CLINICAL PRACTICE

Stimulation to self-care in patients with heart failure: A quasi-experimental study

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Abstract

Background: Patients with Heart Failure (HF) live with a serious disease, and need long term rehabilitation care. Rehabilitation takes place in the hospital as well as in the primary care setting. Elements in rehabilitation for patients with HF are based on the recommendations from the European Society of Cardiology and focuses on self-care and adherence in general. There are no specific guidelines for primary health care. Focus in this study is when the patient is discharged from the outpatient clinic to a primary care setting. The aim of this study is to test a protocol for individual planning of rehabilitation for HF patients with mild to moderate symptoms and to test the effect of individually prepared rehabilitation plans.

Methods: The study design is quasi-experimental. Patients in the control group follow the conventional rehabilitation. For the patients in the intervention group an individual rehabilitation plan was prepared and supplemented with telephone follow up after 4 and 12 weeks. All patients' health status and self-care behaviors were measured at study inclusion (baseline) and after 4 and 12 weeks.

Results: 162 patients were included in the study of which 137 (84.6%) consented to participate. There were no differences in total self-care behavior between the groups at the beginning of the trial ($p = .161$). After 4 weeks the total score in the control group was 25.3 and in the intervention group the total score was 22.2 ($p = .049$). After 12 weeks the score in the control group was 26.8, which was similar to the score at the beginning of the trial, and in the intervention group the score was 22.6, which gives a difference in total score of 6.2 ($p = .007$).

Conclusion: A systematic prepared intervention leads to a significant increase in total self-care behavior scores in HF patients

Key words

Heart failure, Self-care behavior, Rehabilitation, Primary care setting

Background

Heart Failure (HF) is a disease with one of the highest mortality rates in the Western world [1, 2]. HF patients have a poor prognosis, with a five years mortality of 68.7%, a median survival time of 2.4 years [3], and is associated with poor quality

of life and frequent readmissions to hospital [4, 5]. The guideline developed by the European Society of Cardiology (ESC) [6, 7] operates with the pharmacological and non-pharmacological response in HF patients. The pharmacological treatment has undergone a significant development in recent years, but cannot stand alone [6-8]. The non-pharmacological treatment must be systematically incorporated into treatment and rehabilitation of HF patients [7]. The non-pharmacological treatment is mainly based on lifestyle changes such as smoking cessation, increasing exercise, reduced alcohol intake and systematic identification and reactions on the symptoms of HF [6, 7]. These behavioral changes can be interpreted as a significant part of the individual's self-care and a component of their future health behavior.

Self-care

Self-care relates to the activities that individuals engage in relation to health seeking behaviors [9, 10]. Supporting self-care practices through tailored and relevant information can provide patients with resources and advice on strategies to manage their condition. Evidence-based approaches to improve adherence to self-care practices in patients with HF are not often reported. Low health literacy can result in poor understanding of the information about HF and is related to adverse health outcomes. Also a lack of knowledge can lead to non-adherence with self-care practices such as following fluid restriction, low sodium diet and daily weighing routines. These issues need to be addressed to improve self-management skills [4, 10-13]. Self-care requires active involvement of the patient who takes responsibility for the care and treatment. It is an underestimated element in the improvement of clinical outcomes [6, 7, 14, 15].

Based on a review of eleven systematic reviews and meta-synthesis, one integrative review, one prospective Randomized controlled trial RCT and one review [16-29], multidisciplinary interventions, combinations of education in clinic/MD office visits, home visits, monitoring and telephone support have been tested among patients with HF.

Mostly the interventions are hospital based and focus on the elements in phase II rehabilitation with a follow up time between 3 and 12 month. Multidisciplinary teams seem to have a positive effect on readmission to the hospital and mortality. Especially interventions lead by a clinical nurse specialist (CNS) has shown positive effect on readmission rates.

Studies focusing on primary health care are based on a literature review [5]. The articles used in the review are not critically appraised which reduces the possibility to make unbiased conclusions [5].

In a spot test in two of the articles in the literature review there is an insufficient description of the interventions. The interventions are based on articles such as editorials and a RCT which does not include nurses after patients are discharged from the hospital. The nurse's roles in the rehabilitation are primarily as cardiologist nurses in outpatient clinics to follow up after discharge from the hospital. Therefore it can be concluded that studies in Primary health care with focus on nurse's role in the rehabilitation are sparse and needed.

