

ORIGINAL RESEARCH

Randomized controlled trial of comprehensive nursing intervention on readmission, mortality and quality of life among Egyptian heart failure patients: A 12 month follow up study

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Abstract

Background: Despite major advances in the treatment options for heart failure (HF) patients, morbidity and mortality remain high. Frequent re-admissions are distressful for patients and are associated with large costs for society. Improved self-care behaviour is a goal in educational programmes for patients with HF. The primary outcome measure of this study was to determine the effect of pre-discharge educational intervention and post-discharge intervention carried out by nursing staff on re-admission, mortality and quality of life.

Methods: A randomized controlled clinical trial in patients who were admitted to hospital with a diagnosis of HF. A total of 60 patients were randomly assigned (using a random number table) to either intervention group or a control group of 30 patients each. The intervention group participated in educational programme using face to face education before discharge, outpatient HF nursing intervention and monthly telephone call for over nine months to remind them about the main instruction in addition to the written instruction of HF management with emphasis on self-care behaviour. In each visit, the nurse evaluated the HF status and treatment, gave education about HF and social support to the intervention group. The control group received usual care and given a HF management written instruction.

Results: Patients in the intervention group was found to have a 66.67% decrease in the total number of readmission as compared to the control group (5 vs 25; $p = .001$), fewer death (2 vs 6; $p = .04$), and improved quality of life ($t = 27.06$; $P = .001$). Furthermore, results showed significant improvement in HF knowledge level ($t = 7.85$; $P = .001$) and compliance of health behaviours ($t = 15.72$; $P = .001$), in the intervention group after 12 months of inclusion than those in the control group.

Conclusions: A comprehensive HF nursing intervention substantially reduced re-admission, death, increased compliance with self-management and improved HF QoL. The results of this study building on the work of others, suggest that all patients with HF should be offered pre-discharge education, post-discharge out-patient nursing support and monthly telephone follow up.

Key words

Heart Failure, Compliance of health behaviour, Quality of life, Morbidity, Mortality, Re-admission

1 Introduction

Both prevalence and incidence of people living with heart failure (HF) increases drastically worldwide and the causes for this increase are due to the aging of the population over time and improvement of survival in patients suffering from coronary artery diseases (CAD) ^[1]. Egypt is experiencing a tidal rise of aging population, CAD, hypertension and diabetes ^[2, 3]. This is inevitably reflected in the prevalence of cardiovascular diseases (CVD) in the community that was reported as the most common cause of mortality and health utilization in Egypt ^[4, 5]. HF is a serious and costly CVD not only for patients and their families but also for society, because it associated with high mortality, marked disability and subsequent lack of productivity ^[6, 7]. However, there is no published data about HF in Egypt, the National Heart Institute of Egypt in year 2003 found that Systolic HF patients required frequent re-admission and had a mortality rate of 17.6% vs 11.3% for diastolic HF patients, with a mean age 60 yrs and 63 yrs respectively ^[8].

Heart failure is a complex syndrome in which the heart fails to pump adequately to meet the body's metabolic needs results in various pathological conditions and events which has associated with poor outcomes that result from a repeated de-compensated HF, furthermore this condition requiring multiple medication and frequent admission ^[9-13]. Both pharmacological and non-pharmacological therapy can complicate the treatment regimen from the patients' perspective, which make it more difficult to adherer non compliance with prescribed medical treatment and diet regimen contributes to worsening HF symptoms resulting in decreasing quality of life (QoL), increasing risk of mortality and morbidity, and increasing burden on home and health care system. Furthermore, HF patients often suffer from cognitive impairment, physical, psychological and social, functional disabilities, and multiple co- morbidities that often making normal daily life activity difficult, which further increases the complexity of patient management ^[7,14].

Several studies have demonstrated that non compliance with medical treatment and diet regimen, inability to perform self-care behaviour, including monitoring systems of deterioration and failure to take action in order to prevent further deterioration, as well as the lacking of the professional intensive education and follow up in HF patients are associated with emergency visits and admission with worsening HF. The majority of this admissions is preventable ^[15-19].

Previous researches ^[20-25] found that majority of HF care is done at home by patient and family or caregiver. They identified that patients with HF having lack of knowledge and misconceptions about medication and on how to interpret and treat symptoms of deterioration, they did not understand the importance of daily weighing and one third patient believed they should drink a lot of fluids. Knowledge on self-care has also been shown poor. One of the most cost effective methods is to help people fight illness and disease by avoiding what is avoidable and prevent what is preventable. It is important these patients should believe that it is possible to obtain control over the disease ^[14]. Education and regular follow up that emphasizes self-management intervention are critical components of HF management programs ^[25].

Within the increasingly complex HF management program, there is a significant role for the nurse to provide guidance, education, supportive follow up to those patients and their families ^[1]. The aim of this study was to determine the effect of pre-discharge educational program; post- discharge outpatient intervention and ongoing monitoring follow up carried out by nursing staff on re-admission, mortality and quality of life.

2 Subjects and methods

2.1 Study design

A randomized controlled clinical trial was conducted in Medical department at Menofia University Hospital which serves a wide socioeconomic range of patients in Shebine El-Kome city, Egypt.

