



Effects of a Periodic Assessment of Heart Failure and Depressive Symptoms on Self-Care in Outpatients with Heart Failure: A Randomized Controlled Trial

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Abstract

Background: Periodic symptom assessment in outpatient settings may enhance self-care in heart failure (HF) patients, though its effects are not fully studied. This study examined the impact of periodic HF and depressive symptom assessments on self-care (maintenance, symptom perception, and management) over nine months.

Methods: In this randomized controlled trial, symptom assessments were conducted in the intervention group at baseline and at three, six, and nine months in South Korea between Sep 2022 and Nov 2023. Data on self-care were collected at baseline and at nine-month follow-up. A series of two-way repeated measures analysis of variance were used to address the purpose.

Results: The only variable that showed a significant difference between the intervention group (n=17, age=64.8 yr) and the control group (n=21, age=64.6 yr) from baseline to nine-month follow-up was self-care maintenance. The main effect of time on self-care maintenance was statistically significant, improving from baseline to follow-up regardless of group ($F[1,36]=26.53$, $P<0.001$). A significant group-by-time interaction ($F[1,36] = 26.53$, $P=0.015$) indicated the changes in self-care maintenance varied over time by group membership.

Conclusion: A periodic assessment of HF symptoms and depressive symptoms increased self-care maintenance, but did not affect other self-care behaviors, in outpatients with HF. Clinicians may consider regular outpatient symptom assessment as a tool for educational support to enhance self-care maintenance in patients with HF.

Keywords: Assessment; Heart failure; Depression; Symptoms; Self-care

Introduction

The chronic progressive course of heart failure (HF) involves significant physical and psychological suffering due to the high prevalence of HF symptoms and depressive symptoms (1-3). Pa-

tients with HF commonly experience multiple symptoms, including dyspnea, fatigue, and chest pain (3, 4). Even among patients with mild HF symptoms (77.2% in New York Heart Associa-



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tion [NYHA] class II), 38% report experiencing three or more symptoms (3, 4). Dyspnea was the most common (92.3%) followed by fatigue (50.7%) (3). In Korean patients, fatigue was the greatest burden, followed by dyspnea and sleeping difficulty (2). Additionally, depressive symptoms were also prevalent in patients with HF, affecting more than 30% of patients (5). These HF symptoms and depressive symptoms adversely affect quality of life, morbidity, and mortality (6-9). Thus, these symptoms lead to considerable burdens to patients with HF, society, and healthcare system (1-3, 5). Therefore, HF symptoms and depressive symptoms need to be assessed and managed effectively to reduce the adverse effects.

The symptom burdens of HF (10) and depressive symptoms (11, 12) can hinder patients from undertaking effective self-care behaviors (13, 14). However, research on self-care and physical symptoms remains inconsistent. More severe HF symptoms have been linked to better self-care, though associations vary by types of self-care behaviors (10, 15). For example, HF symptoms were positively associated with self-care management but not self-care maintenance (13). Patients with persistently high HF symptoms over six months also demonstrated better self-care than those with lower HF symptoms (10). Conversely, patients with HF with more severe physical symptoms were less likely to engage in self-care (16). Similarly, more severe depressive symptoms were consistently associated with poor self-care (11, 12). Therefore, both HF symptoms and depressive symptoms need to be considered simultaneously to improve self-care. Notably, outpatients experience significant symptom burdens and hospitalization rates similar to inpatients (17, 18). Therefore, maintaining adequate self-care is critical in outpatients with HF particularly in the long-term management of HF and symptoms (19). Symptom assessment in outpatient settings offer two potential benefits. First, clinicians can identify patients at risk for worsening symptoms and provide appropriate management before the symptoms worsen. Second, clinicians can educate patients to recognize warning signs and symp-

toms, along with their self-care strategies, to eventually reduce those symptoms and the burden (1, 18, 20, 21). A periodic assessment at the outpatient setting could serve dual purposes—monitoring symptoms and providing education—to support effective self-care.

However, limited knowledge exists on the impact of periodic outpatient symptom assessments on self-care. While severe HF symptoms are linked to greater self-care engagement (10), little is known about trajectories of physical and psychological symptoms and their influence on self-care behaviors for less symptomatic outpatients well-managed but still at high risk for symptom burden. This information could be crucial for better understanding of the relationships of symptom assessment and self-care in patients with HF who have suboptimal engagement in self-care worldwide (22, 23). To address this, we developed an intervention involving routine HF and depressive symptom assessments at baseline, three months, six months, and nine months to help patients recognize and interpret symptoms, aiming to improve self-care at the outpatient setting. This study aimed to examine the effects of these periodic assessments on self-care behaviors—maintenance, symptom perception, and management—over nine months in outpatients with HF. We hypothesized that the intervention group would show a greater increase in self-care behaviors from baseline to 9-month follow-up compared to the control group.

