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Effect of a Four-Week Nurse-Led Home-Based Self-Care Program on Quality of Life and Physiological Outcomes in Patients with Heart Failure: A Randomized Controlled Trial

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Abstract

Background: Heart failure (HF) management necessitates effective post-discharge transition. Despite the importance of transitional care, there is limited evidence on the effectiveness of nurse-led home-based self-care programs for patients with heart failure in Iranian post-discharge settings.

Objectives: This study evaluated the impact of a nurse-led home self-care program on the quality of life (QoL) and physiological indicators of patients with HF.

Methods: This randomized controlled trial included 50 patients hospitalized at Dr. Heshmat Educational and Medical Center (Rasht, Iran), who were allocated to intervention and control groups using permuted-block randomization with allocation concealment via sealed opaque envelopes (SNOSE). The intervention group received a bedside educational program comprising seven modules, each lasting 5–15 minutes, followed by four weeks of post-discharge tele-nursing delivered through weekly 15-minute calls. The control group received standard hospital care. Of the 58 patients initially assessed, 50 were included in the final analysis. Outcomes were measured using the SF-12, the Minnesota Living with Heart Failure Questionnaire (MLHFQ), and physiological parameters. Data were analyzed using paired t-tests and ANCOVA.

Results: The participants had a mean age of 60.00 ± 8.87 years (mostly male). After adjusting for baseline values, there were no significant between-group differences in heart failure-specific QoL (MLHFQ: adjusted mean difference -6.7, 95% CI -15.9 to 2.6, P=0.154) or general QoL (adjusted mean difference 0.1, 95% CI -1.4 to 1.6, P=0.891). However, pulse rate was significantly lower in the intervention group (adjusted mean difference: -9.8 bpm; 95% CI: -16.8 to -2.8; P=0.007). No significant adjusted differences were observed in systolic/diastolic blood pressure, respiratory rate, or oxygen saturation

Conclusion: While the four-week nurse-led self-care program did not significantly improve QoL scores, it was associated with a significant reduction in resting pulse rate. This structured tele-nursing model provides a feasible framework for post-discharge management. Future studies with longer follow-up periods are recommended to evaluate potential long-term effects on quality of life and clinical outcomes.

Keywords: Heart failure, home-based self-care,nurse-led, quality of life

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1. Introduction

Heart failure (HF) is a prevalent chronic and progressive cardiovascular syndrome associated with substantial morbidity, mortality, impaired functional capacity, and poor quality of life (QoL) (1,2). Globally, HF affects more than 60 million people and places a major burden on health-care systems due to frequent hospitalizations, long-term treatment requirements, and high economic costs (2). In the United States, approximately 6 million adults currently live with HF, and this number is projected to increase by nearly 3 million by 2030 (3). In Iran, HF remains a significant public health problem. Recent regional and clinical studies indicate a considerable burden of HF, with notable morbidity and mortality among hospitalized patients (4,5). Nevertheless, evidence on the effectiveness of nurse-led home-based self-care programs for patients with HF in Iranian post-discharge settings is still limited (6).

Patients with HF commonly experience symptoms such as dyspnea, fatigue, edema, reduced exercise tolerance, and repeated hospital admissions, all of which can markedly affect daily functioning and well-being (5,6). In addition to symptom burden, physiological indicators such as blood pressure, pulse rate (used in this study as a proxy for heart rate), respiratory rate, and oxygen saturation are clinically relevant markers of hemodynamic and functional status in these patients (7,8). Because HF is a long-term condition requiring ongoing symptom monitoring and adherence to complex treatment regimens, interventions that improve both patient-reported outcomes and physiological stability are particularly important.

Quality of life is a key outcome in HF management. It has been associated with health service utilization, morbidity, mortality, and the cost of care (6,9). Many patients with HF experience limitations in physical, emotional, and social functioning, which may substantially diminish their QoL. Consequently, improving QoL has become an important goal for comprehensive HF care.

Self-care is a central component of heart failure management. It includes medication adherence, symptom monitoring, and dietary and lifestyle modification. Effective self-care has been associated with improved symptom control, fewer complications, greater patient engagement, and more efficient use of health-care resources (10). In this context, nurse-led interventions are particularly important because nurses play a key role in patient education, discharge planning, follow-up, and reinforcement of self-care behaviors (11,12). Through structured education and ongoing support, nurses can help patients better understand their condition and develop the skills needed for long-term self-management(13).

Previous studies on nurse-led and home-based self-care interventions in HF have reported inconsistent results. A study conducted in Singapore in 2021 found that a nurse-led home-based self-care program improved self-care, psychological outcomes, and health-related QoL (14). In contrast, a study from the United Kingdom reported no evidence that a nurse-led self-management program improved QoL in patients with HF (10). Similarly, research from the Netherlands suggested that further evidence is needed to clarify the long-term effectiveness of self-management programs in this population (15). These inconsistencies may be related to differences in intervention design, duration, follow-up intensity, sociocultural context, and health-system organization. In addition, because these studies were conducted in high-income settings, their findings may not be directly generalizable to the Iranian context, where patterns of care delivery and post-discharge support may differ.