2.2 Participations

All patients in this convenience sample were recruited as a part of randomized control trial during their hospitalization and followed up after discharge in outpatient clinics monitored monthly via telephone calls. Sixty HF patients have completed this study. The inclusion criteria includes all those who had chronic HF, New York Heart Association (NYHA) class I to III symptoms, over 18 years of age to 80 years, residing within the surrounding area in Shebine –El-Kome, mentally alert, cared for themselves, able to read and write, had a telephone, and willing to participate. Patients were excluded if they had dementia documented by their attending physician, planned surgical correction for HF within 12 months as confirmed by patient medical record and history; cor-pulmonale, chronic renal failure on dialysis; psychiatric illness that made it impossible to respond to education; visual or auditory impairment; sever alcohol or drug abuse; terminal illness with life expectancy less than 6 months; or declined participation. Institutional Review Board approved the protocol and then consent was obtained from the patient who met the inclusion criteria. The participants' right was protected by explaining the study information form, significance of the study and their role for voluntary participation in this study, with the emphasis of no penalty or negative if they withdraw or quit at any time during the study. Flow chart in figure 1.

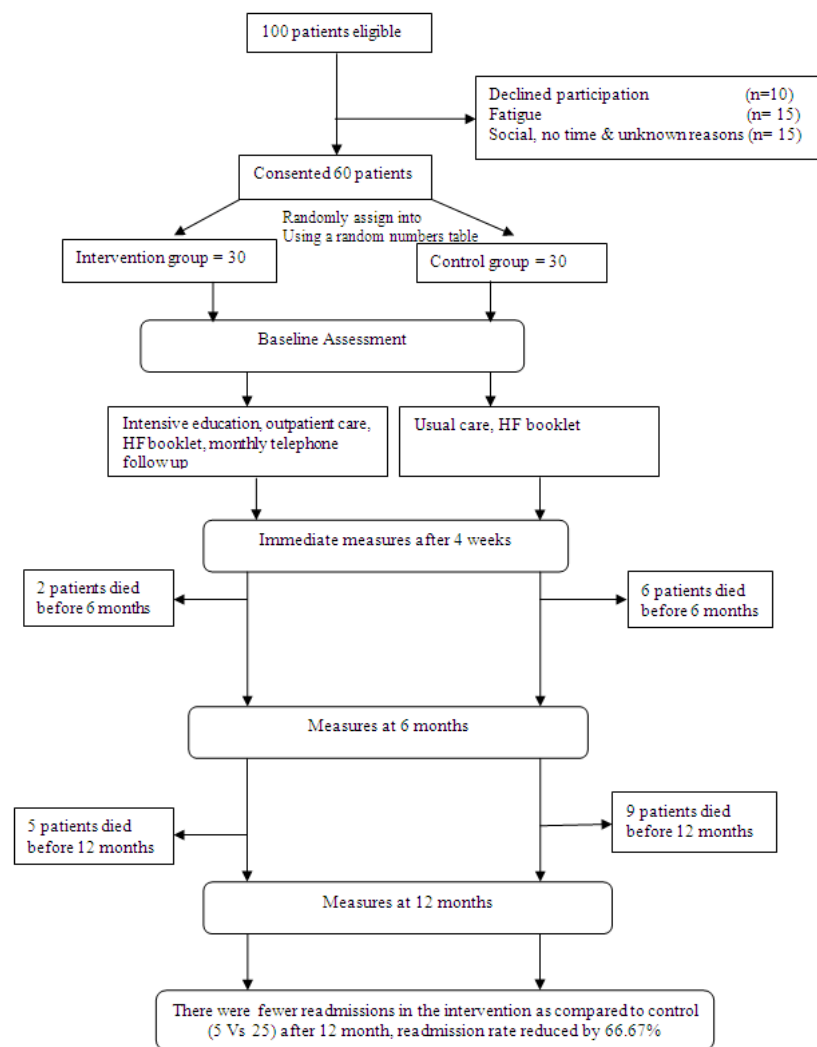


Figure 1. Flow Chart of the Study

The clinical and sociodemographic variables (baseline) were measured before randomization for the study. Patients were assigned to the groups of 30 patients each (intervention and control) before hospital discharge using random number table. The intervention group participated in intervention program plus usual care and a control group received usual care.

2.3 Hypothesis

The researchers hypothesized that a pre-discharge educational intervention and post-discharge nursing support intervention, intended to increase compliance and empower patients to manage their disease, would significantly reduce the rate of readmission, death and demonstrate less health related quality of life impairment for patients with HF.

2.4 Procedure

Before data collection, the researchers developed HF booklets for this study and conducted training program for two nurses to assist in implementing the intervention program and data collection. They received four sessions about HF pharmacological and non-pharmacological management, patient interview, particularly on how to perform a monthly telephone interviews, each session lasting two hours. The use of the instrument was discussed extensively. At the time of enrolment, the patient was interviewed in his/her own bed to collect baseline data. the data gathering took place from December 2008 up to the end of March 2010.

