Effectiveness of Heart Failure Nursing Protocol (HF-NP) on quality of life of patients with heart failure

Bandna Kumari, Sukhpal Kaur, Monika Dutta, Ajay Bahl[1], Parag Barwad[1], Sudip Bhattacharya[2]

Abstract:

BACKGROUND: Effective management of heart failure (HF) requires an integrated approach involving pharmacological and non-pharmacological interventions. Available evidence shows that patients benefit from adjunctive therapies along with guideline-directed medical therapy (GDMT). Still, there is an inadequacy in the use of the best available evidence and the self-management of symptoms by the patients. This study aimed to evaluate the effectiveness of a Heart Failure Nursing Protocol (HF-NP) on selected parameters, that is, symptoms, self-care adequacy, episodes of hospitalizations, depression, exercise capacity, medication adherence, activities of daily living (ADLs), and quality of life (QOL) of the HF patients.

MATERIAL AND METHODS: A pre-experimental study was conducted in a tertiary care hospital in Northern India. A total of 101 patients were enrolled using a convenient sampling technique. Participants were trained individually through demonstrations and educational sessions about self-management of HF at home. An informational booklet was given to all the participants consisting of information about HF, dietary instructions, individual exercise schedules based on the New York Heart Association (NYHA) class, identification of worsening symptoms, daily monitoring of vital parameters, and self-management of HF at home. Telephonic encouragement was provided on day 15, 1 month, and 3 months of baseline visits. The data were checked for normality using the Kolmogorov–Smirnov test and analyzed using a paired t-test, Wilcoxon's signed-rank test, and McNemar's test as appropriate.

RESULTS: There was significant improvement in outcomes, such as breathing difficulty ($P = 0.028$), activity intolerance ($P = 0.013$), self-care adequacy ($P = 0.001$), depression ($P = 0.001$), exercise intensity ($P = 0.001$), QOL ($P = 0.001$), and medication adherence ($P = 0.001$) after 3 months of intervention.

CONCLUSION: HF-NP was effective in improving HF outcomes. It can be used to train patients and their family members regarding the debilitating illness, after doing a large study, and it can be incorporated into the health policy later.

Keywords:

Activities of daily living, heart failure, medication adherence, nursing interventions, quality of life, self-care adequacy

National Institute of Nursing Education, Post Graduate Institute of Medical Education and Research, Chandigarh, India, [1]Department of Cardiology, Post Graduate Institute of Medical Education and Research, Chandigarh, India, [2]Department of Community and Family Medicine, All India Institute of Medical Sciences Deoghar, Jharkhand, India

Address for correspondence:
Dr. Sukhpal Kaur, National Institute of Nursing Education, Post Graduate Institute of Medical Education and Research, Chandigarh -160 055, India. E-mail: drsukhpalkaur@ gmail.com

Introduction

Heart failure (HF) is a complex disease that occurs as a result of impairment in the structure and function of the ventricles. In India, it is difficult to estimate the exact prevalence of HF due to the unavailability of population-based data. Moreover, the estimation of disease burden is hindered by the lack of standardized HF definition in the Indian subset of patients, where the large number of HF patients is contributed by rheumatic heart disease, coronary heart disease, and pericardial tuberculosis.

Approximately 1% or about 8–10 million patients with a mortality rate of 0.1–0.16 million per year have been estimated.[1] It has been widely accepted that HF with exacerbated symptoms, such as breathlessness, orthopnea, cough, and edema, results in frequent hospital visits or admissions and a poor quality of life (QOL).[2]

Despite the improvement in many treatment modalities of detection and treatment, patients continue to have repeated hospital admissions and high mortality rates. In India, due to a lack of institutional facilities for specialized HF management, the burden of HF is rising. Patients who suffer from acute exacerbations of breathing difficulty, acute coronary syndrome, unstable angina, etc., do not reach the hospital on time due to fewer resources, and hence, mortality increases. It has been evident from the research studies that a large proportion of patients can be prevented from the development of HF by identifying and treating modifiable factors.[3] The role of nurses has proven pivotal in making families and patients cope with illness and its consequences and following therapeutic regimens to have better outcomes.[4] Nurse-led disease management programs for HF have known to exist since long ago, for example, OMADA Chronic Heart Faliure,[5] to facilitate the care of patients through physician and nurses' collaboration, and to optimize medical treatment of patients. Such programs focus on self-management, identification of worsening health conditions, and adherence to lifestyle changes and medications and have been proven beneficial worldwide. A systematic review was conducted in 2017 taking into account the studies from 1999 to 2016, which highlighted that the concept of a nurse-led clinic is widely known, but still there is a dire need for trained nurses to manage HF patients in nurse-led clinics in developing countries, such as India. A team approach to tackle the needs of patients is recommended.[6] In India, many barriers, such as guideline-directed therapy and clinical practice for HF, lack of system-level attention as compared to other cardiovascular illnesses, and longitudinal costs due to readmissions, hamper optimal care.[7] Poor communication between healthcare providers and HF patients or their caregivers also acts as a barrier to delivering the appropriate care to these patients, especially the medication adherence part.[7] However, the nurse-led HF management programs are in India, but their number is very low. Moreover, these are functional in tertiary-level institutes, such as the All India Institute of Medical Sciences, Delhi. This study is a novel approach to cater a vast majority of HF patients via specialized HF training in clinical settings. Keeping this in view, this study was planned to operationalize the Heart Failure Nursing Protocol (HF-NP) and establish the efficacy of non-pharmacological interventions for HF outcomes in a tertiary care institute in Northern India.

Material and Methods

Study design and setting

A pre-experimental study was conducted on a convenient sample of patients with HF attending an outpatient department (OPD) in a tertiary care hospital in Northern India.

