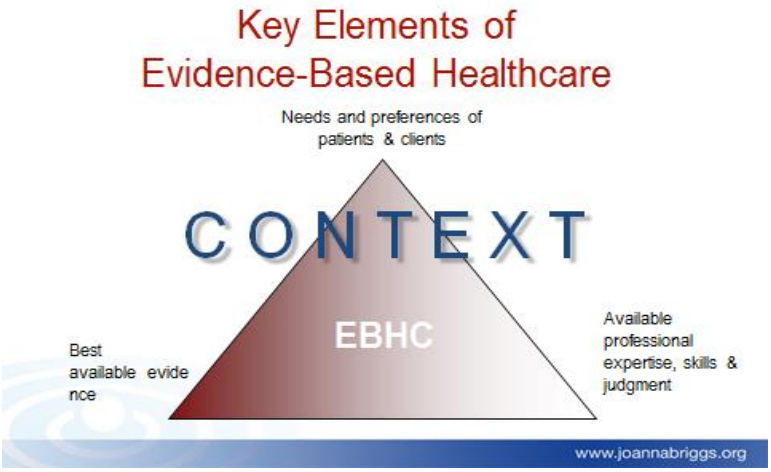
The National Health Service (NHS) points out that the following three elements are fundamental in EBHC [21, 22] : *Best external evidence*: This requires research involving patients in clinical settings with the aim to develop more effective treatments; *Individual clinical expertise*: This refers to the staff's use of clinical skills and judgment and *Patient choice*: Patient preferences play a central role in determining whether interventions *t*ake place and what kind if any.

These three areas must also be considered in light of the available resources. Most health care decisions have implications for the use of resources and there may be instances where the potential costs of the intervention at the individual level outweigh the potential advantages on an aggregated level. Figure 1.: Key elements in evidence-based Health Care, shows the interrelationship of these three areas.

Patients must be able to make informed choices based on the existing research and on the available skills, professionals' expertise and judgement from the health care staff. Best available evidence includes specific information on the topic, the patient's values and preferences, but also research on how to incorporate patients in

the clinical decisions. Available professional skills, expertise and judgment require that healthcare staff have access to research, have the skills to transform the research findings and make them relevant for the individual patient.

Figure 1. Key elements in evidence-based Health Care



At the Joanna Briggs institute (JBI) the model for EBHC focuses not only on Efficacy and Effectiveness [23], but also on Feasibility, Appropriateness and Meaningfulness [22]: Pearson et al. describe it in this way:

"Feasibility: is the extent to which an activity is practical and practicable. Clinical feasibility is about whether or not an activity or intervention is physically, culturally or financially practical or possible within a given context."[22]

"Appropriateness is the extent to which an intervention or activity fits with or is apt in a situation. Clinical appropriateness is about how an activity or intervention relates to the context in which care is given." [22]

"Meaningfulness is the extent to which an intervention or activity is positively experienced by the patient. Meaningfulness relates to the personal experience, opinions, values, thoughts, beliefs and interpretations of patients or clients." [22]

"Effectiveness is the extent to which an intervention, when used appropriately, achieves the intended effect. Clinical effectiveness is about the relationship between an intervention and clinical or health outcomes." [22]

The definition of EBHC put forward by Sackett [24] as a new way of looking at knowledge, involving using the research literature in a more effective way is focused on epidemiological, economical and stastical principles.[25] There has been some critique of this way looking at EBHC. The concern is that the hierarchy of evidence does not seem to weigh qualitative and quantitative research equally. [26] This is related to the epistemological level. [22, 27] Joanna Briggs Institute of Evidence Based Health Care (JBI) highlights the fact that qualitative research makes it possible to get an insight of the patient's experiences, which is beneficial and important in EBHC. Evidence-based nursing is a well-established discipline with the goal to train practising nurses so that they can deliver effective evidence based care following all types of available research. [28]

Traditionally EBHC has been connected with effectiveness. [19] Later on, it became clear that effectiveness did not capture all the knowledge needed to make a proper clinical judgment. As a consequence, new models were developed incorporating feasibility, appropriateness and meaningfulness. [22]

To sum up, the concept of EBHC has been developed over the last twenty years. However, the incorporation or more precise implementation of the concept into daily clinical practice has been and continues to be a major challenge for clinical practitioners. In order to practice evidence-based health care, practitioners need to have competences and access to:

Research on coherent patient pathways including effectiveness, feasibility, appropriateness and meaningfulness of interventions on an aggregated level
Patients' preferences in coping with the specific symptoms and the disease
Research methods to assess and combine specific patient values and experience with research findings

The staff must be able to switch between the aggregated level and the individual and specific patient situation

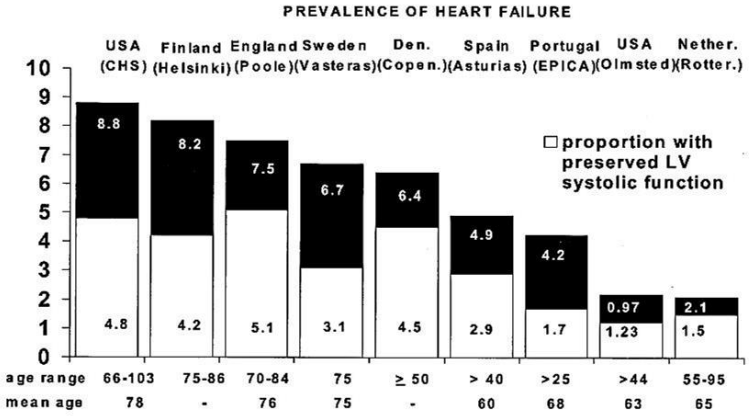
Identification of patient preferences is necessary to individualize the interventions

Furthermore, it is essential that health care staff experts in their field, have sufficient insight about the disease, and have access to updated recommendations for treatment and rehabilitation for the patients, in this case patients with HF

2.2 Heart failure

Cardiovascular disease is one of the most common diseases in the Western world, and is characterized by high morbidity and mortality as well as a high degree of readmissions to hospitals. [4, 5] Patients with HF have a poor prognosis, with a 5 year mortality of 68.7% and a median survival time of 2.4 years [3] after the diagnosis and HF is associated with poor Quality of Life (QoL). [2] In the Western world, the prevalence of HF is estimated to be 1-2 %. The incidence approaches 5-10 per 1000 persons per year. [29] In Europe, the prevalence is estimated to be 2-3 % [1] and in Denmark 1-2 %. [30] There is an increasing incidence of HF with age and prevalence in patients more than 75 years of age of 5-10 %. [31] An overview of the prevalence from selected countries is shown in Figure 2.[1]

Figure 2. Prevalence of HF in cross-sectional, population-based, echocardiographic studies. Black bars show % prevalence; the lower portion of the bars show the proportion of cases associated with preserved systolic function. LV left ventricular. [1]



HF is a syndrome with the features described in Figure 3. [6] The physiological significance of HF is that the cardiac output is too low and this prevents the body from getting enough oxygen to meet its needs. [6, 32-35]

HF is a progressive disease, which occurs in acute or chronic form. The development of the disease ranges from an asymptomatic patient to a decompensated patient with severe symptoms. The most common form of HF is systolic *dysfunction.* [35] Systolic dysfunction is reduced function of the left ventricle with Left Ventricular Ejection Fraction/Ejection Fraction (LVEF/EF). It is clinically and prognostically significant if the EF is reduced to <40% (normal range of 50 to 60%). In recent years, it has become clear that early detection and treatment of HF can slow down its progression.[31, 32, 35-37] HF is the final diagnosis of all heart diseases. [38] An overview of definition, type and characteristics of HF are presented in (Table 1).