2.4.1 Intervention group

The intervention group received intensive educational session during their hospitalization for HF problem and then followed up by trained nurse during their scheduled visit at out-patient clinic. During patient clinic visit, the nurse did the history taking and physical examination, then recorded the vital signs and body weight. The nurse also completed health education that was initiated in the hospital before patient discharge. In Addition, the patient could communicate with the nurse any time the need arises.

The first visit was scheduled 1-4 weeks after discharge. The researchers evaluated the patient condition, if their condition is optimized, the researchers reviewed and updated their HF management knowledge, provided medical advice and social support. The physician met with the patient for his/her check up and the intervention plan was revised by nurses based on any changes in the patients prescription. Each visit continue for 1 hour and 30 minutes

Patient education can be defined as the process of improving knowledge and skills in order to influence the attitudes and behaviour required to maintain or improve health^[19]. The educational intervention was based on guidelines and aimed to improve the patient's understanding of HF knowledge and improve self-management and lifestyle behaviours. As a part of the educational sessions, the patients were taught HF signs and symptoms and pharmacological and non-pharmacological management strategies that includes drugs, restrict fluid, fluid restriction along with sodium and alcohol intake, sodium and alcohol intake, perform daily weight assessment, detect the early signs of sodium and water retention "such as breathlessness, edema or weight gain up to 1.5-2 kg/week", and prevent malnutrition.

The educational program took nearly 40 to 60 minutes, divided into 2-3 sessions depending on the patient's tolerance. The education was individualized including written, verbal and interactive educational material that focused on the individual patient's learning needs and skills. The patients were given the educational booklet including management scenarios. The nurse and patient reviewed the booklet together. For example, the nurse first educated the patient about HF pharmacological and non-pharmacological management strategies, then engaged the patient in the discussion to solve the given self-management scenarios and encouraged him/her to use brain-storming to help the patient incorporate self-management into their lives.

The researchers then made scheduled telephone follow up carried out monthly for 9 months period (starting the third month of intervention). Each call lasting 5-15 minutes and were designed to reinforce the educational session and provide motivation for the patients to comply with the management strategies. The nurse led telephone follow up emphasized body

weight status, compliance of medication, fluid intake, and side effects of medication. Patients were also instructed to promptly call the nurse to report symptoms or any other problem during the weekdays. Patients experiencing worsening symptoms were scheduled for acute visits with their physician. Plan of care was changed accordingly

2.4.2 Control group

The control group did not receive nursing intervention program. Apart from this fact, both groups received the usual care during their hospitalization or at the time of discharge. Both groups received HF management booklet in advance as a data gathering tool. The control group received a monthly phone call as well, but the goal of these calls were to match the frequency of contact with the intervention group, there was no attempt made to match the duration of the telephone contact between groups.

2.4.3 Evaluation and follow up

Patient assessment and follow up were done with the single-blinded technique. The follow up was scheduled by their attending physician, who decided on the treatment and the date of discharge and was not aware of the group to which the patient had been assigned, in contrast to the research assistances and the person in charge of the statistical analysis.

All participants in both groups were assessed 4 times, first, baseline before intervention, second was immediately after the intervention (4 weeks after the start), third was six months and the fourth was twelve months after first intervention. Data were collected by means of personal interviews with patient and/or family and by reviewing the patient's medical records. All participants have a follow up card and a telephone contact to maintain communication during the study. .

2.5 Instruments

Based on review of relevant literature seven instruments were used in this study as the following:

2.5.1 Sociodemographic and clinical data

Sociodemographic variables were measured using designed survey, including age, gender, educational level, occupation, marital status and financial status Clinical information was obtained primarily from medical record such as, HF class, duration of HF, prescribed medication, previous HF hospitalization, hospital days and medical history.

Clinical characteristics New York Heart Association (NYHA) functional class and Charlson Comorbidity Index score were collected by the demographic and clinical questionnaires, medical records reviews, and the patient interviews. Comorbid illness was measured using the Charlson Comorbidity Index ^[26]. The Charlson Comorbidity Index was developed to assess the number and the seriousness of comorbid conditions that may impact the risk of mortality at enrollment. Patients' were queried about pre-existing disease. The final Charlson Index score was the sum of 19 predefined co-morbidities that were assigned weights of 1, 2, 3, or 6. Validity was supported in prior research in which comorbidity category predicated mortality and complications ^[6, 22-28].

The NYHA functional classification was developed to evaluate the effect of cardiac symptoms on daily activities of a cardiac patient, the limitations/symptoms are in regards to normal breathing and varying degree in shortness of breath, fatigue, palpitation and/or angina pain. The categories consists of 4 classes ranging from NYHA I (no symptoms that have an impact on ordinary daily activities) to IV (symptoms occur even at rest). The NYHA functional class was determined by in-depth interviews with patient using a standardized instrument by trained nurse research assistance ^[9, 28].

2.5.2 Heart failure compliance questionnaire

WHO defined the compliance as the extent to which a persons' behaviour (taking medication, following diet, and/or executing lifestyle changes) match with agreed recommendations from a health care provider ^[30]. Heart Failure Compliance Scale was used to assess patient's compliance of health behaviours. This scale consisted of six health behaviours include, appointment keeping, medication, sodium restriction, fluid restriction, daily weighing, and exercise.