Study participants and sampling

The primary investigator initially screened the OPD cards for primary and secondary diagnoses so that eligible participants could be identified. Eligible participants were then approached for informed written consent for their participation in the study. Our inclusion criteria were as follows: 1) diagnosed HF patients for more than 6 months; 2) ejection fraction less than equal to 40%; and 3) functional class ranging from New York Heart Association (NYHA) class II to ambulatory class IV. Patients with unstable HF or acute decompensation were excluded from the study.

Data collection tool and technique

HF-NP was operationalized on 101 patients with HF meeting inclusion criteria at the time of enrollment in the study. It was operationalized by holding one-to-one educational session about what HF is, medications scheduled with their indications and therapeutic effects, how to take care of a patient with HF at home, and preventive measures to avoid exacerbations and follow-up. Patients were empowered about when to seek medical attention using the Heart Failure Action Plan as depicted in the informational booklet. They were demonstrated about self-care interventions, such as dietary modifications that included foods to be avoided, menu plan of a day, amount of water to be consumed as per NYHA class, and weekly weight monitoring; NYHA class-based exercises included warm-up, breathing, range of motion exercises, and slow, normal, and brisk walks. The informational booklet was customized for three main etiologies of HF, viz., coronary artery disease, valvular heart disease, and cardiomyopathies, as these diseases lead to HF in different ways. It consisted of information regarding HF and its causes, symptoms, management at home, preventive measures, and etiology-specific self-care interventions. Patients were asked to perform return demonstrations at hospital visits about how they monitor themselves at home and perform NYHA class-based exercises. Telephonic encouragement was provided by the investigator at day 15, 1 month, and 3 months of baseline visits regarding self-care activities and completing the daily diary log. After completion of the self-care education session, patients received an informational booklet regarding HF, its causes, risk factors, signs and symptoms, and its home management, as well as a diary to record their vital parameters. Patients were told to bring the

records while visiting the hospital for follow-up. They were demonstrated how to assess themselves and maintain a diary log. The protocol was developed to be implemented by HF patients in their home settings. It comprises a set of interventions having the following parts: structured teaching to individual patients using an "Informational Booklet for Heart Failure Patients" available in English and Hindi languages. The booklet included the following:

- Introduction to HF
- Causes, risk factors, and brief pathophysiology
- Signs and symptoms, diagnostic methods, and treatment options
- Care at home, including dietary and lifestyle modifications and prevention
- Management of HF due to cardiomyopathies and valvular heart diseases separately.

Patients were demonstrated individually regarding daily exercise based on their NHYA class. Return demonstrations were taken regarding how they were doing at home at their follow-up visits.

A diary was provided to note their vital parameters [Figure 1], such as pulse rate, blood pressure, 24-hour urine output, weight once per week, symptoms such as cough and edema, duration of exercise, absenteeism from work, and hospital visits other than scheduled visits. Patients were told to note them daily, either by themselves or with the help of family members. Both the patient and his or her caregiver were trained regarding how to check the pulse for one minute, blood pressure, weight, and urine output. Telephonic encouragement was provided at day 15, 1 month, and 3 months of baseline visits. In this, the patients were asked about their symptoms, any difficulties while noting down their vital

parameters, or any adverse events. Their doubts were clarified if any, and positive reinforcement was provided.

The effectiveness of HF-NP was measured on the following outcome variables: 1) HF symptoms, 2) self-care adequacy, 3) episodes of hospitalizations, 4) depression, 5) exercise capacity, 6) medication adherence, 7) activities of daily living (ADLs), 8) and QOL of the patients suffering from HF. There was no distinction between primary and secondary outcomes.

Participants who were pre-assessed at enrollment and to whom interventions were provided were told to report after 3 months. They were post-assessed for HF outcomes. Telephonic encouragement was provided at day 15, 1 month, and 3 months of baseline visits.

Ethical consideration

A written informed consent was obtained from all the participants or their legal representatives before enrollment in the study. The study was approved by the Institute Ethics Committee (ref. no. INT/IEC/2018/000542) and registered in the Clinical Trials Registry (CTRI/2018/05/014047). Confidentiality of the information obtained and anonymity of participants were ensured.

Instruments

Tools were prepared by reviewing the literature from various sources and consulting expert nursing and medical (cardiology) faculty of the same institute (Advance Cardiac Centre, Postgraduate Institute of Medical Education and Research (PGIMER), India) and other experts in this field who provided the basis for the construction of the tool. It was divided into the following parts:

Daily Diary for recording the vital parameters/symptoms/ activities

You have to note symptoms/vital parameters/ activities every day and write them date wise except weight monitoring. Weight should be monitored once a week only (in the morning time, after urinating and before breakfast). If you find yourself unable to monitor and write these things in diary, take help of family members who can do it for you.

Symptoms/ Parameters/ Activities	Week1							Week 2							Week 3							Week 4									
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Pulse rate																															
Blood Pressure																															
Weight/ week																															
24 hr Urine output																															
Cough																															
Pedal oedema																															
Absenteeism from work																															
Duration of brisk walk																															
Duration of normal walk																															
Hospital visit due to worsening of symptoms other than regular follow-ups																															

Figure 1: Daily diary log to maintain the record of vital parameters (available in Hindi and English based on patient's preference)

a. **Informational profile:** To assess the demographic information of the subjects, such as name, age in years, educational status, marital status, occupation, religion, monthly income, socioeconomic status, and personal profile, including dietary habits, lifestyle, activity level, and substance use currently and in the past.

b. **Clinical profile**: To know the diagnosis, details of medical and surgical treatment, comorbidities, signs and symptoms, vital parameters, diagnostic tests, and medications.