Despite the recognized importance of post-discharge support in HF management, evidence regarding the effectiveness of nurse-led home-based interventions remains inconclusive, particularly in non-Western settings. Therefore, we evaluated whether a structured nurse-led home-based self-care program improves QoL and selected physiological parameters, including blood pressure, pulse rate, respiratory rate, and oxygen saturation, compared with usual care in Iranian patients with HF over one month.

2. Methods

2.1. Study Design and Setting

This study was a single-center, parallel-group randomized controlled trial (RCT). The trial was prospectively registered with the Iranian Registry of Clinical Trials (IRCT identifier: [IRCT20101019004971N6]). The study was conducted at Dr. Heshmat Educational and Medical Center, a specialized cardiovascular tertiary referral hospital in Rasht, Iran. Eligible patients were randomized into two parallel groups: an intervention group that received a nurse-led home-based self-care program and a control group that received usual discharge care. The intervention was developed based on Orem's Self-Care Deficit Nursing Theory and adapted from previously published nurse-led self-care frameworks that have demonstrated validity and reliability among Iranian patients. The primary outcome of this trial was quality of life. Secondary outcomes included physiological indicators. The assessment instruments used to evaluate quality of life, including the MLHFQ and SF-12, had been previously validated in Iranian populations; therefore, a preliminary pilot study was not deemed necessary. Because of the nature of the intervention, participants and outcome assessors for physiological measures were not blinded. To reduce measurement bias, physiological outcomes were collected using a standardized protocol: measurements were taken at the same time points, with participants in the same position after a fixed rest period, using the same calibrated devices. SpO_2 and pulse rate were recorded directly from the device display.

2.2. Participants and Eligibility Criteria

Participants were recruited from patients hospitalized at Dr. Heshmat Educational and Medical Center, Rasht, based on the following inclusion criteria: age 20–75 years, confirmed diagnosis of heart failure (according to ICD codes), NYHA functional class II–III, and residence in the Rasht metropolitan area. The Charlson Comorbidity Index (CCI) was assessed at baseline for all participants and reported descriptively in the results. Patients were excluded if they were candidates for cardiac surgery, were enrolled in another trial, withdrew consent, or failed to adhere to the follow-up protocol during the study period.

2.3. Sample Size Estimation

The sample size was calculated using a standard formula for comparing two independent means. Based on prior literature and expecting a clinically meaningful difference, a large effect size (Cohen's $d = 0.8$) was assumed to be the primary outcome. Assuming a two-tailed alpha level (α) of 0.05 and a statistical power ($1 - \beta$) of 0.80, the minimum sample size required was determined to be 26 patients per group. To accommodate an anticipated 10% attrition rate, the final target sample size was established at 29 patients per arm (total $N = 58$).

$$n = \frac{2\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{d^2} + \frac{z_{1-\alpha/2}^2}{4} = \frac{2(1.960 + 0.841)^2}{0.8^2} + \frac{(1.960)^2}{4} = 26$$

2.4. Randomization and Recruitment

Participants were recruited via convenience sampling between May 23 and November 12, 2023. Eligible patients were randomly assigned to either the nurse-led home-based self-care intervention or the

usual care control group in a 1:1 allocation ratio. Randomization was performed using a permuted block design (with variable block sizes of 4 and 6) generated through the Sealed Envelope online service (Sealed Envelope Ltd., London, UK). To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) were utilized. While the sample size calculation determined the initial target, the final analysis included 50 participants who completed the full follow-up and posttest assessments; attrition was primarily due to a lack of cooperation during the follow-up phase (Figure 1).