Methods

Study design and setting

This randomized controlled study explored the effects of periodic HF and depressive symptom assessments on self-care behaviors in HF outpatients. Participants were recruited from a university-affiliated hospital outpatient clinic in South Korea between Sep 2022 and Nov 2023 and randomly assigned to intervention or control groups via computer-generated randomization. The intervention group underwent assessments at baseline, three, six, and nine months, while self-care

behavior data were collected from both groups at baseline and nine months.

Sample

The inclusion criteria for this study were: a diagnosis of HF, age ≥ 19 yr, an optimal regimen of prescribed medications (including beta-blockers, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, angiotensin receptor-neprilysin inhibitors, and diuretics), and regular outpatient visits verified by medical records. Exclusion criteria focused on consent and self-care capacity and included neurocognitive disorders (e.g., dementia), serious medical conditions with significant symptoms (e.g., chronic respiratory, renal, or liver diseases), terminal comorbidities (e.g., cancer), or end-stage HF, as determined through medical record review.

The estimated sample size for this study was 46 patients with HF (medium effect size = .25, significance level (α) = .05, power = .90, 2 groups, and 2 measurements). Considering a 15% attrition rate in a HF trial (24), the required sample size was 54 patients, with 27 in each group. Among the 54 participants at baseline, 38 completed the follow-up visits.

Measures

Heart failure symptoms were evaluated using the Symptom Status Questionnaire-Heart Failure, which assess seven symptoms, each with four sub-items rated on a 3-point Likert scale (4). Higher scores indicate more severe HF symptoms, with reliability and validity supported in the United States and South Korea (4, 25). Depressive symptoms were evaluated using the Patient Health Questionnaire-9, a nine item tool rated on a 4-point Likert scale (26). Higher scores indicate greater depressive symptoms, with reliability and validity supported in patients with HF in the United States (27) and in Korean adults (28) and elderly patients (29). Self-care behaviors were evaluated using the Revised Self-Care of Heart Failure Index (v7.2), comprising three scales: Self-care Maintenance (10 items), Symptom Perception (11 items), and Self-care Management (8 items) scales (30). Scores are standardized (0–100), with higher scores indicating better self-care

behaviors. Reliability and validity have been established in individuals with HF from the United States (31), Italy (32), and South Korea (30). Baseline data on sociodemographic and clinical characteristics were collected using a standard questionnaire, and comorbidity was evaluated using the Charlson Comorbidity Index (33).

Procedure

This study was approved by the Institutional Review Board of the university-affiliated hospital (ethical code#: GCIRB2022-232). A nurse coordinator, a doctoral nursing student, screened and recruited eligible patients and managed the randomization. Two trained research assistants, college nursing students, obtained written informed consent and collected baseline data through face-to-face interviews in a private hospital setting. If patients in the intervention group missed a follow-up visit, standardized calls were made for the three- and six-month assessments. The research assistants also conducted final nine-month data collection during regular outpatient visits. Throughout the study, the principles of Declaration of Helsinki were followed (34).

Data analysis

IBM SPSS Statistics ver. 28 (IBM Corp., Armonk, NY, USA) was used for data analysis with a significance level of <0.05 and two-tailed tests. Descriptive statistics outlined sample characteristics and key variables. Independent t-tests or Mann-Whitney U tests compared HF symptoms, depressive symptoms, and self-care behaviors between the intervention and control groups at each time point. Two-way repeated measures ANOVA assessed changes in self-care behavior scores from baseline to the nine-month follow-up for both groups.

Results

Initially, 54 patients were enrolled and evenly randomized into two groups. Over the nine-month study, 16 patients (29.6%) were lost to follow-up due to death, lack of interest, refusal,

or inability to contact (intervention: 10; control: 6). Non-completers were older, but no other demographic (sex, education, marital status) or clinical differences were found between groups. The final sample included 38 patients (control group: $n=21$, 64.6 yr; intervention group: $n=17$, 64.8 yr) (Table 1). The mean age was 64.7 yr (± 11.35), with 28.9% female and 81.6% married. Most

were asymptomatic (NYHA class I: 73.7%). There were no significant differences between groups in age, sex, marital status, education, comorbidity, left ventricular ejection fraction, or NYHA status. Only 11 patients (28.9%) had HF education, with no group difference (28.6% vs. 29.4%, $\chi^2 = 0.003$, $P=0.955$).