c. **Self-Care of Heart Failure Index (SCHFI) v. 6.2**: It was used to assess self-care adequacy. It is a standardized tool validated for HF patients by Riegel. B *et al* (2009).[8] For SCHFI v. 6.2, the reliability is 0.56 for self-care maintenance, 0.70 for self-care management, and 0.80 for self-care confidence, indicating good test–retest reliability. The questionnaire consists of 22 items that are divided into three subscales: self-care maintenance, self-care management, and self-care confidence. Self-care maintenance is meant to measure a patient's ability to maintain health by following treatment advice and monitoring vital parameters, such as daily weight, medication adherence, and consuming a low-salt diet. This subscale maintenance has 10 questions with minimum and maximum scores of 10 and 40, respectively (Barbaranelli *et al.*, 2014). Self-care management is meant to measure patients' ability to identify worsening symptoms and act to manage symptoms when they occur. The minimum and maximum scores range from 4 to 24. The third subscale, that is, self-care confidence, measures how confident patients feel while identifying and managing their symptoms to maintain health. The minimum and maximum scores range from 6 to 24. Responses are made to be reported on a 4-point Likert scale: 1 (never or rarely), 2 (sometimes), 3 (frequently), and 4 (always or daily). Scores were standardized as 0–100 for all the subscales so that they can be interpreted easily. A score of greater than 70 or equal in each subscale indicates good self-care behavior.

d. **Borg Rating of Perceived Exertion (RPE) Scale**[9]: It was used to measure patients' exertion, breathlessness, and fatigue during physical activities. The scale has been validated for patients who are undergoing cardiac rehabilitation. Participants were asked to rate their level of exertion on this numerical scale during the activity. They were told to focus on the whole feeling of exertion. The validity of the Borg RPE scale is 0.63, indicating a satisfactory valid measure of exercise intensity. Participants were made to rate their perceived exertion on a numerical scale ranging from 6 to 20 with descriptors, viz., very very light (6–7), very light (8–9), fairly light (10–11), somewhat hard (12–13), hard (14–15), very hard (16–17), and very very hard (18–20). The numbers gave a rough estimate of heart rate with exertion (e.g. if a patient is exercising somewhat hard (12–13), then his heart rate will be approximately $12 \times 10 = 120 - 13 \times 10 = 130$ per minute).

e. **Patient Health Questionnaire-9 (PHQ-9):** It was used to screen, diagnose, monitor, and measure the severity of depression.[10] It is a self-rated tool based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) diagnostic criteria for depression. For PHQ-9, the internal reliability is found excellent, with Cronbach's alpha of 0.89. This scale has 88% sensitivity and 88% specificity for diagnosing major depression. The instrument has a total of 10 items. Participants were asked during the last 14 days how they had been bothered by symptoms. Nine of 10 responses were rated on a 4-point Likert scale with descriptors such as not at all (0), several days (1), more than half the days (2), and nearly every day (3). The tenth item is rated on a separate scale with descriptors such as not difficult at all, somewhat difficult, very difficult, and extremely difficult. The minimum and maximum scores ranged from 0 to 27. The sum of the scores of the first nine items was taken, and the severity of depression was estimated as minimal depression (1–4), mild depression (5–9), moderate depression (10–14), moderately severe depression (15–19), and severe depression (20–27). A number of participants rating the tenth item (difficulty in handling things, people, and work) were mentioned as frequency and percentages.

f. **EuroQoL-5D-5L:** It was used to assess the QOL of HF patients. The EuroQoL Group introduced this instrument in 2009.[11] It has two parts: the EQ-5D descriptive system and the EQ visual analog scale (EQ-VAS). The first part, that is, EQ-5D, comprises five dimensions of QOL, viz., mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The participants were asked to mention their current health status by marking the box against the most appropriate line. It resulted in a single digit that expressed the level selected for that dimension. On combining, the digits for the five dimensions showed a 5-digit number describing the health state of the patient. The patient's self-rated health status was recorded on a vertical VAS ranging from 0 to 100, where 100 meant "The best health you can imagine" and (0) meant "The worst health you can imagine." The mean score of EQ-VAS is taken.

a. **London Chest Activity of Daily Living (LCADL) Scale:** It is a tool aimed at assessing the level of dyspnea during ADL.[12] The internal consistency is

excellent, with Cronbach's alpha of 0.90. It has four domains: self-care, household activities, physical activity, and leisure activities. The tool has 15 items, which are scored on 5 points as 1—"I do not perform this activity as I never wanted to do it or it is irrelevant," 2—"I do not feel any breathlessness while performing this activity," 3—"I feel moderately breathless while carrying out this activity," 4—"I feel severely breathless while performing this activity or require assistance," and 5—"I can't do this activity any long due to breathlessness and require somebody to help." LCADL total score and percentage score were used for analysis.

b. **Medication Adherence Questionnaire:** It is a self-reported adherence measure (alpha reliability = 0.61) developed by Morisky *et al*. in 1986.[13] The sensitivity and specificity of the scale for medication adherence are 88% and 44%, respectively. The scale has four items with dichotomous responses (yes or no). All the items were negatively written, for example, do you forget to take medicines? Thus, the higher the scores, the less will be the adherence. Frequency and percentages were used for the analysis. The sum of the scores was taken to categorize the level of adherence of participants as high adherence (0), medium adherence (1–2), and low adherence (3–4).

Statistical analysis

Data were entered in an Excel sheet and later imported to the Statistical Package for Social Sciences (IBM SPSS Statistics version 22, IBM, Armonk, New York, Westchester) for analysis. For continuous variables, the results were described as the mean ± standard deviation. Frequency (percentages) was used to describe the categorical variables. The normal distribution of the continuous data was tested using the Kolmogorov–Smirnov test. An independent-samples *t*-test was used for the comparison of continuous data with a normal distribution. For the comparison of categorical data, the Chi-square test was used with or without simulation. The level of statistical significance was kept at $P = <0.05$ (two sided).