Patients were asked to rate their own estimation of complying with each health behaviour on a 5-point Likert scale (0, never; 1, seldom; 2, half of the time; 3, mostly; and 4, always). Patients were asked to rate their compliance the last week (medication, diet, fluid restriction, and exercise), the last month (daily weighing), or the last 3 months (appointment keeping) before hospitalization. Patients were considered overall compliant when they comply with four or more of the six specific recommendations. Internal consistency of the scale was tested by using Cronbach's alpha (0.68) ^[30, 31].

2.5.3 Patient HF knowledge questionnaire

The patients' general knowledge of HF and its treatment were measured using a questionnaire. The questionnaire was a slight modification of a version used in the earlier studies. The questions in this scale were based on content of the CD-ROM program that based on issues of the European Heart Failure Self-Care Behaviour Scale ^[32-35]. The researchers developed 10-items scale. Patients were presented with 10 statement about heart failure as weight check is important to evaluate fluid retention, and were asked to response "yes", "No", or "I do not know". A correct answer was scored 1; an incorrect answer or an answer of "I do not know" was scored 0. Scores for each item were summed, giving range of total score from 0 to 10. Higher scores indicated greater knowledge about HF. The content validity of the scale was confirmed by an expert panel of experienced academic nurses in medical and surgical nursing field, physicians and cardiologists. Minor revisions of the wording were made based on the recommendations of these reviewers. Internal consistency of this questionnaire was tested by using Cronbach's alpha was .74.

2.5.4 Health related quality of life (HRQOL)

Quality of Life, defined as the degree to which aspects of patient's physical, social, functional, and emotional well-being are impacted by health ^[36]. Quality of Life was measured using the Minnesota Living with HF Questionnaire (MLHFQ) that developed by Rector, Kubo & Cohn (1987). It consisted of 21 structured questionnaire that measures patient perceptions about the effects of a variety of physical, emotional and related impairment that relate to HF. MLHFQ items rated on 6-point of scale from 0 (no effect on quality of life) to 5 (greater effect), with a total maximum score of 105. High scores on the MLHFQ scales indicate worse quality of life. Respondents are asked to rate the degree to which each HF related impairment prevented them from living as they wanted during the previous month. The items combined to form an overall HRQOL score as well as physical health (8 items) and emotional health (5 items) scores. The physical subscale contained items associated with the fatigue and dyspnea of HF. The emotional subscale consisted of items such as being worried or feeling down. An additional 8 separate items, which do not assess a single construct or dimension of HRQOL, measure social and economical impairments patients related to their HF and are a part of the overall score ^[37, 38]. The MLHFQ has been chosen in this study because it is a widely used disease-specific HRQOL questionnaire for HF with well documented validity, reliability and sensitivity in general population based samples, easily understood by ill and elderly individuals, and easy score. The reliability of MLHFQ has been reported with Cronbach's alpha ranging from .73 to .93 ^[39-42].

2.5.5 Rehospitalisation

Rehospitalisation was determined by a combination of medical record review of hospital administrative records, and patient and family interview. Dates and reasons for all hospitalization were noted. Patients and families were interviewed to obtain self reports of admission that were used to validate data because of the possibility that a patient was admitted to a different hospital. In addition, patients were asked to keep a diary of all hospital admissions. The use of a variety of methods for tracking rehospitalizations ensured that all hospitalization were tracked and reasons for each were appropriately assigned ^[43].

2.5.6 Mortality

Mortality was determined by a combination of medical record review, discussion with family, review of hospital records and review of death records to obtain date and cause of death. At enrolment, patients were asked for their contact information or a relative or close friend to be used if they are unable to be contacted. For patients whom the researcher was unable to reach by telephone, health care providers were contacted and hospital records were checked first to see whether

the patient had died. If such evidence was not found, the friend or relative was contacted. If the patient or these contacts could not be located during follow-up, the death records were searched. These methods were used successfully to accurately categorize deaths in previous studies^[43, 44].

3 Data analysis

Analysis was conducted according to the intention- to-treat approach, with readmission, mortality and quality of life as the primary outcome measure. Secondary end points included HF patient knowledge, compliance of health behaviour, causes of HF, duration of the disease, and length of hospital stay. Patients, who withdrew from the study after first and / or second visit, did not have outcome data for analysis. Data were summarized as numbers; percent; mean & SD. Baseline differences between groups were assessed using chi – square for categorical variables and Mann-Whitney test for continuous variables and Student's *t* test for continuous, parametric variables. For HF knowledge, compliance of health behaviour and QoL, we used two-sample *t*-tests. Pearson correlations were calculated to identify the variables that significantly correlated with overall and individual scores of HF knowledge, compliance of health behaviour, numbers of re-admission, number of death and QoL score. All statistical analysis was performed using SPSS software package (Version 12.0). $P < .05$ was considered significant.

