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Efficacy of a self-monitoring traffic light diary on outcomes of patients with heart failure: A randomized controlled trial

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ABSTRACT

Background and objective: Patients with heart failure experience high hospitalization. However, patients cannot recognize symptoms according to current approaches, which needs to be improved by new self-monitoring instruments and strategies. Thus, we aimed to assess a self-monitoring traffic light diary on outcomes of patients with heart failure.

Methods: This was a single-blind, two-arm parallel group randomized controlled trial at the heart failure clinic of Tehran Heart Center (Tehran, Iran). Adult patients with a definitive diagnosis of heart failure with reduced ejection fraction (i.e., ejection fraction of less than 40 %), and New York Heart Association functional classes II–IV were included. A block-balanced randomization method was used to assign eligible subjects to the intervention or control group. Baseline data were collected before random allocation. Participants in the intervention group received a comprehensive intervention consisting of (1) self-care education by an Australian Heart Foundation booklet on heart failure, (2) regular self-monitoring of weight and shortness of breath at home, and (3) scheduled call follow-ups for three months. Patients in the control group received usual care. The primary outcome was heart failure self-care; the secondary outcomes were heart failure quality of life, knowledge, and all-cause hospitalization.

Results: From June to August 2017, 68 patients were included in the study. The overall age of participants was 55 (13.6) years old, and 71 % of patients were male. A significant association between the intervention and self-care maintenance (β 5.1; 95 % CI 2.50 to 7.70, $P < 0.001$), self-care management (β 10.6; 95 % CI 6.50 to 14.8, $P < 0.001$), self-care confidence (β 8.0; 95 % CI 5.0 to 11.0, $P < 0.001$) and heart failure knowledge (β 1.7; 95 % CI 1.30, 2.04; $P < 0.001$) was found. However, there was no association between the intervention and quality of life (β 2.5; 95 % CI −0.79, 5.88, P 0.135) and hospitalization-free survival of the two groups (Log-Rank P 0.540).

Conclusion: A self-monitoring traffic light diary can improve self-care behaviors and heart failure knowledge in patients with heart failure with reduced ejection fraction.

RCT approval ID: Iranian Registry of Clinical Trials IRCT2017021032476N1.

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What is already known

- Researchers have reported that patients with heart failure perform suboptimal self-care behaviors, which can have a negative impact on their quality of life.

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- Conventional graphical heart failure diaries can be challenging for some patients, which makes them unable to take full advantage of these diaries.

What this paper adds

- A self-monitoring traffic light diary can improve self-care behaviors and knowledge of heart failure patients with reduced ejection fraction.
- Patient adherence to the self-monitoring diaries was high.
- Patients with heart failure reported a positive perspective regarding weight and shortness of breath self-monitoring.

1. Introduction

Heart failure presents a global healthcare challenge, affecting over 64 million individuals worldwide (James et al., 2018). Consequently, addressing its socioeconomic burden has become a top global public health priority (Savarese et al., 2023). In Asia, heart failure is emerging as a pandemic, exacerbated by demographic shifts and an aging population (Shimokawa et al., 2015). As a low to middle-income Asian nation, Iran reflects this trend, with a growing prevalence of heart failure, particularly among the elderly (Ahmadi et al., 2016; Sarrafzadegan et al., 2013).

The American Heart Association recommends heart failure patients actively participate in self-care practices, such as medication adherence, symptom monitoring, dietary restrictions (2–4 g sodium), avoiding excessive alcohol, managing weight (BMI > 40 kg/m^2), prescribed exercise, oral hygiene, smoking cessation, and annual flu vaccination (Riegel et al., 2017). However, a systematic review and meta-analysis (2021) revealed inadequate self-care among these patients (Aghajanloo et al., 2021). Iranian heart failure patients also exhibited suboptimal self-care behaviors, with many neglecting practices like daily weight monitoring, salt and fluid restrictions, minimal physical activity, and medication adherence, emphasizing the need for substantial improvement in self-care practices in Iran (Siabani et al., 2016; Zamanzadeh et al., 2012).

Self-care positively correlates with the quality of life in heart failure patients, with inadequate self-care resulting in a lower quality of life (Seid et al., 2023). Several factors influence better self-care, including demographic factors (e.g., female gender, higher income, and education), disease-related factors (e.g., NYHA functional class and instrumental activities of daily living), and environmental factors (e.g., social support and residing in developed areas) (Zhang et al., 2023). Therefore, strategies should focus on enhancing cognitive function, health literacy, and social support to promote satisfactory self-care in heart failure patients (Kim and Son, 2023).

According to the Theory of Self-care for Chronic Illness, self-care is a multifaceted process involving health-promoting practices and disease management by individuals and their families (Riegel et al., 2012). It comprises self-care maintenance (e.g., medication adherence and physical activity), self-care monitoring (e.g., regular weighing), and self-care management (e.g., adjusting diuretic dosage based on symptoms) (Jaarsma et al., 2021). Evidence from a systematic review and meta-analysis of randomized controlled trials (2020) underscores the benefits of self-management interventions, including educational programs, cognitive-behavioral therapy, disease management, and self-care practices, in enhancing heart failure knowledge and quality of life and reducing hospitalizations (Zhao et al., 2020).

Self-care monitoring involves observing oneself for changes in signs and symptoms, a critical component of heart failure self-care (Jaarsma et al., 2021). Monitoring can take various forms, including patient self-monitoring, clinician-led assessments, or remote monitoring, even using implanted devices with structured telephone support (Ponikowski et al., 2016). Key heart failure symptoms like shortness of breath and fluid retention leading to weight gain are pivotal indicators of decompensation (Chaudhry et al., 2007). Accurate monitoring of weight and shortness of breath can facilitate early detection of heart failure decompensation (Jones et al., 2012; Jones et al., 2014).

Diaries are valuable self-monitoring tools that empower patients in self-care (White et al., 2010). Evidence suggests that using a diary for tracking weight and heart failure symptoms was associated with improved clinical outcomes, reduced hospital stays (by 58 %), lower costs (by 56 %), and longer survival (Eastwood et al., 2007; Park et al., 2017). While prior studies using paper-based diaries demonstrated lower heart failure-related hospitalizations, reduced mortality, and enhanced self-care (DeWalt et al., 2006; Eastwood et al., 2007; Jurgens et al., 2013), these diaries were in tabular or textual formats.

Research indicates that graphical representations are superior to tabular formats for conveying risk-related information (Goodyear-Smith et al., 2008; Price et al., 2007). Patients comprehend the risk better through visuals than through verbal communication (Garcia-Retamero and Dhami, 2011, Neuner-Jehle et al., 2011a, 2011b), and graphical formats maintain attention longer and are preferred by patients for their ease of use (Smerecnik et al., 2010). The traffic light system is a familiar risk assessment and disease management approach, with green indicating stability, yellow signaling worsening condition, and red alerting to a medical emergency (Ashir and Marlowe, 2009; Croucher and Williamson, 2013). Patients prefer visual, individualized, color-coded systems for self-care monitoring (Goodyear-Smith et al., 2008; Powers et al., 2011; Price et al., 2007), as they improve understanding and simplify data extraction (Neuner-Jehle et al., 2011a, 2011b, Zikmund-Fisher et al., 2010).

Color-coded systems have been applied to guide self-care monitoring and management of heart failure (Jaarsma et al., 2021). For instance, a color-coded blood pressure diary led to better self-monitoring and improved adherence to treatment (Steurer-Stey et al., 2010). While a study in 2016 found that a color-coded diary alone did not significantly enhance self-care, patients still found it helpful (Wakefield et al., 2016). Similar approaches have also shown promise in cardiac rehabilitation (Dalal et al., 2019; Frost et al., 2019; Greaves et al., 2016).

Given the complexity of heart failure, high-quality randomized controlled trials are crucial to determining the most effective self-management interventions (Zhao et al., 2020). It is worth noting that many studies on heart failure self-care improvement, including diary usage, have been conducted in developed countries, which may not be directly applicable to low and middle-income countries with different healthcare systems. Additionally, conventional graphical heart failure diaries can be challenging for some patients (Kristiansen et al., 2017; Wakefield et al., 2016), which makes them unable to take full advantage of these diaries (Kristiansen et al., 2017, Wakefield et al., 2016). Thus, newer diary designs are required to achieve improved outcomes with patients' complete comprehension.

Therefore, in this study, we introduce a novel paper-based heart failure diary, combining a color-coded traffic light system with a tabular format, and we aimed to assess the efficacy of a self-monitoring traffic light diary on outcomes of patients with heart failure, including self-care as the primary outcome, and heart failure quality of life, knowledge, and hospitalization as secondary outcomes through a randomized controlled trial.

2. Methods

2.1. Trial design and setting

This study was a single-blind, two-arm parallel group randomized controlled trial (IRCT registration number: IRCT2017021032476N1). The study protocol was approved by the institutional review board at the Tehran University of Medical Sciences (Approval ID: IR.TUMS.FNM.REC.1395.1653) and was previously published (Nomali et al., 2018).

The study setting was the heart failure clinic at the Tehran Heart Center, a tertiary heart center affiliated with the Tehran University of Medical Sciences (Poorhosseini and Abbasi, 2018). Informed consent was obtained from all patients for participation and anonymous data report after fully disclosing the intervention and its potential benefits and risks. Patients had the right to withdraw from the study at any time. The CONSORT checklist was used when writing our report (Schulz et al., 2010).

2.2. Participants

Adult patients with a definitive diagnosis of heart failure with reduced ejection fraction (i.e., ejection fraction of less than 40 % by transthoracic or transesophageal echocardiography) and New York Heart Association functional classes II–IV by a heart failure specialist, access to a telephone, telegram mobile application, and ability to answer phone calls, ability to read and write in the Persian language, having a functional weighing scale at home and being able to weigh daily and with stable hemodynamic status were included in the study from the heart failure clinic of Tehran Heart Center. The eligibility criterion details have been provided previously (Nomali et al., 2018). As recommended, the New York Heart Association functional class was used to determine the trial eligibility (Caraballo et al., 2019). It was determined based on patients' self-report regarding the limitation of physical activity and physical activity-induced symptoms (Ponikowski et al., 2016) as assessed by heart failure specialists and research nurses.

2.3. Intervention

In this study, we used a comprehensive intervention, which was a combination of three following components and is as follows: (1) heart failure self-care and self-monitoring education through face-to-face instruction by the nurse, (2) regular home self-monitoring of weight and shortness of breath through a paper-based colored diary, and (3) scheduled call follow-ups by the nurses. The intervention details were explained in the study protocol (Nomali et al., 2018).

1) Heart failure self-care and self-monitoring education through face-to-face instruction by the nurse:
   It was a total of 60 min for each individual, consisting of a 40-minute face-to-face individual session for self-care education and a 20-minute personal session for symptom self-monitoring at home. The research nurse provided heart failure self-care education individually to the participants according to the Australian Heart Foundation educational booklet entitled “Living well with chronic heart failure” through a 40-minute face-to-face individual session between 8 AM and 1 PM in the heart failure clinic of the Tehran Heart Center (Nomali et al., 2018).
   Additionally, the research nurse instructed patients on daily weight and shortness of breath measurements and how to document them in the daily diary through a 20-minute individual session between 8 AM and 1 PM.
   At the end of the one-hour educational session in the heart failure clinic, a plastic folder containing the educational booklet, weight, and shortness of breath paper based-colorful diaries, pen, pencil, eraser, and a pencil sharpener was given to each study participant in the intervention group. They were asked to perform daily monitoring of weight and shortness of breath, document it in colored diaries, keep diaries clean, and deliver them to the research nurse at the end of the study (Nomali et al., 2018).
2) Regular home self-monitoring of weight and shortness of breath through a paper-based colored diary:
   Patients were asked to weigh themselves daily at home at the same time points, after going to the toilet, before breakfast, with the same type of clothing, and contact the research nurse in case of sudden weight gain of 1 kg in one day (yellow zone) and 2.5 kg in one week (red zone) according to the weight paper-based colored diary. They were asked to complete the weight diary, a seven-page paper-based colored diary with instructions on the first page and 6 blank pages to record daily weight for 15 continuous days (Nomali et al., 2018).
   In addition, the participants were asked to rate breathing difficulty for the entire day after taking evening medications and at the end of each day for three months (Wakefield et al., 2016) and record it in the shortness of breath diary, which was a four-page colored diary that included instructions on the first page and three blank pages to record the difficulty of breathing for 30 continuous days on each page. The shortness of breath diary was categorized as none (score 0), mild (score 1 to 3), moderate (score 4 to 6), and severe (score 7 to 10), specified by green, yellow, and red colors, respectively. The color zones were explained to participants as no new or worsening by green (none or mild shortness of breath), worsening with activity or at night when lying down by yellow (moderate shortness of breath), and struggling to breathe at rest or while sitting by red (severe shortness of breath). For the shortness of breath diary, participants were asked to contact the research nurse in case of being at the yellow color zone to increase the diuretic dosage and contact the emergency medical services while being in the red color zone according to the shortness of breath paper-based colored diary (Nomali et al., 2018).
3) Scheduled call follow-ups by the nurses:
   The research nurse followed the participants through the scheduled call follow-ups (days 1, 3, and 7 after referral to the heart failure clinic and every week after that) for three months. A list of call dates was given to the participants, and the research nurse called each subject in the evenings between 6 and 9 PM. During each follow-up call, the research nurse reviewed the contents of the instructional session with the participants and encouraged them to continue self-monitoring their weight and shortness of breath at home and record the results in their daily diaries. The research nurse also asked the participants about the color zone during the previous week and recommended the appropriate action, as explained previously (Nomali et al., 2018).

2.4. Control

Participants in the control group received usual care, which was limited to a brief instruction by heart failure specialists on limiting water and salt intake, taking medications regularly as prescribed, being physically active, monitoring weight, and increasing the diuretic dosage in case of peripheral edema, weight gain, and shortness of breath. Also, they received a monthly phone call for three months and an educational booklet at the end of the study to respect research ethics (Nomali et al., 2018).

