



**PROTOCOL TO TEST THE EFFECTIVENESS OF INDIVIDUAL PLANNED NURSING REHABILITATION ON SELF-CARE BEHAVIOR AND HS IN PATIENTS WITH HEART FAILURE - A QUASI-EXPERIMENTAL STUDY**

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**ABSTRACT**

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. Most research is done in hospital settings and therefore the knowledge of rehabilitation in the rural setting is limited. The aim of the planned study therefore is to test a protocol for rehabilitation of patients after completing rehabilitation in the outpatient clinic. The protocol is based on the principles of Evidence Based Health Care and will test the effect of systematic involvement of patients in their rehabilitation in their own home by stimulating increased self-care. Outcomes of the Interventions will be functional level, health status and self-care ability. Design: The study is designed as a controlled longitudinal study with an intervention and control group, including 144 patients. Based on the findings of our literature review, this is the first study that focuses on the relationship between the individualized needs of the patient's knowledge and the impact on individuals' self-care behavior as the basis for rehabilitation after heart failure.

**Key words:** Self-care, Heart failure, Health Related Quality of life, rehabilitation.

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**INTRODUCTION**

Heart failure (HF) is still the most common cause of morbidity and mortality in the Western world [1]. European Society of Cardiology (ESC) define Heart Failure as: “an abnormality of cardiac structure or function leading to failure of the heart to deliver oxygen at a rate commensurate with the requirements of the metabolizing tissues, despite normal filling pressure.” [2]

In clinical practice, there is an increased understanding of the importance of giving advice to patients with heart failure (HF), which allows them to gain a greater insight into positive self-care and possible risk reducing behavior [2-4]. Self-care is defined as the decision and strategies undertaken by the individual in

order to maintain life, healthy functioning and well-being [5].

The European Society of Cardiology (ESC) published the first guidelines for diagnosis of HF in 1995 and updated those for diagnosis and treatment of HF latest in 2012 [2] This has strengthened the medical treatment of HF. The guidelines also emphasize that the medical treatment must be supported by the patients' self-care skills [2]. The choices of healthy food, smoking cessation, controlling weight, and participation in physical activities have come to constitute the major part of the non-pharmacological rehabilitation for patients with heart failure [6-8]. These behavioral changes can be interpreted



as a significant part of the individual's self-care and a component of their future health behavior.

### **Rehabilitation for patients with heart failure**

Cardiac rehabilitation is defined as, "the sum of activities required to influence favorably the underlying cause of the disease, as well as the best possible physical, mental and social conditions so that they may by their own efforts preserve or resume when lost as normal a place as possible in the community" [7]. There is a significant positive effect of CR measured by health status (HS), continuously measured with the Short Form-36, measured 6 months after rehabilitation.

Good adherence to rehabilitation programs decrease morbidity and mortality and improves Health Status, functional level and well-being [2]. Two aspects of the definition of rehabilitation are noteworthy. The first is that self-care behavior is important for the outcome of rehabilitation and the second that the focus should be on health in the patient's own setting.

Rehabilitation includes assisting the patient to compensate for deficits that cannot be reversed medically. Most of the studies related to CR are related to the hospital or the outpatient clinic and focus on exercise based rehabilitation [9, 10]. Rehabilitation can be divided into three or four phases [11, 12]. Phase I is acute rehabilitation, starting immediately after hospitalization. Phase II is rehabilitation for outpatients from discharge continuing for the next 8 to 12 weeks. Phase III rehabilitation has traditionally take place in the outpatient clinic linked to the hospital. The new possibility is that it can take place in the patient's own community, without connection to the hospital system [12, 13]. Phase III is still seen as a part of the rehabilitation program and will benefit the patient if it is based on the professional recommendations with emphasis on optimization and maintenance of symptomatic treatment, physical training, psychosocial support, lifestyle interventions and patient education [14-16].

Rehabilitation has traditionally been managed by the hospital staff either by appointments in outpatients' clinics or by telephone support [17]. The results of exercise based cardiac rehabilitation are well documented in several systematic reviews [10, 18-22], but the overall effects of rehabilitation are unknown since the rate of participation in the established rehabilitation shows that less than 5% of patients with HF participate in rehabilitation in all three phases, so knowledge of the overall effect of existing rehabilitation practices is limited [23].

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 [24]. The systematic literature search identified 11 SR [25-35], which were critically appraised using a validated instrument [36]. 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 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.