Table 1. Definition of heart failure [6]

Heart failure is a clinical syndrome in which patients have the following features:
Typical Symptoms of heart failure **breathlessness at rest or in exercise, fatigue, tiredness, ankle swelling**
Typical Signs of heart failure **tachycardia, tachypnoea, pulmonary rales, pleural effusion, raised jugular venous pressure, peripheral oedema, hepatomegaly**
Objective evidence of a structural or functional abnormality of the heart at rest **cardiomegaly, third heart sound, cardiac murmurs, abnormality on the echocardiogram, raised natriuretic peptide concentration**

Different diseases may lead to HF. The most common causes are: heart attack and atherosclerosis. Other causes of HF, when the heart muscle is overloaded, are: high blood pressure, heart disease, disease of the heart muscle, atrial Tachycardia and certain types of chemotherapy. [39]

Classification of HF functional class can be done by the use of the New York Heart Association Classification (NYHA) (Table 2). In clinical practice, the grade of HF symptoms is important. A study concluded that there is a strong and graded association between NYHA functional class and mortality and hospitalization in community dwelling chronic patients with HF. [40]

Table 2. NYHA Classes [39]

NYHA I	**Heart failure without limitation in ordinary physical activity** **Ordinary physical activity does not result in feelings of fatigue, dyspnea, palpitations or angina** **No symptoms**
NYHA II	Heart failure with slight limitation of physical activity The patient's well-being at rest and during light physical exertion, but larger loads cause fatigue, dyspnoea, palpitations or angina Light limitation of physical activity
NYHA III	Heart failure with significant reduction in physical activity The patient's well-being at rest, but light physical activity such as dressing or time in gently rolling terrain fatigue, dyspnea, palpitations or angina Severe limitation of physical activity
NYHA IV	Heart failure, which does not allow any physical activity without causing discomfort Symptoms caused by heart failure, present at rest

During the last decade the effectiveness of the treatment and the rehabilitation of HF has improved and this is linked to recommendations in the international clinical practice guidelines (CPG). [9, 10, 41-45] CPG's for treatment and rehabilitation of HF in Europe and other continents are similar. [6-8, 45, 46] The guidelines give recommendations for treatment and rehabilitation and are internationally agreed. The aims of rehabilitation are to reduce progression in HF, morbidity, mortality and to increase QoL. Furthermore, interventions to improve self-care are seen as important in the CPG's. Patients with HF have a poor prognosis, although it has improved during the last decade; with increased self-care ability adherence to treatment is increased and thereby progression in HF reduced.

2.3 Self-care in patients with HF

The recommendations in the guidelines give advice related to pharmacological and non-pharmacological treatment and rehabilitation [6-8, 45, 46] and they state that the non-pharmacological treatment is vital and highlight the importance of improvement in self-care management. The recommendations highlight the importance of self-care in successful HF rehabilitation and found that the following elements are essential: good relations between the caregiver and the patient; the patient's knowledge of the disease; patients' awareness of the expected consequences of the disease and finally, interventions that improve adherence to the advice given by the health care providers. [6]

The patient must be able to see the link between an increase of daily body weight and ankle oedema and that this is a symptom of a worsening in their condition and then act appropriately. Therefore, the essential part of rehabilitation is the patient's understanding of the situation.

It can be concluded that education of patients is a fundamental non-pharmacological intervention. However, education alone does not help the patient to improve adherence. The interaction between the caregiver and the patient is essential, and the caregiver´s priority should be to ensure that the individual patient obtains

understanding of the disease and is able to act accordingly. This calls for self-care behaviour skills.

Self-care relates to the activities that individuals engage in terms of health seeking behaviours. Increased self-care behaviour seems to be correlated to reduced mortality rates, reduced number of readmissions to hospital [47-49] and better QoL. [47, 50] It is essential to assess whether the individual patient has the skills and autonomy needed to manage self-care. Supporting self-care practices through tailored and relevant information may provide patients with strategies to manage their condition and promote health.[41, 51] The concept of self-care has been discussed for years and has often been related to Orem's general theory. [41] However, there are at least 139 definitions of self-care identified.[42] The authors of the review concluded that when interventions for improving self-care are planned health-care professionals must consider some general concepts: health; illness; disability; general outcomes; the performer of self-care; the action of self-care; the relation to healthcare professionals and the relation to the healthcare system.[42] Self-care in this thesis is defined as: "*A process of maintaining health through health promoting practices and managing illness,".* [43,52] The main components in this definition are self-care maintenance, self-care monitoring and self-care management. [52]
Self-care is a way of maintaining and promoting health and managing illness. In relation to the rehabilitation of patients with HF, it is relevant to examine whether the effectiveness of the interventions is related to the context. In order to relate to the patient's preferences it is necessary to tailor and individualize the interventions.

A systematic review (SR) of the literature has been carried out to get an overview of the existing research on interventions to improve self-care management in patients with HF. The systematic literature search identified 11 SR which were critically appraised using a validated instrument. [53] The result is summarized in Table 3. The research questions were: Which interventions and approaches are effective to improve self-care ability in patients with HF during their rehabilitation in primary and community care settings, measured on readmission and all-cause mortality? Studies were included if they specified a definition of self-care.[54] A number of

approaches and interventions in order to improve self-care ability are identified and are often complementary [55]. Most of the studies are focused on patients in hospital or outpatient clinics. [54]

Table 3. Overview of intervention types in the HF management

Study	Patient	Setting	Rehab phase	Intervention	Conclusion
Mc Alister et al. 2004 [56]	SR including twenty-nine trials 5,039 patients	Hospital based, outpatient clinic, primary care physician	Unknown	1) A multidisciplinary HF clinic; multidisciplinary team providing specialized follow-up but not in a hospital or practice-based clinic; 2) Telephone follow-up or telemonitoring and enhanced communication with primary care physician 3) Educational programs Education was a key component of all four types of intervention	Multidisciplinary strategies for the management of patients with HF reduce HF hospitalizations
Holland R, J et al. 2005 [57]	SR 30 studies 1296 patients	Hospital based	II Follow up period 183 -365 days	Multidisciplinary interventions	Multidisciplinary interventions reduce hospital admission and all-cause mortality. The most effective interventions were delivered at least partly in the home.

Ditewig et al. **2010** [49]	SR Nineteen randomized controlled trials 2149 patient's	Hospital based		Self-management Interventions (written, verbal, visual, audio)	SM programs reduce mortality, readmission
Maric et al. 2009 [58]	SR including 56 articles	Hospital based	II – III	Device-based telemonitoring modalities Telephone touch-pad-based Telemonitoring modalities Video-consultation-based studies Website-based telemonitoring modalities Combination of telemonitoring Modalities	More research in a number of areas is needed with focus on directly comparing different modalities and evaluating their success and feasibility
Inglis S. C et al 2011[59]	SR Twenty-five studies and five published abstracts 16 evaluated structured telephone support (5613 participants) 11 evaluated telemonitoring (2710 participants), and two tested both interventions	Hospital based	II	Telemonitoring and structured telephone support	Reduce all-cause mortality and CHF-related hospitalizations.

Boyde et al 2010 [60]	SR; nineteen studies 2686 patients	Hospital based, but different settings	II-III Follow up 3-12 month	A one-on-one didactic session conducted by nurses supplemented by written materials and multimedia approaches.	Unclear
Chaudhry et al **2010** [61]	SR 1653 patients	Hospital based	II-III	Telephone-based interactive voice response system that collected daily information about symptoms and weight that was reviewed by the patients' clinicians compared to usual care	Telemonitoring did not improve outcomes
Kent B et al.[62] **2011**	SR; Thirteen studies	Clinic	II	Supportive education Video education Motivational interviewing Telephone delivered empowerment	The review confirmed that education alone is less effective than a combination of education and the use of personal diaries to promote daily weighing. There is some evidence to suggest that motivational interviewing has potential for use in the heart failure population and may be more beneficial than standard education. Furthermore, education should be tailored to individual learning

					needs.
Barnason et al. 2011 [63]	Integrative review 19 studies 3166 patients	Primary Hospital based few studies in outpatient clinics' an 2 studies in primary cardiology clinics	I-II (III)	Intervention delivery methods used included traditional in person one-to-one or group counselling and education sessions	Improved patient outcomes are reached when standard patient education for HF is augmented using cognitive–behavioural strategies that include additional evidence-based education and counselling.
Takeda et al. 2012 [64]	SR Twenty five trials 5942 people	Hospital	I-II	Case management interventions CHF clinic interventions Multidisciplinary interventions	Good evidence that case management type interventions led by a heart failure specialist nurse reduce CHF related readmissions It is not possible to say what the optimal components of these case management type interventions are. Multidisciplinary interventions may be effective. Limited evidence to support interventions whose major component is follow up in a HF clinic.