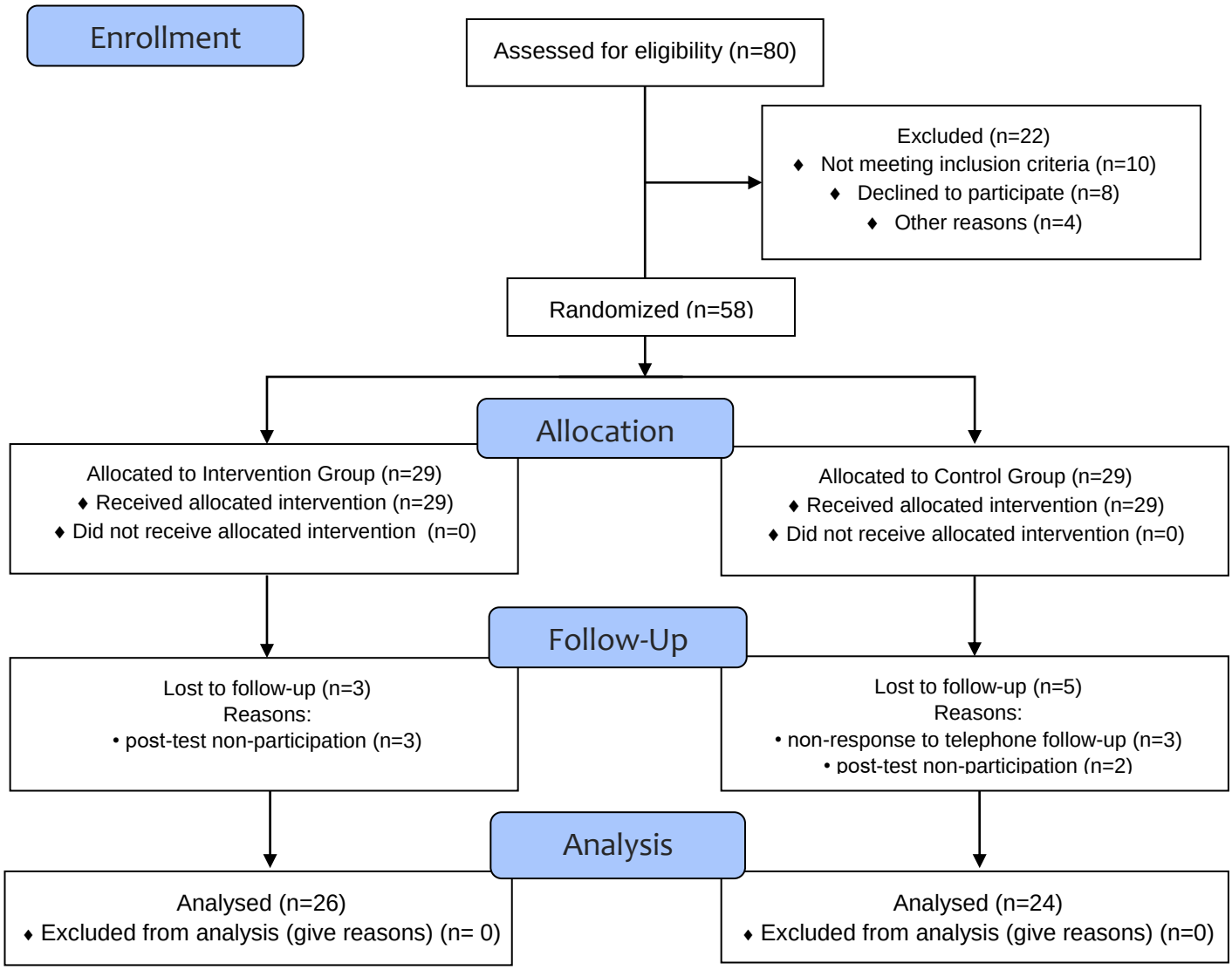

Figure 1. CONSORT flow diagram of participant recruitment, allocation, follow-up, and analysis.

2.5. Data Collection and Instruments

Baseline demographic and clinical data—including age, sex, marital status, parity, education level, employment, income, household size, medical history, and insurance status—were retrieved from medical records and supplemented by structured patient interviews.

2.6. Quality of Life (QoL) Assessment

Generic QoL was evaluated using the 12-item Short Form Health Survey (SF-12), a condensed version of the SF-36 developed by Ware et al. (1996). The SF-12 encompasses eight subscales: general health, physical functioning, role-emotional, bodily pain, social functioning, vitality, role-physical, and

mental health. Higher scores indicate superior QoL. The psychometric properties of the Persian version were previously validated by Montazeri et al. (2009), with reported internal consistency (Cronbach's alpha) of 0.73 and 0.72 for physical and mental components, respectively.

Disease-specific QoL was assessed using the Minnesota Living with Heart Failure Questionnaire (MLHFQ). This 21-item instrument measures the impact of HF on physical (8 items), emotional (5 items), and socioeconomic (7 items) dimensions. Responses are recorded on a 6-point Likert scale (0 = no limitation to 5 = maximum limitation), with total scores ranging from 0 to 105; higher scores reflect poorer QoL. The Persian version's reliability and validity were confirmed by Eskandari et al. (2016), demonstrating high internal consistency (α = 0.95) and excellent test-retest reliability (r > 0.90).

2.7. Physiological Indicators

Hemodynamic and respiratory parameters, including systolic and diastolic blood pressure (BP), pulse rate (PR), respiratory rate (RR), and arterial oxygen saturation (SpO_2), were measured. BP was recorded using a calibrated mercury sphygmomanometer. PR and SpO_2were monitored via pulse oximetry, and RR was assessed by observing chest excursions over one full minute.

2.8. Intervention Protocol and Fidelity

The intervention protocol's content validity was established through a formal review by an expert panel comprising five nursing faculty members with expertise in cardiology, critical care, and clinical research. Their feedback was systematically integrated to finalize the protocol.

2.9. Procedure

Eligible participants were recruited and allocated to either the intervention or control group. Assessments were conducted once patients achieved clinical stability, defined as: vital signs within normal limits (BP: 90–140) mmHg; PR: 60–100 bpm; RR: 12–20 bpm; SpO_2: 96–100%) and a Glasgow Coma Scale (GCS) score of 15/15.