4 Results

4.1 Demographic and clinical characteristics

A total of 100 patients met the inclusion criteria, 10 patients declined to refuse participation, 15 patients declined to participate mainly due to fatigue, and 15 patients declined due to social, no times, & unknown reason. A total of 60 patients consented to participate and were enrolled in the study. They were randomized assigned to either the intervention group (n=30) or to control group (n=30). Flow chart of the study trial profile is shown in figure 1 Demographic and clinical characteristics of both the intervention and control group are presented in table 1.

Table 1. Distribution of the studied sample according to their demographic and clinical characteristic

Item	Study group (n = 30)		Control group (n= 30)		P – value
	No	%	No	%	
Sex					
Men	22	73.3	21	70.0	Z= -1.317
Women	8	26.7	9	30.0	P= .188
Martial Status					
Married	23	76.7	20	66.67	Z= - 1.009
Widowed	7	23.3	10	33.3	P= .313
Education					
Primary education	5	16.7	3	10.0	Z = - 1.052 P = .293
Secondary	19	63.3	18	60.0	
University	6	20.0	9	30.0	
Employment					
Employed	25	83.3	24	80.0	Z = - .331
Unemployed	5	16.7	6	20.0	P = .741
Alcohol intake					
Non drinker	24	80.0	23	76.7	Z = -.350 P = .727
< 3 times/wk	4	13.3	4	13.3	
≥ 3times/wk	2	6.7	3	10.0	

(Table 1 continued on page 21)

Table 1. (continued)

Item	Study group, n = 30		Control group, n= 30		P – value
	No	%	No	%	
Smoking					
Yes	11	36.7	16	53.3	Z = - 1.287
No	19	63.3	14	46.7	P = .198
Living situation					
Living with relatives	23	76.7	21	70.0	Z = -.654
Living alone	7	23.3	9	30.0	P = .531
Duration of HF diagnosis, y					t= - 1.194
Mean $\pm$ SD	2.37 $\pm$ 1.43		2.90 $\pm$ 1.99		P = .238
LOS* at inclusion / days					t= .258
Mean $\pm$ SD	8 $\pm$ 2		8.27 $\pm$ 2		P=.798
Previous hospitalization					
With HF hospitalization	12	40.0	13	43.3	Z= -.260
Fist HF hospitalization	18	60.0	17	56.7	P= .795
Causes of HF					
Ischemic heart disease	13	43.3	9	30.0	Z= -1.700 P= .073
Cardiomyopathy	10	33.3	10	33.3	
Valvular disease	3	10.0	5	13.4	
Congenital heart disease	2	6.7	3	10.0	
Hypertension	2	6.7	3	10.0	
Medication					
ACE inhibitors	10	33.3	10	33.3	Z = -.100 P = .920
Diuretics	9	30.0	8	26.7	
Digoxin	4	13.3	5	16.7	
Beta blocker	7	23.3	7	23.3	
*Co-Morbidities					
Ischemic heart disease	13	43.3	9	30.0	Z = - .463 P = .643
Peripheral vascular disease	5	16.7	5	16.7	
Chronic pulmonary disease	6	20.0	5	16.7	
Liver disease	4	13.3	3	10.0	
Diabetes	6	20.0	7	23.3	
Renal failure	4	13.3	3	10.0	
NYHA*					
I	8	26.6	6	20.0	Z = .709 P = .478
II	11	36.7	10	33.3	
III	11	36.7	14	46.7	
Age : Mean $\pm$ SD	63.70 $\pm$ 8.9		64.30 $\pm$ 7.15		t= - 1.397; P = .168

Note. BP= blood pressure; LOS = Length of hospital stay, Co-Morbidities percent, patient may have more than one problem, NYHA= New York Heart Association Classification

The groups were matched at baseline for age, sex, marital status, education, employment, alcohol intake and living situation. About 36.7% of the intervention group and 53.3% of the control group were smokers. The clinical characteristic of the study groups were matched for baseline duration of HF diagnosis, of previous hospitalization, HF cause, medication, NYHA class, Co-morbidities and length of hospital stay.

4.2 Hospitalization or mortality

It is clear from table 2, a fewer patients with events (hospitalization, death) among intervention group compared to the control group. The number of cardiac hospitalization during first 6 months follow up was significantly lower among intervention group compared to control group ($P < .002$). Twelve months after inclusion, the number of patients who died

almost twice higher in the control ($p < .001$) and the readmission rate reduced by 66.67% in intervention group compared to in control group (5 vs 25; $Z = -1.989$; $P = .04$).

Table 2. Hospitalization and death Number in both intervention and control group after 6 and 12 months

Clinical events	Study group (n=30)	Control group (n=30)	P-value
Number of deaths			
After 6 months	2	6	$Z = -2.316$; $P = .02$
After 12 months	5	9	$Z = -1.989$; $P = .04$
No. of patient with readmission			
After 6 months	27	45	$Z = -3.079$; $P = .002$
After 12 months	5	25	$Z = -4.619$; $P = .001$

4.3 Compliance rates, level of HF knowledge and quality of life

Heart failure related knowledge; compliance of health behaviour, and quality of life improved more in the intervention group than in the control groups illustrated in figures 2 to 4.