Table 1: Sample Characteristics

Variable		Total (N = 38)	Control (n = 21)	Intervention (n = 17)		
		Mean (SD)			<i>t</i>	<i>p</i>
Age, years		64.66 (11.35)	64.57 (12.62)	64.76 (9.93)	-.051	.959
Education, years		11.05 (3.78)	10.48 (4.33)	11.76 (2.95)	-1.087	.284
LVEF, %		33.95 (7.75)	34.90 (8.25)	32.76 (7.15)	.844	.405
Comorbidity		2.24 (1.20)	2.29 (0.90)	2.18 (1.51)	.277	.784
		n (%)			χ^2	<i>p</i>
Sex	Male	27 (71.1)	14 (66.7)	13 (76.5)		*.721
	Female	11 (28.9)	7 (33.3)	4 (23.5)		
Marital status	Married	31 (81.6)	17 (81.0)	14 (82.4)		*1.000
	Single	4 (10.5)	3 (14.3)	1 (5.9)		
	Divorced	3 (7.9)	1 (4.8)	2 (11.8)		
NYHA functional class	I	28 (73.7)	16 (76.2)	12 (70.6)		*.727
	II	8 (21.1)	3 (14.3)	5 (29.4)		
	III	1 (2.6)	1 (4.8)	0 (0.0)		
	IV	1 (2.6)	1 (4.8)	0 (0.0)		
HF education	Yes	11 (28.9)	6 (28.6)	5 (29.4)	.003	.955
	No	27 (71.1)	15 (71.4)	12 (70.6)		

* Fisher's exact test. HF = heart failure. LVEF = left ventricular ejection fraction. NYHA = New York Heart Association. SD = standard deviation.

Note. In the group comparisons (χ^2 analyses) for categorical variables, marital status was categorized as "married" versus "others" (single/divorced); and NYHA functional class was categorized as "Class I" versus "other" (Class II/III/IV).

Self-care did not differ significantly between groups at baseline or the nine-month follow-up (Table 2). Depressive symptoms also showed no significant differences at either time point. However, the intervention group had more severe HF

symptoms at baseline (median score: 8 vs. 3, Mann-Whitney U statistic=254.50, $P=0.024$). By nine months, HF symptom levels were similar between groups (median score: 7 vs. 5, Mann-Whitney U statistic=223.00, $P=0.182$).

Table 2: Comparisons of Self-care, Depressive Symptoms, and Heart Failure Symptoms from Baseline to 9-Month Follow-up (N = 38)

Variable	Time	Control (n = 21)	Intervention (n = 17)	Independent t-test	
		Mean (SD)		<i>t</i>	<i>p</i>
Self-care maintenance	Baseline	52.62 (12.21)	50.44 (11.43)	0.562	.577
	9-Month Follow-up	58.57 (14.22)	68.09 (17.58)	-1.846	.073
Symptom perception	Baseline	44.62 (20.29)	49.36 (18.29)	-.747	.460
	9-Month Follow-up	50.10 (21.40)	61.25 (20.36)	-1.632	.111
Self-care management	Baseline	76.92 (22.07)	83.26 (18.66)	-.942	.352
	9-Month Follow-up	65.51 (23.54)	73.98 (17.38)	-1.235	.225
		Median (25 th , 75 th)		Mann-Whitney U	<i>p</i>
Depressive symptoms	Baseline	1.00 (0.00, 5.00)	3.00 (1.00, 7.50)	244.00	.051
	9-Month Follow-up	3.00 (3.00, 5.00)	4.00 (1.50, 8.50)	211.00	.337
Heart failure symptoms	Baseline	3.00 (0.00, 9.00)	8.00 (6.00, 19.00)	254.50	.024
	9-Month Follow-up	5.00 (0.00, 10.00)	7.00 (3.00, 13.00)	223.00	.182

SD = standard deviation

In two-way repeated measures ANOVA, self-care maintenance was the only variable showing a significant difference between groups over time (Table 3). Although the overall self-care maintenance scores did not differ by group ($F(1,36)=0.87$, $P=0.358$), there was a significant main effect of time, indicating improvement from baseline to follow-up, assuming sphericity ($F(1,36)=26.53$, $P<0.001$). A significant group-by-time interaction ($F(1,36)=6.51$, $P=0.015$) sug-

gests that changes in self-care maintenance varied by group (Fig. 1). Additionally, significant main effects of time were observed for symptom perception ($F(1,36)=8.64$, $p=0.006$) and self-care management ($F(1,36)=12.39$, $P=0.001$). Symptom perceptions improved in both groups, while symptom management decreased. However, group-by-time interactions for these variables were not significant.