Wakefield B et al. 2013 [65]	SR and Meta-analysis including 35 studies, 8071 participants	Hospital based	I-II	1 = face to face, 2 = clinic/MD office visits, 3 = home visits 4 = remote vital signs monitoring, 5 = remote videophone, 6 = remote messaging, 7 = scheduled telephone calls 8 = telephone 9 = availability of staff	Multicomponent HF management programs have found positive effects on important patient outcomes Future studies of chronic disease interventions must include descriptions of recommended key program components to identify critical program components.

Note: Rehabilitation Phase I is during the acute hospitalization, Phase II is the first 8-12 weeks after discharge from hospital, but takes place in outpatient clinic; Phase III takes place after discharge from outpatient clinics in the primary and community care setting.[66]

The review of the literature shows that interventions are effective in reducing readmission rates. It seems that a combination of education and other methods such as diaries and counselling is most effective. It is possible to improve the patient's ability to self-care through these interventions. However, the impact on patients', functional level, well-being and Health Status (HS) has not been investigated.

In hospital settings, the most effective interventions are multidisciplinary. Furthermore, multidisciplinary interventions led by a Clinical Nurse Specialist (CNS)[1] have been shown to have the most positive effect on reduction of readmission rates.

The review shows that the studies focus on rehabilitation primarily in the outpatient clinics and therefore rehabilitation and self-care management related to primary and

[1] " *Clinical nurse specialists (CNSs) are registered nurses, who have graduate level in nursing preparation at the master's or doctoral level as a CNS."*

community care settings is sparsely investigated. Although it has been noted that the most effective interventions are those partly delivered in patients' homes, further studies are needed in this regard. Education of patients seems to be a cornerstone in self-care management, but it is not clear whether the education should be delivered in groups or individually.

Specific interventions are sparsely described and not described in details, which makes it difficult to directly transfer the specific intervention into a clinical practice.

Telemonitoring seems to be most effective in combination with telephone support. There are no results of a combination of individualized educational intervention combined with telephone follow up.

Based on the review of the literature it can be concluded that there is a need for studies that investigate how patients can be supported and how patients' self-care ability after discharge from hospital - or outpatient clinic can be increased during rehabilitation. Telemonitoring or telephone follow up seems to have a potential to be a sustainable intervention but is has to be investigated further. Likewise, the effect of self-care interventions on patients' functional level and well-being need to be investigated.

2.4 Clinical Practice Guidelines

Within the frame of EBHC, research findings need to be transferred into recommendations for daily clinical practice. One method is to develop CPGs. A CPG is a systematically developed statement that can be used by professionals and patients for appropriate and proper health care practices in specific clinical situations. International Heart Failure guidelines have been published since the beginning of the 1990s and are continuously updated. [9, 10, 44, 67] CPGs are a synthesis of the research literature the aggregated level. Overall, the guidelines emphasize three components that are fundamental in the treatment of patients with HF:

- Reduce progression of HF by general reduction of risk factors for cardiovascular disease
- Management of symptoms and their impact on daily life
- Adherence to treatment and rehabilitation activities

The CPG synthesises the evidence and give recommendations [68] for pharmacological and non-pharmacological treatment. Medical treatment of cardiovascular disease has resulted in reduction in mortality and is essential, but cannot stand alone. [69] Non-pharmacological treatment includes risk reduction and lifestyle changes through improved self-care management. The published CPG all highlight the importance of non-pharmacological treatment and that they must be systematically incorporated into the overall treatment for patients with HF. [6, 7, 9, 10, 44-46, 67, 70]

In order to assess the methods used to develop CPG it is recommended that CPG is both internally and externally validated before it is approved in order to ensure a high level of trustworthiness of recommendations. [71] Recommendations based on research can change according to the findings in recent research. CPGs need to be updated regularly to maintain validity. [72]

One of the important recommendations in relation to patients with HF is that patients reduce their daily intake of sodium chloride, but recent studies have shown that this might be harmful to some patients with HF. [73] However, this knowledge has not yet been incorporated in the recommendations.

In summary, it can be concluded that the CPGs translate research findings and thus, provide the framework for rehabilitation in clinical practice and that self-care is an important factor in the treatment and care for patients with HF. As CPG are based on studies primarily carried out within hospitals or outpatient clinics, research on supporting patients' self-care ability when discharged is needed.

2.5 Summary

Treatment and rehabilitation for patients with HF have improved internationally during recent decades partly due to the publication of international guidelines.[9, 10, 41-45] CPGs provide the framework for treatment and rehabilitation for patients with HF. In all CPGs, it is emphasized that ability to self-care and adherence to treatment are essential non-pharmacological interventions.

Self-care is an important part of the rehabilitation process and one of its goals is to stimulate increased self-care behaviour. According to EBHC, the context is important. Related to the rehabilitation for patients with HF, it is important to identify whether patients will benefit from interventions to support their self-care ability after discharge from hospital or outpatient clinic. Furthermore, studies identifying the impact of increased self-care ability on patients' HS are lacking.

The specific interventions described in the systematic reviews are sparsely described and not directly transferrable to clinical practice. Therefore, we need studies that explicitly describe how research findings and instruments can be transferred to be used in daily clinical practice, in order to facilitate the implementation of evidence.

Telemonitoring seems to be most effective in combination with telephone support. There are no studies of a combination of individualized educational intervention combined with telephone follow up after discharge form hospital or outpatient clinics.

Recommendations from CPGs must be updated regularly in order to constantly reflect the actual level of evidence. It seems that recently published research might change core recommendations for management of patients' daily intake of sodium chloride, but before changes can be incorporated into a CPG, a SR must be carried out.

3.0 Aim of the thesis

To develop and test a protocol for rehabilitation of patients after completing rehabilitation in an outpatient clinic. The protocol is based on the principles of EBHC and tests the effect of systematic involvement of patients in their rehabilitation in their own home by seeking to stimulate an increase in self-care. Outcomes of the interventions are functional level, HS and self-care ability. (Paper 1, 2, 3 and 6.)

In order to contribute to the pool of evidence when updating CPG with recommendations for patients with HF a SR has been carried out. The review focused on the effectiveness of reducing daily intake of sodium chloride in patients with HF to reduce morbidity, mortality and readmission to hospitals. (Paper 4 and 5)

4.0 Papers

Paper 1 Larsen P, Pedersen PU. Protocol to test the effectiveness of individual planned nursing rehabilitation on self-care behavior and HS in patients with HF - a quasi-experimental study. *Submitted*

Paper 2 Larsen P, Pedersen PU. Stimulation to self-care in patients with heart failure: A quasi-experimental study. Journal of Nursing Education and Practice. 2013;4(3):p143 - 54.

Paper 3 Larsen P, Pedersen PU. The effectiveness of individual rehabilitation on Health Status in patients with Heart Failure: a quasi-experimental study. International Journal of Evidence Based Health Care. *Accepted*

Paper 4 Larsen P, Pedersen PU, Tsiami A. The effectiveness of reducing dietary sodium intake versus normal dietary sodium intake in patients with heart failure in reducing readmission rate: a systematic review protocol. The JBI Database of Systematic Reviews and Implementation Reports; 2014;Vol 12 (2):125 -31.