2.5. Outcomes

The details of study outcomes, measurements, and their interpretation were previously published in the study protocol (Nomali et al., 2018). The primary study outcome was self-care behavior assessed monthly by the Self-Care of Heart Failure Index Version 6.2 (Vellone et al., 2013). It ranged between 0 and 100, and a score ≥70 was considered optimal self-care (Riegel et al., 2009). The secondary outcomes included heart failure knowledge, quality of life, and all-cause hospitalization. Heart failure knowledge was assessed at baseline and the end of the study by a translated version of the Dutch Heart Failure Knowledge Scale with Cronbach alpha = 0.62, which assesses patients' knowledge on a scale of 0 to 15 (van Wal et al., 2005), with higher scores indicating higher knowledge (van Wal et al., 2005). Quality of life was evaluated monthly by the Persian version of the Minnesota Living with Heart Failure Questionnaire with Cronbach alpha = 0.95 (Eskandari et al., 2015), with a lower score reflecting better quality of life (Carvalho et al., 2009). All-cause hospitalization was a self-reported measure assessed as a binary outcome.

2.6. Sample size

The study protocol comprehensively explains the sample size calculation (Nomali et al., 2018). The sample size was calculated using a minimal clinically important difference method to detect a ten or higher score difference between the two groups for the primary outcome measured by the self-care heart failure index. To the best of our knowledge, and based on searching in the PubMed database, there was no specific minimal clinically important difference for the self-care heart failure index. Since the suggested minimal clinically important difference for assessing dyspnea using the visual analog scale (0 to 100 score) was the range 10 to 20 (Make, 2007), we considered improving ≥10 scores from the baseline at the end of the study as a minimal clinically important difference for the present study to obtain a larger sample size. Thus, with 80 % statistical power for the primary outcome with three-time measurements, the sample size was set at 68 participants with a 10 % overall attrition rate (34 participants in each group) by the G*Power free software (version 3.1.9.2) (Nomali et al., 2018).

2.7. Randomization

A block-balanced randomization method was utilized for participant group assignments. Twenty blocks of 4 for the intervention group (group A) and the control group (group B) were prepared. Randomized blocks were prepared by a statistician using the Randomization.com website (Dallal, 2017) and kept in coded envelopes in the recruitment center. For each eligible patient, the research nurse randomly selected one of the envelopes after shuffling and allocated participants into the intervention or control group. The study protocol explains the allocation method and concealment details (Nomali et al., 2018).

2.8. Blinding

The outcome assessor was blinded to the study groups and was instructed not to ask the patients regarding their interventions. However, considering the nature of the intervention, blinding the patients to their intervention group was not possible.

2.9. Statistical methods

2.9.1. Baseline data analysis

To describe the baseline characteristics of the study patients, we reported binary variables as numbers and percentages and compared them using a Chi-square test. For continuous variables, we checked the normality assumption graphically (i.e., utilizing a histogram plot) and the Shapiro–Wilk test. Thus, we reported mean and standard deviation for variables with normal distribution. Otherwise, we reported the median and interquartile range. Also, we used Levene's test to assess the equality of variance between the two groups to compare continuous variables, whether using an independent sample *t*-test or the Mann–Whitney *U* test. We reported the results of the statistical analysis according to the "Statistical Analyses and Methods in the Published Literature" (SAMPL) guidelines (Lang and Altman, 2015).

2.9.2. Primary outcome analysis

The advantage of a complete case analysis or per protocol analysis is that it tells us how the treatment performs in an ideal situation, that is, when patients take the treatment for the specified duration (Andrade, 2022). Since the dropout was less than the predetermined amount (i.e., 10 %) for each time point, we used the per-protocol approach for the outcome analysis. In this approach, we included participants in the analysis if they completed the study and study outcome measurements. The longitudinal data were analyzed using generalized estimating equations with an exchangeable correlation structure. The generalized estimating equation model permits controlling the correlation between repeated measures for an individual. Beta coefficients and 95 % CI for each heart failure self-care behavior component were subsequently reported.

2.9.3. Secondary outcome analysis

We used the same strategy as heart failure self-care analysis to analyze heart failure quality of life and knowledge. For all-cause hospitalization, we depicted the survival functions of the two groups using the Kaplan–Mayer survival curve and compared them using the Log-Rank test.

Patient compliance with the study intervention was reported as frequency and percentage. Also, the reason for non-compliance was recorded according to the patient's self-reports. In addition, we asked the patients in the intervention group to mention their experiences and perspectives on the study intervention through an open question. Then, we transcribed and analyzed their opinions using qualitative conventional content analysis. First, we read the transcripts repeatedly to determine the open codes. Then, based on similarities, subcategories were divided into categories, and finally, categories, subcategories, and key phrases were extracted from transcripts, and the final analysis was narratively reported.

All statistical analyses were performed using STATA statistical software version 14.2 (Stata Corp., College Station, TX).

3. Results

3.1. Participant flow and recruitment

From June 11 to August 16, 2017, we screened 552 patients for eligibility criteria. Of those, 68 eligible patients were included in the study, and four patients in each group were lost to follow-up during the study follow-up (Fig. 1). The enrollment ended when we reached the number of participants needed for predetermined statistical power. Follow-up data collection was completed within three months after the recruitment date for each participant. The trial was closed on November 16, 2017. Fig. 1 shows the flow of patients through the trial.

3.2. Baseline data

Participants had an average age of 55 (13.6) years, with 71 % being male at randomization. Table 1 presents the baseline characteristics for both the intervention and control groups. The mean age were 53.4 for the intervention group and 56.5 for the control group. Both groups had participants in the overweight category based on body mass index. According to self-reports, 56 % of intervention group patients and 65 % of control group patients reported sufficient income. Daily weight measurement was reported by 24 % of intervention group patients and 18 % of control group patients.

Heart failure health literacy scores were similar between the two groups, with a mean of 35.2 for the intervention group and 33.2 years for the control group. Additionally, the median time of living with heart failure was 13 months for the intervention group and 14.5 months for the control group. Ischemic heart disease was the most common cause of heart failure in both groups, with 44 % in the intervention group and 68 % in the control group.

Most patients in both groups had New York Heart Association functional class III, left ventricular ejection fraction of 20 to 40 %, mild Charlson comorbidity index, and a history of previous hospitalization. The two groups had no significant differences in baseline demographic and clinical characteristics ($P > 0.05$).

3.3. Outcomes and estimation

3.3.1. Primary results

3.3.1.1. Heart failure self-care. The mean (standard deviation) of heart failure self-care maintenance at baseline were 63.0 (15.0) and 60.0

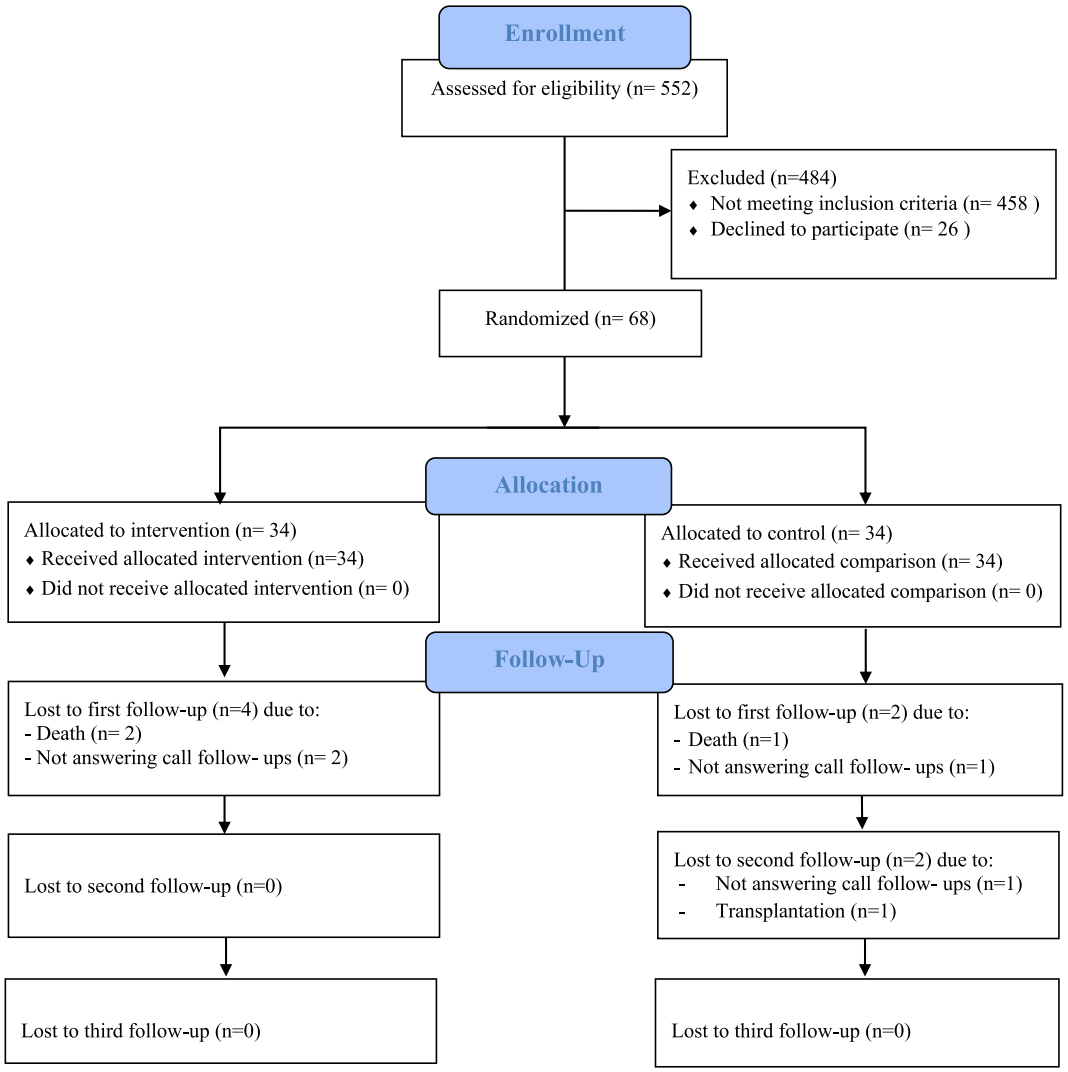

Fig. 1. Trial flow diagram of study enrollment, allocation, and follow-up.

(13.0) in the intervention and control groups, respectively (Table 2). Fig. 2.A shows the changes in heart failure self-care maintenance of the study subjects in the two groups over time. A significant association between the intervention and self-care maintenance was found, with a difference of 5.1 in the trend of the two groups over time (β 5.1; 95 % CI 2.50 to 7.70, $P < 0.001$).

Fig. 2.B represents heart failure self-care management changes in the two groups over the study period. In the intervention group, self-care management increased over time, while there was a decrease in patients' self-care management in the control group (Fig. 2.B). Table 2 shows changes in heart failure self-care management in the two groups at baseline and after 1, 2, and 3 months. The mean (standard deviation) of heart failure self-care management at baseline in the intervention and control groups were 46.0 (16.0) and 42.0 (33.0), respectively (Table 2). The intervention was associated with self-care management with a difference of 10.6 in the trend of the two groups over time (β 10.6; 95 % CI 6.50 to 14.8, $P < 0.001$).

Changes in heart failure-self-care confidence in the two groups over the study period are demonstrated in Fig. 2.C. There was an increase in self-care confidence in the intervention group over time compared to the control group (Fig. 2.C). Table 2 shows heart failure self-care confidence changes in the two groups over the follow-up. The levels of self-care confidence at baseline in the intervention and control groups were 53.0 (16.0) and 45.0 (22.0), respectively. There was a significant association between the intervention and self-care confidence, with a difference of 8.0 in the trend of the two groups over time (β 8.0; 95 % CI 5.0 to 11.0, $P < 0.001$).

3.3.2. Secondary results

3.3.2.1. Heart failure quality of life. The mean (standard deviation) of heart failure quality of life at baseline were 47.0 (25.0) and 46.0 (27.0) in the intervention and control groups, respectively (Table 2). Fig. 3.A indicates changes in heart failure quality of life over time, suggesting no association between the intervention and quality of life over time (β 2.5; 95 % CI −0.79, 5.88, P 0.135).

3.3.2.2. Heart failure knowledge. Fig. 3.B illustrates the changes in heart failure knowledge of the study subjects in the two groups over time. At baseline, the mean (standard deviation) were 9.0 (3.0) and 8.0 (3.0) in the intervention and control groups, respectively (Table 2). The intervention significantly improved the heart failure knowledge, with a difference of 1.7 in the trend of the two groups over time (β 1.7; 95 % CI 1.30, 2.04; $P < 0.001$).

Table 1
Patients' characteristics at the baseline in the intervention and comparison groups.

Assessments (demographic/clinical)	Total (n = 68)	Intervention group (n = 34)	Comparison group (n = 34)
Age (years) [mean (SD)]	55.0 (13.6)	53.4 (13.3)	56.5 (14.00)
Sex n (%)			
Woman	20 (29.0)	9 (26.5)	11 (32.0)
Man	48 (71.0)	25 (73.5)	23 (68.0)
Body mass index (kg/m^2) [mean (SD)]	26.9 (4.1)	27. 4 (3.7)	26.4 (4.4)
Income n (%)			
Sufficient	41 (60.0)	22 (65.0)	19 (56.0)
Insufficient	27 (40.0)	12 (35.0)	15 (44.0)
HF health literacy score [mean (SD)]	34.2 (8.00)	35.2 (7.6)	33.2 (8.4)
Time with HF (months) [median (IQR)]	14 (6–29)	13 (4–37)	14.5 (6–37)
HF etiology n (%)			
Ischemic heart disease	38 (56.0)	15 (44.0)	23 (68.0)
Cardiomyopathy	19 (28.0)	12 (35.0)	7 (20.0)
Hypertension	9 (13.0)	6 (18.0)	3 (9.0)
Heart valve disease	2 (3.0)	1 (3.0)	1 (3.0)
NYHA functional class n (%)			
II	32 (47.0)	16 (47.0)	16 (47.0)
III	33 (48.5)	16 (47.0)	17 (50.0)
IV	3 (4.5)	2 (6.0)	1 (3.0)
Previous hospitalization (3 months ago) n (%)			
Yes	59 (87.0)	28 (82.0)	31 (91.0)
No	9 (13.0)	6 (18.0)	3 (9.0)
Charlson comorbidity index n (%)			
Mild (1–2 diseases)	54 (79.4)	29 (85.0)	25 (74.0)
Moderate (3–4 diseases)	13 (19.2)	4 (12.0)	9 (26.0)
Severe (≥5 diseases)	1 (1.4)	1 (3.0)	0 (0.0)
Ejection fraction n (%)			
<20 %	13 (19.0)	7 (21.0)	6 (18.0)
20–40 %	55 (81.0)	27 (79.0)	28 (82.0)
SBP (mm Hg) [mean (SD)]	111.0 (17.6)	111.53 (17.8)	110.50 (17.6)
DBP (mm Hg) [mean (SD)]	72.5 (10.6)	72.0 (10.5)	73.0 (11.0)
HR (bpm) [median (IQR)]	78 (65.5–82)	77.0 (68–80)	79.5 (65–86)
Daily weight measurement, n (%)	14 (21.0)	8 (24.0)	6 (18.0)
Medications n (%)			
ACE inhibitors or ARBs	61 (90.0)	32 (94.0)	26 (85.0)
Diuretics	67 (98.0)	34 (100.0)	33 (97.0)
Vitamin K antagonists	20 (29.0)	9 (26.0)	11 (32.0)
Allopurinol	8 (12.0)	4 (12.0)	4 (12.0)
Beta-blocker	64 (94.0)	34 (100.0)	30 (88.0)
Digitals	13 (19.0)	8 (23.0)	5 (15.0)
Prior cardiac surgery, n (%)	19 (28.0)	9 (26.0)	10 (28.0)
Laboratory parameters [median (IQR)]			
Sodium (mmol/L)	138 (136.0–139.5)	138 (136.0–140.0)	136 (136.0–139.0)
Potassium (mmol/L)	4.2 (3.6–4.6)	4.3 (4.1–4.6)	4.1 (3.5–4.6)
Urea (mg/dL)	25.5 (18.0–42.1)	23.5 (18.0–44.0)	26.0 (18.0–38.1)
Creatinine (mg/dL)	1.2 (0.9–1.4)	1.1 (0.9–1.3)	1.2 (1.1–1.6)
Uric acid (mg/dL)	6.8 (6.0–8.0)	6.6 (5.7–8.0)	7.2 (6.4–8.0)
Hemoglobin (g/dl)	13.4 (12.5–14.0)	13.6 (12.6–14.0)	13.3 (12.3–14.2)
FPG (mg/dL)	93.0 (86.0–118.0)	92.0 (82.0–133.0)	94.0 (86.0–103.0)