2.10. Intervention Group

Participants received a nurse-led program designed as a focused, brief educational intervention. Prior to discharge, patients participated in two 5–15-minute bedside sessions. To prevent information overload during the acute post-discharge transition, the seven key domains— (1) recognition of warning signs, (2) medication adherence, (3) dietary management, (4) physical activity, (5) stress/anxiety management, (6) sexual health, and (7) lifestyle modifications—were introduced in a condensed, high-yield format. An educational booklet was provided as a takeaway reference. Crucially, the bedside sessions were supplemented by four weekly 15-minute post-discharge tele-nursing calls, which served as the primary reinforcement mechanism to consolidate the knowledge, clarify doubts, and support behavioral adaptation over time.

2.11. Control Group

Participants received routine hospital discharge education in accordance with standard institutional guidelines.

2.12. Intervention Fidelity

To ensure rigor, the intervention followed the TIDieR (Template for Intervention Description and Replication) framework. All sessions were delivered by a trained nurse using a manualized protocol. Fidelity was prospectively monitored using a standardized checklist to document session duration, content delivery, and participant engagement. The research team periodically reviewed adherence; no significant protocol deviations were observed.

2.13. Ethical Considerations and Data Management

The study was conducted in accordance with institutional ethical guidelines. Data access was strictly limited to the research team, and participant confidentiality was maintained throughout all stages. Data will be securely stored for 5 years after publication, then destroyed.

2.14. Statistical Analysis

Data were analyzed using SPSS version 26.0. Data normality was assessed using the Shapiro-Wilk test. Within-group comparisons (pre- and post-intervention) for QoL and physiological parameters were performed using paired t-tests. Between-group differences in post-intervention outcomes were analyzed using Analysis of Covariance (ANCOVA), adjusting for baseline values as covariates. The significance level was set at $p < 0.05$. Given the low-risk nature of the intervention, an independent data monitoring committee was not required; the principal investigator performed monitoring.

3. Methods

3.1. Participant Flow and Baseline Characteristics

A total of 58 patients with heart failure were initially randomized (n=29 per group). During the follow-up period, eight participants were excluded due to non-compliance or failure to complete posttest assessments, resulting in a final sample of 50 participants (Intervention: n=26; Control: n=24) for the complete-case analysis. The flow of participants through the trial is summarized in Figure 1. Recruitment commenced on May 23, 2023, and the final follow-up was completed on November 12, 2023. No adverse events or unintended harms associated with the nurse-led intervention were reported.

The study population had a mean age of 60.0 years (SD = 8.87). Most participants were male (58.0%), married (86.0%), and lived with family members (92.0%). Baseline demographic and clinical characteristics were balanced across the two groups, as expected by randomization (Table1).

Table 1. Demographic and clinical characteristics of the patients included in the control and intervention groups

Total (n=50)		Group	
		Control (n=24)	Intervention (n=26)
Age (years)	60.00 (8.87)	59.46 (8.08)	60.50 (9.68)
Sex			
Male	29 (58.0)	12 (50.0)	17 (65.4)
Female	21 (42.0)	12 (50.0)	9 (34.6)
Marital status			
Married	43 (86.0)	21 (87.5)	22 (84.6)
Single/Widow (er)	7 (14.0)	3 (12.5)	4 (15.3)
Education level			
Illiterate	12 (24.0)	5 (20.8)	7 (26.9)
Under diploma	23 (46.0)	13 (54.2)	10 (38.5)
Diploma	11 (22.0)	3 (12.5)	8 (30.8)
University education	4 (8.0)	3 (12.5)	1 (3.8)
Insurance			
Yes	47 (94.0)	23 (95.8)	23 (95.8)
No	3 (6.0)	1 (4.2)	1 (4.2)
Complementary insurance			
Yes	14 (28.0)	9 (37.5)	5 (19.2)
No	36 (72.0)	15 (62.5)	21 (80.8)
Social living conditions			
Living alone	4 (8.0)	3 (12.5)	1 (3.8)

Living with others	46 (92.0)	21 (87.5)	25 (96.2)
Occupational condition			
Unemployed	27 (54.0)	16 (66.7)	11 (42.3)
Employed	23 (46.0)	8 (33.3)	15 (57.7)
Income			
Under 2.5 million Tomans	16 (32.0)	9 (37.5)	7 (26.9)
2.5-5 million Tomans	9 (18.0)	3 (12.5)	6 (23.1)
5-10 Million Tomans	17 (34.0)	9 (37.5)	8 (30.8)
10 Million Tomans and more	8 (16.0)	3 (12.5)	5 (19.2)

Quantitative variable values are shown as "mean (standard deviation)", and qualitative variables as "frequency (percentage)". Income is reported in Tomans; approximate USD equivalents are provided for international readers.