Self-care and measuring of self-care behavior in patients with heart failure

Self-care is important for adherence to treatment and for the understanding of the disease and its symptoms [2]. Heart failure has a major impact on the individual's HS and lifestyle [2]. Often it is necessary to make lifestyle changes, which influence adherence to medication, dietary intake, especially salt, and to the awareness of signs and symptoms of heart failure[2]. A lack of professional follow up for patients with mild to moderate symptoms of HF will often result in readmission to hospital [37-39]. Several researchers have developed instruments for measuring HF patients' self-care behavior. The Self-care HF Index [40] and the European HF Self-care Behavior Scale [5] are the only two which are consistent, valid and reliable and have been demonstrated to be sensitive in measuring disease specific performance changes in self-care behaviors and skills [41]. The European HF self-care behavior scale actually measures the patient's self-care behavior in relation to the items mentioned by the ECS guidelines [2].

In hospital settings and through visits to patients' homes the first week after discharge, an intensive, systematic, tailored and planned education and support



program delivered by a nurse can increase patients' self-care behavior [42].

Increased positive health behavior [43-45] can be achieved by actively involving patients in their own rehabilitation. It has been shown that patients, if they have been actively involved in their own rehabilitation, show significantly improved HS and preserved and/or increased functions of daily activities four months after discharge, from the physical, psychosocial and mental points of view [43, 45]. Active involvement occurs when the health professionals' actions are based on the patients' perception of the individual's situation, and include follow-up conversations that focus on the patients' need for information, guidance and teaching and when continuity is ensured by a permanent contact person with a high level of professional insight. This approach has shown efficacy with both direct meetings between patient and health professional and in follow-up by telephone contact [43, 45]. The most important activities are those related to what the patients can do by themselves. It means that the patient intervenes on their own behalf rather than passively receiving treatment. Involving the patients in planning their own rehabilitation is the opposite of the "one size fit all" approach.

The growing number of patients with heart failure has increased both the pressure on hospital resources and the need for community management of the condition. Improving hospital-to-home transition for this population is a logical step in responding to current practice guideline recommendations for coordination and education. It has been shown that HF management programs in Phase III in the outpatient setting produced positive outcomes. There is a pronounced effect in terms of increase in health related quality of life [HRQOL] and a reduction in the financial cost to society [46]. In this study the following hypothesis will be tested: a systematic, tailored and individual care plan including education and support, delivered by a nurse for the first three months after the patient is discharged from an outpatient clinic will lead to an increase in the patient's self-care behavior and HS, compared to traditional Phase III rehabilitation at the outpatient clinic. In a danish context rehabilitation have been developed in a comprehensive program. The phases in the program are shown in table 1. The aim of the planned study therefore is to test a protocol for rehabilitation of patients after completing rehabilitation in the outpatient clinic. The protocol is based on the principles of Evidence Based Health Care [47-49] and will test the effect of systematic involvement of patients in their rehabilitation in their own home by stimulating increased self-care. Outcomes of the Interventions will be functional level, health status and self-care ability.

## METHOD

The study will recruit patients from cardiac wards at two teaching Hospitals in Zeeland, Denmark. Patients will be included in the study if they are 18 years or older

and assessed to have mild to moderate HF symptoms and have completed Phase I and II rehabilitation. Patients who do not understand the information [mental disorders, language and hearing problems] and patients diagnosed with neurological deficits will be excluded.

To achieve sufficient statistical power the sample size will be calculated as follows: Type I error 5%, Expected effect rate of 30% and minimal difference between effect rates not to be overlooked 30%, Type II error, 20%. The sample size will be calculated to be 60 in each group [control and intervention]. With an expected drop-out rate of 20%, 72 patients will be included in each group. Calculations are based on changes in physical Health Status measured by SF 36 and EQ5D [45].

## Design

The study design will be quasi-experimental. Patients in the control group follow the conventional rehabilitation offered by the hospital and the primary health care sector. When the number of patients in the control group is reached, the inclusion of patients to the intervention group will begin. For the patients in the intervention group, an individual rehabilitation plan will be prepared. For all patients HS and self-care behavior will be measured at inclusion in the study [baseline] and after 4 and 12 weeks. There is an agreement with the hospitals that treatment, care and rehabilitation will not be changed during the study period to ensure that all included patients receive the same treatment care and rehabilitation in Phase I and Phase II.