To date, trials of specialist, multidisciplinary CHF management programs have tested multifaceted approaches (multi-disciplinary input, home/clinic visits, telemonitoring and telephone support). As a consequence, it has been difficult to identify the incremental benefits of the components of each intervention. Most of the interventions are focused on rehabilitation in phase I and II [30]. There is a need to investigate the combination of telemonitoring or telephone support based on individualized interventions and their effectiveness in primary care setting in phase III of the rehabilitation.

Future studies of chronic disease interventions must include descriptions of recommended key program components to identify critical program components in hospital settings as well as in primary care setting.

Measuring self-care behavior

Several researchers have developed instruments for measuring HF patients' self-care behavior. Self-care HF Index [31] and European HF Self-care Behavior Scale [10] are the only two which both are consistent, valid and reliable and have demonstrated to be sensitive in measuring disease specific performance changes in self-care behaviors and skills [32]. The

European HF self-care behavior scale actually measures the patient's self-care behavior in relation to the items mentioned by the ESC guidelines [6, 7].

Cardiac rehabilitation (CR) 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 (people) may, by their own efforts preserve or resume when lost, as normal a place as possible in the community" [33]. Most of the studies related to CR are related to the hospital or the outpatient clinic and with exercise based rehabilitation in focus [34, 35]. In recent years there have been a growing interest to telemedicine initiatives and test of programs have supported patient compliance and has been a combination of interviews and telephone support [36-42]. Home based rehabilitation for HF patients [43, 44] have increased over the last years, but still we need to know which interventions benefit patients after discharge from the outpatient clinic.

It is important to assess the relationship between self-care behavior and the education the patient receives, in order to support the rehabilitation for the patient when they are discharged from the outpatient clinic and referred to the primary setting.

The question remains if similar gains as reached in the outpatient clinic could be achieved in primary care by community nurses. In this study the following hypothesis was tested: a systematic, tailored and individual care plan including education and support, delivered by a nurse for the first three month after the patients are discharged from an outpatient clinic, will lead to an increase in the patient's self-care behavior and health status, compared to patients who participate in traditional rehabilitation at the outpatient clinic.

The aim of the study reported in this article was to test a protocol for individual planning of rehabilitation for HF patients with mild to moderate symptoms and to test the effect of individually prepared rehabilitation plans. The effect was assessed in relation to self-care behavior.

Method

The study included patients from cardiac wards at two regional Hospitals in Zeeland, Denmark. Inclusion in the study: patients who were 18 years or older, assessed to have mild to moderate HF symptoms and who have completed phase I and II rehabilitation. Exclusion from the study: patients who did not want to participate, patients who did not understand the information (mental disorders, language and hearing problems) and patients diagnosed with neurological deficits.

To achieve sufficient statistical power the sample size was calculated. Type 1 error: 5percent. Expected effect rate of 30% and minimal difference between effect rates not to be overlooked, 30%, Type II error, 20%. The sample size was calculated to be 60 in each group (control and intervention). With an expected drop-out rate at 20 percent, 162 patients were included in the study. Calculations were based on changes in physical health status [45].

Design

The study design is quasi-experimental. Patients in the control group follow the conventional rehabilitation. When the number of patients in the control group was reached, the inclusion of patients to the intervention group began. For the patients in the intervention group an individual rehabilitation plan was prepared. For all patients health status and self-care behaviors were measured at inclusion in the study (baseline) and after 4 and 12 weeks.

Model of theoretical frame of reference

The nursing interventions in this study were based on motivational theories combined with the theory of development in which the main goal is to promote and maintain patients' active involvement in their own care [46]. The model includes 4 main elements:

- Admission interview assessing the patient's normal activities in relation to health issues and activities of daily living. This interview is based on theories of motivation and theory on subjective and objective press for human activities (beta-press and alpha-press) [46]. This interview should be carried out within 24 hours of admission. The key is the patient's behavior in relation to health, where the actual behavior seems to be controlled by the predispositions of the individual, the individual's ability to achieve a health-promoting behavior and finally the factors that stimulate motivation [46-48].

- Continued dialogues between the patient and the nurse, to ensure information sharing, teaching and individual care.

- Planning of the nursing care with reference to the patient's usual activities of daily living.

- Use of the principles embedded in primary nursing care.