SD: standard deviation; IQR: interquartile range; NYHA: New York Heart Association; SBP: systolic blood pressure; mm Hg: millimeter mercury; DBP: diastolic blood pressure; HR: heart rate; BPM: beats per minute; ACE: angiotensin converting enzyme; ARBs: angiotensin receptor blockers; FPG: fasting plasma glucose.

3.3.2.3. All-cause hospitalization. During the study period, 33.3 % (n = 10) of patients in the intervention group and 27 % (n = 8) in the control group experienced hospitalization. Fig. 4 shows the Kaplan–Meier overall survival plot in the two groups. There was no difference between the values of hospitalization-free survival of the two groups (Chi^2 statistics 0.38, df = 1, Log-Rank *P* 0.540).

3.3.2.4. Adherence to the study intervention. The mean (standard deviation) of patient adherence in the intervention group was 85.0 (7.0) days for the weight and shortness of breath self-monitoring diary. The reported reasons for non-adherence included going on a trip and inaccessibility to weighing scale (50 %), hospitalization (29 %), forgetfulness (14.0 %), and a defective scale (7 %).

Also, Table 3 shows the conventional content analysis of the patient's perspective on weight and shortness of breath self-monitoring at home. We found five main categories: “Sticking in mind and preventing forgetfulness”, “Improving patients' self-confidence to control their disease”, “Improving patients' hope and disease awareness”, “Persuasiveness and feeling supported”, and “Self-monitoring is like a preventive program and not a time-consuming process”.

4. Discussion

In this randomized controlled clinical trial, we utilized a self-monitoring traffic light diary comprising three components: (1) face-to-face instruction by the nurse through a 60-minute individual session; (2) paper-based colored diaries, which were completed by the patients at home; and (3) follow-up calls by the nurse. With these innovative strategies, we provided an easy-to-understand and follow method of motivating people to encourage their self-care and improve their knowledge. Specifically, we found a high level of adherence to the study intervention. We used the graphical format instead of the tabular

Table 2
Mean and standard deviation of heart failure self-care, heart failure quality of life, and heart failure knowledge in the treatment groups over time.

	Intervention group				Comparison group				*P* value
	Baseline (n = 34)	1 month (n = 30)	2 months (n = 30)	3 months (n = 30)	Baseline (n = 34)	1 month (n = 32)	2 months (n = 30)	3 months (n = 30)	
Primary outcome									
Self-care [mean (SD)]									
Maintenance	63.0 (15.0)	81.80 (9.0)	82.0 (12.0)	88.0 (7.0)	60.0 (13.0)	65.0 (10.0)	68.0 (11.0)	68.0 (12.0)	<0.001*
Management	46.0 (16.0)	60.0 (20.0)	57.0 (16.0)	64.0 (18.0)	42.0 (33.0)	37.0 (22.0)	30.0 (18.0)	27.0 (19.0)	<0.001*
Confidence	53.0 (16.0)	72.0 (16.0)	76.0 (15.0)	84.0 (9.0)	45.0 (22.0)	47.0 (17.0)	50.0 (14.0)	51.0 (12.0)	<0.001*
Secondary outcomes									
HF QOL	47.0 (25.0)	35.0 (24.0)	31.0 (24.0)	19.0 (21.0)	46.0 (27.0)	38.0 (26.0)	27.0 (24.0)	27.0 (26.0)	0.135*
HF knowledge	9.0 (3.0)	–	–	14.0 (1.0)	8.0 (3.0)	–	–	9.0 (3.0)	<0.001*

HF: heart failure; QOL: quality of life.
* *P* value of interaction term for time and group in the GEE model.

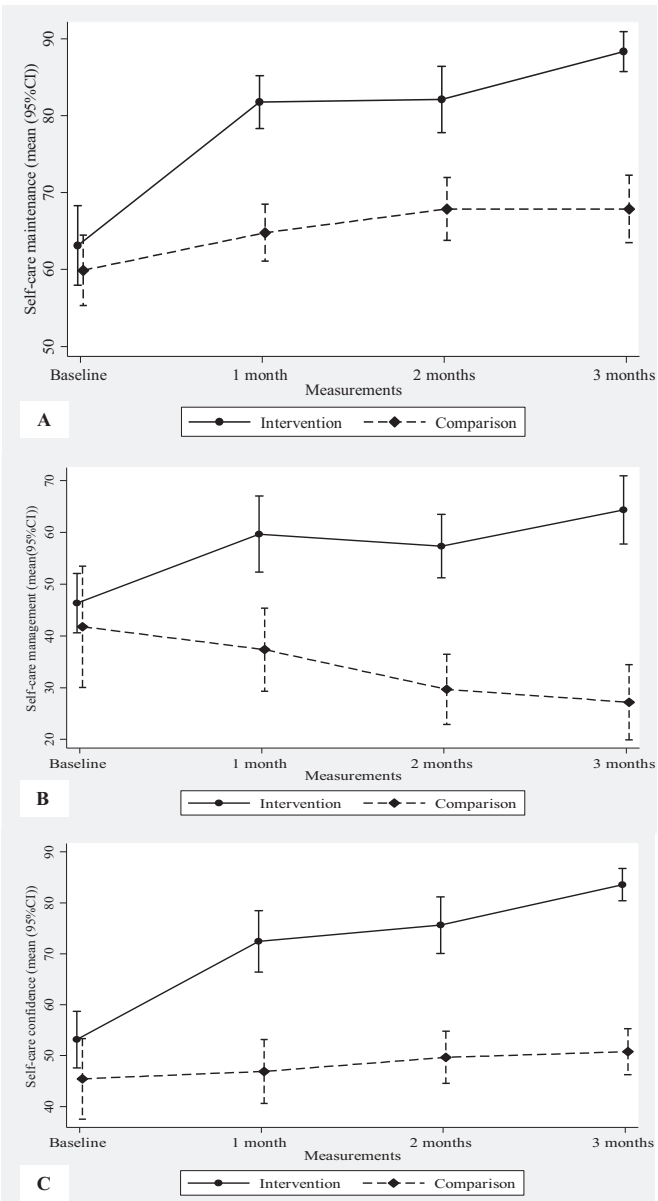

Fig. 2. (A) Self-care maintenance, (B) management, and (C) confidence in the intervention and comparison groups over time.

format in previous studies, which helps patients attract their attention to their condition and helps them connect with medical professionals easily. Also, we found that these creative strategies help patients to keep self-monitoring of their symptoms in mind and prevent forgetfulness, improve their self-confidence to control their disease, improve their hope and disease awareness, and feel supported. According to patient statements, this intervention was a straightforward and efficient preventive program.

The baseline characteristics were remarkably comparable between intervention and control groups, with no statistically significant difference. Our study revealed that the intervention significantly affected self-care maintenance, management, and confidence during the three-month follow-up period. Furthermore, we observed a substantial difference in the self-care trend over time. In addition, the intervention significantly improved heart failure knowledge over time. However, the two groups had no significant differences in quality of life and all-cause hospitalization during the follow-up.

As a low- and middle-income country, Iran's healthcare system faces challenges in providing self-care instructions and conducting follow-up calls for heart failure patients. We employed a multifaceted strategy to create a comprehensive self-care program, including an educational booklet, a diary for self-monitoring weight and shortness of breath, and scheduled follow-up calls. These calls enhanced patients' knowledge of heart failure, ability to recognize symptoms, and capacity to determine appropriate actions, and provided a platform for patients to ask any related questions. Also, we referred patients to the appropriate healthcare service in the early stages of heart failure exacerbation.

A global study on patients with heart failure documented sub-optimal self-care behaviors among these patients (Jaarsma et al., 2013). In addition, a systematic review and meta-analysis in 2021 revealed inadequate self-care practices across all three dimensions of self-care (Aghajanloo et al., 2021). It has also been reported that self-care needs significant improvements among Iranian heart failure patients (Siabani et al., 2016). Likewise, our study revealed initial deficiencies in self-care across all three dimensions among heart failure patients. Nonetheless, in the intervention group, significant enhancements were observed in all three dimensions of self-care by the study's conclusion.

A meta-analysis involving 974 individuals detected a notable enhancement in medication adherence among heart failure patients after receiving health education. However, the findings indicated that health education had no statistically significant impact on self-care practices (Tinoco et al., 2021). Two distinct randomized controlled trials also evaluated the effect of an educational application and home telemonitoring system on heart failure patients (Wonggom et al., 2020; Yanicelli et al., 2021). Yanicelli et al. (2021) reported a significant improvement in self-care due to the intervention. Conversely, Wonggom et al. (2020) observed that while their intervention did

improve heart failure knowledge among patients, it did not have a notable impact on their self-care behavior. Several determinants influence the effectiveness of self-care interventions, including patient attributes such as personality, gender, number of medications, and cognitive abilities, as well as external factors like social support, family income, and characteristics of the intervention itself (Ausili et al., 2016; Massouh et al., 2020). The variability in these determinants across different populations contributes to the heterogeneous outcomes observed in randomized controlled trials.

A quasi-experimental study enrolled 131 Taiwanese heart failure patients to examine the impact of a self-care program comprising educational and telemonitoring strategies (Liou et al., 2015). The study's results revealed notable improvements in self-care maintenance, self-care management, self-care confidence, and heart failure knowledge among the experimental group. Notably, the program had the most substantial impact on self-care management and heart failure knowledge during the three-month follow-up period. We identified similar patterns in self-care management and heart failure knowledge, and additionally, we noted a positive correlation between self-monitoring traffic light diary and improvements in self-care maintenance, management, and confidence.

Self-care strategies have been investigated in various chronic diseases. Riegel et al. (2021) have documented the application of self-care interventions in chronic conditions such as heart failure, type 2 diabetes mellitus, hypertension, chronic obstructive pulmonary disease, asthma, and coronary artery disease. Despite the advancements in treating chronic conditions, the persistent challenge of patients failing to adhere to lifestyle recommendations and medical regimens continues to pose a substantial hurdle in effective disease management (Tsutsui, 2022; Writing Committee et al., 2009). This failure results from an insufficient understanding of medications, symptoms, and the ability to interpret the progression of the disease (Grange, 2005). Additionally, challenges with follow-up and access to healthcare services exacerbate the problem (Rogers et al., 2002). As a result, we aimed to address all of the factors mentioned above in our study.

Over the past decade, numerous studies have recommended self-care interventions to improve the behavior of heart failure patients, fostering a sense of responsibility for their health (Aghajanloo et al., 2021; Barnason et al., 2012; Boren et al., 2009). Various interventions have been employed to improve self-care education, such as cognitive training, telemonitoring, culturally tailored approaches, in-home visits, and support groups (Riegel et al., 2021; Tinoco et al., 2021). These strategies focus on three essential aspects of self-care: *self-care maintenance* aids patients in adhering to their treatment regimen and recommended lifestyle, *self-care management* teaches individuals to identify and effectively respond to their symptoms, and *self-care confidence* mediates the other two by improving patients' self-esteem (Massouh et al., 2020).

Despite the improvement in all aspects of self-care and knowledge among heart failure patients in our study, the intervention did not lead to an improvement in their quality of life during the three-month follow-up period. Furthermore, there was no significant difference in hospitalization proportion between the two groups, possibly attributable to the relatively short duration of our follow-up and the small sample size, which limited our ability to detect differences in quality of life and all-cause hospitalization. However, a systematic review and meta-analysis of randomized controlled trials conducted in 2020 revealed that self-management interventions notably impacted heart failure knowledge, quality of life, and heart failure-related hospitalization (Zhao et al., 2020). Although they assessed various self-management interventions, including those grounded in self-efficacy theory, cognitive behavioral therapy, disease management, and self-care education, the most effective approach for patients with heart failure remains uncertain.

