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Effects of an Educational Intervention on Heart Failure Knowledge, Self-Care Behaviors, and Health-Related Quality of Life of Patients with Heart Failure: Exploring the Role of Depression

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Abstract

Objectives: To test effects of an educational intervention on patient-reported outcomes among rural heart failure (HF) patients and to examine whether effects differed between patients with and without depression.

Methods: Patients (N=614) were randomized to usual care (UC) or 1 of 2 intervention groups. Both intervention groups received face-to-face education, followed by either 2 phone calls (LITE) or biweekly calls until they demonstrated content competency (PLUS). Follow-up lasted 24 months. Statistical analyses included linear mixed models and subgroup analyses by depression status.

Results: Both intervention groups showed improvement in HF knowledge at 3 months (LITE–UC, $p=0.003$; PLUS–UC, $p<0.001$). Improvement lasted 24 months only in the PLUS group. Compared to UC, both intervention groups exhibited better self-care at 3 months (LITE–UC, $p<0.001$; PLUS–UC, $p<0.001$) and 12 months (LITE–UC, $p=0.001$; PLUS–UC, $p=0.002$). There were no differences in health-related quality of life (HRQOL) among groups. In subgroup analyses, similar effects were found among non-depressed, but not among depressed patients.

Conclusion: The educational intervention improved HF knowledge and self-care, but not HRQOL. No intervention effects were observed in patients with depressive symptoms.

Practice Implications: The simple educational intervention is promising to improve HF knowledge and self-care. Additional strategies are needed for depressed patients.

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Keywords

Heart failure; patient education; self-care; disease knowledge; quality of life; depression

1. Introduction

Heart failure (HF) presents a growing burden on healthcare, affecting 6.5 million individuals in the United States [1]. In 2012, the overall annual cost of HF was estimated as \$30.7 billion, of which \$20.9 billion was direct costs [2]. Because hospitalization is responsible for 80% of the total HF costs [3] and symptom exacerbation is the most common reason for HF hospitalization [4], the majority of effort by health care systems has been directed at managing HF symptoms and preventing HF exacerbation.

Management of HF requires continual effort from patients to monitor their symptoms, adhere to fluid and diet restrictions, engage in physical activity, and follow medication regimens as well as promptly seek care when symptoms worsen [5]. Therefore, many investigators have tested strategies to help patients with HF improve their self-care skills [6–11]. Most of the studies were conducted in large tertiary medical centers located in urban areas with specialized clinics involving interdisciplinary teams [6, 8–11], or interventions were delivered by advanced practice nurses [7, 9]. Because residents in rural areas tend to have lower household incomes compared with those in urban areas and have limited access to specialized care [12], simple strategies that can be implemented with limited resources are needed for patients with HF living in rural areas. In addition, previous investigators demonstrated favorable short-term effects on knowledge about HF [10] and self-care [6, 7, 9, 11], but long-term effects have rarely been assessed [6, 7, 10, 11] or reported [9]. The effect on health-related quality of life (HRQOL) also needs to be further examined. Although HRQOL has been measured as one of the main outcomes in randomized trials testing self-care interventions, no strong conclusion regarding the effect of self-care interventions on HRQOL has been made [13, 14].

Depression is an important factor affecting self-care practice in patients with HF. In a recent systematic review, depression was the only factor consistently reported as being associated with poor self-care in patients with HF [15]. In addition, the effects of self-care interventions differed by comorbid depression. Combining results from 14 randomized trials of HF self-care interventions, Jonkman et al. [14] found no significant intervention effects on mortality in patients without depression, but found significantly higher all-cause mortality in patients with moderate/severe depression. The mechanism of the differential effects has yet to be determined, but the findings suggest the need for different approaches to HF patients with and without depression and warrants further investigations on whether such differential effects also exist on patient-reported outcomes.

The REMOTE-HF (Rural Education to Improve Outcomes in Heart Failure) trial was a multicenter, randomized controlled trial, with a primary aim to test an educational intervention program designed for rural patients with HF [16]. An educational intervention with two different doses (Fluid Watchers LITE and Fluid Watchers PLUS) were compared with usual care. Factors that have been reported as affecting self-care behaviors, such as

functional status and health literacy [17], were also assessed in this trial. In the report of the primary findings from the REMOTE-HF trial [16], no significant differences were found in the combined end point of cardiac mortality or HF-related hospitalization among the three study groups, and the intervention with additional telephone contacts by nurses (Fluid Watchers PLUS) did not improve clinical outcomes. In the present report, we analyzed patient-reported outcomes from the REMOTE-HF trial to examine the effects of the educational intervention program on the level of HF knowledge, self-care behaviors, and HRQOL over a period of 24 months. Additionally, we performed subgroup analyses to examine whether the effects of the educational intervention on patient-reported outcomes differed between patients with and without depression.