3.2. General Quality of Life (SF-12)

Within-group comparisons revealed no statistically significant improvements in general QoL scores from baseline to one-month post-intervention in either the intervention or control group (Table 2). Specifically, the total QoL score in the intervention group changed from 29.6 (SD = 3.3) to 30.7 (SD = 2.9) ($p = 0.207$, Cohen's $d = 0.25$). Similarly, the control group showed no significant change ($p = 0.452$). Between-group analysis demonstrated that the nurse-led home-based intervention did not yield a superior effect on generic physical or psychological health domains compared to routine care during the follow-up period.

Table 2. Comparison of general quality of life scores and physiological indicators in control and intervention groups before and after.

		Time		Mean of differences (95% CI)	t	P	Cohen's d
		Pretest	Posttest				
General QoL (SF-12)	**Physical Component**						
	Control	11.8 (1.9)	12.6 (1.4)	0.9 (-0.1, 1.8)	1.99	0.059	0.406
	Intervention	12.6 (1.4)	12.5 (1.5)	-0.1 (-0.8, 0.7)	0.10	0.916	0.021
	Mental Component						
	Control	18.2 (2.5)	18.0 (2.1)	-0.2 (-1.6, 1.1)	0.38	0.702	0.079
	Intervention	17.0 (2.7)	18.1 (2.5)	1.1 (-0.3, 2.5)	1.57	0.128	0.309
	Total score						
	Control	30.0 (3.4)	30.6 (2.4)	0.6 (-1.1, 2.3)	0.77	0.452	0.156
	Intervention	29.6 (3.3)	30.7 (2.9)	1.1 (-0.6, 2.7)	1.30	0.207	0.254
Specific QoL (MLHFQ)	**Physical Domain**						
	Control	20.4 (7.6)	17.7 (8.7)	-2.7 (-6.3, 1.0)	1.52	0.142	0.310
	Intervention	21.8 (8.6)	15.6 (9.8)	-6.2 (-9.8, -2.6)	3.58	0.001	0.702
	Emotional Domain						
	Control	7.5 (4.6)	7.9 (4.5)	0.5 (-1.6, 2.5)	0.46	0.648	0.094
	Intervention	10.2 (5.8)	7.4 (5.9)	-2.8 (-5.7, 0.1)	1.97	0.059	0.388
	Total score						
	Control	48.8 (16.7)	45.2 (17.5)	-3.6 (-10.2, 3.0)	1.12	0.273	0.229
	Intervention	52.2 (20.7)	40.6 (21.4)	-11.6 (-19.5, -3.8)	3.04	0.005	0.597
Physiological indicators	**Systolic blood pressure**						
	Control	109.3 (17.2)	109.6 (19.0)	0.3 (-6.4, 7.1)	0.10	0.919	0.021
	Intervention	107.4 (17.4)	109.1 (21.8)	1.7 (-6.8, 10.1)	0.40	0.691	0.079
	Diastolic blood pressure						
	Control	68.5 (11.0)	69.0 (16.7)	0.5 (-5.4, 6.5)	0.18	0.853	0.038
	Intervention	68.7 (12.6)	67.2 (13.2)	-1.5 (-7.1, 4.1)	0.56	0.576	0.111

	Pulse rate						
	Control	78.9 (10.2)	83.5 (13.7)	4.6 (0.8, 8.4)	2.51	0.019	0.513
	Intervention	81.0 (20.9)	74.5 (13.3)	-6.5 (-14.9, 1.9)	1.60	0.121	0.315
	Respiratory rate						
	Control	19.5 (4.1)	19.8 (3.8)	0.2 (-1.4, 1.9)	0.26	0.797	0.053
	Intervention	18.8 (4.6)	18.2 (5.1)	-0.7 (-3.1, 1.8)	0.54	0.593	0.106
	SpO_2						
	Control	96.5 (2.0)	96.6 (3.1)	0.2 (-0.7, 1.1)	0.38	0.706	0.078
	Intervention	96.3 (2.3)	97.0 (2.5)	0.6 (-0.4, 1.7)	1.21	0.238	0.237

Abbreviations. QoL: Quality of Life; CI: Confidence Interval; SF-12: 12-Item Short Form Survey; MLHFQ: Minnesota Living with Heart Failure Questionnaire.
Cohen's d values of 0.2-0.5, 0.5-0.8, and >0.8 indicate small, medium, and large effect sizes, respectively. P-values are based on a paired t-test.

3.3. Disease-Specific Quality of Life (MLHFQ)

Adjusted analysis of covariance (ANCOVA), controlling baseline values, showed no statistically significant between-group difference in the total MLHFQ score post-intervention ($F(1.47) = 2.09\ p = 0.154\ \eta_p^2 = 0.043$).

The adjusted mean difference between the intervention and control groups was -6.7 (95% CI: -15.9 to 2.6).

While the intervention group showed a numeric decrease in total MLHFQ scores (indicating improvement), this did not reach statistical significance in either the physical ($p = 0.206$) or psychological ($p = 0.353$) subscales. The effect sizes for disease-specific QoL were categorized as small to negligible (Table 3).