Paper 5 Larsen P, Pedersen PU, Tsiami A. The effectiveness of reducing dietary Sodium intake versus normal dietary sodium intake in patients with Heart Failure in reducing readmission rate: A Systematic Review. The JBI Database of Systematic Reviews and Implementation Reports. 2014. *In Review.*

Paper 6 Larsen P, Thomsen T, Pedersen PU. Effect of Clinical Nurses Specialists intervention on rehabilitation outcomes in patients with heart failure. Clinical Nursing Studies. 2015;3 (2):31-9. Epub 29.12 2014.

Paper 1,2,3 and 6 are related to the first aim in this thesis and paper number 4 and 5 are related to the second aim.

5.0 Method

Two studies were carried out: first, an intervention study with the involvement of patients in their rehabilitation in their own home by use of a systematic self-care behaviour screening tool and secondly a SR and meta-analysis to test the validity of one of the core recommendations in the guidelines for rehabilitation of patients with HF published by the European Society of Cardiology (ESC).[6]

5.1 Method in the Intervention study

The study included patients from cardiac wards at two teaching hospitals in region Zeeland, Denmark. Patients included were 18 years or older and diagnosed with mild to moderate HF and had completed hospital based rehabilitation. Patients who did not understand the necessary information due to mental disorders, language and hearing problems and patients diagnosed with neurological deficits were excluded. An overview is presented in Figure 3.

5.1.1 Material

Approximately 100 - 120 patients completed the hospital based rehabilitation program yearly. The study design was a controlled trial study.[74-76] Patients who had completed the rehabilitation program in the period from October 2010 to July 2011 were included in the control group and patients who had completed their rehabilitation program in the period from November 2011 to July 2012 were included in the intervention group.

5.1.2 Design

Patients in the control group were discharged to follow up by their own General Practitioner (GP). Patients in the intervention group were discharged to follow up by their supplementary received individual rehabilitation by a CNS for twelve weeks. The intervention was carried out by the same CNS (first author) and consisted of the following:

Assessing level of self-care behaviour, functional level and HS.
Developing of individual care plan with the patient.

Telephone follow up after four weeks based on the care plan.

Telephone follow up after twelve weeks.

For all patients HS and self-care behaviour were measured at inclusion in the study (baseline) after four and after twelve weeks.

5.1.3 Sample size

To achieve sufficient statistical power the sample size was calculated. Type I error: 5%. The expected effect rate was estimated to be 30% and the minimal difference between effect rates not to be overlooked was 30%. Type II error was estimated to 20%. The minimum sample size was calculated to be 60 in each group (control and intervention), a total of 120 patients. With an expected drop-out rate at 20%, 70 patients were included in each group. Calculations of patient numbers are based on a power calculation.[77, 78]

5.1.4 Elements in the intervention

The basis for the CNS's interventions was factual knowledge about HF from research and from recommendations in the CPGs and on methods on how to assess and incorporate the preferences of the patients. [6, 7, 22, 79, 80]

The CNS made an assessment through observation and dialogue. Based on the patient's preferences, the knowledge gained from the observation, the dialogue, and an assessment of the patient's predisposing, reinforcing and enabling factors, the care plan and goals were developed for the next 12 weeks. This required that the CNS be communicator, coach, trainer and supervisor at the same time, which is in line with other studies [81]. Differences in rehabilitation between the intervention and the control group are shown in Table 4.

Table 4. Differences in rehabilitation in the control and the intervention group

	Controle Group	Intervention Group
Rehabilitation Phase I	Yes	Yes
Rehabilitation Phase II	Yes	Yes
Rehabilitation Phase III		
After discharge followed up by:		
GP	Yes	Yes
Developing of Individual Rehabilitation Care Plan	No	Yes
Telephone follow up after 4 weeks	No	Yes
Telephone follow up after 12 weeks	No	Yes

5.1.5 Measurements

Functional level was measured with EuroQol 5 Dimensions (EQ5D) [82] and with Short Form 36 (SF-36).[83] Both tools are validated and translated into Danish. Self-care behaviour was measured with the European Heart Failure Self-Care Behaviour Scale (EHFSCBS), which is a validated tool, translated into Danish.[84]

5.1.6 Statistical analysis

Data were analyzed using SPSS version 20 program.[85] Ratio-scale data from both groups were tested by F-test for distribution. Normally distributed data were compared by the Student's t test. Nominal scale data were compared by chi-square tests or by the use of the 95% confidence intervals.[78] All calculations were based on "intention to treat" analysis.[86, 87] Cronbach's alpha was used to assess the reliability of the questionnaires used in the study. Level of significance was set at $p < .05$. Missing data were replaced by mean scores where possible and by last observation carried forward where mean scores were not available within the control and intervention groups respectively.[87, 88] We used logistic regression analysis to examine variables associated with increased self-care. Pearson's correlation analyse were carried out in order to tests for correlations between ratio scale data.

5.1.7 Ethical considerations

Patients were included in the study after informed consent was given and were informed about the possibility of abandoning participation in the study at any time without any consequence for future treatments. The experiment are reported to the research ethics committee (2013-41-1935) and www.clinicaltrial.gov (NCT01239667)

5.2 Method in the meta-analysis

The SR was carried out using the methodology outlined by the Joanna Briggs Institute and based on a peer-reviewed and published protocol.[89]

5.2.1 Literature search

Literature search was carried out based on a predefined strategy and relevant databases were searched according to the protocol.[89] The selection of studies was carried out according to inclusion and exclusion criteria and critical appraise of the selected studies and extraction of data were done independently by three reviewers.

5.2.2 Data synthesis

Data was pooled in a statistical meta-analysis using Joanna Briggs Institutes: Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI). All results are 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 are calculated for analysis. Heterogeneity was assessed statistically using the standard chi-square test.[90]

6.0 Results

6.1 Intervention study (Paper 1, 2, 3 and 6)

162 patients were included in the study of whom 137 (84.6%) completed it (see Figure 3). The groups were equivalent with regard to gender, age, NYHA class, body mass index, living alone and dependence on help (see Table 5). Drop out analysis shows no differences between the groups in relation to demographic variables (p =0.106 – 0.907). There were no differences in total self-care behaviour between the groups at baseline (p = .161). Within the control group, no changes in the self-care score were observed. Within the intervention group a significant change was observed, indicating a higher degree of self-care (see Table 6).

Total EQ5D scores showed no significant differences between the groups at baseline. Subgroup analyses showed a significant difference in usual activities in the intervention group with an increase from 34.4 % at baseline to 51.4 % after 12 weeks (p=.002). There were a significantly reduced number of patients reporting anxiety/depression in the intervention group (Table 7). In order to analyze whether the changes in number of patients reporting anxiety after 12 weeks is related to group or other variables a binary logistic regression analyses were performed. (see Table 8). SF-36 scores showed no changes between or within the groups from baseline to twelve weeks (Table 6).