Results

Of the 101 participants, the mean age was 52.59 years. Approximately 70% (71) were males. The majority (86.1%) were married, and 71.3% had a sedentary lifestyle. The average left ventricular ejection fraction (LVEF) was 30.15%. The rest of the demographic, personal, and clinical characteristics are shown in Table 1. Regarding the prescription pattern of HF medications, it was seen that diuretics were the most common drugs prescribed (86 (85.1%)), followed by beta-blockers (82 (81.2%)) and antiplatelets (76 (75.2%)).

Of 101 participants, only 70 could return after 3 months of baseline visits. They were post-assessed for outcomes. The reasons for not turning up for follow-up are shown in Figure 2. To evaluate the effectiveness of HF-NP, a comparison of 70 patients before and after the intervention was performed.

Symptoms

Significant improvement in symptoms of HF, such as crackles, elevated jugular venous pressure, ascites, breathing difficulty, and activity intolerance, was noticed, as shown in Table 2. Thirteen (18.6%) patients moved to NYHA class I. However, no significant difference was seen in patients belonging to NYHA class IV after interventions ($P = 0.083$). Vital parameters were comparable in the pretest and posttest groups.

Table 1: Sociodemographic and clinical characteristics of the participants *n*=101

| Sociodemographic and clinical characteristics	Frequency(%), Mean +-SD
Age (in years)*	
Mean±SD	52.59±12.39
Gender (f (%))	
Male	71 (70.3)
Female	30 (29.7)
Habitat (f (%))	
Urban	27 (26.7)
Semi-urban	42 (41.6)
Rural	32 (31.7)
Marital status (f (%))	
Single	06 (05.9)
Married	87 (86.1)
Separated/widow/widower	08 (07.9)
Lifestyle pattern (f (%))	
Sedentary	72 (71.3)
Mild worker	22 (21.8)
Moderate worker	05 (04.9)
Heavy worker	02 (01.9)
Dietary habits (f (%))	
Vegetarian	58 (57.4)
Nonvegetarian	43 (42.6)
Medications (f (%))	
Diuretics	86 (85.1)
Angiotensin-converting enzyme inhibitors	33 (32.7)
Angiotensin receptor blockers	37 (36.6)
ARB and neprilysin inhibitors (ARNIs)	07 (06.9)
Beta-blockers	82 (81.2)
Antiarrhythmics	20 (19.8)
Antiplatelet agents	75 (74.2)
Antihyperlipidemics	68 (67.3)
Oral hypoglycemic agents	18 (17.8)
Substance use (f (%))	
At present	10 (09.0)
In past	44 (43.6)
LVEF[a]	
(mean±SD)	30.15±6.76

[a]LVEF: Left ventricular ejection fraction
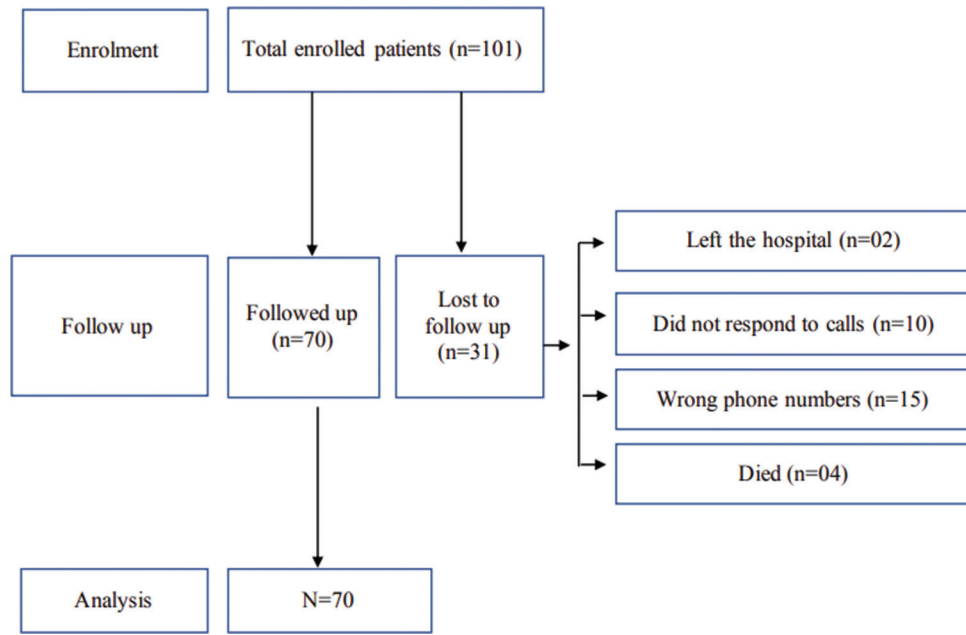
Figure 2: Study flow diagram

Hospitalizations and mortality

After enrollment, 14 (33%) required emergency consultation for their worsening symptoms. Of these, four (28.6%) were admitted to the coronary care unit and the rest (10 (71.4%)) were managed on an OPD basis. The most common reason for hospitalizations was upper respiratory tract infections (29%), followed by breathing and chest congestion (22%), breathing difficulty alone (14%), chest pain (14%), and others (21%). Forty-nine (60%) patients were able to record their vital parameters in the diary provided to them at enrollment. Of these, 16 (32.7%) patients maintained it completely for 3 months and 33 (67.3%) maintained it partially.