Figure 2. Health behaviour compliance mean score (theoretical range from 0 to 24), at baseline and after 3, 6, 12 months. Higher scores indicate better health behaviour compliance. The intervention group had better health behaviour compliance in the three assessments than the control group as compared to baseline.

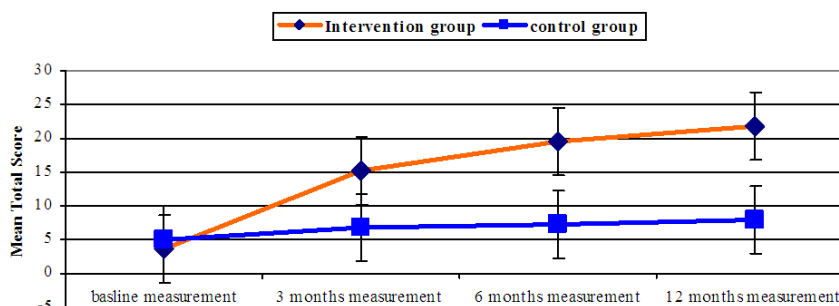


Figure 3. Total HF knowledge mean score (theoretical range from 0 to 10) at baseline and after 3, 6, 12 months. Higher mean score indicate good knowledge. The intervention group had better knowledge than control group compared to baseline. However the level of knowledge declined in the intervention group but still better than control group.

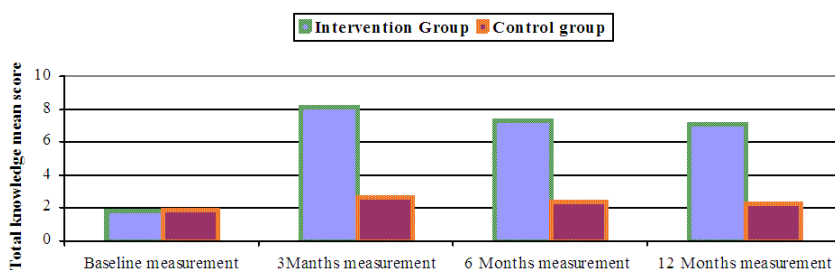
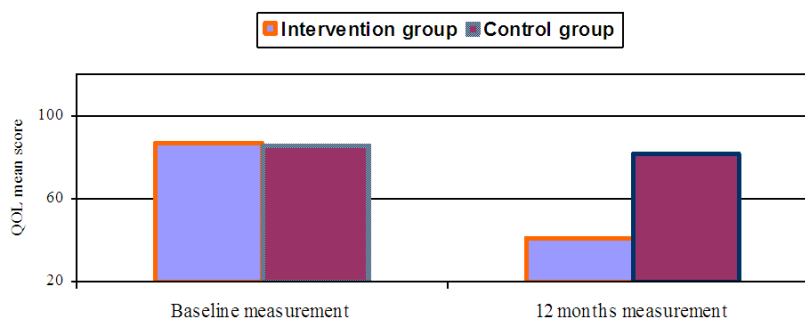


Figure 4. Overall QOL mean scores (theoretical range from 0 to 105), Higher mean score indicate poor quality of life. At the baseline, both groups were similar QoL level. and 12 months later, the intervention group had better QOL than control group



4.4 Mean changes in HF patient's compliance of health behaviours, HF knowledge and quality of life in the both groups

Table 3, shows mean score changes in HF patient's compliance of health behaviours, HF knowledge and HF quality of life over 12 months period among intervention and control group. Before the treatment, the compliance of health behaviour mean score was poor (3.53) among both the intervention and control group (4.94), and *t*-test indicated that the both groups did not significantly differ before the study intervention, ($t = 1.48$; $P = .144$). Twelve months after inclusion, the intervention group' compliance mean score was increased from 3.53 to 21.93 indicating that the intervention group had significantly improved compliance with health behaviour than those in the control group ($t = 15.72$, $P < .01$), with mean difference 13.96 between the both groups.

Table 3. Change in compliance of health behaviours, HF knowledge level and QoL over 12 month period among intervention and control group

Variable	Intervention group Mean ($\pm$ SD)	Control group Mean ($\pm$ SD)	Group difference	P –value
HF compliance				
Pre intervention	3.53 (3.98)	4.94 (3.32)	- 1.40	$t = - 1.479$; $P = .14$
After 12 months	21.93 (2.25)	7.97 (3.62)	13.96	$t = 15.719$; $P = .001$
Total knowledge score				
Pre intervention	1.83 (1.87)	1.90 (2.05)	.10	$t = - .131$; $P = .896$
After 12 month	7.16 (2.51)	2.27 (2.24)	4.89	$t = 7.58$; $P = .001$
QoL				
<i>Emotional domain</i>				
Pre intervention	21.23 (3.61)	20.83 (3.49)	.400	$t = .436$; $P = .664$
After 12 month	.667 (1.60)	20.20 (3.59)	-19.53	$t = -27.24$; $P = .001$
<i>Physical domain</i>				
Pre intervention	33.03 (5.24)	32.23 (5.37)	.800	$t = .584$; $P = .561$
After 12 month	2.60 (2.74)	30.667 (5.23)	-28.07	$t = -26.02$; $P = .001$
<i>General domain</i>				
Pre intervention	32.73 (5.20)	31.83 (5.408)	.900	$t = .657$; $P = .514$
After 12 month	2.80 (2.86)	30.53 (5.26)	-27.73	$t = -25.362$; $P = .01$
Total QoL score				
Pre intervention	87.00 (13.87)	84.90 (14.12)	2.100	$t = .581$; $P = .563$
After 12 month	40.66 (1.23)	81.40 (13.69)	40.74	$t = -27.059$; $P = .001$