Also, we conducted a conventional content analysis to assess patients' perceptions of self-monitoring weight and shortness of breath at home. Patients expressed a positive perspective on the self-monitoring diary, noting that they found it helpful in maintaining regular monitoring, managing their condition effectively, increasing their disease awareness, and experiencing a sense of support. Huygens et al. (2017) were the first to suggest a potential link between patients'

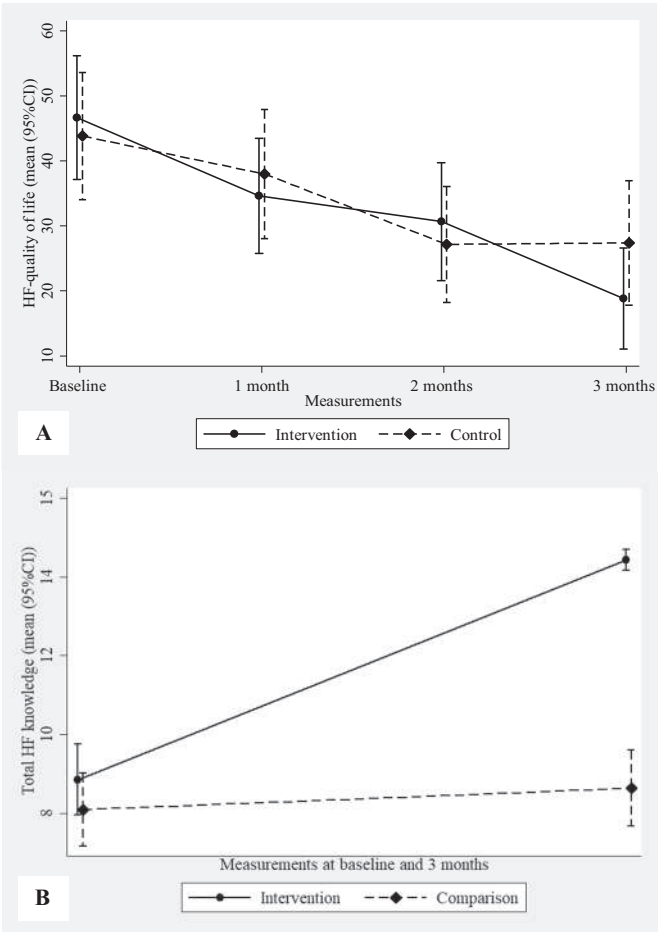

Fig. 3. (A) Total HF quality of life in the intervention and control groups over time; (B) total HF knowledge score at baseline and three months in the intervention and control groups.

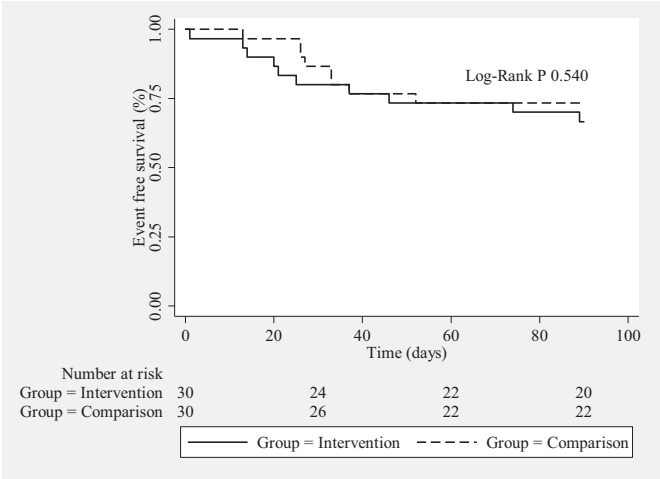

Fig. 4. Time to the first event (all-cause hospitalization) in the intervention and control groups over time.

Table 3
Perspective of patients with heart failure with reduced ejection fraction on weight and shortness of breath self-monitoring at home: A conventional content analysis.

Categories	Patients' quotations
Sticking in mind and preventing forgetfulness	Code 124: Because I used to check my weight and shortness of breath every day, they stuck in my mind, and I never forgot them. Code 66: Before this, I forgot to check the symptoms when the doctor told me to. But in this program, because of the repetitions, I never forgot. Code 162: It was a handy program. I used all aspects of this program. I got used to weighing and reporting shortness of breath. Code 68: After three months, I weigh myself daily, consume fewer fluids and salt, and perform these cares automatically. I have learned to check myself even if the nurse is absent.
Improving patients' self-confidence to control their disease	Code 66: It gave me the confidence to speak up if there was a problem. Code 161: It was a comprehensive education with no defects. I got good information on the disease and was trained to increase and decrease the medicine. The program should be done for all patients with any literacy. However, further explanation of the drugs and their use is needed. Code 68: Little by little, I could control the symptoms. Drink enough water and limit salt. It was hard at first. With awareness and knowledge, I could control the symptoms. After three months, I weigh myself daily and consume less fluid and salt. Code 165: Through this three-month process, I got better; this improvement was not possible before this program. I check my food, water, weight, and blood pressure every day. If you didn't teach me, I would have drunk 10 to 12 glasses of water daily, and if I were thirsty, I would have consumed a pitcher of water in an hour. It was not time-consuming. Even if you don't call me anymore, I will continue. Code 62: I can increase and decrease the medicine myself. If there are no other complications, I feel that I can control my disease.
Improving patients' hope and disease awareness	Code 43: I only knew that my heart muscle was weak. This program taught me a lot about my disease; now, I know how to care for myself. Code 42: You informed me and gave me information about my illness through this free plan. This program increased my awareness about my disease. Code 63: It was the ideal study to get complete information. I received information that I did not know where to find. The booklet was straightforward and understandable. Code 69: This plan increases the patient's awareness. It educates with frequent questions. For example, if the weight increases, the problem will be solved; if it is not, go to the doctor. Without awareness, it is more likely to get worried. When patients do not adjust their water and salt intake, they get hospitalized. Phone calls are very effective. As the patient's awareness increases, the risk of hospitalization decreases. Code 130: It's a good program. The patient thinks about himself, reports if he has any problems, and knows his disease. Code 45: Through awareness, the plan removes negative thoughts and makes me more hopeful. There are many like me; this plan causes more familiarity and is a deliberate plan. Code 125: I became more aware of the problems and dangers. It will certainly be helpful. This plan made my life better, with fewer worries. Code 129: It was a good program, beneficial. I realized what to do and what not to do. It was a good process. Code 68: It was great for me as a patient with no previous history. I have been able to recognize my disease and cope with it. There was nothing wrong with this program. It was perfect, in my opinion. As a patient with severe disease, I could control the symptoms little by little with your guidance, drink enough water, and limit salt in food. The beginning is challenging. With awareness and knowledge, I can control the symptoms of the disease. After three months, I weigh myself daily and consume fewer fluids and salt.
Persuasiveness and feeling supported	Code 46: Besides not worrying, it was my comfort zone. At least it forces patients to have a daily check-up and get used to it after three months. Code 69: I felt that a doctor was with me and cared for me. This plan is a tremendous help and support for patients. It increases awareness about the disease. Code 64: It gave a lot of hope and spirit. I was encouraged to live again and forget the disease. I felt that there was someone who cared about my illness and was constantly asking about my well-being. It gave me spirit. Code 47: This program strengthened my heart so I don't feel helpless and alone. Code 164: This plan encouraged and supported me; someone always watched over me.
Self-monitoring is like a preventive program and not a time-consuming process	Code 69: Like vaccination, this was a preventive plan. It taught me how not to be hospitalized. I was satisfied with my performance in these 90 days. Code 42: It was not time-consuming; it only took a maximum of 3 min a day. Health is so valuable that this time should be devoted to it. Code 146: It didn't take much time; I dedicated fifteen minutes to myself. If I had known earlier, I wouldn't end up in CCU. No one had explained it to me. Now, I know the symptoms of the disease. Weight was significant to me. It felt excellent that someone was paying attention to me.

willingness to engage in self-monitoring and the level of controllability of their disease.

4.1. Study implications

The results of this study can have significant implications for the remote management of heart failure patients, which has become significantly more critical after the pandemic. Healthcare professionals in Iran and other countries can use the results of this study to improve heart failure patient management and awareness. In addition, other researchers can use our protocols to design mobile health applications and evaluate their effectiveness. Also, considering the efficacy of this intervention on self-care, its cost-effectiveness can be evaluated through further research to be applied as an integrated part of outpatient clinics.

4.2. Limitations and strengths

To the best of our knowledge, this is the first clinical trial to investigate heart failure self-monitoring instruments within Iran, a low- and middle-income country. This practical intervention holds the potential for implementation in Iran and similar countries, benefitting heart failure patients. We used a combination of self-care education, creative self-monitoring diaries using a traffic light color-coding system, and scheduled follow-up calls. This prescribed self-care activity was well-received and easy to follow by the patients. However, it is essential to acknowledge the limitations of our study. Given its single-center design, specific characteristics may not encompass the broader heart failure patient population. Additionally, the absence of recorded data on unplanned clinic visits is a notable limitation. Finally, while our study

focused on evaluating the efficacy of the intervention, the nuances of cost estimation fell outside the aim and scope of our research.

5. Conclusion

Our study showed that a self-monitoring traffic light diary can significantly improve self-care behaviors across all three dimensions, including maintenance, management, and confidence, in heart failure patients with reduced ejection fraction. Furthermore, it can potentially enhance heart failure knowledge among these patients. However, during the three-month follow-up, this intervention did not immediately affect the quality of life or the proportion of all-cause hospitalization among heart failure patients. Further investigation over an extended study period may be necessary to assess these aspects comprehensively.

Patient consent for publication

We obtained written informed consent from all eligible participants before participating in the study and committed to informing them of the study results in case of their interest.

Ethics approval

This study was approved by the Research Ethics Committee at Tehran University of Medical Sciences on February 5, 2017 (No. IR.TUMS.FNM.REC.1395.1653).

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CRediT authorship contribution statement

Mahin Nomali: Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation, Conceptualization, Formal analysis. **Ramin Mohammadrezaei:** Supervision, Methodology, Data curation. **Mehdi Yaseri:** Methodology, Formal analysis. **Amirhossein Tayebi:** Writing – original draft, Data curation. **Aryan Ayati:** Writing – review & editing, Writing – original draft, Data curation. **Gholamreza Roshandel:** Methodology, Formal analysis. **Abbasali Keshtkar:** Methodology. **Shahrzad Ghiyasvandian:** Methodology. **Kian Alipasandi:** Methodology, Investigation. **Hossein Navid:** Supervision, Investigation. **Masoumeh Zakerimoghadam:** Supervision, Methodology, Data curation, Conceptualization.

Data availability

We confirm that the data supporting the findings of this study is available within the study. The study's raw data is available from the corresponding author, upon reasonable request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Protocol

Self-Monitoring by Traffic Light Color Coding Versus Usual Care on Outcomes of Patients With Heart Failure Reduced Ejection Fraction: Protocol for a Randomized Controlled Trial

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Abstract

Background: Patients with heart failure (HF) reduced ejection fraction (HFrEF) have symptoms that are more severe and experience a higher rate of hospitalization compared with HF preserved ejection fraction (HFpEF) patients. However, symptom recognition cannot be made by patients based on current approaches. This problem is a barrier to effective self-care that needs to be improved by new self-monitoring instruments and strategies.

Objective: This study describes a protocol for the self-monitoring daily diaries of weight and shortness of breath (SOB) based on the traffic light system (TLS). The primary objective is to compare the self-care between the intervention and control group. Comparison of HF knowledge, HF quality of life (HFQOL), and all-cause hospitalization between the 2 groups are the secondary objectives.

Methods: A single-blind randomized controlled trial is being conducted at the HF clinic at Tehran Heart Center (Tehran, Iran). Sixty-eight adult patients of both genders will be enrolled during admission to HF clinic. Eligible subjects will be assigned to either the intervention or control group by a block balanced randomization method. Baseline surveys will be conducted before random allocation. Participants in the intervention group will receive an integrated package consisting of (1) HF self-care education by an Australian Heart Foundation booklet on HF, (2) regular home self-monitoring of weight and SOB, and (3) scheduled call follow-ups for 3 months. Patients in the control group will receive no intervention and they only complete monthly surveys.

Results: This study is ongoing and is expected to be completed by the end of 2018.

Conclusions: This is the first trial with new self-monitoring instruments in Iran as a low and middle-income country. If the findings show a positive effect, the package will be applied in different regions with the same health care status.

Trial Registration: Iranian Registry of Clinical Trials IRCT2017021032476N1; https://en.irct.ir/trial/25296?revision=25296 (Archived by WebCite at http://www.webcitation.org/73DLICQL8)

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International Registered Report Identifier (IRRID): PRR1-10.2196/9209

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KEYWORDS

heart failure; outcome; self-monitoring; clinical trial

Introduction

Heart failure (HF) is a complex clinical syndrome that results from any structural and functional impairment of ventricular filling or ejection of blood. Based on left ventricle dysfunction and the left ventricle ejection fraction (LVEF), HF can be categorized as preserved ejection fraction (with LVEF≥50%, known as HFpEF or diastolic HF) and reduced ejection fraction (with LVEF ≤40%, known as HFrEF or systolic HF) [1].

As a global burden, HF affects more than 37.7 million individuals worldwide [2] and is a common condition with 1%-2% total health resources allocated in high-income countries. In low- and middle-income countries (LMICs) like Iran, HF may displace infectious diseases as the major public health issue [3]. In Iran and other Asian LMICs, HF is described as a pandemic [4], the prevalence greatly increased with age and range between 0.5% to 9.0% among different cities, regardless of time distribution [5], thus supporting the need for better HF surveillance and management strategies [3]. Patients with HF can experience various clinical outcomes including mortality, morbidity, and other patient-reported outcomes [6]. Although mortality and morbidity rates are similar for HFpEF and HFrEF, the hospital admission rates in patients with HFrEF are much higher than HFpEF [7].

HF is a leading cause of hospitalizations [8], mortality [8,9], rising health care costs (over US $39 billion annually in the United States and US $53.1 billion by 2030) [2,8-10], suboptimal self-care behavior [11], and reduced quality of life (QOL) [12]. According to a recent European Society of Cardiology Heart Failure Long-Term Registry prospective observational study, the rate of all-cause mortality and hospitalization at one-year follow-up was 8.1% and 28.2%, respectively [13]. Compared to Western countries, patients with HF in Asia and Iran are younger, have more severe signs and symptoms, and receive lower levels of treatment compared to the European Society of Cardiology and American College of Cardiology Foundation/American Heart Association Guidelines [14]. Moreover, Callender et al [3] reported that Iranian patients with HF experience significantly lower rates of admission (0.3%).

Poor self-care and low QOL among patients with HF are major global health issues [11] that are also affecting Iran [15-17]. Adequate self-care is associated with an improved health status [18], fewer symptoms, higher QOL [19], and reduced hospitalizations [18]. A lack of knowledge of symptom recognition and psychological problems have been identified as 2 key barriers [20]. Therefore, effective educational methods are essential for improved self-care [11,20]. Previous studies have shown that self-care programs for patients with HF are most effective when specialized education is combined with symptom monitoring and response management [21,22]. Practical and user-friendly self-monitoring tools can help patients recognize, monitor, report, and manage the symptoms appropriately. Without these tools, HF decompensation may not be detected in the early stages and could lead to preventable hospitalizations [23].