Self-care management

The mean score in the self-care maintenance domain increased from 33.6 ± 9.4 at baseline to 60.1 ± 12.4 after the interventions. Although a mean score of >70 is required to say adequate self-care maintenance, a statistically significant difference ($P = 0.001$) was noted in the scores before and after the interventions. Twenty-eight (40%) participants complained of difficulty managing their breathing difficulty or edema before the intervention, while this number was reduced to 15 (21.4%) after the intervention. The mean score in the self-management domain increased from 29.5 ± 10.7 at baseline to 37.3 ± 11.8 after the interventions, which was statistically significant (0.02). In the self-care confidence domain, the mean score increased significantly from 29.2 ± 22.7 before the intervention to 64.2 ± 18.4 after the intervention, with a statistically significant difference ($P = 0.001$).

Health-related depression

As evaluated using PHQ-9, it was determined that 53 (75.7%) patients met the criteria of depression before the intervention as compared to 16 (22.8%) patients after the intervention. A significant difference ($P = 0.001$) was noticed between the total scores of patients before and after the interventions. Based on the sum of the scores, the severity of depression is depicted in Figure 3.

Exercise intensity

As evaluated using the Borg RPE scale, the exercise intensity of the participants was significantly improved ($P = <0.001$) after the intervention, as depicted in Table 2.

QOL

Analysis of the effect of interventions on the QOL of HF patients revealed significant improvement in all domains of the scale, as shown in Table 2. All the participants rated their health on EQ-VAS. The average scores of self-rated health status as per EQ-VAS of participants in the post-intervention group were significantly higher as compared to the pre-intervention group ($P = 0.001$). Age-wise self-reported health status is as follows: age <30 years ($P = 0.04$), 31–45 years (0.03), 46–60 years (0.001), and 61–75 years (0.001).

Medication adherence

Using the Morisky 4-point scale, it was found that all four items of the medication adherence questionnaire differ significantly ($P = 0.01$) before and after the intervention. Considering a mean score of "0" as

Table 2: Effectiveness of Heart Failure Nursing Protocol (HF-NP) on heart failure outcomes

Outcome variables	Pre-intervention *n*=70	Post-intervention *n*=70	*P*
NYHA class (f (%))			
• I	0	13 (18.6)	0.001*
• II	52 (74.3)	37 (52.9)	0.020*
• III	15 (21.4)	05 (07.1)	0.018*
• IV	03 (04.3)	05 (0.00)	0.083
Vital parameters (mean±SD)			
Heart rate	78.7±14.5	79.6±16.6	0.72
Systolic BP	119.7±20.9	118.3±21.8	0.70
Diastolic BP	76.0±12.3	75.1±14.3	0.69
Weight	63.4±14.2	59.9±19.9	0.23
Signs and symptoms (f (%))			
Crackles	20 (28.6)	01 (01.4)	0.001*
Elevated jugular venous pressure	11 (15.7)	0	0.002*
Ascites	19 (27.1)	05 (07.1)	0.016*
Peripheral edema			
• Pitting	18 (25.7)	13 (18.6)	0.125
• Non-pitting	05 (07.1)	01 (01.4)	0.700
Cough			
• Nonproductive	32 (97.0)	24 (34.3)	0.327
• Productive	01 (03.0)	06 (08.6)	0.289
Breathing difficulty	26 (37.1)	07 (10.0)	0.002*
Activity intolerance	45 (64.3)	08 (11.4)	0.002*
Self-care adequacy (mean±SD)			
• Self-care maintenance	33.6±09.4	60.1±12.4	0.001*
• Self-care management	29.5±10.8	37.3±11.8	0.02*
• Self-care confidence	29.2±22.7	64.1±11.4	0.001*
PHQ-9 total score (mean±SD)	10.3±05.8	03.9±04.0	0.001*
Exercise intensity (mean±SD)	13.9±4.0	8.3±3.0	0.001*
Borg Rating of Perceived Exertion			
EuroQoL-5D-5L domains (median, range)			
• Mobility	2, 1–5	1, 1–4	0.001*
• Self-care (bathing or dressing)	1, 1–4	1, 1–2	0.008*
• Usual activities (work, study, leisure)	2, 2–4	1, 1–3	0.001*
• Pain/discomfort	2, 1–4	1, 1–4	0.022*
• Anxiety/depression	2, 1–5	2, 1–3	0.001*
• EQ-VAS total score (mean±SD)	47.2±26.8	74.4±16.3	0.001*
LCADL domains			
• Toilet	1, 1–2	1, 1–2	0.317
• Feeding	1, 1–4	1, 1–2	0.001*
• Grooming	1, 1–4	1, 1–2	0.003*
• Physical ambulation	2, 1–5	1, 1–4	0.13
• Bathing	1, 1–4	1, 1–2	0.14
Medication adherence (f (%))			
• Ever forget to take medicines	49 (70.0)	25 (35.7)	0.001*
• Careless at times about taking medicines	52 (74.3)	12 (17.1)	0.001*
• Sometimes stop taking medicines when feel better	30 (42.9)	11 (15.7)	0.001*
• Sometimes stop taking medicines when feel worse	30 (42.9)	05 (07.1)	0.001*

*P<0.05

high adherence, "1–2" as medium adherence, and "3–4" as low adherence, the number of highly adherent participants increased from 18.6% to 62.8%. Medium adherence was noticed in only 22.8% after the intervention as compared to 35.7% before the intervention. A significant difference can be seen in participants from the low adherence group, that is, from 45.7% to 14.3%.