2. Methods

2.1. Participants

The REMOTE-HF trial [16] was reviewed and approved by the Institutional Review Board of each participating institution and was carried out in accordance with the Code of Ethics of the Declaration of Helsinki. Patient recruitment took place at multiple cardiology practices in rural areas of California, Kentucky, and Nevada. The inclusion criteria were: 1) 18 years of age or older; 2) having a clinical diagnosis of HF; 3) having been hospitalized for HF within the past 6 months; 4) being able to read and write English; 5) living in a rural area (i.e., a town of < 2,500 persons, a metropolitan center of < 50,000 persons, or open country) [18]; and 6) living independently (i.e., not institutionalized). Patients were excluded if they: 1) were participating in a HF disease management program; 2) had a complicating serious co-morbidity (e.g., a psychiatric illness, untreated malignancy, renal failure requiring dialysis, or a disease or illness with life expectancy of 12 months or less); or 3) had cognitive impairment defined as a word recall score of 0 or a word recall score of 2 with an abnormal clock drawing on the Mini-Cog [19].

2.2. Procedures

The study design and procedures have been described in detail elsewhere [16]. After obtaining written informed consent, we asked patients to complete a set of questionnaires to collect data on sociodemographics and patient-reported outcomes. Using a standardized form, trained research nurses abstracted clinical information from medical records.

Following baseline data collection, patients were randomized into one of three groups: usual care (control) or one of two intervention groups (Fluid Watchers LITE [LITE] or Fluid Watchers PLUS [PLUS]). At each site, block randomization with a 1:1:1 allocation ratio was performed using a pre-prepared randomization list. Allocations were concealed in sequentially numbered envelopes and were opened by the research nurse when baseline evaluation was completed. Patients and their physicians, research assistants making follow-up phone calls related to outcomes, and investigators were blinded to group assignment. Data collection was repeated at 3, 12 and 24 months from baseline. Patients were compensated \$25 for completing each visit.

2.3. Enhanced usual care

Patients in the control group received their usual medical care. In addition, educational materials on HF from the American Heart Association were provided to all patients, regardless of their group assignment. All patients also received logs to document their healthcare usage (i.e., telephone calls to physicians, medical appointments, emergency department (ED) visits, and hospitalizations), which were returned monthly to the research team.

2.4. Intervention

Patients in the two intervention groups received a face-to-face educational session with a registered nurse, which lasted about 50 minutes. Family members were invited to join the session. The educational intervention was designed to increase knowledge about HF symptoms and to improve self-care by patients. To ensure intervention fidelity across sites, we used a structured flip chart based on current clinical guidelines [5, 20]. The education included signs and symptoms of HF along with their causes and consequences, the importance of medication adherence, diet, and symptom monitoring, and supportive coaching on identifying barriers to seeking care and developing action plans. Additionally, patients in the two intervention groups were given a script to use when calling their healthcare provider to notify them of worsening HF symptoms. They also received diaries to record daily weight and HF symptoms, along with weight scales.

Patients in the LITE group received two biweekly phone calls from the same nurse who had done the educational session to reinforce the information. Patients in the PLUS group were provided with an audiotape of the education session, which allowed them to review the content at home. The PLUS group also received telephone follow-up calls on a biweekly basis until they demonstrated content competency (average 5.3 ± 3.6 calls). Patients' level of understanding was determined by the nurse using the teach-back technique [21].

2.5. Outcome measures

We assessed patients' level of knowledge about HF using the Heart Failure Knowledge Scale [22]. The 21 questions in the questionnaire cover the following areas: the nature of HF (3 true/false questions), HF self-care management (3 multiple-choice questions), and symptoms of HF (14 yes/no questions asking whether each item is a symptom of HF). The scores range from 0 to 100%, and higher scores indicate higher knowledge about HF. The items in the 9-item European HF Self-care Behavior Scale cover a range of self-care behaviors of patients with HF [23]. Each item is scored on a scale of 1 (completely agree) to 5 (don't agree at all), and the total score can range from 9 to 45. Lower scores represent better HF self-care. HRQOL was measured with the Minnesota Living with Heart Failure questionnaire, which contains 21 questions asking about the extent to which HF has prevented the respondent from living as they wanted over the past 4 weeks [24]. Each question is rated on a scale of 0 (no) to 5 (very much) with total scores ranging from 0 to 105, and therefore, lower scores indicate better HRQOL.