The table also shows the comparison of HF knowledge mean score before treatment and 12 months post treatment that displayed a significant increase in the score of intervention group as compared with control group. Mean score was 1.83 before treatment to become 8.16 at second assessment and become 7.16 in the last assessment among in the intervention group, however the level of knowledge declined in the intervention group but still better than control group. The mean difference between the two groups was 4.89 at the last follow up ($t = 7.85$; $P < .01$).

When we compared QoL mean scores before and after intervention between both groups, results indicated that after intervention, QoL mean score in the intervention group was less than that before intervention. In contrast QoL mean scorers before and after intervention of the control group were almost same (high) respectively. High scores on the MLHFQ scales indicate worse quality of life, as described in the instruments. When using “group difference score” on QoL between both groups, the mean difference was 40.74. The *t* test for the differences in the QoL change scores between two groups showed the intervention group had a significantly greater mean change score, as compared to the control group ($t = 27.06$; $P < .01$; see Table 3). These findings support the research hypothesis.

4.5 Correlation between HF knowledge and compliance of health behaviours, admission, mortality and QoL

Table 4 shows that improvement in HF patient knowledge was positively correlated with the compliance of health behaviour ($r = .720$; $p = 0.001$) and reduce number of readmission ($r = .396$; $p = 0.001$) and negative correlation with quality of life ($r = -.687$; $p = 0.001$). It is clear from the table, quality of life negatively correlated with knowledge, re-admission and mortality. It may be that those patients who are relatively younger are used to making decisions about their health care, whereas older patients expect decisions to be made by the provider. Another interpretation is that older patients struggle relatively more with symptom recognition because of age-related change in interoception^[45].

Table 4. Correlation between HF knowledge, compliance of HF patient's of health behaviour, re-admission, mortality rate and QoL

	LS	Re-admission	Death rate	HF comp.	TKS	Quality of Life
Living Situation	1.00	.028	-.137	-.109	.058	.113
Re-admission	.028	1.00	.292*	.480**	.396**	-.559**
Death numbers	-.137	.292*	1.00	.263*	.136	-.256*
HF compliance. S	-.109	.480**	.263*	1.00	.720**	-.873**
Total know. Score	.058	.396**	.136	.720**	1.00	-.687**
Quality of Life	.113	-.559**	-.256*	-.873**	-.687**	1.00

Note. LS= Living Situation , TKS = total knowledge score , HF camp S = HF patient' compliance health behaviour score

5 Discussion

Effective management of HF is one of the major challenges in health care today^[15, 29, 46]. Non-compliance with the recommended treatment regimes is a widespread problem for HF patients, which can result in exacerbation of symptoms and hospital readmission, consequently become a costly exercise for both the patients and healthcare system. In recent studies, non-compliance with medication and diet was shown to be responsible for 21 to 55% of readmission and increase hospital stay^[47, 48]. Shearer et al.^[49] stated that increasing patient knowledge and the ability to recognize and manage symptoms are essential in the treatment of HF. Nurses play a substantive role in this endeavor, because they are the health care provider who most often provide support and teach self-care and symptom recognition and management to HF patient. They can offer discharge instruction and ongoing education that result in better patient self-care. Prevention of even a small number of readmissions to hospital could yield enormous saving in terms of hospital recourses and social cost and helping patients to live with optimal quality of life^[50-54].

In Egypt, nurse led heart failure clinics is not an established model for following up HF patients after discharge, in addition to a limited data in this field. There are many studies in Europe and USA evaluated nurse led follow up after hospitalization^[6, 46, 55-58] found prolonged time to readmission in patients followed up at the nurse-led outpatient clinic and a trend towards reduced number of admission and days in hospital and health costs. The different part in the current intervention, patient can easily access nurses by telephone, nurses facilitated compliance of health behaviour through education and remained with a correction of any misunderstand information and schedule for visit with doctor when they experiencing worsening signs and symptoms, especially edema, fatigue, dizziness or light-headedness, and dyspnea at rest or with activity. In addition to, we provide all participants with a written HF booklet about HF pharmacological and non-pharmacological management and explained the importance of HF education and self-care. In addition, the patients were followed up for 12 months period in attempt to make sure the patients takes maximum time to change behaviours and lifestyle that are enhanced from lifetime of habit.