Of 101 patients included in the study, four (5.7%) died before completing 3 months of follow-up. The period of follow-up ranges from 0 to 12 weeks. All deaths were
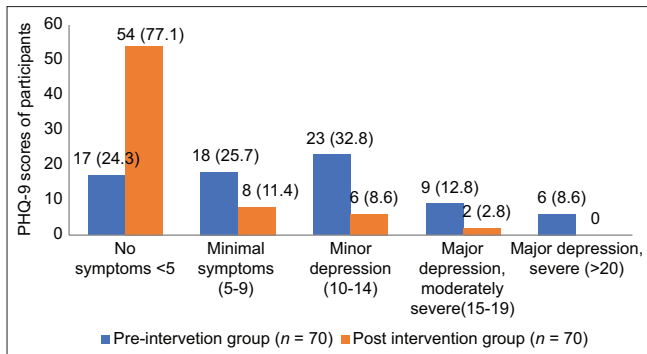
Figure 3: Severity of depression as per PHQ-9. Blue is for Preintervention group and Orange is for post intervention group

because of cardiovascular disease. The average time to death in the patients who died because of cardiovascular illness was 8.4 weeks.

Discussion

The study was meant to evaluate the effectiveness of HF-NP on HF outcomes. The findings of this study highlighted an improvement in a) functional class, b) symptoms of HF, c) self-care adequacy, d) health-related depression, e) exercise capacity, f) health-related QOL, g) ADLs, and h) medication adherence. Symptomatic improvement in patients with HF was accompanied by an upswing in health-related QOL and enhanced self-care adequacy.

The main key difference from routine HF management is that the patients were taken care of more comprehensively, considering their comorbidities, functional capacity, and ejection fraction. Some of the interventions were planned based on their NYHA class and level of ADLs. We developed the interventions, which were already proven effective in managing HF patients.[14,15] Our interventions were individualized, where the participants were trained and empowered to monitor themselves at home and seek medical attention whenever necessary. They were educated about the symptoms of HF, dietary and lifestyle modifications, and medication adherence. Similar interventions were found in the literature that were used to effectively bring improvement in HF outcomes.[16-21] The results of a hospital-based study on the awareness of patients regarding self-management of HF revealed that 66.3% of the patients had inadequate knowledge. Hence, the role of caregivers is pivotal in managing these patients at home.[22] In this study, one of the family caregivers was also involved in a one-to-one session so that the interventions could be implemented effectively. Much of the evidence in the literature supports that the involvement of family members along with patients brings success in such educational sessions about self-management in HF.[23,24] Patients and caregivers face

a lot of challenges in tackling the debilitating symptoms of HF. A study regarding the opinions of stakeholders, such as doctors, nurses, HF patients, and their caregivers, on HF management, revealed many barriers, such as lack of awareness of lifestyle and dietary modifications, lack of time to teach self-monitoring, and management skills, thereby necessitating a customized self-care management tool for these patients.[25]

This study suggests that the protocolized management of HF in addition to routine care brought significant improvement in HF signs and symptoms. The reasons for this improvement are contributed to their enhanced self-care adequacy, adherence to medications, and therapeutic interventions. The auxiliary response of such improvement may also account for fewer readmissions. It has been evident that education programs emphasizing self-care management are effective in lowering readmissions in HF patients.[26-29] This is in line with the present study, where only four participants were readmitted to the coronary care unit. The rest of the participants (n = 10) who needed emergency consultation were managed on OPD. Although the mean scores to say adequate self-care adequacy were <70 (minimum score to say adequate self-care), a statistically significant difference (P = <0.05) was seen between these scores before and after the intervention. Clinical improvement in self-care was also seen among the participants. Our study revealed a lack of self-care adequacy, poor QOL, and high PHQ-9 scores among HF patients before the intervention similar to the findings of Wang Q *et al*.[30] These variables have synergistic effects on poor HF outcomes, such as readmissions and death,[31,32] so a supportive education program is necessary. PHQ-9 scores were significantly reduced after the education and training about HF, hence contributing toward better self-care and QOL. Patients verbalized that constant redressal of their queries reduced their stress and had a positive attitude toward their disease. A study conducted by Kumari B *et al* revealed that 75% of the patients with HF and 90% of their caregivers are satisfied with specialized nursing services, especially when they were explained individually about HF and self-management skills at home.[33]

In this study, patients were prescribed and trained individually for exercises to be performed at home based on their functional capacities. It has been suggested that session RPE can be used after discharge from the hospital or for a long time in HF patients when supervision is not available.[34] Our patients benefitted in terms of their increased exercise performance as measured using Borg RPE. The findings were consistent with Lellamo *et al.*, where individualized exercise prescription increased the RPE of patients in unsupervised settings and medically supervised settings.[35] A Lancet review revealed that

depression is positively associated with increased RPE and, hence, blunted cardiovascular stress response.[36] Reduced physical activity due to depression leads to HF worsening and, hence, faster progression.[37,38] Therefore, we planned our interventions, including exercise training and education regarding HF. The improvement in our patient was similar to that of Gary *et al*., where combined behavioral therapy plus exercise training benefitted HF patients.[39]

One of the goals of this study was to improve QOL among HF patients. A statistically significant difference was noted in all domains and self-rated QOL of patients before and after this educational and training program. Similar interventions and telephonic follow-up after 3 months of enrollment brought significant improvement in QOL among HF patients.[40,41] A study conducted by Meyer *et al*. evaluated the effect of a comprehensive program on the QOL of HF patients.[42] Their results revealed significant improvement in scores after 3 months of training. It is well known in the literature that QOL and medication adherence predict health outcomes in elderly HF.[43,44] High medication adherence has a strong positive correlation with positive health outcomes in HF, such as QOL and functionality.[45,46] Our study demonstrated significant improvement in terms of medication adherence too. The number of highly adherent participants increased from 18.6% to 62.8%. This could have probably caused less number of readmissions in the current scenario.