Table 3. Comparison of mean quality of life scores and physiological indicators in heart failure patients between control and intervention groups.

		Group		**Adjusted mean difference** (95% CI)	**ANCOVA results**		
		Control	Intervention		**$F_{(1, 47)}$**	**P**	**η_p^2**
General QoL (SF-12)	**Physical Component**						
	Pretest	11.8 (1.9)	12.6 (1.4)				
	Posttest	12.6 (1.4)	12.5 (1.5)	-0.2 (-1.1, 0.6)	0.28	0.596	0.006
	Mental Component						
	Pretest	18.2 (2.5)	17.0 (2.7)				
	Posttest	18.0 (2.1)	18.1 (2.5)	0.2 (-1.1, 1.6)	0.13	0.720	0.003
	Total score						
	Pretest	30.0 (3.4)	29.6 (3.3)				
	Posttest	30.6 (2.4)	30.7 (2.9)	0.1 (-1.4, 1.6)	0.02	0.891	0.001
Specific QoL (MLHFQ)	**Physical Domain**						
	Pretest	20.4 (7.6)	21.8 (8.6)				
	Posttest	17.7 (8.7)	15.6 (9.8)	-3.0 (-7.6, 1.7)	1.65	0.206	0.034
	Emotional Domain						
	Pretest	7.5 (4.6)	10.2 (5.8)				
	Posttest	7.9 (4.5)	7.4 (5.9)	-1.4 (-4.4, 1.6)	0.88	0.353	0.018
	Total score						
	Pretest	48.8 (16.7)	52.2 (20.7)				
	Posttest	45.2 (17.5)	40.6 (21.4)	-6.7 (-15.9, 2.6)	2.09	0.154	0.043
Physiological indicators	**Systolic blood pressure**						
	Pretest	109.3 (17.2)	107.4 (17.4)				
	Posttest	109.6 (19.0)	109.1 (21.8)	0.6 (-9.5, 10.7)	0.01	0.905	<0.001
	Diastolic blood pressure						

	Pretest	68.5 (11.0)	68.7 (12.6)				
	Posttest	69.0 (16.7)	67.2 (13.2)	-2.0 (-9.5, 5.6)	0.27	0.603	0.006
	Pulse rate						
	Pretest	78.9 (10.2)	81.0 (20.9)				
	Posttest	83.5 (13.7)	74.5 (13.3)	-9.8 (-16.8, -2.8)	7.99	0.007	0.145
	Respiratory rate						
	Pretest	19.5 (4.1)	18.8 (4.6)				
	Posttest	19.8 (3.8)	18.2 (5.1)	-1.4 (-3.8, 1.1)	1.21	0.277	0.025
	SpO_2						
	Pretest	96.5 (2.0)	96.3 (2.3)				
	Posttest	96.6 (3.1)	97.0 (2.5)	0.4 (-0.9, 1.8)	0.40	0.531	0.008

Abbreviations. QoL: Quality of Life; CI: Confidence Interval; SF-12: 12-Item Short Form Survey; MLHFQ: Minnesota Living with Heart Failure Questionnaire.
Partial eta squared (η2p) values of 0.01-0.06, 0.06-0.14, and >0.14 indicate small, medium, and large effect sizes, respectively.

3.4. Physiological Indicators

The primary physiological finding was a significant reduction in pulse rate (PR) within the intervention group. After adjusting for baseline levels, the post-intervention pulse rate was significantly lower in the intervention group compared to the control group (Adjusted Mean Difference = -9.8 bpm; 95% CI: -16.8 to -2.8; $p = 0.007$). This finding was associated with a large effect size ($\eta_p^2 = 0.145$).

In contrast, no significant between-group differences were observed for other physiological parameters, including systolic blood pressure ($p = 0.905$), diastolic blood pressure ($p = 0.603$), respiratory rate ($p = 0.277$), and arterial oxygen saturation ($p = 0.531$). Detailed comparisons of physiological indicators are presented in Table 3.

3.5. Intervention Fidelity and Concomitant Care

The intervention was implemented according to a standardized, manualized protocol based on the TIDieR framework, with 100% of planned sessions delivered by a trained nurse. Fidelity checklists confirmed high adherence to the educational domains and session durations. Throughout the study, participants in both groups remained on their physician-prescribed pharmacological regimens, and no significant differences in concomitant medical care were identified between the groups.