Patients with HF experience weight gain and other serious decompensation symptoms including shortness of breath (SOB) due to pulmonary edema, fatigue, and leg swelling [24-26]. Weight gain resulting from fluid retention is a marker of HF decompensation, and therefore, frequent weight monitoring can identify high-risk periods in the early stages to prevent hospitalization [24]. However, low compliance with weighing has been reported among patients with HF [27].

Diaries in a textual/tabular format are acceptable and creative self-monitoring tools because they reinforce patient education and facilitate their disease management [28]. Improved HF clinical and hospital outcomes have been reported by weight and symptom self-monitoring diary users [29]. However, despite the lower rate of HF-related hospitalizations [21,30], reduced mortality rate [21], and improved self-care [22], the previously reported studies used tabular format diaries and were conducted in developed countries with a higher quality of health care. The results may not apply to developing countries with significantly different health care systems and levels of health care quality.

Graph format diaries have been reported to attract and hold a person's attention for more extended periods and are the preferred format due to improved patient comprehension and information extraction [31]. Recently, a traffic light system (TLS) of diaries in graphical format have been developed [32]. The system consists of 3 different color codes: (1) red for medical alert, (2) yellow for a situation that is worsening and requires the patient to take quick-relief medications, and (3) green to show that the patient is doing well and adequately adhering to the treatment plan [33]. The TLS has been shown to be more effective in transforming information on risk assessment and disease management [32].

Wakefield et al [23] employed a pretest-posttest longitudinal design study to assess weight, and SOB self-monitoring by graphical instrumentation (other than TLS) in patients with HF. The paper revealed that self-monitoring HF patients could not complete the appropriate actions for each zone. Consequently, new strategies and instruments to actively engage patients in symptom recognition and monitoring require further research [23].

This study will combine graphical and tabular formats with TLS color coding to design weight and SOB self-monitoring diaries. Each color zone has been designed for patients to perform specified actions following symptom monitoring. The efficacy of this intervention will be compared with the usual care for

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patients with HF. This is the first practical study with new user-friendly self-monitoring tools that will be conducted in Iran as an LMIC to compare the primary outcome of self-care behavior and the secondary outcomes of HF-knowledge, QOL, and all-cause hospitalization between intervention and control groups.

Methods

Study Design

This study is a parallel, single-blind, randomized controlled trial. The study protocol has been reviewed and approved (No. 9411449005) by the Institutional Review Board (IRB) at Tehran University of Medical Sciences (TUMS, Tehran, Iran). The study protocol is based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 guideline [34].

Study Setting

This study will be conducted at the Tehran Heart Center (THC) HF clinic affiliated with TUMS. THC is one of the best equipped diagnostic and therapeutic cardiology centers with full-time specialists and well-trained nursing staff in the region and is a referral center for cardiology in Iran with more than 1,300,000 outpatient visits, and 280,000 patient hospitalizations from 2001 to the end of 2017 [35].

Eligibility Criteria

The research nurse (author MN) will screen the medical records of adult patients (≥18 years of age) of both genders for the following inclusion criteria in the HF clinic. The eligibility of each participant will be confirmed by the HF specialist (see Textbox 1).

Intervention

In this study, the intervention is an integrated package consisting of 3 components: (1) HF self-care education, (2) regular home self-monitoring of weight and SOB, and (3) scheduled call follow-ups.

The first component of the package includes HF self-care education that will be delivered in the HF clinic of the THC according to the Australian Heart Foundation educational booklet entitled "living well with chronic HF" [38]. Individual education will be provided by the research nurse (MN) according to the participants understanding and literacy for a 40-minute face-to-face session between 8 am to 1 pm. A Farsi version of the booklet will be given to each participant. Also, during the educational session, the instructor and the participant will review the booklet content together, and the instructor will answer any questions. The booklet contains information on disease definition, diagnosis, symptoms, and ways to manage them, lifestyle issues, medicines, and other treatments. In order to obtain permission to translate the booklet to Farsi language for local use in Iran, one of the authors (MN) contacted the Australian Heart Foundation on April 5, 2016. After obtaining permission, it was translated to the Farsi language by an individual who was also proficient in the English language and knowledge of cardiovascular terminologies. Two nursing faculty members and 2 cardiology faculty members affiliated with TUMS approved the Farsi version of the booklet.

Textbox 1. Participant eligibility criteria.

Inclusion criteria

- Definitive diagnosis of heart failure by an heart failure specialist documented on the clinical record
- Heart failure reduced ejection fraction where ejection fraction ≤40% [36,1] by any method (transthoracic, or transesophageal echocardiography, and angiography)
- New York Heart Association function class II-IV
- Access to a telephone, telegram mobile application, and ability to answer phone calls
- Ability to read and write in the Farsi language
- Having a functional weighing scale (digital or analog) at home to weigh daily [23]
- The absence of diagnosed hearing loss and sight defects
- A stable hemodynamic status
- Non-smoking, no drinking alcohol, and no addiction to drugs
- Living at home and not in a homeless shelter [37]

Exclusion criteria

- Diagnosed psychiatric and cognitive conditions during the study
- Sudden death, migration, or unavailability of patients during the follow-up phase
- Recording weight and shortness of breath in the daily diary for less than 60% (<54 days) during the study
- Undergoing cardiac or other kinds of surgery with a lengthy hospital stay during the study
- Awaiting or receiving a transplanted heart or a left ventricular assistive device

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The second component of the package includes regular home self-monitoring of weight and SOB and recording them in the appropriate 3-color daily diaries for 3 months. Since the graphical display of values help patients to recognize their symptoms and contact their health care provider [23], we created a paper-based weight and SOB self-monitoring daily diary color-coded system that was analogous to TLS.

Based on previous studies, a graphical representation of health-related information is the preferred method for patients compared to numerical/tabular displays [39,40] for communicating medical risk information [41]. This approach results in better participant comprehension. The patient pays attention and extracts more information with less effort [31]. Thus, both research diaries have been designed in 3 colors and categorize the participants' condition into 3 color-coded zones: green (excellent), yellow (use caution), and red (warning). The green, yellow, and red color-coded zones have been defined based on a combination of American Heart Association self-check plan for HF management [42] and the HF self-monitoring toolkit [43]. The colored diary will display recorded data in both graphical and tabular format. It is expected that this will result in a better participant understanding of their condition.

In the HF clinic, participants will be instructed by the research nurse on the daily measurement of weight and SOB and recording them in the daily diary during a 20-minute individual session between 8 am and 1 pm. The weight diary is a 7-page colored diary with instruction on the first page followed by 6 blank pages to record daily weight for 15 continuous days on each page.

At the time of referral to the THC, the HF specialist will measure the weight of eligible participants by analog weight scale (RASA scale, model 230, Iran). Then, 2 upper control limits will be determined for participants by the research nurse to identify 1 and 2.5 kg greater than the baseline weight that is considered as yellow and red zones in the weight diary, respectively [23] (see Figure 1). During instruction, the participants will be asked to weigh themselves daily after going to the toilet, before breakfast, with the same type of clothing, at the same time [38] and record it regularly in the weight diary for 3 months. If participants miss a weight measurement for any reason, they will be asked to record the reason for the missed date. They also will be instructed to contact the research nurse in case of sudden weight gain of 1 kg in one day (yellow zone) and 2.5 kg in one week (red zone) [44].

The SOB diary is a 4-page colored diary that includes instructions on the first page and 3 blank pages to record the difficulty of breathing for 30 continuous days on each page. The participants will be instructed on how to use the SOB colored diary, and how to rate the difficulty of breathing for the entire day after taking evening medications and at the end of each day for 3 months [23]. They will also be instructed to record the reason for any missed measuring dates.

The SOB rating scale was designed based on 0 to 10 pain assessment visual analog scale. In this scale, scores are categorized as follows: none (0), mild (1-3), moderate (4-6), and severe (7-10) [45] that have been marked by green, yellow, and red colors, respectively. Green, yellow, and red color zones will be explained to participants as no new or worsening (none-mild SOB), worsening with activity or at night when lying down (moderate SOB), and struggling to breath or at rest or while sitting (severe SOB), respectively [42] (see Figure 2). Participants will be instructed to contact the research nurse if they reach the yellow color zone to increase the diuretic dosage and contact with the emergency medical services in the red color zone [38].

The third component of the package includes scheduled follow-up phone calls (days 1, 3, and 7 after referral to the HF clinic and every week after that) for 3 months [21]. The research nurse will give participants a list of call dates and will call each subject in the evenings between 6 pm and 9 pm. Each follow-up phone call will last 5-15 minutes [21] and is designed to review the content of the instructional session, encourage participants to continue weight and SOB self-monitoring, and record them in the daily diaries. Also, the research nurse will ask the participants about the color zone during the previous week and will recommend the appropriate action (see Figure 3). Also, we predict that during the call follow-ups, participants in the intervention group will report another symptom that may be due to a side effect of the medications or the disease. The research nurse will be able to provide the appropriate recommendation for each symptom reported in the intervention group during these (see Figure 4).

At the end of the one-hour instructional session in the HF clinic, a plastic folder containing the instructional booklet, weight, and SOB colored diaries, pen, pencil, eraser, and a pencil sharpener will be delivered to each subject in the intervention group. They will be asked to keep diaries clean and deliver them to the research nurse at the end of the study.

Control

After randomization and allocating participants to 2 groups, those in the control group will receive the usual care. In HF clinic at THC, usual care for patients with HF is limited to a brief instruction by HF specialists on limiting water and salt intake, taking medications as prescribed, physical activity, weight monitoring and increasing the diuretic dosage in the condition of peripheral edema, weight gain, and SOB. They will receive 1 monthly phone call for 3 months. Out of respect for the ethical principles of human research, HF self-care instruction will be provided to the participants in the control group, and they will receive an educational booklet at the end of the study.

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Figure 1. Colored weight daily diary. EMS: emergency medical services.

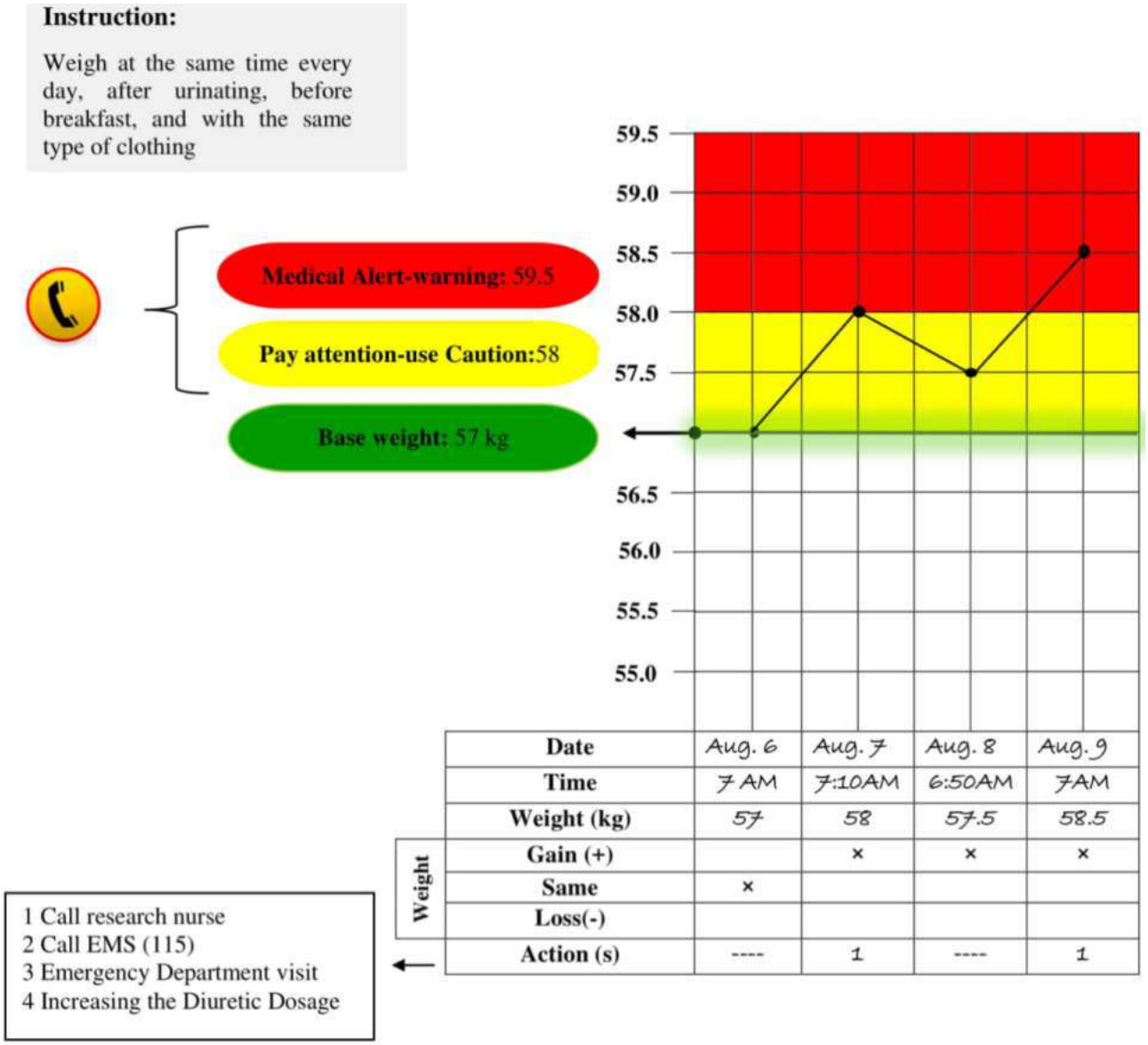

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Figure 2. Colored shortness of breath daily diary. EMS: emergency medical services.