Figure 3. Flowchart

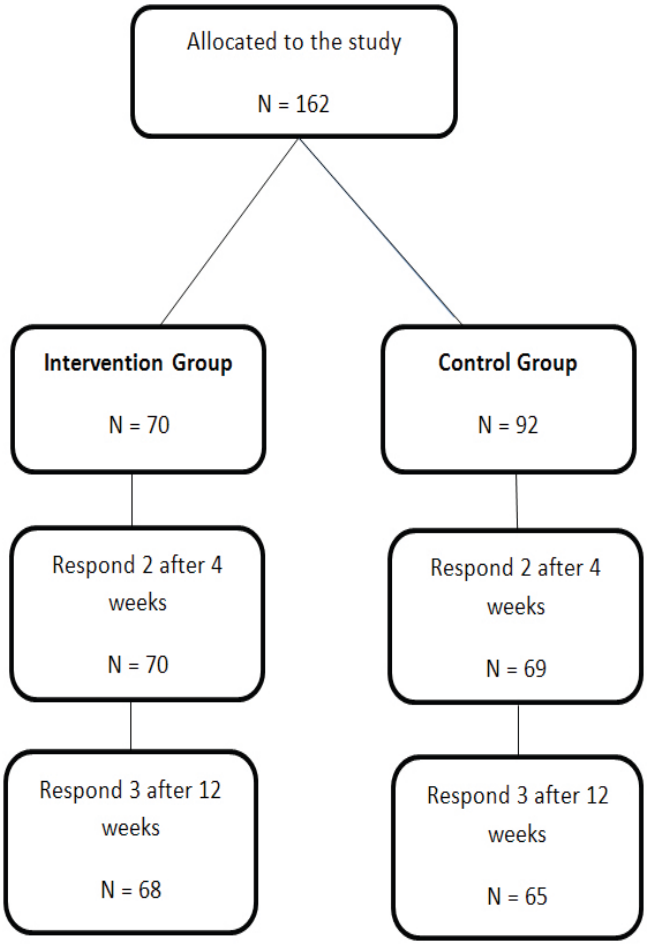


Table 5. Baseline characteristics of participating patients

	Control N = 92	Intervention N = 70	*P*
Gender			
Male N (%)	68 (73.9)	49 (70)	0.600
Female N (%)	24 (26.1)	21 (30)	
Age			
Mean (SD)	67.8 (10.8)	66.3 (11.3)	0.833
(min.-max.)	(37-89)	(39-89)	
NYHA			
Class II	67 (72,8)	56 (80)	0.355
Class III	25 (27.2)	14 (20)	
BMI kg/m² (SD)	27.7 (5.1)	27.6 (5.2)	0.759
(min.-max.)	(15.6-46.4)	(18.2-46.2)	
Living alone			
Yes N (%)	19 (20.7)	15 (21.5)	1.0
No N (%)	73 (79.3)	55 (78.6)	
Dependent of help			
Yes N (%)	13 (14.1)	9 (12.9)	1.0
No N (%)	79 (85.9)	61 (89.1)	

Table 6. Self-care behaviour scores, EQ5D scores and SF-36 scores

	Control	Intervention	*P*
Self- care behavior Total score (SD)			
Baseline	26.5 (8.0)	28.4 (7.2)	.161
After 4 weeks	25.3 (7.4)	22.2 (7.7)	.049
After 12 weeks	26.8 (8.9)	22.6 (8.2)	.007
EQ5D Total score (SD)			
Baseline	.81 (.14)	.78 (.16)	.2
After 4 weeks	.8 (.15)	.8 (.16)	.55
After 12 weeks	.66 (.22)	.71 (.22)	.21
Functional scores SF 36 (SD)			
PCS			
Baseline	39.31 (9.6)	41.24 (9.5)	.207
After 4 weeks	40.7 (8.9)	41.2 (8.8)	.738
After 12 weeks	40.0 (10.6)	40.3 ((9.5)	.838
MCS			
Baseline	49.8 (9.5)	47.9 (9.3)	214
After 4 weeks	48.0 (11.9)	50.1 (8.8)	.276
After 12 weeks	49.6 (9.1)	48.2 (9.4)	.364

Table 7 EQ5D scores

	Baseline		4 weeks		12 weeks	
	Control n = 92 (%)	Intervention n=70 (%)	Control n = 92 (%)	Intervention n=70 (%)	Control n = 92 (%)	Intervention n=70 (%)
Mobility						
I have no problems in walking about	51 (55.4)	46 (65.7)	58 (63)	46 (65.7)	64 (69.6)	46 (65.7)
I have some problems in walking about	41 (44.6)	24 (34.3)	34 (37.0)	24 (34.3)	28 (30.4)	24 (34.3)
I am confined to bed	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Self-Care						
I have no problems with self-care	81 (88.0)	66 (94.3)	82 (89.1)	65 (92.9)	79 (85.5)	66 (94.3)
I have some problems washing or dressing myself	11 (12.0)	4 (5.7)	10 (10.9)	5 (7.1)	13 (14.1)	4 (5.7)
I am unable to wash or dress myself	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Usual Activities						
I have no problems with performing my usual activities	46 (50.0)	34 (34.4)	45 (48.9)	30 (42.9)	47 (51.1)	36 (51.4)*
I have some problems with performing my usual activities	44 (47.8)	38 (54.3)	40 (43.5)	31 (44.3)	39 (42.4)	39 (42.9)
I am unable to perform my usual activities	2 (2.2)	8 (11.4)	7 (7.6)	9 (12.9)	6 (6.5)	4 (5.7)
Pain/Discomfort						
I have no pain or discomfort	49 (53.3)	36 (51.4)	46 (50.0)	39 (55.7)	41 (44.6)	38 (54.3)
I have moderate pain or discomfort	42 (45.7)	30 (42.9)	44 (47.8)	29 (45.1)	49 (53.3)	30 (42.9)
I have extreme pain or discomfort	1 (1.1)	4 (5.7)	2 (2.2)	2 (2.9)	2 (2.2)	2 (2.9)
Anxiety/Depression						
I am not anxious or depressed	69 (75.0)	51 (72.9)	65 (70.7)	47 (67.1)	54 (58.7)	57 (81.4)*
I am moderately anxious or depressed	23 (25)	19 (27.1)	26 (28.3)	23 (30.2)	38 (41.3)	13 (18.6)
I am extremely anxious or depressed	0 (0)	0(0)	1 (1.1)	0 (0)	0(0)	0 (0)

* Significant increase in intervention group related to Usual activities and Anxiety

Table 8. Results of regression analysis

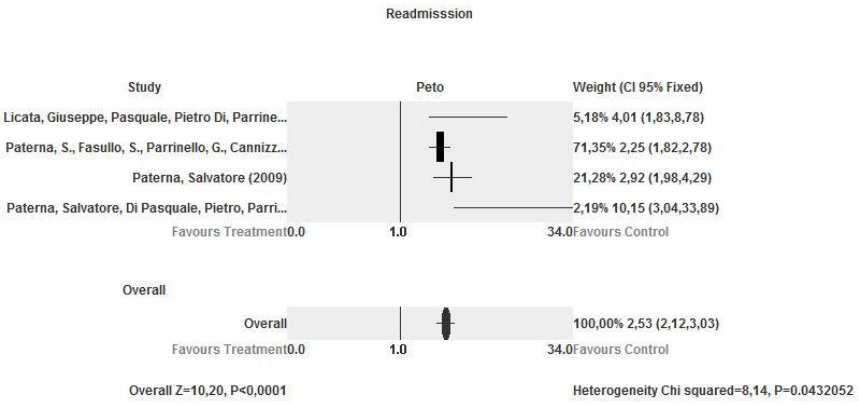
Variables in the Equation								
Anxiety	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
							Lower	Upper
Group	-1.391	.409	11.565	1	.001	.249	.112	.555
Self care	-.817	.408	4.007	1	.045	.442	.199	.983
Age	-.037	.019	3.937	1	.047	.963	.928	1.000
Dependent of help	-.938	.533	3.096	1	.079	.391	.138	1.113
NYHA	.195	.453	.185	1	.667	1.215	.500	2.955
Weight	-.028	.011	5.971	1	.015	.972	.951	.994
Constant	5.239	2.123	6.089	1	.014	188.539		

6.2 Result from the Meta-analysis (Paper 4 and 5)

6.2.1 Readmission

All four studies (n=2382) reported hospital readmissions due to HF. There was a significant increase in hospital readmissions for a low sodium diet compared with a normal sodium diet, OR PETO 2.53 (2.12 - 3.03) (Table 9)