## Data collection and data handling

Data will be collected by the research team, when patients are discharged from the out patient Theoretical frame of reference The nursing intervention in this study will be based on motivational theories combined with a theory of development in which the main goal is to promote and maintain patients' active involvement in their own care[45]. The model includes four main elements:

- 1) Assessing the patient's normal activities in relation to health issues and daily functioning. This assessment will be based on motivational theory and theory on subjective and objective press for human activities [43, 50]. The central element is the patient's behavior in relation to health, where actual behavior seems determined by the predispositions of the individual, the individual's enabling factors for achieving health-promoting behavior and, finally, reinforcing factors that stimulate motivation [11, 51].
- 2) Continued dialogue between patient and nurse, to ensure information sharing, teaching and individual care.
- 3) Planning of nursing care with reference to the patient's usual activities of daily living.
- 4) Use of the principles embedded in primary nursing care [first author].

This model has been tested in studies including patients suffering from various medical and orthopedic



diseases and the findings confirm that patients cared for with this model experienced more personal activity and growth during their hospital stay compared to patients receiving usual care 38.

### **Intervention**

Before the appointment with the CNS the patient [alone or with a relative] will assess the importance of their own self-care behavior, and health status - using questionnaires Based on the assessment the CNS will explore the patient's reason for prioritizing self-care behavior. The European Heart Failure Self-Care Behavior Scale [EHFScB] Scale will be used as an interview guide and actually help to individualize the intervention. All 12 self-care behavior elements will be discussed and the patients have to set up goals for their activities related to the specific items, for the next 4 weeks. It is then the patients preferences which will be the fundament in developing the plan an evaluation of progressions which will be evaluated by tele phone follow up.

After 4 and 12 weeks the patients will fill out and return the self-administered questionnaires. Based on the scores and the goals in the care plan, the clinical nurse specialist will continue the dialogue with the patient by telephone.

### **Measurement**

Health Status will be measured with the Short Form 36 (SF-36) [52-54] and EuroQol (EQ5D) [44] and self-care behavior with the European Heart Failure Self Care Behavior Scale (EHFScBS) [5]. SF 36 is a validated tool for measuring Health Status and has been translated into Danish. In the present study, the internal consistency reliability of the eight SF-36 scales was above 0.70 for all scales. The questionnaire consists of 36 questions, summarized into eight subscales. Four subscales can be combined into an overall measurement of physical health (PCS) and the four subscales can be combined into an overall measurement of mental health (MH) which together produces a rating of overall Health Status. Responses are transformed into a score on a scale from zero (lowest score) to 100 (highest score) with a higher score indicating better Health Status [52-54].

EQ5D has been translated into Danish and is a generic, validated instrument for measuring Health Status 44. It obtains a rating of self-perceived overall health 44. The instrument is descriptive and consists of five dimensions measuring the individual's Health Status. The five dimensions are: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression/. Responses rate three levels of severity (no problems, moderate problems or extreme problems)½ 1 within a particular EQ-5D dimension. It is combined with a visual analogue scale from zero to one hundred measuring general health perception. EQ5D has been tested in different populations, including patients with cardiovascular disease, with satisfactory validity, reliability and responsiveness.

Self-care behavior will be measured with the EHFScBS which is a 12-item, self-administered questionnaire that covers items concerning self-care behavior of Heart Failure patients, with a high reliability. Face- validity and concurrent validity has been established, and the internal consistency of the scale has been tested and shows Cronbach's alpha of 0.81 [5] . The instrument is a valid, reliable and practical scale to measure the self-reported self-care behavior of HF patients 5 based on the aspects of self-care. EHFScBS measures behavior that maintains self-care. In this context self-care is defined as the decisions and strategies undertaken by the individual in order to maintain life, healthy functioning and well-being 5. EHFScBS measures compliance with medical regimens, observation of edema, the ability to respond adequately to observed progression in HF and adjust daily activities in accordance with current physical abilities. Each item will be scored on a 5-point Likert scale. The patient can obtain a score between 12 and 60 points, where 12 points indicates a very high self-care behavior and 60 points a very low self-care behavior. A total score is calculated by summing all items as recommended by Jarsmaa et al. 5 If more than three items are missing the total score can not be obtained. In case of three missing items the value three will be used to replace the missing score per item 5. The Cronbach's alpha in this study was 0.81 Heart Failure will be clarified by a cardiologist using the New York Heart Failure scale (NYHA) (48). The cardiologist will be blinded for the allocation of the patients to the intervention or control group.

Information on gender, age, marital status and dependence on help will be self-reported by patients. We will obtain Information on weight and height from the patients' medical records.

### **Ethical considerations**

Participation is voluntary. Patients will be included in the study after giving informed consent including information about: freedom to withdraw without penalty, anonymity and minimal risk of harm in relation to likely benefits. The experiment are reported to the research ethics committee (2013-41-1935) and w ww.clinicaltrial.gov (NCT01239667) and data will be handled in accordance with the specified rules.