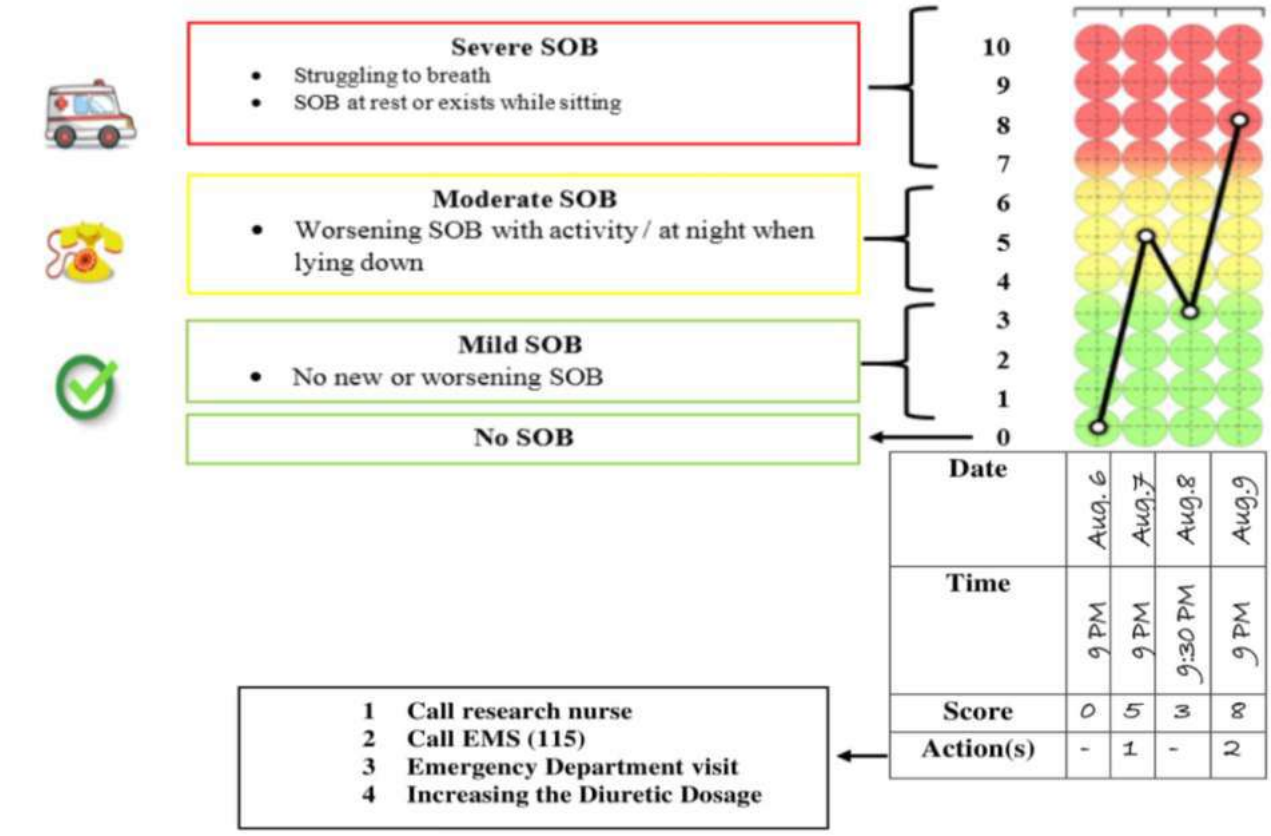

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Figure 3. Flowchart of actions recommended by research nurse based on color zones of each subject's self-monitoring daily diary during call follow-ups. ED: emergency department; EMS: emergency medical services; SOB: shortness of breath.

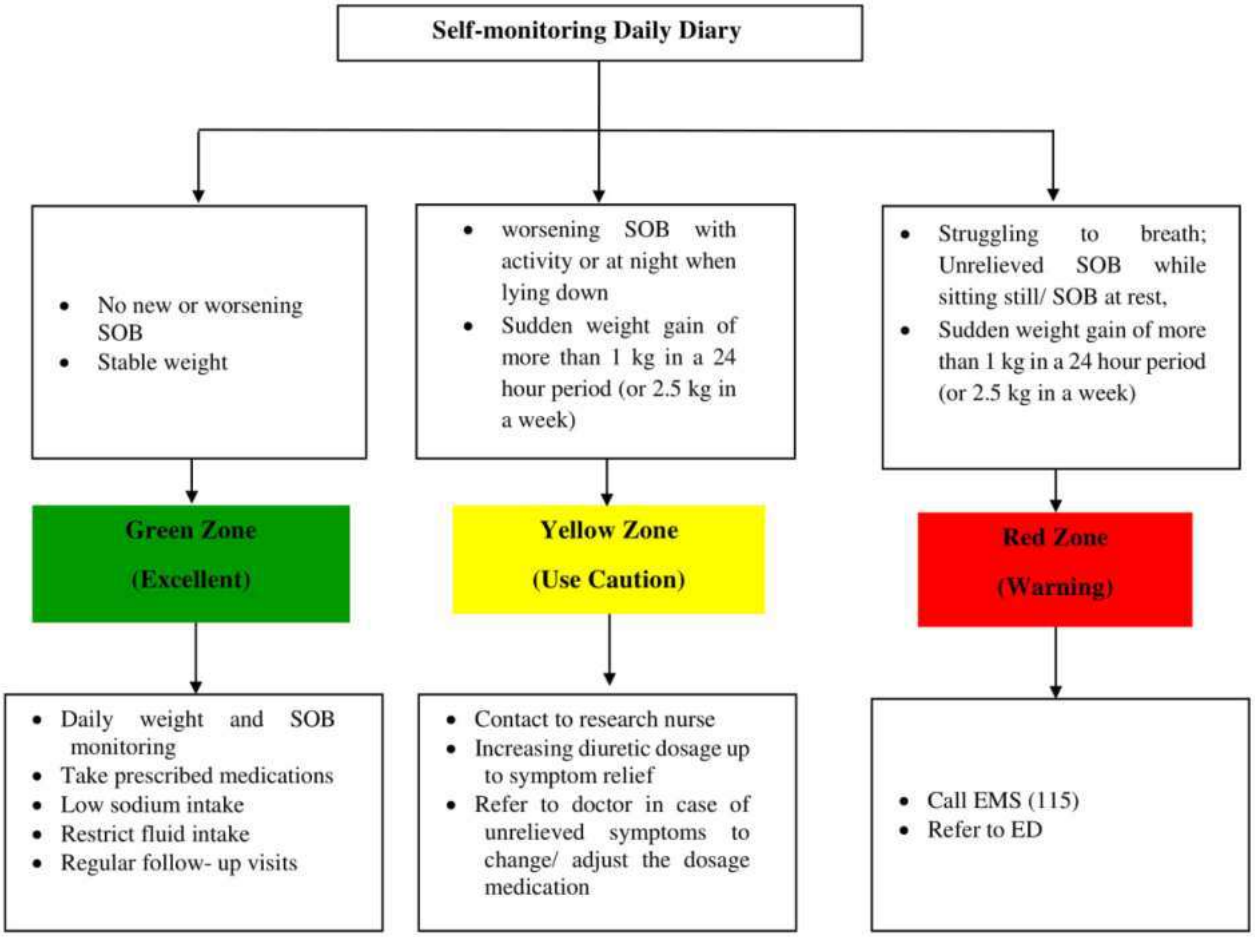
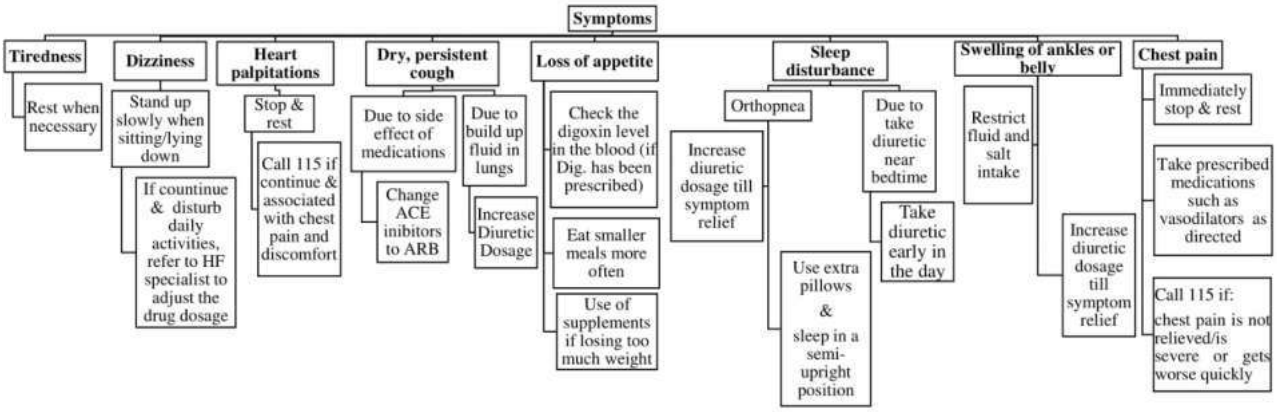


Figure 4. Flowchart of the research nurse recommendations for each symptom reported by subjects in the intervention group during the call follow-ups.



Study Measures

Primary Outcome

Self-Care Behavior

Effective self-care improvement is a priority of all clinicians caring for patients with HF [46]. In a developing country like Iran, there is a growing need to improve patient's self-care [15]. However, there is a low rate of reported admissions for HF in Iran [3]. Thus, in contrast to previous studies where hospitalization was considered the primary outcome [21,22,30] and self-care as the secondary outcome [21,22], self-care has been identified as the primary outcome in this trial.

Self-care behavior will be measured by the Self-Care of Heart Failure Index (SCHFI) version 6.2 [47] by self-reporting at baseline and monthly intervals for 3 months. SCHFI was translated into Persian and validated for Persian speaking people by Siabani et al in 2014 [48]. It consists of 3 separate scales and 22 questions: 10 for self-care maintenance, 6 for self-care management, and 6 for self-care confidence [49]. Cronbach alpha was determined for self-care maintenance (.56),

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management (.64), and confidence scales (.79) [48]. Scale scores can range between 0 to 100, and a score ≥70 will be considered as adequate self-care [49]. We will ask participants to complete SCHFI by themselves at baseline and then monthly for 3 months.

Secondary Outcomes

Heart Failure Knowledge

In order to assess the effect of education and counseling on knowledge of participants with HF, the Dutch Heart Failure Knowledge Scale (DHFKS), with Cronbach alpha=.62, will be used. This scale consists of a 15 multiple-choice self-administered questionnaire concerning: general knowledge on HF (4 questions), knowledge on HF treatment (6 questions on diet, fluid restriction, and activity), and symptoms and their recognition (5 questions). The participants will be asked to choose the correct option from the three choices. The minimum score for this scale can range from 0 (no knowledge) to a maximum score of 15 (excellent knowledge) [50].

While there is no Iranian version of this scale, it was translated into the Persian language by forward-backward translation methods after obtaining permission from the scale developer [50]. The face and content validity were evaluated by an expert's opinion and discussion with patients with HF. The reliability was assessed through a pilot study among 30 patients with HF (Cronbach alpha=.62). This coefficient alpha was identical to the original one, and the internal consistency could not be improved by deleting any of the 15 items [50]. Thus, all items have been retained. Participants will be asked to provide answers to the DHFKS by themselves at baseline and the end of the study.

Quality of Life

Heart failure quality of Life (HFQOL) will be assessed by the Iranian version of the Minnesota Living with Heart Failure Questionnaire (MLHFQ) with Cronbach alpha=.95 [51]. The psychometric properties of the questionnaire were evaluated by Middel et al in 2001 (Cronbach alpha≥.80 for the scales) [52]. The MLHFQ consists of 21 questions with a 6-point Likert scale ranging from 0 (without limitation) to 5 (maximum limitation). It consists of physical and emotional dimensions. The physical dimension is the sum of the question scores (questions 1 to 7, 12, 13) while the emotional dimension is based on questions 17 to 21. Questions 8 to 11 and 14 to 16 are related to lifestyle, financial situations, and side effects of medications. The total is the sum of the 21-question score, and a lower score reflects better quality of life [53]. Since this instrument assesses HFQOL in the previous month [54], we will ask participants to complete MLHFQ by themselves at baseline and then monthly for 3 months.

All-Cause Hospitalization

Data related to all-cause hospitalization during the previous month (ie, cause, date of admission, discharge, and length of stay) will be obtained from participants in both groups by an outcome assessor blinded to study group assignment during monthly call follow-ups. In the case of admission to other health care settings except for THC, data will be collected according to the participants' self-reporting. If the participant is admitted to THC, data will be confirmed by the hospital information system following participant self-reporting.

Causes of hospital admissions will be classified according to 3 categories of cardiac admission for HF: SOB and edema relieved by diuretics, other cardiac causes (ie, chest pain, arrhythmias, or syncope), and non-cardiac causes [21]. All-cause hospital admissions will be obtained by trained research assistants who are blinded to the allocation.

Data Collection

Eligible patients will be asked to read and sign a written informed consent form. The research nurse will then collect demographic and clinical characteristics by participant self-reporting and from a medical chart and then record these in data collection forms (see Table 1). Also, participants will be asked to complete baseline surveys (SCHFI, HF knowledge, HFQOL, and health literacy) by themselves in the HF clinic before randomization.

In order to assess participant health literacy, we will use the Heart Failure-Specific Health Literacy Scale with Cronbach alpha=.71. It consists of 12 items each with 4 possible scores (1 to 4): inapplicable (1) to strongly applicable (4) where a higher score indicates a higher level of health literacy except items 1 to 4 [55]. The Iranian version of this scale was prepared after getting the developer's permission. Thus, it was first translated into Persian by a forward-backward translation method. Then, face and content validity were approved by an expert's opinion (nursing faculty, nurse practitioners, and cardiologists) and discussion with patients with HF. A pilot study was conducted to assess the reliability with 30 HF patients and where a Cronbach alpha value of .77 was determined. Deletion of items could not improve the value similar to the original scale. Therefore, we decided to retain all items [55]. We will ask the participants to complete the health literacy scale as a baseline survey.

In order to measure the HF knowledge at the end of the study, monthly self-care behavior, and the HFQOL, the outcome assessor will be blinded to study group assignments. The assessor will send the DHFKS, SCHFI, and MLHFQ to the participants in both groups by telegram mobile application in the morning of each monthly call follow-up and ask them to send answers before 6 pm of the same day.

Participant Timeline

The SPIRIT 2013 template was used to schedule enrolment, interventions, and assessments (Table 1) [34]. A schematic representation of the study design is shown in Figure 5.

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Table 1. Time schedule for enrolment, interventions, and assessments in this study.