2.6. Other measures

Patients also completed the 9-item Patient Health Questionnaire (PHQ-9), a valid screening instrument for depression [25]. The 9 items correspond directly to the 9 diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual of Mental Disorders [26]. Responses to each item are rated from 0 (not at all) to 3 (nearly every day), with a total score ranging from 0 to 27. Scores of 10 or greater suggest clinical depression [25].

We measured the level of patients' health literacy using the reading comprehension section of the Short-form Test of Functional Health Literacy in Adults (S-TOFHLA) [27]. It is a timed test with two health-related passages containing 36 cloze items.

Functional status was assessed with the New York Heart Association (NYHA) classification system [20], which places patients in one of four categories based on the degree to which their symptoms limit their physical activity. Class IV refers to symptoms even at rest [20]. Each patient's NYHA class was determined by the research nurse prior to randomization. Using the Charlson Comorbidity Index [28], data on comorbid conditions were collected from medical records. The index summarizes the number and severity of comorbid conditions based on 19 major disease categories [28].

2.7. Statistical Analysis

Data were analyzed using IBM-SPSS version 22.0 software (IBM Corporation, Armonk, NY) and SAS software version 9.4 (SAS Institute, Cary, NC). Analyses were conducted on all randomized patients according to the intention-to-treat principle. Characteristics of patients and other study variables were analyzed as means and standard deviations for continuous variables and as frequencies and ranges for categorical variables. Baseline characteristics of patients in the 3 study groups were compared using analysis of variance (ANOVA), Kruskal-Wallis tests, chi-square tests, or Fisher's exact test, as appropriate.

We used linear mixed models with restricted maximum likelihood estimation and an unstructured covariance structure to evaluate the effects of the intervention over time on HF knowledge, self-care behaviors, and HRQOL, respectively. Each model included time, study group, and the time by study group interaction as fixed effects. A significant time by study group interaction indicated a difference in the outcome over time among the study groups. Although there was no significant difference in baseline characteristics among the three groups except for a history of hypertension, we ran each model with and without potential confounders (i.e., age, gender, NYHA class, health literacy) and compared the results.

For the outcomes with a significant time by study group interaction, we assessed the effects of the intervention on outcomes within subgroups divided by presence of clinical depression at baseline. For the subgroup analyses, the study sample was divided into two groups (depressed vs. non-depressed) based on their baseline PHQ-9 scores using the established cut-off of 10 [25]. The same analyses described above were run within each subgroup.

Model assumptions were checked using standard diagnostics for all analyses. The statistical significance level was set at $p < .05$. For pairwise comparisons of group means, we corrected

for multiple comparisons using the Bonferroni method (i.e., $\alpha = 0.05/3$ for 3 pairwise comparisons).

3. Results

Data from all 614 patients who were randomized were included in the analysis (Figure 1). Baseline characteristics of patients are presented in Table 1. The majority of the patients were male, non-Hispanic white, and currently married. The average age of the patients was 65.92 (SD 12.94) years. Thirty-five percent of patients in the LITE group and 37% patients in the PLUS group had family members present during the educational session ($p = .64$). There was no significant difference among the three study groups in their sociodemographic, clinical, and psychological characteristics at baseline except for a history of high blood pressure. In addition, we found no significant difference among the three groups in their baseline levels of HF knowledge, self-care, and HRQOL. At baseline, 31% of patients reported a PHQ-9 score of 10 or greater, which suggests clinical depression. The three groups were not significantly different in the prevalence of depression at baseline.

3.1. Intervention effects on HF knowledge, self-care behaviors, and HRQOL

The linear mixed model for HF knowledge showed significant effects for time ($p < .001$), study group ($p = .001$), and time by study group interaction ($p < .001$). Both intervention groups showed higher HF knowledge than the usual care group at 3 months (mean differences, LITE vs. usual care, 3.45 [95% CI, 1.19 to 5.70], $p = .003$; PLUS vs. usual care, 6.25 [95% CI, 4.0 to 8.50], $p < .001$; PLUS vs. LITE, 2.81 [95% CI, 0.51 to 5.10], $p = .017$) (Table 2). The PLUS group had significantly higher HF knowledge scores than the LITE and usual care groups at 12 and 24 months (all p -values $< .0167$).