This study also evaluated the effectiveness of HF-NP on ADLs. Functional disability in HF patients is difficult to measure due to patient-reported status. Still, ADLs can be a surrogate for functional disability.[47] We found statistically significant improvement in the feeding and grooming domain of ADL, but no difference was found in toileting, physical ambulation, and bathing before and after the intervention. Many risk factors contribute toward masking the actual difficulty with ADL, such as dementia, and comorbidities, such as diabetes, morbid obesity, anemia, and female sex. The improvement in overall functional status was demonstrated by an advanced practice nurse-led program by Rhiantong J *et al*.[48,49] Still, there is a lot of uncertainty regarding how much ADL in such patients is masked by the above-said risk factors.

Limitation and recommendation

The current study was limited to a small sample and single center only limiting its generalizability. Participants were followed up for a relatively short time period. The chances of the researcher's bias cannot be excluded. We excluded the patients just for practical feasibility, but those patients could have represented the HF population in a better way. Specialized HF training can be percolated down to the district hospital and improve the QOL of HF patients. We recommend that the multicentric study should be conducted for better evidence generation. Training for healthcare workers must be performed for the strengthening of the health system. Specialized HF training modules can be incorporated into the preventive cardiology curriculum in the future after obtaining expert consensus.

Conclusion

The non-pharmacological interventions have been proven beneficial and recommended as adjunctive therapy in the care of HF patients. The current study demonstrated improvement in selected parameters, such as HF symptoms, self-care adequacy, RPE, ability to carry ADLs independently, QOL, and knowledge of participants regarding HF symptoms. Thus, these interventions can be added to the routine care of HF patients. Patients and family members can be trained by the nurses to evaluate troublesome symptoms of HF and ways to manage them at home, and they can seek medical attention when necessary.

Abbreviation

CHF = chronic heart failure; OPD = outpatient department; HF-NP = Heart Failure Nursing Protocol; VHD = valvular heart disease

Conflicts of interest
There are no conflicts of interest.

References

1. Chaturvedi V, Parakh N, Seth S, Bhargava b, Ramakrishnan S, Saxena A, *et al*. Heart failure in India: The INDUS (INDia, Ukieri Study. J Prac Cardiovasc Sci 2016;2:28-35.
2. Inamdar AA, Inamdar AC. Heart failure: Diagnosis, management and utilization. J Clin Med 2016;5:62.
3. He J, Ogden LG, Bazzano LA, Vupputuri S, Loria C, Whelton PK. Risk factors for congestive heart failure in US men and women: NHANES I epidemiologic follow-up study. Arch Intern Med 2001;161:996.
4. Evangelista LS, Shinnick MA. What do we know about adherence and self-care? J Cardiovasc Nurs 2008;23:250-7.
5. Grange J. The role of nurses in the management of heart failure. Heart 2005;91(Suppl 2):ii39–42.
6. Urvashi. Heart failure specialist nurse "need of time" for developing countries: An old concept but a newer initiative—A review article. J Indian College Cardiol 2018;8:11–3.

7. Agarwal A, Davies D, Goenka S, Prabhakaran D, Huffman MD, Mohanan PP. Facilitators and barriers of heart failure care in Kerala, India: A qualitative analysis of health-care providers and administrators. Indian Heart J 2019;71:235–41.

8. Riegel B, Lee CS, Dickson VV, Carlson B. An update on the self-care of heart failure index. J Cardiovasc Nurs 2009;24:485–97.

9. Borg G. Psychophysical bases of perceived exertion. Med Sci Sports Exerc 1982;14:377–81.

10. Kroenke k, Spitzer RL, Williams JB. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med 2001;16:606-13.

11. EQ-5D-5L – EQ-5D. Available from: https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/. [Last accessed on 2020 Aug 02].

12. Garrod R, Bestall J, Paul E, Wedzicha J, Jones P. Development and validation of a standardized measure of activity of daily living in patients with severe COPD: The London Chest Activity of Daily Living Scale (LCADL). Respir Med 2000;94:589–96.

13. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care 1986;24:67–74.

14. Harrison M, Browne G, Roberts J. Quality of life of individuals with heart failure: A randomized trial of the effectiveness of two models of hospital-to-home transition. Med Care 2002;40:271-82.

15. Hope C, Wu J, Tu W. Association of medication adherence, knowledge, and skills with emergency department visits by adults 50 years or older with congestive heart failure. Am J Health Syst Pharm 2004;61:2043-9.

16. Sethares K, Elliott K. The effect of a tailored message intervention on heart failure readmission rates, quality of life, and benefit and barrier beliefs in persons with heart failure. Heart Lung 2004;33:249–60.

17. Koelling TD, Johnson ML, Cody RJ, Aaronson KD. Discharge education improves clinical outcomes in patients with chronic heart failure. Circulation 2005;111:179–85.

18. Krumholz HM, Amatruda J, Smith GL, Mattera JA, Roumanis SA, Radford MJ, *et al*. Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol 2002;39:83-9.

19. Jaarsma T, Halfens R, Huijer Abu-Saad H, Dracup K, Gorgels T, van Ree J, *et al*. Effects of education and support on self-care and resource utilization in patients with heart failure. Eur Heart J 1999;20:673–82.

20. Cline CM, Israelsson BY, Willenheimer RB, Broms K, Erhardt LR. Cost effective management program for heart failure reduces hospitalization. Heart 1998;80:442–6.

21. Ross SE, Moore LE, Earnest ME, Wittevrongel L, Chen-Tan L. Providing a web-based online medical record with electronic communication capabilities to patients with congestive heart failure: Randomized trial. J Med Internet Res 2004;6:e12.

22. Kumari B, Kaur S, Dutta M, Bahl A, Barwad P. Awareness of patients regarding self-management of heart failure attending a tertiary care hospital of North India. Int J Non-Commun Dis 2020;5:158-64.