This model has been tested in studies including patients suffering from various medical and orthopedic diseases and the findings confirmed that patients cared for with this model experienced more personal activity and growth during a hospital stay compared to patients cared for by using customary care [45].

Intervention

Patients' self-care behaviors were assessed using the European HF Self Care Behavior Scale (EHFScBS) [10]. Based on the scores an individual care plan with goals was set up. The care plan and goals were developed in collaboration between the CNS and the patient

When transferred to phase III rehabilitation patients completed questionnaire SF 36 [49, 50] and EHFScB scale [10]. Based on the patient's answers the nurse assessed the patient's self-care behavior, as well as risk factors identified in relation to the patient's management of daily life, which formed the base for teaching. The clinical nurse specialist based the teaching on the patients' scores and an assessment of predisposing, reinforcing and enabling factors with the aim to stimulate motivation optimally [46, 47, 51].

After 4 and 12 weeks the patients received the SF 36 and EHFScB scale. Based on the scores and the goals in the care plan, the CNS continued the dialogue with the patient by telephone in exactly the same way as just described.

Measuring instruments

Self-care behavior was measured with the EHFScBS. EHFScBS is a 12-item, self-administered questionnaire that covers items concerning self-care behavior of HF patients, with a high reliability. Face-validity, concurrent validity has been established, and the internal consistency of the scale has been tested and shows Cronbachs's alpha 0.81 [10]. The instrument is a valid, reliable and practical scale to measure the self-reported self-care behavior of HF patients [10] based on the aspects of self-care EHFScBS measures behavior that maintains self-care. In this context self-care is defined as the decision and strategies undertaken by the individual in order to maintain life, healthy functioning and well-being [10]. EHFScBS measures compliance with medical regimens initiated observation of edema, the ability to responds adequately on observed progression in HF and adjusts the daily activities of the current physical abilities. Each item is 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. If more than three items were missing the total score was not obtained. In case of three missing items the value three was used to replace the missing score per item [10, 12]. Cronbachs alpha in this study was 0.81

Ethical considerations

Patients were included in the study after informed consent and were informed about the possibility of abandoning participation in the study at any time. The experiment are reported to the research ethics committee Danish Data Surveillance Authorities and www.clinicaltrial.gov

Statistical analysis

Data was analyzed by using the statistics program SPSS version 20 [52]. Ratio-scale data from both groups was tested by *F*-test for distribution. Normally distributed data are compared by using parametric methods, *t*-test, and otherwise non-parametric methods, Mann-Whitney and / or Rank Sum Tests. Nominal scale data are compared by chi-square test or by use of the 95 percent confidence interval [45]. Cronbach's alpha was used to assess reliability in this study. Level of significance p was set to be <0.05. Correlation analyses are made where relevant.

Results

One hundred sixty two patients were included in the study of which 137 (84.6 percent) consented (see Figure 1). The groups were equivalent in regard to gender, age, NYHA classes' body mass index, living alone and dependent of help (see Table 1). Drop out analysis showed no differences between the groups ($p = .106$). There were no difference in total self-care behavior between the groups at intervention ($p = .161$). After four weeks the total score for control group was 25.3 and in the intervention group total score was 22.2 ($p = .049$). After twelve weeks the score in the control group was 26.8, which was similar to the score at intervention, and in the intervention group 22.6, which gives a difference in the total score on 6.2 ($p = .007$) (see Table 2). No correlation was detected between age and total self-care at baseline, four and twelve weeks after inclusion in the study. The correlation coefficient at baseline, one and three month was ($r = -.119$, $r = .112$, $r = -.117$).
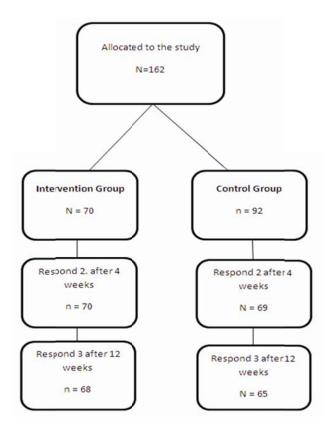

Figure 1. Flow chart

Changes in total self-care behavior were analyzed in subgroups from baseline to three month after inclusion in the study (see Table 3). No difference were detected in changes in the total score related to gender, degree of HF, marital status or dependency of help in daily living either in the control or the interventions group. No correlation between age and changes in total self-care score were detected in either the control or intervention croup ($r = -.118$, $r = -.190$)