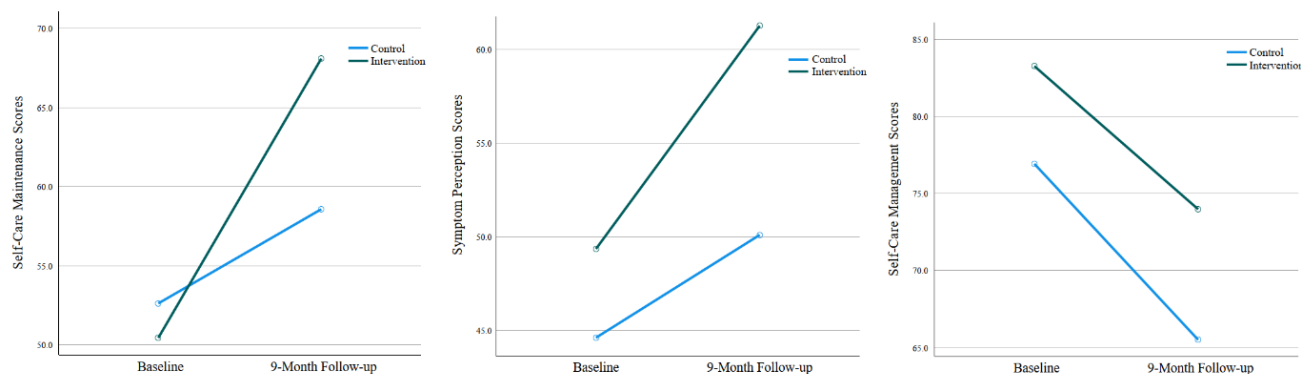
**Fig. 1:** Baseline-to-9-month changes in self-care between the intervention and control groups

Table 3: Results of Two-Way Repeated Measures Analysis of Variance (N = 38)

Self-care behaviors	Source of variation	Type III sum of squares	Mean square	F	p
Maintenance	Group(G)	253.00	253.00	.867	.358
	Time(I)	2616.12	2616.12	26.53	<.001
	G×T	642.438	642.438	6.515	.015
Symptom perception	Group(G)	1185.74	1185.74	303.82	.186
	Time(I)	1417.33	1417.33	8.64	.006
	G×T	193.484	193.484	1.18	.285
Management	Group(G)	1030.51	1030.51	1.46	.235
	Time(I)	2012.12	2012.12	12.39	.001
	G×T	21.350	21.350	.131	.719

Discussion

In this randomized controlled trial on the effects of periodic HF and depressive symptom assessments on self-care behaviors, self-care maintenance significantly improved over time, varying by group. While symptom perception and self-care management also changed over time, they were unaffected by group membership. Regular outpatient symptom assessments can enhance self-care maintenance in patients with HF. Clinicians may integrate routine physical and depressive symptom assessments into outpatient care, enabling patients to monitor symptoms and receive timely support. This proactive, collaborative approach may improve HF management.

The burdens of HF symptoms (10, 35) and depressive symptoms (11, 12, 35) could serve as barriers to undertaking self-care in patients with HF (13, 14), while symptom exacerbation could be preventable through therapeutic adherence to pharmacological and non-pharmacologic recommendations (36, 37). One important strategy for HF management is systematic and continuous symptom assessment (38), which, when incorporated into routine care, has the potential to im-

prove self-care among patients with HF. However, the effects of nurse-led outpatient symptom assessment have been relatively understudied. This study evaluated its impact on self-care behaviors in HF patients and found that the intervention group showed significant improvements in self-care maintenance compared to the control group. Notably, the intervention group had more HF symptoms at baseline. Periodic symptom assessment may have enhanced self-care maintenance by increasing patients' awareness of their symptoms and the need for self-care. This regular attention to symptoms may have contributed to better self-care behaviors, as patients became more aware of their condition and the need for regular maintenance behaviors. Prior studies report mixed findings on the relationship between HF symptoms and self-care—some indicating that more symptoms lead to better self-care (10, 13, 15), while others suggest the opposite (16, 35). Our findings align with research indicating that patients with sustained high HF symptoms demonstrate better self-care compared to those with sustained low levels of HF symptoms over 6 months (10). These results further support the notion that symptom awareness is a key driver of

improved self-care (10, 15), highlighting the significant role of symptom assessment in promoting self-care behaviors (10).