23. Phillips C, Wright S, Kern D, Singa R. Comprehensive discharge planning with post discharge support for older patients with congestive heart failure: A meta-analysis. JAMA 2004;219:1358-67.

24. Doughty R, Wright S, Pearl A. Randomized, controlled trial of integrated heart failure management: The Auckland Heart Failure Management Study. Eur Heart J 2002;23:139-49.

25. Kumari B, Kaur S, Dutta M, Barwad P, Bahl A. Exploring the opinion of stakeholders about self-care, home care and hospital management of heart failure patients: A qualitative study. Int J Care Coordination 2020;23:137-46.

26. Buck HG, Lee CS, Moser DK, Albert NM, Lennie T, Bentley B, *et al*. Relationship between self-care and health-related quality of life in older adults with moderate to advanced heart failure. J Cardiovasc Nurs 2012;27:8-15.

27. Vreeland DG, Rea RE, Montgomery LL. A Literature review on heart failure and discharge education. Critical Care Nurse 2011;34:235-45.

28. Akosah KO, Schaper AM, Havlik P, Barnhart S, Devine S. Improving care for patients with chronic HF in the community: The importance of a disease management programs. Chest 2002;122:906-12.

29. Koelling TM, Johnson ML, Cod RJ, Aaronson KD. Discharge education improves clinical outcomes in patients with chronic HF. Circulation 2005;111:179-85.

30. Wang Q, Dong L, Jian Z, Tang X. Effectiveness of a PRECEDE-based education intervention on quality of life in elderly patients with chronic heart failure. BMC Cardiovascular Disorders 2017;17:262.

31. Bhatt KN, Kalogeropoulos AP, Dunbar SB, Butler J, Georgiopoulou VV. Depression in heart failure: Can PHQ-9 help? Int J Cardiol 2016;221:246–50.

32. Loo DW, Jiang Y, Koh KW, Lim FP, Wang W. Self-efficacy and depression predicting the health-related quality of life of outpatients with chronic heart failure in Singapore. Appl Nurs Res 2016;32:148–55.

33. Satisfaction of patients and caregivers with specialized nursing services for heart failure patients | Nursing Midwifery Research [Internet]. [cited 2024 Jan 1]. Available from: https://nrfninechd.com/satisfaction-of-patients-and-caregivers-with-specialized-nursing-services-for-heart-failure-patients.

34. Iellamo F, Manzi V, Caminiti G, Vitale C, Massaro M, Cerrito A, *et al*. Validation of rate of perceived exertion-based exercise training in patients with heart failure: insights from autonomic nervous system adaptations. Int J Cardiol 2014;176:394-8. doi: 10.1016/j.ijcard.2014.07.076. Epub 2014 Aug 1. PMID: 25129282.

35. Iellamo F, Manzi V, Caminiti G, Vitale C, Massaro M, Cerrito A, *et al*. Validation of rate of perceived exertion-based exercise training in patients with heart failure: Insights from autonomic nervous system adaptations. Int J Cardiol 2014;176:394–8.

36. Jones S, James SN, Tillin T, Hughes AD, Richards M, Chaturvedi N. Association between depressive symptoms and perceived exertion during exercise: observational population-based cohort study of European, Indian Asian, and African-Caribbean older adults. Lancet 2019;394:S62.

37. Vaccarino V, Kasl S, Abramson J, Krumholz HM. Depressive symptoms and risk of functional decline and death in patients with heart failure. J Am Coll Cardiol 2001;38:199–205.

38. Rutledge T, Reis VA, Linke SE, Greenberg BH, Mills PJ. Depression in heart failure a meta-analytic review of prevalence, intervention effects, and associations with clinical outcomes. J Am Coll Cardiol 2006;48:1527–37.

39. Gary RA, Dunbar SB, Higgins MK, Musselman DL, Smith AL. Combined exercise and cognitive behavioral therapy improves outcomes in patients with heart failure. J Psychosom Res 2010;69:119–31.

40. Lakdizaji S, Hassankhni H, Mohajjel Agdam A, Khajegodary M, Salehi R. Effect of educational program on quality of life of patients with heart failure: A randomized clinical trial. J Caring Sci 2013;2:11–8.

41. Rezaie Luye H, Dalvandi A, Hosseini M, Rahgozar M. Effect of self-care on quality of life of patients with heart failure. J Rehabil 2009;10:21–6.

42. Meyer K, Laederach-Hofmann K. Effects of a comprehensive rehabilitation program on quality of life in patients with chronic heart failure. Prog Cardiovasc Nurs 2003;18:169–76.

43. Sorensen L, Stokes JA, Purdie DM, Woodward M, Roberts MS. Medication management at home: Medication-related risk factors associated with poor health outcomes. Age Ageing. 2005;34:626–632.

44. Dorr DA, Jones SS, Burns L, Donnelly SM, Brunker CP, Wilcox A, *et al*. Use of health-related, quality of life metrics to predict mortality and hospitalizations in community-dwelling seniors. J

Am Geriatr Soc 2006;54:667–73.

45. Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. Med Care 2005;43:521–30.

46. Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: A randomized controlled trial. J Am Med Assoc 2006;296:2563–71.

47. Katz S. Assessing self-maintenance: activities of daily living, mobility, and instrumental activities of daily living. J Am Geriatr Soc 1983;31:721–7.

48. Rhiantong J, Malathum P, Monkong S, McCauley K, Viwatwongkasem C, Kuanprasert S. Outcomes of an advanced practice nurse-led continuing care program in people with heart failure. Pacific Rim Int J Nurs Res 2019;23:32–46.

49. Mohebbi B, Sabouri M, Tol A. Application of health education and promotion theory-based interventions on patients with cardiovascular disease: A systematic review. J Educ Health Promot 2021;10:236.