### **Statistical analysis**

Data will be analyzed using SPSS version 20 [55]. Ratio-scale data from both groups will be tested by F-test for distribution. Normally distributed data will be compared by the Student's t test. Nominal scale data will be compared by chi-square tests or by the use of the 95% confidence intervals . All calculations will be based on "intention to treat" analysis [56, 57]. Cronbach's alpha will be used to assess the reliability of the questionnaires used in the study.



Level of significance was set at  $p < 0.05$ . Missing data will be replaced by mean scores where possible and by last observation carried forward where mean scores will not be available within the control and intervention groups respectively. Logistic regression analysis will be used to examine variables associated with increased self-

care. Pearson's correlation analysis will be carried out in order to test for correlations between ratio scale data.

## RESULTS

The results of this study will be reported once data analysis is completed.

**Table 1. Rehabilitation Phases and interventions**

Rehabilitation Phases	Interventions
<p><b>Rehabilitation Phase I</b> (2- 3 days)</p>	<p>In the hospital when admitted Information and group based education</p> <ul style="list-style-type: none"> <li>- Dietary</li> <li>- Smoking Cesasion</li> <li>- Alcohol reduction</li> <li>- Increase in exercise/activities</li> </ul>
<p><b>Rehabilitation Phase II</b> (8 – 12 weeks)</p>	<p>Outpatient clinic Consultations with the multidiciplinary team. Fok´cus is on</p> <ul style="list-style-type: none"> <li>- Dietary</li> <li>- Smoking Cesasion</li> <li>- Alcohol reduction</li> <li>- Increase in exercise/activities</li> </ul>
<p><b>Rehabilitation Phase III</b> (from 12 weeks - )</p>	<p>In the primary and community care setting when the patient are discharged from the outpatient clinic Consultations with the patients GP Different offers in the different municipalities</p>

## DISCUSSION

The internal validity of the study concerns the stringency of the survey, the relevance of the selected concepts and variables, and the existence of a causal relationship between those [58], and the importance of the patient's ability to identify whether they are receiving active treatment or whether they are in the control group [55, 56]. In this study, it is practically difficult to blind the patients and the nurses. It could be possible to blind the statistician. The selected concepts and the approach of the intervention are guided by a theoretical framework that has been tested and it has an effect in relation to stimulating positive changes in relation to patients' health behaviors. Furthermore, it has been shown that the result of close and individual teaching and guidance of the patient can be subsequently captured quantitatively [57]. When planning a study the aim is to maximize internal validity. This is done by identifying the risk of the presence of bias and confounding. For this purpose, the randomized clinical controlled double blind trial is the strongest design. A randomization would eliminate the variations which could be attributed to patients, time and personnel-related influences. In this study randomization of the patients and blinding of the intervention will be difficult. To reduce the risk of attrition bias analyzes are carried out by intention to treat principle. Intervention will take place in two different hospitals. We could have considered cluster randomization as a method, but there could be differences in socio-demographic data, rehabilitation programs etc. between patients in the 2

hospitals. The chosen quasi-experimental design will eliminate these problems. The clinical controlled trials with a control group and an intervention group without randomization [48, 59] may cause selection problems, due to change in the groups and the personnel involved, and there may be changes in treatment and opportunities [56]. Inclusion of patients will proceed over approximately one year. It is unlikely that the patient population for the two participating hospitals will change dramatically in this period. All patient contacts will be made by the same health professional so that there is no change in relation to staff, which also will increase inter-variability rates.

Finally, there is not currently offered specific Phase III rehabilitation in primary health care to this patient group, and it is unlikely to be developed during the investigation period. Furthermore, tested and validated instruments are used for data collection and data is collected at defined times in both groups. The numbers of patients are determined based on a power calculation, and the patients are recruited from two comparable regional hospitals. Patients live in major provincial cities and in rural areas, so it must be assumed that the patient population is representative of a large part of the Danish population.

## CONCLUSION

Based on the findings of our literature review, this will be the first study that tests a systematic, tailored and individually planned teaching and care plan delivered



by a specialist nurse including telephone support for the first three months after the patients are discharged from an outpatient clinic. Data, or rather the results of the study, will be used to develop an intervention program in the primary and municipal sector in future.

#### COMPETING INTERESTS

The authors declare that they have no competing interests

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#### AUTHORS' CONTRIBUTIONS

PLa have made substantial contributions to conception and design.

PLa have developed the draft of the manuscript and PUP have been involved in drafting the manuscript or revising it critically for important intellectual content

PUP have given final approval of the version to be published.

PLa and PUP have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

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