4. Discussion

The present study examined the effects of a nurse-led home-based self-care program on quality of life (QoL) and physiological indicators in patients with heart failure (HF). No statistically significant difference was found between the intervention and control groups in overall QoL after the intervention. Several factors may account for this finding. First, the four-week duration and the low-intensity nature of the intervention (i.e., 15-minute weekly calls) might have been insufficient to foster substantial changes in QoL. Second, the intervention was predominantly informational, lacking intensive psychological or behavioral counseling components, which are often necessary to drive significant improvements in patient-reported outcomes. Third, a possible ceiling effect should be considered; participants reported moderate baseline QoL scores (MLHFQ mean ≈ 50), which may have limited the potential for further improvement within a short timeframe. These observations are consistent with previous reports; for instance, Mårtensson et al. noted that the overall benefits of nurse-led self-management programs can be

limited, suggesting that telephone follow-up alone may not be sufficient to sustain improvements (16). Similarly, Bakitas et al. found no significant effect on QoL in their trial (17), underscoring the complexity of translating self-care education into measurable improvements in patients' QoL.

In contrast, Oliveira et al. demonstrated that a structured two-session psychoeducational intervention significantly improved QoL and promoted positive psychological growth in patients with HF (18). This discrepancy may be related to differences in the design, intensity, and content of the interventions, particularly the inclusion of targeted psychological strategies, which may have had a stronger influence on patient-reported outcomes. Our intervention was predominantly informational and self-care focused. In contrast, psychologically focused interventions may be more effective for improving patient-reported outcomes. Likewise, Jiang et al. reported that self-management programmes improved self-management behaviours, self-efficacy, and health-related QoL, while also reducing unplanned visits among patients with coronary artery disease (19). Zhang et al. also found a positive association between self-management behaviours and health-related QoL (20). Taken together, these findings suggest that self-care interventions may be more effective when comprehensive, psychologically focused, and sustained over a longer period.

The interpretation of QoL outcomes should also consider the broader cultural, social, and economic context in which self-care interventions are implemented. Quality of life is a multidimensional construct that may be influenced by factors beyond the intervention itself, such as socioeconomic status, health literacy, and access to health care. These contextual differences may partly explain the variability in findings across studies. In the Iranian context, social and family factors may shape patients' engagement in self-care programs and perceptions of QoL; however, family support was not measured in the present study. Therefore, its potential influence should be considered cautiously. Differences in health-care systems, availability of home-based services, and social support structures across countries may limit the generalizability of the present findings. Further studies should examine the role of family support and other sociocultural factors in diverse settings.

Regarding disease-specific QoL, the intervention group showed a favorable numerical trend after the intervention. In contrast, no similar improvement was observed in the control group. However, after adjustment for baseline values using ANCOVA, the between-group difference was no longer statistically significant. This pattern may indicate a potentially beneficial effect of the nurse-led home-based self-care program on disease-specific QoL. However, the magnitude of the effect was insufficient to demonstrate clear superiority over usual care during the study period. The lack of statistical significance may be attributable to the relatively small sample size, limited statistical power, and short follow-up period. It is also possible that improvements in disease-specific QoL require longer-term behavioral reinforcement and sustained clinical support before meaningful changes become evident. In line with this interpretation, Aghakhani et al. reported a positive effect of a self-care program on QoL in patients with HF (21). Ware et al. suggested that an HF telemonitoring program could reduce health-service utilization while improving QoL and self-care (22). However, conflicting findings reported by Jarsma et al. suggest that more intensive and longer-lasting interventions may be necessary to achieve significant improvements in QoL (23).

No significant within-group changes were observed in systolic blood pressure, diastolic

blood pressure, respiratory rate, or SpO_2 in either group. In addition, ANCOVA showed no statistically significant between-group differences in these variables after adjustment for baseline values. These findings are consistent with those of Kerry et al., who reported that home monitoring did not improve blood pressure control in hypertensive patients with a history of stroke (24), and Zhu et al., who found no significant differences in blood pressure, QoL, or self-efficacy between study groups (25). In contrast, Koleva et al. found that a complex nurse-led program tailored to patients with uncontrolled blood pressure significantly improved blood pressure reduction and control in primary care (26). Similarly, Iyngkaran et al. reported reductions in systolic and diastolic blood pressure, mean arterial pressure, heart rate, and respiratory rate, along with an increase in SpO_2 after the intervention (27).

Sustained improvement in physiological indicators often requires longer interventions, more intensive follow-up, and closer clinical monitoring. Therefore, the short duration of the present intervention and the use of telephone-based follow-up may have limited the ability to detect significant changes in blood pressure, respiratory rate, and SpO_2. In addition, differences between the present findings and those of previous studies may be partly explained by the heterogeneous nature of HF and the presence of comorbid conditions, especially respiratory disorders. Because both cardiac dysfunction and pulmonary impairment may influence SpO_2, the absence of detailed data on respiratory comorbidities may have introduced residual confounding. Future studies should therefore account for major comorbid conditions through stratified or adjusted analyses.

An important finding of the present study was the significant between-group difference in pulse rate after adjustment for baseline values. Although pulse rate increased significantly over time in the control group, this pattern was not observed in the intervention group. This finding may suggest that structured nurse-led follow-up, including reinforcement of self-care education, regular monitoring, and supportive communication, contributed to greater physiological stability. The lower post-intervention pulse rate in the intervention group may therefore indicate a potentially beneficial effect of continued nurse-led support. Consistent with this finding, Kord Salarzehi et al. reported significant post-intervention differences in heart rate and mean arterial pressure (28). However, Rajabloo et al. found no significant difference in pulse rate between the pre- and post-intervention periods in either group (29). Variations in measurement methods, device calibration, and study protocols may partly explain these inconsistencies across studies.