Time point	Staff member	Study period						
		Enrollment: $-t_1$[a]	Allocation: 0	Post-allocation				Close-out: t_x[b]
				t_1[c]	f_1	f_2	f_3[d]	
Enrollment								
Eligibility screen	Research nurse and HF[e] specialist	✓	—[f]	—	—	—	—	—
Informed consent	Research nurse and HF specialist	✓	—	—	—	—	—	—
Baseline characteristics and surveys	Research nurse	✓	—	—	—	—	—	—
Allocation	Research nurse	—	✓	—	—	—	—	—
Intervention								
Integrated package plus usual care	Research nurse	—	—	✓	✓	✓	✓	—
Control								
Usual care	—	—	—	✓	✓	✓	✓	—
Assessments (demographic/clinical)								
Age (years)	Research nurse	✓	—	—	—	—	—	—
Gender (male/female)	Research nurse	✓	—	—	—	—	—	—
Ethnicity	Research nurse	✓	—	—	—	—	—	—
Marital status (married/single)	Research nurse	✓	—	—	—	—	—	—
Income	Research nurse	✓	—	—	—	—	—	—
Level of education								
Elementary	Research nurse	✓	—	—	—	—	—	—
High school	Research nurse	✓	—	—	—	—	—	—
Academic	Research nurse	✓	—	—	—	—	—	—
HF-Specific Health Literacy Scale	Research nurse	✓	—	—	—	—	—	—
Body mass index (kg/m^2)	Research nurse	✓	—	—	—	—	—	—
Job (yes/no)	Research nurse	✓	—	—	—	—	—	—
Insurance (yes/no)	Research nurse	✓	—	—	—	—	—	—
Time with HF	Research nurse	✓	—	—	—	—	—	—
HF etiology (yes/no)								
Ischemic heart disease	Research nurse	✓	—	—	—	—	—	—
Cardiomyopathy	Research nurse	✓	—	—	—	—	—	—
Hypertension	Research nurse	✓	—	—	—	—	—	—
Heart valve disease	Research nurse	✓	—	—	—	—	—	—
NYHA[g] functional class (II–IV)	Research nurse	✓	—	—	—	—	—	—
Previous hospitalization (yes/no)	Research nurse	✓	—	—	—	—	—	—
Hospitalization last 3 months? (yes/no)	Research nurse	✓	—	—	—	—	—	—
Charlson comorbidity index	Research nurse	✓	—	—	—	—	—	—
Ejection fraction (%)	Research nurse	✓	—	—	—	—	—	—
Systolic blood pressure (mm Hg)	Research nurse	✓	—	—	—	—	—	—
Diastolic blood pressure (mm Hg)	Research nurse	✓	—	—	—	—	—	—
Heart rate (bpm)	Research nurse	✓	—	—	—	—	—	—

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Time point	Staff member	Study period						
		Enrollment: $-t_1$[a]	Allocation: 0	Post-allocation				Close-out: t_x[b]
				t_1[c]	f_1	f_2	f_3[d]	
Daily weight measure (yes/no)	Research nurse	✓	—	—	—	—	—	—
Medications (yes/no)								
Angiotensin-converting enzyme inhibitor	Research nurse	✓	—	—	—	—	—	—
Angiotensin receptor blocker	Research nurse	✓	—	—	—	—	—	—
Diuretics	Research nurse	✓	—	—	—	—	—	—
Aspirin	Research nurse	✓	—	—	—	—	—	—
Statins	Research nurse	✓	—	—	—	—	—	—
Vitamin k antagonists	Research nurse	✓	—	—	—	—	—	—
Allopurinol	Research nurse	✓	—	—	—	—	—	—
Beta blocker	Research nurse	✓	—	—	—	—	—	—
Digitals	Research nurse	✓	—	—	—	—	—	—
Implantable cardiac devices (yes/no)	Research nurse	✓	—	—	—	—	—	—
Prior cardiac surgery? (yes/no)	Research nurse	✓	—	—	—	—	—	—
Arrhythmia in electrocardiography? (yes/no)	Research nurse	✓	—	—	—	—	—	—
Laboratory parameters (serum)								
Sodium	Research nurse	✓	—	—	—	—	—	—
Potassium	Research nurse	✓	—	—	—	—	—	—
Urea	Research nurse	✓	—	—	—	—	—	—
Creatinine	Research nurse	✓	—	—	—	—	—	—
Uric acid	Research nurse	✓	—	—	—	—	—	—
Hemoglobin	Research nurse	✓	—	—	—	—	—	—
Hematocrit	Research nurse	✓	—	—	—	—	—	—
Fasting blood glucose levels	Research nurse	✓	—	—	—	—	—	—
Baseline surveys								
Self-Care of HF Index	Research nurse	✓	—	—	—	—	—	—
Minnesota Living with HF Questionnaire	Research nurse	✓	—	—	—	—	—	—
Dutch HF Knowledge Scale	Research nurse	✓	—	—	—	—	—	—
Primary outcome: Self-Care of HF Index	Research assistant	—	—	—	—	✓	✓	✓
Secondary outcomes								
HF knowledge	Research assistant	—	—	—	—	—	—	✓
HF quality of life	Research assistant	—	—	—	—	✓	✓	✓
All-cause hospitalization (yes/no)	Research assistant	—	—	—	—	✓	✓	✓

[a]$-t_1$: Time at enrollment.

[b]t_x: Time at the end of study.

[c]t_1: Time at allocation.

[d]f_1: Time at first month follow-up; f_2: Time at second month follow-up; f_3: Time at third month follow-up.

[e]HF: heart failure.

[f]Not applicable.

[g]NYHA: New York Heart Association.

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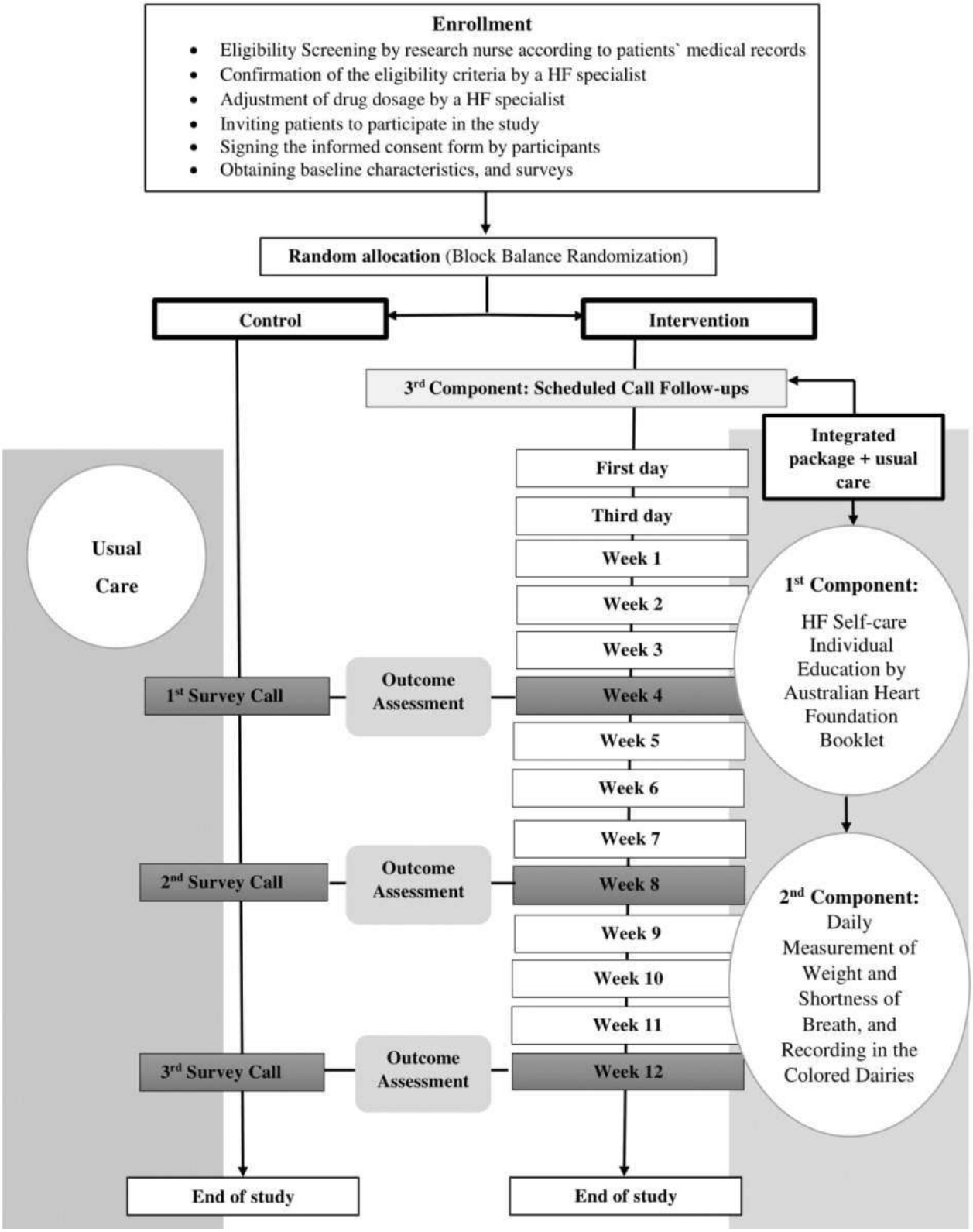
Figure 5. Schematic representation of the study design. HF: heart failure.



Sample Size

In this study, the sample size was calculated based on the minimal clinically important difference (MCID) approach for self-care as measured by SCHFI for the primary outcome. No specific MCID for SCHFI was available to the best of our knowledge and based on our search of the PubMed database. The suggested MCID for assessing dyspnea with the visual analog scale (0-100 score index) was the range 10-20 [56]. Thus, improving self-care for ≥10 scores from the baseline at the end of the study has been considered as MCID for the present study in order to reach a large sample size. According to the Jurgens et al [22] study in 2013, a mean of 70.8 for self-care in the control group at the end of study (90-days) and a fixed standard

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deviation of 27.2 (the largest SD) have been considered. In order to calculate sample size by G*Power free software (version 3.1.9.2), the input parameters are as following: effect size (Cohen *f*) of 0.168, the alpha error probability of .05, a statistical power of 80% to detect MCID≥10 scores between the 2 groups at the end of the study, 3 times measurement of outcome with monthly intervals, and a correlation coefficient of .5 among repeated measurements. Thus, by considering the overall attrition rates of 10%, the sample size was set at 68 participants (34 participants in each group).

Participant Recruitment

During the run-in phase of the study, the research nurse at the HF clinic will be present Sunday through Wednesday of each week from 8 am to 1 pm. The nurse will screen the patients for the eligibility criteria at the time of admission. Participant screening will continue until the target population is achieved. Simultaneously, an HF specialist will confirm the subject`s eligibility and adjust the drug dosages of the eligible participants. Also, the specialist will provide each patient with additional details about the study. This is our main strategy for achieving adequate participant enrollment.

Allocation: Method and Concealment Mechanism

The block balanced randomization method will be used for allocation. Before initiation of the run- in phase of the study, the statistician (AAK) will generate the randomization plan by website Randomization.com [57]. Therefore, twenty blocks of 4 for both the intervention group (group A) and the control group (group B) will be prepared. The statistician will fold the paper containing 4-size blocks 2 times, put them in the standard envelopes and write the serial numbers on them. All envelopes will be kept at the recruitment center. Thus, for every eligible patient, the research nurse randomly selects one of the envelopes after shuffling and assign participants into intervention and control groups.

Blinding

Due to the nature of the intervention, it is impossible to blind the participants assigned to the study groups to the data collector. However, the outcome assessor will be blinded and instructed not to ask the participants whether or not they received the intervention.

Data Management

Data will be collected in paper format. A file for each subject will be stored in numerical order in a secure place and manner. Files will be maintained at the recruitment center for 3 years after completion of the study. The statistical expert will prepare the data generated by the IBM/SPSS statistical software (version 16). This expert will train the data clerk to enter the data by specific codes and labels. Also, after finishing the data entry, all data will be double checked. All forms related to the study will be kept in a locked cabinet with restricted access in the recruitment center. All reports will be prepared in a manner in which no individual participants can be identified.

Data Monitoring

Three researchers from TUMS not involved in the study and chosen by the university will monitor data and supervise the conduct of the study.

Statistical Methods

Statisticians will prepare the data sheets to collected data. Data will be entered into the SPSS software (version 16). The Kolmogorov-Smirnov test will be used to normality. A transformation approach will be used to handle non-normal distribution. For the between-group comparison of continuous and categorical baseline characteristics, independent *t* test and chi-square test will be used. For categorical variables between the 2 groups, the two-tailed Fisher exact test will be used instead of the chi-square test in the case of too small expected cell frequencies. A P value <.05 will be considered statistically significant.

Primary Analysis

Baseline scores for each scale of SCHFI including self-care maintenance, management, and confidence will be compared in both groups by an independent *t* test. Due to the measurement of self-care behavior at baseline and at monthly time intervals, we will calculate the mean of monthly self-care scores in order to compare the mean of self-care behavior after the intervention in both groups. Also, because of the frequent measurement of self-care behavior, we will also use P value correction based on the Bonferroni method [58]. A linear logistic regression procedure will be applied to determine the factors affecting self-care behavior. The odds ratio will be reported with 95% CI.

Secondary Analysis

Independent *t* tests between 2 groups will compare the mean of the HF knowledge score before and at the end of the study. The HFQOL at baseline and at monthly time intervals will be compared by the P value correction based on the multiple comparisons.

In order to describe the surveillance, the median of admissions to health care settings will be used. Also, the Kaplan-Meier survival analysis will be applied for a descriptive comparison of the surveillance and, a log-rank test will be used to detect the significance difference between the 2 groups. A hazard ratio will be reported with 95% CI.

Ethics Approval and Consent to Participate

The study protocol, data collection forms, educational booklet, and the template of informed consent form was reviewed and approved by the Research Ethics Committee (REC) at TUMS on February 5, 2017 (No. IR.TUMS.FNM.REC.1395.1653). Researchers are committed to updating the agreement with the IRB and REC at TUMS for any administrative and methodological changes of the study protocol which may affect the study.

In order to obtain the informed consent, the research nurse and HF specialist will introduce the trial to each eligible participant. Every eligible participant will receive an information sheet and a written informed consent. The research nurse will then obtain

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written informed consent from all participants willing to participate in the trial.

The participant informed consent form will be prepared according to the Declaration of Helsinki. It gives the subject information on what the research is about and what happens following participation in the study. It contains information on "purpose of the trial, potential benefits and risks; subject`s right to refuse participation or to withdraw consent at any time; institutional affiliation and potential competing interests of the researcher; and sources of trial funding" [59].

One critical issue that the researchers will be experiencing is posttrial care. Due to the nature of the intervention, this trial will not have any harm for participants that need to be treated during or after the trial. However, the HF specialist is the responsible physician and will assess and manage participants in the event of worsening of the symptoms.