Table 1. Baseline characteristics of participating patients

	Controls N = 92	Interventions n = 70	p
Gender			
Male N (%)	68 (73.9)	49 (70)	.600
Female N (%)	24 (26.,1)	21 (30)	
Age			
Mean (SD)	67.8 (10.8)	66.3 (11.3)	.833
(min.-max.)	(37-89)	(39-89)	
NYHA			
Class II	67 (72,8)	56 (80)	.355
Class III	25 (27.2)	14 (20)	
BMI			
kg/m^2 (SD)	27.7 (5.1)	27.6 (5.2)	.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 2. Changes in total self-care behavior from baseline, to 1 month and to 3 month

Total score (SD)	Control	Intervention	p
Baseline	26.5 (8.0)	28.4 (7.2)	.161
After 1 month	25.3 (7.4)	22.2 (7.7)	.049
After 3 month	26.8 (8.9)	22.6 (8.2)	.007

Table 3. Changes in self-care behavior from baseline to end of intervention

	Control			Intervention		
	Baseline	difference	p	Baseline	difference	p
1. I weigh myself every day	2.5 (1.5)	-0.30	0.038*	3.2 (1.4)	1.2	0.002*
2. If I get short of breath, I take it easy	1.5 (1.2)	-0.05	0.654	1.5 (6.8)	0.05	0.73
3. If my shortness of breath increases, I contact my doctor or nurse	2.5(1.5)	0.1	0.404	2.4 (1.4)	0.5	0.032*
4. If my feet/legs become more swollen than usual, I contact my doctor or nurse	2.3 (1.8)	0.1	0.559	2.5 (1.5)	0.9	0.250
5. If I gain 2 kg in 1 week, I contact my doctor or nurse	2.6 (2.0)	0.05	0.804	2.3 (1.5)	0.15	0.500
6. I limit the amount of fluids I drink (not more than (1.5–2l/day)	2.4 (1.8)	0.08	0.694	2.6 (1.6)	0.5	0.04*
7. I take a rest during the day	2.0 (1.4)	-0.04	0.741	1.8 (1.3)	0.1	0.601
8. If I experience increased fatigue, I contact my doctor or nurse	2.8 (1.5)	0.4	0.056	2.7 (1.4)	0.4	0.06
9. I eat a low salt diet	2.8 (1.5)	0.3	0.173	2.4 (1.3)	0.5	0.02*
10. I take my medication as prescribed	1.4 (1.4)	0.07	0.728	1.0 (0.4)	-0.2	0.100
11. I get a flu shot every year	2.3 (1.6)	-0.1	0.559	2.8 (1.9)	0.2	0.200
12. I exercise regularly	2.9 (1.6)	0.05	0.773	2.2 (2.3)	-0.1	0.600

Notes. A total score is calculated by summing all items. If more than three items are missing a total score cannot be obtained .In case of -3 missing items the 3 is used to replace the missing score per item. Copyright: Jaarsma, Strømberg, Mårtensson, Dracup, 1999.

Discussion

Significantly higher scores were found in total self-care behavior in the intervention group after twelve weeks, and sub analysis showed significant better scores in four of the items (see Table 2). The intervention group and the control group were similar regarding to the demographic variables, age, gender, living alone and dependency on help, NYHA classes' and self-care behavior at inclusion in the study. Sub group analysis can be seen as an indicator for the individualization in the study. In In the subgroup analyzes there were no differences between the groups, which indicates ´that the intervention had been individualized. In a systematic review based on 35 studies subgroup analysis has not been presented [53] subgroup analyses, and therefore it can be difficult to evaluate the effects of the interventions.

The randomized controlled trial (RCT) is considered to be the strongest design when testing hypotheses. RCT is based on randomization, control over the experimental situation including a control group and manipulation as some subjects receives treatment and other do not. The treatment should be blinded for the subjects and the staff [54-56].