An important finding of the present study was the significant between-group difference in pulse rate after adjustment for baseline values. Although pulse rate increased significantly over time in the control group, this pattern was not observed in the intervention group. This finding suggests that the structured nurse-led follow-up—encompassing reinforcement of self-care education, regular monitoring, and supportive communication—may have contributed to improved physiological parameters. Specifically, the lower post-intervention pulse rate in the intervention group might reflect enhanced medication adherence (e.g., to beta-blockers) or improved autonomic regulation through better self-management of HF symptoms. However, as medication titration and adherence were not specifically monitored in this study, these remain potential confounding factors. Similar findings regarding heart rate modulation in HF self-management interventions have been reported in other settings(30). In contrast,

Rajabloo et al. found no significant difference in pulse rate(29). These inconsistencies may stem from variations in intervention intensity, measurement protocols, or patient characteristics.

4.1. Limitations

Several limitations should be considered when interpreting our findings. Although there were no statistically significant baseline differences between participants who dropped out and those who completed the study, the 13.7% attrition rate may still have introduced attrition bias. Moreover, the analyses were based on complete-case data rather than an intention-to-treat approach, so the potential influence of missing outcome data cannot be ruled out. Outcome assessment was not blinded, and because the same nurse-researcher delivered the intervention and collected the data, both social desirability and detection bias are possible, particularly for self-reported outcomes such as the SF-12 and MLHFQ. This lack of blinding is also relevant to the physiological outcomes, including resting pulse rate, despite the use of standardized measurement procedures. In addition, some potentially important clinical covariates were not fully measured or adjusted for, which may have led to residual confounding. Because multiple outcomes were examined without formal adjustment for multiple comparisons, the isolated statistically significant difference observed in resting pulse rate should be interpreted cautiously. The internal consistency of the Persian SF-12 in this sample was acceptable but modest (Cronbach's alpha = 0.72–0.73), which may have reduced measurement precision.

Furthermore, the intervention itself may have limited the magnitude of observable effects: it was primarily informational, did not include intensive psychological or behavioral counseling, and was delivered over only four weeks through brief weekly telephone calls. This intensity and duration may have been insufficient to generate the behavioral changes required for measurable improvements in quality of life or physiological status. Finally, the study may have been underpowered to detect small but clinically meaningful effects, as the sample size calculation was based on a large, anticipated effect size (Cohen's d = 0.8). In contrast, behavioral self-care interventions often produce more modest effects. Future multicenter trials with blinded outcome assessment, intention-to-treat analysis, longer follow-up, and more comprehensive intervention strategies are needed to strengthen the evidence base.

5. Conclusion

This study evaluated the impact of a nurse-led home-based self-care program on quality of life and physiological indicators in patients with heart failure. Within the one-month follow-up period, the intervention did not result in measurable improvement in quality of life. Although a statistically significant difference in resting pulse rate was observed, this finding should be interpreted cautiously given the study limitations, including the lack of blinding for physiological outcome assessment, the use of complete-case analysis, the absence of some potentially relevant clinical covariates, and the lack of adjustment for multiple comparisons. Nevertheless, nurse-led telephone follow-up appears to be a feasible and low-cost adjunct to standard care for post-discharge support and monitoring. Further studies with larger samples, longer follow-up, and more rigorous outcome assessment are needed to determine whether such interventions produce clinically meaningful and reproducible benefits.

List of Abbreviations:

HF=Heart Failure
CHF= congestive heart failure
QOL =quality of life
HRV= heart rate variability

ICD= International Classification of Diseases-
GCS=Glasgow Coma Scale
MLHFQ=Minnesota Living with Heart Failure Questionnaire
NYHA= New York Heart Association

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Ethics approval and consent to participate: We confirm that all experiments conducted in this study were performed in accordance with the Declaration of Helsinki. The study focused solely on implementing a self-care education program, and no changes were made to the patients' treatment plans.

This study began after approval by the Ethics Committee of the Deputy Research of Guilan University of Medical Sciences (GUMS), with the ID IR.GUMS.REC.1402.008 was obtained on April 19, 2023, and the study was registered with the IRCT. Informed consent was subsequently obtained from the participants. The data, including identifying information, were kept confidential, and participants were free to participate in the study or withdraw.

Trial registration: IRCT20101019004971N6 on 2023-05-09.

Authors' contributions: M.M: Collecting data and editing the article. M.J.S.N: Supervising the entire execution of the research, writing, and editing the article. S.M: writing the results and conducting statistical analysis. Z.B: Collecting data. M.T.M: Supervising the entire execution of the research and editing the article. All authors have approved the final manuscript.

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