Availability of Data and Material

All study-related forms will be stored securely in the recruitment center by code number. Informed consent containing names and other personal identifiers will be stored separately from the forms identified by code number.

Intellectual property of the data belongs to the TUMS research and technology deputy. Thus, the final trial dataset/analysis will be available from the corresponding author upon request and by permission of the TUMS research and technology deputy.

Results

This paper is the first version of the protocol that has been submitted. At the time of manuscript submission, the trial is actively enrolling the participants, and the recruitment started on June 11, 2017. The study is expected to be completed in November 2017. Data will be analyzed and published by the end of 2018.

Discussion

The major concerns among patients with HF are the lack of information on the medications, worrying about both the quantity and combination of prescribed drugs, having trouble differentiating between the side effects of medications and symptoms of HF, and the lack of knowledge required to interpret symptoms or treat worsening symptoms [60]. The most critical participant issues are poor accessibility to a health care provider, receiving poor follow up, and having poor medication adherence [61].

Due to the nature of the intervention and the application of an integrated package including self-care educational booklet, graphical self-monitoring diaries based on TLS, and scheduled call follow-ups, we expect that this trial will address the patients' concerns and issues.

We anticipate that the self-care educational booklet will improve the patient`s knowledge of HF. Graphical colored self-monitoring weight and SOB diaries will improve the patients' ability to recognize their HF symptoms and help them determine the appropriate action whenever symptoms worsen. Also, scheduled call follow-ups will allow the patients to ask questions related to the disease, treatment options, and adverse effects. This will help them with referral to the proper health care setting in the early stages of the disease decompensation.

Iran is an LMIC and its health care system provides for only a brief verbal self-care instruction without any follow-up calls to patients with HF. Thus, at the end of this trial, patients in the intervention group and their caregivers may feel they are being deprived of standard care and a lack of support.

Thus, if the research findings provide positive effects, this practical intervention will be implemented for patients with HF in Iran and other countries similar to Iran. Also, the results of the research project plus the integrated package will be delivered to the noncommunicable diseases center at the Iran Ministry of Health, Education, and Treatment for consideration in the usual care of patients with HF.

Acknowledgments

This study protocol relates to the thesis of MN for an MSc degree in Critical Care Nursing (no. 882) at Tehran University of Medical Sciences (TUMS). We thank the Educational, Research and Technology Deputy and the Critical Care Nursing Department at the School of Nursing and Midwifery affiliated with TUMS for the thesis approval. We also thank the Noncommunicable Diseases Research Center (NDRC) of Endocrinology and Metabolism Research Institute affiliated with TUMS for critically reviewing and approving the research project. We thank Dr Neda Mehrdad for kindly supporting the research project approval process.

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Conflicts of Interest

None declared.

Authors' Contributions

MN is the principal investigator of this trial. MN, RM, AAK, GR, SG, and MZ initiated the study design. RM is the responsible physician at the Tehran Heart Center. MZ is the executive manager of the project. MN, RM, and KA helped with implementation and data collection. MN, RM, MZ, and KA prepared the informed consent and data collection forms and the educational booklet. MN and KA prepared the data for statistical analysis. AAK and GR provided statistical expertise in clinical trial design and performed the statistical analysis. All authors contributed to the refinement of the study protocol and are accountable for all aspects of the work.

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Abbreviations

DHFKS: Dutch Heart Failure Knowledge Scale
HF: heart failure
HFpEF: heart failure preserved ejection fraction
HFQOL: heart failure quality of life

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HFrEF: heart failure reduced ejection fraction
IRB: institutional review board
LMIC: low- and middle-income country
LVEF: left ventricle ejection fraction
MCID: minimal clinically important difference
MLHFQ: Minnesota Living with Heart Failure Questionnaire
NYHA: New York Heart Association
QOL: quality of life
REC: research ethical committee
SCHFI: Self-Care Heart Failure Index
SOB: shortness of breath
SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials
THC: Tehran Heart Center
TLS: traffic light system
TUMS: Tehran University of Medical Sciences

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راهنمای نمودار ثبت تنگی نفس روزانه

مددجوی گرامی؛
شما در طرح پژوهشی با عنوان" بررسی تاثیر اجرای برنامه ی خود پایشی بر پیامدهای نارسایی قلبی" شرکت می کنید. شرکت شما در این طرح اختیاری است و تمامی اطلاعات محرمانه خواهد ماند.
نمودار رو به رو راهنمای استفاده از نمودار ثبت تنگی نفس روزانه را نشان می دهد.
پژوهشگر ابتدا نحوه ی استفاده از این نمودار را به شما آموزش می دهد. سپس، شما بایستی "سطح تنگی نفس خود را بعد از دریافت دارو های روزانه در پایان هر روز" مشابه " نمودار روبه رو " بررسی، ثبت و به هم متصل نمایید.
در این نمودار تنگی نفس از صفر (عدم وجود تنگی نفس) تا ده (تنگی نفس شدید) نمره داده شده است. مجموعه ی اقداماتی که شما باید در هر محدوده ی رنگی سبز، زرد و قرمز انجام دهید؛ در مقابل نمودار آورده شده است.

در صورت بروز هر نوع مشکل، با پژوهشگر با شماره ..... تماس بگیرید.

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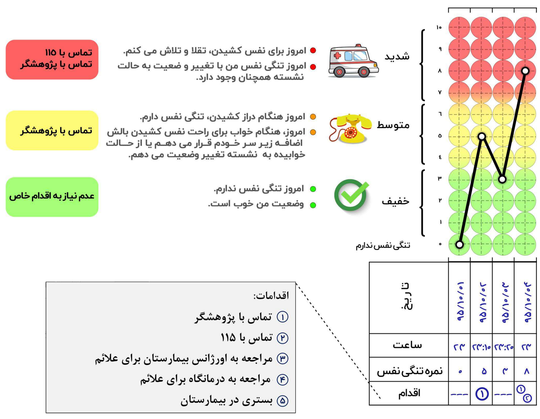
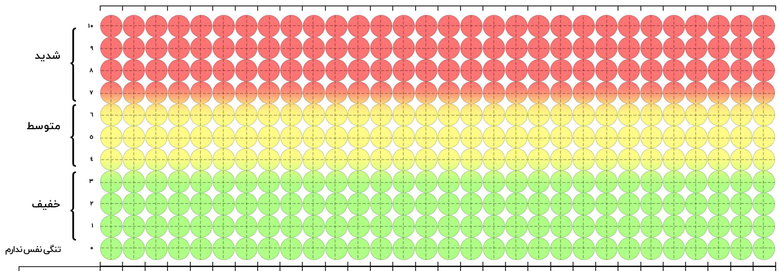


تاریخ	۹۵/۱۰/۰۱	۹۵/۱۰/۰۲	۹۵/۱۰/۰۳	۹۵/۱۰/۰۴
ساعت	۲۴	۲۳:۱۰	۲۳:۲۰	۲۳
نمره تنگی نفس	۰	۵	۳	۸
اقدام	---	①	---	①②

اقدامات:
① تماس با پژوهشگر
② تماس با ۱۱۵
③ مراجعه به اورژانس بیمارستان برای علائم
④ مراجعه به درمانگاه برای علائم
⑤ بستری در بیمارستان

کلیه حقوق مربوط به این نمودار متعلق به طرح پژوهشی با عنوان "بررسی تاثیر اجرای برنامه ی خود-پایشی بر پیامدهای نارسایی قلبی" مصوب دانشگاه علوم پزشکی تهران می باشد.

نمودار ثبت تنگی نفس روزانه



تاریخ																														
ساعت																														
نمره تنگی نفس																														
اقدام																														

دشواری تنفس خود را بعد از دریافت دارو های روزانه در پایان هر روز بررسی نمایید.
به تنگی نفس خود از صفر(عدم وجود تنگی نفس) تا ده (تنگی نفس شدید) نمره دهید و نمرات را به هم متصل نمایید.
در صورت بدتر شدن تنگی نفس فورا با پژوهشگر با شماره..... تماس بگیرید.

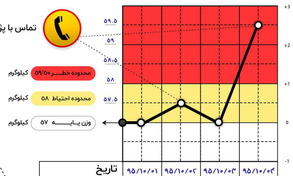
کلیه حقوق مربوط به این نمودار متعلق به طرح پژوهشی با عنوان "بررسی تاثیر اجرای برنامه ی خود-پایشی بر پیامدهای نارسایی قلبی"مصوب دانشگاه علوم پزشکی تهران می باشد.

راهنمای استفاده از نمودار ثبت وزن روزانه

مددجوی گرامی؛
شما در طرح پژوهشی با عنوان" بررسی تاثیر اجرای برنامه ی خود-پایشی بر پیامدهای نارسایی قلبی "شرکت می کنید. شرکت شما در این طرح اختیاری است و تمامی اطلاعات محرمانه خواهد ماند.
نمودار و جدول زیر راهنمای استفاده از نمودار ثبت وزن روزانه را نشان می دهد. پژوهشگر ابتدا نحوه ی استفاده از این نمودار را به شما آموزش می دهد و وزن پایه و محدوده های قرمز و زرد را برای وزن شما تعیین می کند و وزن پایه ی شما را نیز بر روی نمودار علامت می زند.
سپس، بایستی روزانه خود را بر اساس " شرایط وزن کردن روزانه" وزن نمایید و وزن خود را با تاریخ و ساعت در نمودار ثبت و نقاط را به هم متصل نمایید. در این نمودار، "افزایش وزن یک کیلوگرم بیشتر از وزن پایه" با رنگ زرد و "افزایش وزن ۲/۵ کیلوگرم بیشتر از وزن پایه" با رنگ قرمز مشخص شده است.
در صورت بروز هر نوع مشکل، با پژوهشگر با شماره ..... تماس بگیرید.

"شرایط وزن کردن روزانه"
- صبح بعد از بیدار شدن از خواب
- بعد از رفتن به دستشویی
- قبل از خوردن صبحانه
- بدون کفش
- با لباس های مشابه
- در زمان های یکسان

توجه:
خواهشمند است وزن خود را با خط خوانا وارد نمایید و این نمودار را تا پایان مطالعه نزد خود به صورت تمیز و مرتب نگه دارید و به پژوهشگر تحویل دهید.



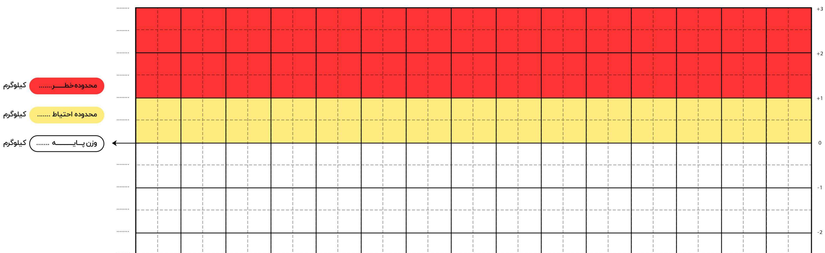
تاریخ	۹۵/۱۰/۰۱	۹۵/۱۰/۰۲	۹۵/۱۰/۰۳	۹۵/۱۰/۰۴
ساعت	۷:۰۰	۷:۱۰	۶:۵۰	۷:۱۵
وزن	۵۷	۵۷/۵	۵۷	۵۹/۵
مقدار تغییر وزن	---	۰/۵	---	۲/۵
وضعیت: اضافه وزن		✓		✓
وضعیت: مشابه روز قبل	✓		✓	
وضعیت: کاهش وزن				
اقدام	---	①	---	①
علائم	---		---	①

اقدامات:
① تماس با پژوهشگر
② تماس با ۱۱۵
③ مراجعه به اورژانس برای علائم
④ مراجعه به درمانگاه برای علائم
⑤ بستری در بیمارستان
⑥ مصرف دارو طبق دستور پزشک

علائم دیگر:
① ورم
② خستگی
③ سرگیجه
④ تپش قلب
⑤ سرفه
⑥ درد قفسه ی سینه

کلیه حقوق مربوط به این نمودار متعلق به طرح پژوهشی با عنوان "بررسی تاثیر اجرای برنامه ی خود-پایشی بر پیامدهای نارسایی قلبی"مصوب دانشگاه علوم پزشکی تهران می باشد.

نمودار ثبت وزن روزانه



تاریخ																														
ساعت																														
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وضعیت: کاهش وزن																														
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روزانه خود را با شرایط ذکر شده در راهنما، وزن نمایید و وزن خود را با تاریخ و ساعت در نمودار ثبت و نقاط را به هم متصل نمایید.
در صورتی که وزن شما در هر یک از محدوده های زرد رنگ (افزایش وزن یک کیلوگرم بیشتر از وزن پایه) و قرمز رنگ (افزایش وزن ۲/۵ کیلوگرم بیشتر از وزن پایه) قرار گرفت، فورا با پژوهشگر با شماره..... تماس بگیرید.

کلیه حقوق مربوط به این نمودار متعلق به طرح پژوهشی با عنوان "بررسی تاثیر اجرای برنامه ی خود-پایشی بر پیامدهای نارسایی قلبی"مصوب دانشگاه علوم پزشکی تهران می باشد.

LIVING WELL WITH
CORONARY HEART DISEASE

زندگی روزانه با بیماری قلبی کرونری

LIVING WELL WITH CORONARY HEART DISEASE

دکتر مهرداد رضوی
دکتر مهرداد رضوی
دکتر مهرداد رضوی

مقدمه

فهرست

مقدمه
بیماری قلب چیست؟
بیماری قلب کرونری چیست؟
بیماری قلب کرونری چگونه ایجاد می‌شود؟
بیماری قلب کرونری چگونه درمان می‌شود؟
چه عواملی بیماری قلب کرونری را تشدید می‌کند؟
چه عواملی بیماری قلب کرونری را بهبود می‌بخشد؟
چه عواملی بیماری قلب کرونری را بدتر می‌کند؟

بیماری قلب چیست؟

بیماری قلب کرونری چیست؟

بیماری قلب کرونری چگونه ایجاد می‌شود؟

بیماری قلب کرونری چگونه درمان می‌شود؟

چه عواملی بیماری قلب کرونری را تشدید می‌کند؟

چه عواملی بیماری قلب کرونری را بهبود می‌بخشد؟

چه عواملی بیماری قلب کرونری را بدتر می‌کند؟

Research Report Booklet
EVALUATION OF SELF MONITORING PROGRAM ON OUTCOMES OF HEART FAILURE