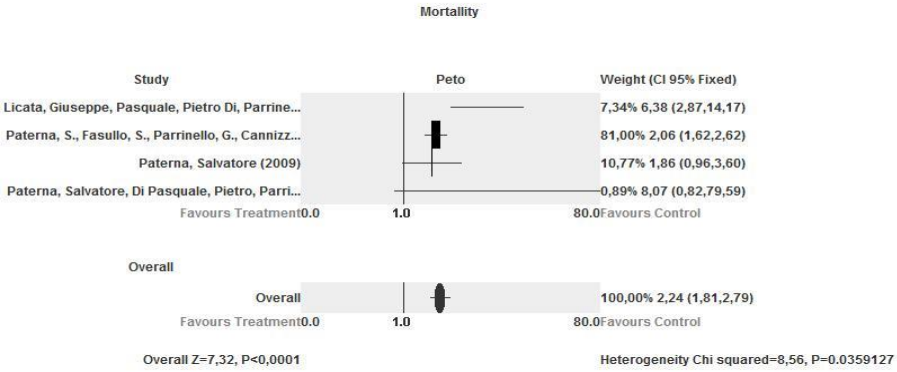
Table 9. Meta-analysis on Readmission



6.2.2 All-cause mortality

All four studies (n=2382) reported results on all-cause mortality. There was a significant increase in mortality for a low sodium diet compared with a normal sodium diet OR PETO 2.24 (1.81 – 2.79). (Table 10)

Table 10. Meta-analysis on Mortality



7.0 Discussion

The main purpose of this thesis was to develop and test a protocol for the rehabilitation of patients after completing rehabilitation in an outpatient clinic. The protocol was based on the principles of EBHC and tested the effect of systematic involvement of patients in their rehabilitation in their own home by stimulating patients with HF to increase their self-care behaviour. Outcomes of the interventions were functional level, HS and self-care ability. (Paper 1, 2, 3 and 6.) Overall, we found that this intervention increased self-care behaviour, but did not change HS in patients with HF. This is similar to other findings. [91, 92] We also found a reduction in anxiety. To the best of our knowledge, this is a new finding.

The intervention was based on principles of EBHC and as during the study it became clear that the recommendations on reduction of sodium intake might be harmful, a secondary purpose was developed.

In order to contribute to the pool of evidence for updating of the CPG to patients with HF a SR was carried out. The review focused on the effectiveness of reducing daily sodium intake in patients with HF by measuring the reduction of mortality and readmission to hospitals. (Paper 4 and 5) The meta-analysis shows that patients with HF in diuretic treatment that adhere to the existing recommendations of reduction of their dietary sodium intake might have an increase in risk for readmission as well as increase in risk for higher mortality. [93]

7.1 EBHC and systematic involvement of patients with HF in their rehabilitation in primary and community care settings (Paper 1, 2, 3 and 6.)

Even though EBHC has been on the agenda for decades, nurses' role, skills and methods for incorporating findings of research in clinical practice have sparsely been described in the case of rehabilitation of patients with HF. [56-65, 94-96]

If nurses are to be, a part of EBHC it must be clear which roles they can perform within their own profession and how research findings can be incorporated into their clinical practice.

As health promoting behaviour is a core element for self-care and for nursing care and essential for the outcome of rehabilitation, the protocol for the interventions focused on self-care and maintaining activities for daily living. The recommendations for practice were based on the ESC guidelines highlighting the importance of self-care.[6, 7] The theoretical frameworks used were based on research demonstrating patients ability to take responsibility of their own care which have been shown to increase patients' health promoting behaviour.[97-99]

A cornerstone of EBHC is a systematic identification of patient preferences. Patients themselves assessed their self-care ability, HS and functional level using validated instruments. This means that the patients' experience of the situation formed the basis for the care plan that was developed and agreed on with the patients. The care plan incorporated activities that made sense for the patients and activities that actually could be performed by the patients.

In the literature there are several studies on HF testing interventions with a variety of components, and furthermore, it is emphasized that patient education can be improved. [100] It seems that various types of Disease Management Programs (DMP) appear to be effective but the implementation of a specific program depends on local health service characteristics, the patient population and the resources available.[101] A current meta-analysis concludes that the essential characteristics or components of a successful HF management program are still to be determined.[102] The study presented in papers 1, 2, 3 and 6 contributes to a better understanding of the effectiveness of actively involving patients and how to identify patients and incorporate patients preferences in a clinical setting. The regression analysis in paper 6 revealed that the primary reason for effect is group relation.

Reducing the daily intake of sodium is a cornerstone of cardiac rehabilitation. In an overview article published in 2013 this approach in patients with HF was

questioned.[103] As EBHC depends on valid recommendations presented in CPGs, CPGs have to be based on a systematic review of the literature and has to be updated regularly.[72] Therefore, it was necessary to carry out a SR of the literature in order to ensure that the best evidence is used in the daily clinical practice.

In order to perform EBHC interventions must be described accurately, but the review of the literature revealed that interventions are often described on a general level. In hospital settings it seems that various types of DMP appear to be effective. A current meta-analysis concludes that the essential characteristics or components of a successful HF management program are still to be determined.[102]

In this study, the aim was to describe the interventions so accurately that they could be directly transferred to nursing practice and implemented in clinical practice. The frame of reference for this intervention has been validated in other patient groups [97, 104] and now new information has been added to the body of knowledge of the effectiveness for the frame of evidence. However, further studies are needed before the frame of reference can be generic. Telephone follow up in primary and community care settings seems to be an effective and acceptable means for patients as well as for the health care provider. In this study, a CNS carried out the interventions in order to test the effectiveness of the intervention. In everyday clinical practice, this may not be realistic. Therefore, some introduction and education will be needed before implementation of the concept into daily clinical practice.

7.1.1 Summary

The interventions were based on research findings and instruments specifically designed to cover important areas for patients with HF

The care plan was developed and agreed on by the patient and nurse; incorporating the patient's preferences, the nurse's skills, expertise and judgement combined with the best available evidence related to the actual context

The intervention was carried out in an everyday setting showing that EBHC is feasible in practice.

7.2 Changes in functions including self-care behaviour and HS function

Significantly higher within-group scores were found in total self-care behaviour in the intervention group after twelve weeks, and subgroup-analyses showed significantly reduced development of anxiety. The intervention group and the control group were similar regarding demographic variables, such as age, gender, living alone and dependency on help, NYHA class and self-care behaviour at inclusion in the study. These factors are also factors that might interact with the health patient's HS on an individual level. Therefore, patients need suggestions to cope with the consequences of HF in order to achieve a positive outcome from the rehabilitation. As the binary logistic regression analysis identified that being in the intervention group had the strongest association for preventing developing of anxiety during the rehabilitation period this might suggest that the intervention had been truly individualized.

In a SR based on 35 studies[65] subgroup analysis was not carried out. Therefore, it can be difficult to evaluate whether individualizing was truly carried out and also difficult to compare our results with others.

Furthermore we found that patients rated their HS to be moderate (scoring range from 0 to 100). The physical and emotional dimensions of HS were also in the middle of the possible scoring ranges. The HS score had a large Standard Deviation (SD) of 25, indicating that the patients had a highly variable HS.

According to total EQ5D scores there were no significant differences between the groups at follow-up. However, it is interesting that we found an increase in scores on usual activities and a reduction in the number of patients' with anxiety/depression at 12 weeks in the intervention group. In the logistic regression analysis we found a significant association between reduction in anxiety/depression and being in the intervention group (OR = .324 CI = .112 -.555) (p = 0.01) and increased self-care

behaviour (OR .468 CI = .199 - .983) p= 0.045). This association indicates a possible beneficial effect of the intervention. After phase two of the rehabilitation, patients were transferred to continued rehabilitation in their own municipality. Our intervention indicates that having access to a healthcare professional may reduce the number of patients who develop anxiety/depression. Evidence to support a link between self-care in patients with HF and health outcomes is limited.[50, 105] The results from our study are in line with the results from the study by Tung et. Al.[50] Furthermore, we found a correlation between self-care behaviour and reduced anxiety/depression. It has previously been asserted that there is a clear relationship between depression and poor HS, a relationship, which seems to be associated with poor self-care. [106] To our knowledge this is one of the first studies, which has actually shown this possible correlation.