Several randomized studies described the effect of interventions with a component of education and counseling on the improvement HF patients' compliance of health behaviours. In these successful programs, patients were educated and

counseled by a nurses at the HF clinic ^[6, 13, 14, 32, 50, 59]. The different parts in the current intervention in this, we engaged the patient in the discussion to solve the given self-management scenarios with a component of education session and encouraged him/ her to use brain-storming to help the patient incorporate self-management into their lives. Furthermore, although there have been smaller studies on the individual aspects of self-reported compliance (medication, appointment keeping, diet, fluid restriction, weighing and exercise) our study examines all dimensions of compliance after a face to face education that initiated before discharge, subsequent visits and monthly monitoring by telephone contact using a randomized controlled clinical trial, furthermore we examined the study outcomes for 4 times to assess the changes over time (before discharge to 12 months after discharge). The current findings of the study is consistent with the findings of van der Wal et al. ^[17] and Evangelista et al. ^[31] who found that the knowledge is important factor to improve HF patients' compliance. This is can be one important factor for the positive effect of the intervention, the patients were active in their self-care in order to prevent and at an early stage to detect any deteriorated in their health and lead them seeking for medical help ^[6].

A growing number of intervention studies have aimed to reduce re-admission and mortality ^[6, 16, 54, 56, 60, 61]. Our findings are consistent with these studies. The findings of this study provides further evidence that number of readmissions and mortality were significantly lower in the intervention group after 6 months and after 12 months compared to the control group. The readmission rate reduced by 66.67% after 12 months, but the major effect in the other studies up to 43% in Krumholz et al. ^[62]. We believe that higher decrease in events observed in this study is mainly due to the fact that, the intervention that implemented in this study, which initiated pre-discharge, provide the patient with HF booklet to help the participant recall what they had been taught by the nurse researcher and monthly telephone visit, which not only provide the opportunity for education, but also for detecting lack of compliance with pharmacological and non-pharmacological treatment and overcoming any barriers, thereby optimizing this factor. Moreover, since the interventions continue for three sessions after discharge, it was possible to detect early decompensation, which occurs in up to 40% of patients at 7-14 days after leaving the hospital ^[63, 64]. This would make possible faster medical assessment, which is could prevent progressive clinical deterioration leading to subsequent hospitalization. Wongpiriyayothar et al. ^[63] reported that providing intervention via the telephone improved physio-psychosocial well-being of patient with HF, in that study the intervention was telephone coaching at least twice weekly for three consecutive weeks, Wongpiriyayothar et al. study ^[63] might support our result.

It is also likely that this type of follow up after hospitalization is cost effective. Data from Stewart et al. ^[64] and Stromberg et al. ^[56] suggest that when the reduction of hospital readmissions is above 40%, the saving exceed the costs for nurse intervention. No attempt was made to calculate the specific financial benefit as a result of the current study intervention. This should take into account the involvement and time spent by each nurse during the education counseling, telephone contact. Therefore, the exact costs could be ascertained only on an arbitrary.

Quality of life is of enormous important to HF patients. HF is one of the chronic disease that most affects QoL ^[65]. Generally, a HF admission is accompanied by severe symptoms that can result in impaired QoL. Patients who survive this phase are expected to recover and stabilize at a higher level ^[66]. This is what observed in our study after comprehensive program. The current study findings show that most of the patients increased their QoL between their admission to the hospital and 12 months after discharge. This consistent with other studies ^[66-71] which founded that a comprehensive HF management program lead to improved functional status, quality of life. It is clear from our study that compliance with health behaviour, re-admission, mortality and QoL were significantly positively related to improvement in the HF knowledge.

There are several potential limitations of this study. First, this study was on a small sample from one hospital. Replication on large sample and other hospitals are needed to support the generalization of the findings. Second, selection bias must be considered due to small convenience sample of patients from one hospital and not blinded for a research assistance nurses. Future studies should be conducted in patients who are newly diagnosed and in a larger sample, with a greater variety in

health care provider included nurses background. Third, research assistances were not blind to group assignment during the assessment of self-reported outcomes. This effect could inflate patient responses to the subjective assessment compliance of health behaviour.

Power

The primary endpoints in this study were re-admission, death, and quality of life assessed at the 4 point longitudinal evaluations as explained above. The study was powered to detect significant differences in the intervention group compared to the control group. In this study, the readmission rate reduced by 66.67% after 12 months in the intervention group. There significant differences were detected between intervention and control group in readmission, death, and quality of life.

6 Conclusions

In conclusion, the comprehensive nursing intervention which includes, face to face pre-discharge education, post-discharge outpatient care and monthly telephone follow up had been shown to result in decrease hospital readmission, fewer deaths and improve in quality of life. Recently, studies ^[72-74] stated that any intervention capable of decreasing even small fraction of the adverse outcome, most notably hospital admission and length of stay, could trigger significant cost saving in the management of HF.

Heart failure patients need education in order to adapt to their chronic condition and perform self-care behavior ^[19, 45]. The results of this study also suggest that nurses need to initiate pre-discharge education to increase patient awareness of HF management and provide them with a written instruction to help them in recalling what they had been taught. The telephone is a feasible way to access patients at home.

We recommend the following for further study: need to assess and treat depressed HF patients, need a health economical analysis including all type of cost (medication, health care utilization, phone calls, booklet) to evaluate the total cost effectiveness of the current intervention, and we need a further research to study the same program with modification in the implementation for literacy patients, this is will be crucial for meeting the health care needs of the illiterate HF patients in Egypt.

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