In this study randomization of the patients and blinding of the intervention was not possible due to the nature of the intervention. Randomization would have led to control and intervention groups being treated at the same time. The control patients could overhear information given as a part of the intervention or the control and intervention patients could share information. The quasi experimental design is characterized by a lower internal validity than a Randomized controlled trial (RCT) [54-56]. The patients were consecutively included first in the control group, and afterwards in the intervention group, to eliminate the risk of interaction between the groups and to eliminate the interference from the ward staff. EHFScBS [10] was used as it is a validated scale to gain insight into the effectiveness of health care interventions to increases self-care behavior. It is stated that the tool is useful for research purposes [10]. In this study the tool has been used for clinical practice, and found to be a useful assessment tool for the patients, and for the staff in individualizing the teaching of the patients. It is recommended that healthcare professionals provide comprehensive HF education and counseling, which typically has been done as group education in Danish health care systems. By the assessment of self-care activities the areas were identified where the patients have a lack of knowledge, and the information was used in collaboration with the patient, to develop a plan, and to set up goals for further action. The EFHFsBC has been useful for the patients as an assessment and evaluation instrument, as it provides indicators for the progress in the treatment and how far the patients are from achieving their goals.

Data collection was conducted by the same clinical nurse specialist (CNS), and controlled observations were used to collect numerical data. The protocol was described so precise that it could be repeated in order to test whether the same results could be obtained in a similar study. It is possible that the Hawthorne effect (HE) [57] has influenced the result in this study as the staffs' awareness on stimulating self-care activities was increased. However, such an affect indicates that the differences between self-care behavior in the intervention and the control group might be even greater than reported in the present study.

Drop out is well known, and in similar studies the dropout rate was described to be between 15%-50% [45, 58]. In this study the dropout rate was 17.3%. The drop out analyses showed, that there were no differences between the dropout patients and the patients in the study related to the demographic data. There were a higher number of dropouts from the control group than from the intervention group, which may be explained by the telephone follow up after 4 and 12 weeks. , and the telephone call can be a motivational factor for the patients to continue in the intervention group [45]. Our study is one of the first studies which looked specifically at the HF patients' rehabilitation in primary health care. Few other studies have focused on rehabilitation in primary care. They have found a limited effect of the intervention [59], but have found that self-management interventions could have the potential to improve self-care and to promote quality of life [60].

This paper contributes to further understanding of the interventions to improve self-care behavior in patients with HF. Based on a review of literature [5, 16, 19, 23, 30, 53, 61-66] four main areas to enhance the outcome of rehabilitation were identified

1) rehabilitation lead by a clinical nurse specialist, 2) education with focus on self-care, 3) telephone support and 4) setting for the intervention.

Rehabilitation Led by a clinical nurse specialist in hospital reduces readmission and mortality [30]. Furthermore, there is a beneficial outcome for patients if nurse led interventions are combined with case management interventions. There is limited evidence for the effect of follow up in HF outpatient's clinics [67].

Education programs that are systematically prepared, theory based and evaluated with focus on the patient's experience of the situation increases self-Care behavior [63, 65]. It has been reporter that one major problem in Standard HF education program is whether the patient adapts to the knowledge and acts appropriate. Poor adaptation has often been associated with poor understanding of self-care behavior and/or the disease [11, 68].

It is stated that patient education used as one of the main components of self-care behavior change programs support patients ability to patients self-care [19]. Most of the studies on education have been carried out in hospital settings, but patient education delivered after discharge from an outpatient clinic seems to be effective in combination with Telephone support [61].

Telemonitoring and//or Telephone support have been tested in hospital setting. Structured telephone support and/or telemonitoring are effective in reducing the risk of all-cause mortality and Readmission in patients with HF [62]. In general the review of the literature shows, that there currently is quite limited evidence for the benefits of telephone support compared with standard therapy, because there is a variation in inclusion criteria such as different NYHA Classes, observation periods and differences in therapy [36, 38-40, 69]. The results from our study show that the use of a combination where a clinical nurse specialist developed a plan for rehabilitation in primary care setting based on the individual patient's self-care behavior scores and used telephone follow up, leads to an increase in self-care behavior. One similar study supports our results [60]. Previous studies have shown that increase in self-management decrease overall readmission to hospital and readmission for HF [70].

Conclusion

A systematic prepared intervention by a clinical nurse specialist based on the patient's self-care behavior scores and telephone follow up 4 and 12 weeks after primary contact leads to a significant increase in the total self-care behavior score in HF patients. It is necessary to discuss and further develop the telephone follow up for patients in the primary care after discharge from the outpatient clinic. Follow up is planned after 18 month to measure the long term effect of the intervention in the study.

Implications for practice

Further research is needed to implement the results from this study into clinical practice. It is possible to use the EHFScBS in practice as a guide for the nurse to assess the educational needs for patients with HF and to guide them to change health behaviors.

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