Furthermore, the effects of periodic symptom assessment on self-care vary by self-care type (10, 13). In this study, the intervention improved self-care maintenance but had limited effects on symptom perception and self-care management. While symptom perception improved and self-care management declined over time, these changes were not linked to group membership. The observed changes in symptom perception and self-care management were not directly influenced by the intervention, but may reflect the distinct nature of the three types of self-care. Self-care maintenance primarily involves autonomous adherence to therapeutic and healthy behavioral recommendations (39), whereas symptom perception and self-care management are cognitively driven, requiring symptom detection, interpretation, and consultative responses to symptom occurrences, respectively (39). These findings highlight the need for more intensive and comprehensive interventions to enhance symptom perception and self-care management. Future studies should explore stronger educational approaches to improve patients' cognitive abilities and symptom responsiveness, aiming to enhance all aspects of self-care. Additionally, further research is needed to understand the mechanisms driving the varying effects of interventions on different self-care behaviors.

Patients in this study showed poor self-care behaviors. Only 5.3% of patients at baseline and 36.8% at nine-month follow-up demonstrated adequate self-care maintenance. Similarly, previous studies in Korea and Brazil reported low rates of adequacy in self-care maintenance (15.9% and 19%, respectively) (40, 41). Patients in this study also showed low adequacy in symptom perception, with only 10.5% meeting adequacy at baseline and 31.6% at the nine-month follow-up. Mean symptom perception scores remained below 70 in both groups, ranging from 44.6 to 61.2, aligning with prior HF research (mean score: 43.4) (30). These findings underscore the need to improve self-care maintenance and symptom

perception in HF patients. Notably, self-care maintenance and symptom perception improved over time in both groups, possibly due to the initial symptom and self-care assessments at baseline. However, given the low adequacy in these areas and the limited effects of periodic symptom assessments, more direct and comprehensive interventions are needed to achieve meaningful self-care improvements.

Unexpectedly, patients with HF in this study showed relatively high rates of adequacy in self-care management at baseline (78.9%) and follow-up (44.7%). Except for the mean score in the control group at baseline, the mean self-care management scores were greater than 70 in both groups at both time points. These findings contrast with those in prior studies, including a systematic review and meta-analysis, which reported inadequate self-care management (mean scores 42.5- 53.1) (13, 30, 41). Interestingly, the mean scores for self-care management at follow-up were significantly lower than the baseline scores in both the intervention (74.0 vs. 83.3) and control groups (65.5 vs. 76.9). Physical and psychological symptoms remained unchanged in both groups between baseline and follow-up. The reasons for the unusually high adequacy rates at both baseline and follow-up, as well as the decrease in scores over time, remain unclear. Further research is needed to gain a better understanding of the state of self-care management and the impact of interventions on self-care management in Korean patients with HF.

Limitation

This study has several limitations. The sample size was smaller than initially calculated due to a higher-than-expected attrition rate (30% vs. 15%). Although the intervention and control groups were homogenous, the small sample size may have affected the results, highlighting the need for further studies with adequately powered sample sizes. Additionally, patients who completed the study were younger than those who dropped out. Furthermore, most participants were asymp-

tomatic or had mild HF symptoms, which may have limited the ability to fully capture the impact of symptom assessment on self-care behaviors.

Conclusion

Outpatients with HF showed inadequate self-care maintenance and symptom perceptions in both the intervention and control groups at baseline and follow-up. Periodic assessment of HF and depressive symptoms improved self-care maintenance but did not significantly affect symptom perception or self-care management. Clinicians may consider regular symptom assessments to enhance self-care maintenance. Given the small sample size, further studies are needed to evaluate the effects of periodic symptom assessments on various aspects of self-care. Additionally, further research is necessary to develop interventions that combine periodic symptom assessment with education on symptoms and strategies for self-care.

Journalism Ethics considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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Conflict of interest

The authors declare that there is no conflict of interests.

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