7.2.1 Discussion of research design and methodology in the intervention study (Paper 1,2,3 and 6)

One of the cornerstones of the study is the internal validity of the study. Internal validity is defined by: the stringency of the survey/trial, the relevance of the selected concepts and variables, the existence of a causal relationship between those [107] and the importance of the patient's ability to identify whether they are receiving active treatment or are in the control group.[108, 109]

The selected concepts and the approach of the intervention were guided by a tested theoretical framework, which has been shown to be effective in relation to stimulating positive changes in relation to patients' health behaviour.[77, 104] Furthermore, it has been shown that the result of close and individual teaching and guidance of the patient can be subsequently captured quantitatively.[110]

When planning a study the aim is to maximize internal validity. This was done by identifying the risk of the presence of bias and confounding. For this purpose, the randomized clinical controlled double blind trial is considered to be the strongest design.

In an EBHCP we work with the elements of best available evidence, patients' preferences and available professional skills, expertise and clinical judgment.[22] The Randomized Controlled Trial (RCT) is considered to be the strongest design in testing hypotheses, due to the randomized allocation of patients and control over the experimental situation, which includes control groups and manipulation according to whether the patient receives treatment or not. An important issue is that, optimally, patients as well as staff should be blinded.[109, 111, 112] Blinding is an important part of a RCT. If blinding is inadequate, results may be biased.[113] The main goal of our study was to generate the best possible evidence for an effect of an individualized rehabilitation intervention for patients with HF. In our study, we did not judge it possible to blind patients or investigators due to the nature of the intervention. That means that it is necessary to use a credible design, which is why the quasi-experimental design was selected, even if it is characterized by a lower internal validity than a RCT. [74-76]

In this study patients were included consecutively. The inclusion started with the control group. When the calculated number of patients based on the power calculation was reached the recruitment to the intervention group started. This was done to eliminate the risk of interaction between the groups and to eliminate the interference from the ward staff. The intervention group and the control group was similar regarding demographic variables, age, gender, living alone and dependency on help and self-care behaviour at inclusion in the study.

7.2.2 Strengths and Limitations (Paper 1,2,3 and 6)

The quasi-experimental trial with a control and an intervention group without randomization may cause selection problems due to the patient groups and the personnel involved, and there may be changes in treatment programs and changes in accessibility to health care during the study period [109]. To reduce the risk of attrition bias analyses were carried out by the "intention to treat" principle.[86, 114] The number of patients was determined based on a power calculation, and the patients were recruited from two regional hospitals. During the data collection period there were no changes in the normal rehabilitation program and no changes in the staff group.

This study was based on a tested theoretical framework and validated instruments made assessments. EHFSCBS [84] is a practical scale which can be used to gain insight into the effectiveness of health care interventions and this tool has proved to be useful for research purposes. In this study, the tool was used for clinical practice. It identified areas for individual education that previous research has documented to be of importance for self-care behaviour for patients with HF. Thus individual HF education and counselling could be planned and implemented in this study. In terms of active involvement of the patient, the EFHFSBS was useful as an indicator for the progress in the treatment and self-care behaviour in relation to the goals that were agreed on. The same specialist nurse conducted data collection, in order to minimise inter-observer variability. The interventions have been described so accurately that they could be repeated in order to test whether the same results could be obtained in a similar study and they could be easily implemented in a clinical setting. The intervention group and the control group were similar regarding the demographic variables, age, gender, living alone and dependency on help and self-care behaviour at inclusion in the study.

Individual behaviour can be altered by the observation itself.[115] Presenting questionnaires on self-care, HS and functional level introduced the importance of these concepts in the control group. This could stimulate patients in this group to change behaviour, which could lead to an underestimation of the effect of the intervention, the so-called Hawthorne effect.[115] In our study this means that the calculated significant positive effect is actually underestimated and therefore the results are even more reliable.

Drop out is a well-known phenomenon and in similar studies the dropout rate has been reported to be between 15 – 50 %.[116-118] In this study, the dropout rate was 17.3 %. Drop out analysis showed no difference between control and intervention group in terms of the demographic data. There are a higher number of dropouts from the control group than from the intervention group, which may be explained by the telephone follow up after one and three months. Telephone support may have been a motivational factor for the patients to fill out questionnaires in the intervention group.[61, 77, 119-121,122,123]

7.3 Meta-analysis (Paper 4 and 5)

7.3.1 Validity of recommendations in guidelines

EBHC relies on valid recommendations built on a SR of literature that has been thoroughly appraised. Few public health policies have been as widely endorsed for lowering (CVD) morbidity and mortality as dietary sodium restriction.[124] This policy can be dated back to Kempner's observation that extreme sodium restriction tempered the hypertensive crisis associated with renal insufficiency.[125]

Reduced dietary sodium intake has been on the agenda worldwide and it is generally recommended to reduce dietary sodium intake to about 5-6 g/day.[126] ESC recommends that patients in general should reduce their daily intake of sodium.[6, 7] The recommended levels of sodium intake has been two to three grams per day with further restriction (below two grams per day) to be considered in patients with moderate to severe HF.[103, 125] The SR presented in this thesis build on four RCTs (including 2382 patients). The conclusion is that a reduced sodium intake significantly increased all-cause mortality and HF readmissions compared with a normal sodium intake in patients with HF who were treated with diuretics.[93] The risk for readmission and mortality was in average 2.5 times higher when dietary sodium intake was reduced.[93] This is in line with the results from a prospective study [127] which found that sodium restriction below 2g/day is not warranted for patients with mild HF. Normal dietary salt intake in the Scandinavian population has been reported to be six grams per day for women and nine grams per day for men.[128] However, the conclusion is that dietary salt intake belove 3/g day may be harmful for patients with moderate to severe HF in diuretic treatment. This means that a narrow balance of dietary sodium intake is needed for patients with HF.

In our study, we used the best available evidence, the ESC guideline from 2008, to form the base for the self-care education.[6], [80] Through the years from 2010 to 2012 the discussion of dietary salt reduction was ongoing and updated in a published review which indicated that dietary sodium reduction might increase mortality and readmission rates for patients with HF.[73]

Continuous updating of knowledge is required when working within the frame of EBHC. Therefore, CPG have been introduced. They summarize the existing knowledge in the specific area and establish the research basis for EBHC. The development of a guideline requires a systematic and transparent process illustrating the systematic search, appraisal and summarizing of the literature, and finally a critical appraisal of the guideline by means of a relevant tool followed by internal as well as external appraisal of the guideline to ensure its internal and external validity.[129-131] In the ESC guideline [68] the search strategy and the appraisal of included studies have not been reported which is an requirement for high quality clinical guidelines.[71, 129, 130] Measuring self-care behaviour was based on the validated EHFSCBS. This is based on three elements: complying with regimen, asking for help and adapting one's activities to the condition. [84] The developing process of the EHFSCBS is well described and the results are validated .Therefore the content was based on the assumption that reduction of dietary salt intake would benefit patients with HF. Newly published research and the meta-analysis presented in the thesis questions this assumption. This means that the instrument ought to be revised in the light of the newly available evidence.

In summary, the use and construction of CPG is important and difficult. The aim is to collect the best available evidence and validate it by use of the recommended tools and methods.[129-131] It is possible to stimulate the patients to change their self-care behaviour through a pedagogical approach.[132] It is an ethical problem if the intervention harms the patient.

7.3.2 Strengths and limitations (Paper 4 and 5)

The meta-analysis is carried out based on an approved peer reviewed protocol. This is required worldwide by the three leading organisations (The Cochrane Collaboration, Joanna Briggs Institute and the Campel Collaboration) within the field of developing and publishing SR.[90, 133, 134] SRs aim to provide comprehensive and unbiased summaries of the evidence on a single topic, bringing together multiple individual studies in a single document. As part of the SR process, individual research studies are subjected to critical appraisal. Even when research

evidence is limited or non-existent, SR summarize the best available evidence on a specific topic providing the best evidence for clinical decision making as well as identifying future research needs. The foundation of SR is a protocol that fosters and promotes objectivity and transparency in the process. The protocol details the criteria the reviewers will use to include and exclude studies, to identify what data is important and how it will be extracted and synthesised. A protocol provides the plan or proposal for the SR and as such is important in restricting the presence of reporting bias. Any deviations between the protocol and report should be discussed in the SR report. The protocol presented and the meta-analysis have been developed according to the guidelines in the manual from JBI.[90] Critical appraisal and extraction of data has been carried out independently by two reviewers. This is a strong design and is the basis in GPC in EBHC. Normally distributed data is assumed with regard to compiling a meta-analysis. In many papers, the distribution of data is not reported. If data is not normally distributed it can result in an over- or underestimation of the effect. In the studies included here we anticipated that data were normally distributed as these are reported as SD and mean values. Limitations of the meta-analysis are that the primary studies are single or double blinded and this therefore increases the risk of selection bias, even if it is limited. Furthermore, the same author carried out the studies included in the meta-analysis. On the other hand, there are no other studies on the subject. The studies included have a relatively small number of patients included and therefore the strength of the study is limited.[135]

8.0 Conclusion

The aims of this thesis were:

To develop and test a protocol for rehabilitation of patients after completing rehabilitation in an outpatient clinic. The protocol was based on the principles of EBHC and tested the effect of a systematic involvement of patients in their rehabilitation. Outcomes of the interventions were functional level, HS and self-care ability (Paper 1, 2, 3 and 6).

In order to contribute to the pool of evidence for updating of the CPG to patients with HF a SR was carried out. The review focuses on the effectiveness of reducing daily intake of Dietary sodium in patients with HF to reduce mortality and readmission to hospitals. (Paper 4 and 5).

The systematic intervention was carried out by a CNS and based on an individual care plan and telephone follow up 4 and 12 weeks after discharge from the outpatient rehabilitation clinic. This intervention led to a significant increase in the total self-care behaviour score in patients with HF. HS (SF-36 and EQ5D) measures showed no significant overall changes in HS between the groups. However, subgroup analysis showed that patients in the intervention group did not increase their level of anxiety within the first 12 weeks after discharge whereas the level of anxiety significantly increased among patients in the control group ($p=0.034$).

There may be a correlation between the increase in self-care behaviour in patients in the intervention group after 12 weeks and a reduction in anxiety measured with EQ5D.

If patients with HF that receive diuretic treatment reduce their dietary salt intake they might increase their risk of being readmitted to hospital and might even increase their mortality risk.

9.0 Implications for research

The present thesis revealed that a systematic intervention to patients with HF led to an increase in self-care behaviour and reduced developing of anxiety after discharge. To our knowledge, this study is the first to investigate this correlation. This must be investigated further in larger scale studies

The elements of rehabilitation described in guidelines worldwide should be the object of deeper investigation and research and not be based on weak evidence only. Therefore, larger scale studies are needed. Traditionally RCT's have been the golden standard for the effectiveness of these interventions. In the future, it is important to discuss whether this is still reasonable or whether other study designs are more beneficial for issues, which are not typical for use of RCTs.

In this thesis, the focus has been on patients in primary and community care settings, an area, which is sparsely investigated. Its results show that a systematic intervention increased self-care behaviour. Further research is needed for a more specific description of the status for patients with HF when they are in the primary and community care setting living in their own home. This thesis found the importance of the evidence based practice with regard to dietary salt intake for patients with HF. Currently there is no knowledge about the optimal dietary sodium intake in patients with HF. A great deal of further research is required in this area.

Further research is also needed to implement the results from this study in clinical practice. It is possible to use the EHFSCBS in practice as a guide for the nurse to discover the educational needs for patients with HF in order to guide them to change their behaviour. The tool should undergo a revision related to the evidence based knowledge in the area of HF before use in clinical practice.

10.0 Implications for practice

The link between evidence based knowledge and CPG has been shown to be an important factor in daily practice. The CPGs may incorporate a system for updating themselves and require a strategy for developing and implementation of the guidelines in practice

The model we used is now a well-documented intervention model, which can be recommended for use in practice as a standard model when stimulation to self-care behaviour is needed

A strong connection between the clinical specialist nurse in the hospital setting and primary care is needed to ensure the continuity in the rehabilitation. One possibility might be that CNS follows the patient after discharge from the outpatient clinic by telephone follow up. Employment of a CNS in the primary and community care setting with specialist knowledge in HF is an alternative.

CPGs have to be used, but with a critical look. The elements in the EBHC have to be used systematically and the nurse's skills have to be developed according to the use of these elements.

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APPENDICES

Appendix 1

Papers

Paper 1 Larsen P, Pedersen PU. Protocol to test the effectiveness of individual planned nursing rehabilitation on self-care behavior and HS in patients with HF - a quasi-experimental study. *Submitted to Springer plus Medicine*

Paper 2 Larsen P, Pedersen PU. Stimulation to self-care in patients with heart failure: A quasi-experimental study. Journal of Nursing Education and Practice. 2013;4(3):p143 – 54. **http://dx.doi.org/10.5430/jnep.v4n3p143**

Paper 3 Larsen P, Pedersen PU. The effectiveness of individual rehabilitation on Health Status in patients with Heart Failure: a quasi-experimental study. International Journal of Evidence Based Health Care. *Accepted*

Paper 4 Larsen P, Pedersen PU, Tsiami A. The effectiveness of reducing dietary sodium intake versus normal dietary sodium intake in patients with heart failure in reducing readmission rate: a systematic review protocol. The JBI Database of Systematic Reviews and Implementation Reports; 2014;Vol 12 (2):125 -31. The Joanna Briggs Institute. **doi:10.11124/jbisrir-2014-1095**

Paper 5 Larsen P Pedersen PU, Tsiami A. The effectiveness of reducing dietary Sodium intake versus normal dietary sodium intake in patients with Heart Failure in reducing readmission rate: A Systematic Review The JBI Database of Systematic Reviews and Implementation Reports;. 2014; *in Review.*

Paper 6 Larsen P, Thomsen T, Pedersen PU. Effect of Clinical Nurses Specialists intervention on rehabilitation outcomes in patients with heart failure. Clinical Nursing Studies. 2015;3(2):31-9. Epub 29.12 2014.

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SUMMARY

Patients with heart failure are living with a serious progressive disease and need long-term rehabilitation and care in hospital as well as in primary and community care settings. There are no specific guidelines for rehabilitation in primary care and community care setting where maintaining rehabilitation takes place. The purpose of this study was to develop and test a protocol for rehabilitation of patients after completing rehabilitation in an outpatient clinic. The protocol is based on the principle of EBHC and tests the effect of systematic involvement of patients in their rehabilitation in their own home by stimulating an increase in self-care.

Outcomes of the interventions are health status, functional level and self-care ability (Paper 1, 2, 3 and 6). In order to contribute to the pool of evidence when updating Clinical Practice Guidelines with recommendations for patients with heart failure an meta-analysis has been carried out. The meta-analysis focused on effectiveness of reducing dietary sodium intake versus normal dietary sodium intake in patients with heart failure on reducing readmission rate (Paper 4 and 5).

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