There were significant effects for time ($p < .001$), study group ($p = .003$), and time by study group interaction ($p < .001$) in the linear mixed model for self-care behaviors. Patients in both intervention groups reported significantly lower (better) scores on self-care behaviors than those in the usual care at 3 months (mean differences, LITE vs. usual care, -2.28 [95% CI, -3.46 to -1.09], $p < .001$; PLUS vs. usual care, -2.55 [95% CI, -3.74 to -1.37], $p < .001$) and 12 months (mean differences, LITE vs. usual care, -2.15 [95% CI, -3.43 to -0.88], $p = .001$; PLUS vs. usual care, -2.05 [95% CI, -3.33 to -0.77], $p = .002$). At 24 months, there was no significant difference in self-care behavior scores among the three groups (mean differences, LITE vs. usual care, -1.53 [95% CI, -2.90 to -0.15], $p = .03$; PLUS vs. usual care, -1.61 [95% CI, -2.98 to -0.24], $p = .021$; PLUS vs. LITE, -0.08 [95% CI, -1.48 to 1.31], $p = .91$).

In the linear mixed model for HRQOL, there was a significant effect for time ($p < .001$), but no significant effect for study group ($p = .10$) or time by study group interaction ($p = .29$). In other words, all three groups showed significant decreases (improvements) in HRQOL scores from baseline to 3 months (usual care, -6.80 [95% CI, -10.19 to -3.41], $p < .001$; LITE, -5.73 [95% CI, -9.26 to -2.20], $p = .001$; PLUS, -9.14 [95% CI, -12.66 to -5.61], $p < .001$), which were sustained throughout the 24-month period. And, there was no significant difference in the change in HRQOL score among the three groups. Adding

covariates (i.e., age, gender, NYHA class, health literacy) to each model did not change the significance of the findings.

3.2. Subgroup analyses

When the sample was stratified by the baseline PHQ-9 scores, there was a significant effect for time ($p = .005$), but no significant effect for study group ($p = .50$) or time by study group interaction ($p = .49$), on HF knowledge in depressed patients (baseline PHQ-9 score ≥ 10) (Figure 2). Among non-depressed patients (baseline PHQ-9 score < 10), all fixed effects, time ($p < .001$), study group ($p = .001$), and the time by study group interaction ($p < .001$), were significant. Among non-depressed patients, patients in both intervention groups had higher HF knowledge than those in the usual care group at 3 months (mean differences, LITE vs. usual care, 3.42 [95% CI, 0.80 to 6.03], $p = .011$; PLUS vs. usual care, 7.06 [95% CI, 4.44 to 9.67], $p < .001$). The significant improvement in the PLUS group was sustained at 12 and 24 months (all p -values $< .0167$), but not in the LITE group.

Similarly, we found no significant effect for study group ($p = .46$) and time by study group interaction ($p = .38$) on self-care in depressed patients, but time ($p < .001$), study group ($p = .004$), and time by study group interaction ($p = .005$) were significant for self-care in non-depressed patients. Among non-depressed patients, self-care scores were significantly lower (better) in the two intervention groups than in the usual care group at 3 months (mean differences, LITE vs. usual care, -2.55 [95% CI, -3.93 to -1.17], $p < .001$; PLUS vs. usual care, -2.69 [95% CI, -4.07 to -1.31], $p < .001$) and 12 months (mean differences, LITE vs. usual care, -2.68 [95% CI, -4.19 to -1.17], $p < .001$; PLUS vs. usual care, -2.22 [95% CI, -3.73 to -0.71], $p = .004$).

4. Discussion and Conclusion

4.1. Discussion

Using patient-reported outcome measures, we examined the long-term effects of an educational intervention program designed for rural patients with HF. Patients in both intervention groups showed significant short-term (3 months) improvements in HF knowledge compared to those in the usual care group. But, long-term (up to 24 months) effects were observed only in those who received the intervention with additional telephone contacts and an audiotape of the educational session (i.e., PLUS group). The two intervention groups showed comparable improvements in HF self-care, which lasted up to 12 months. Knowledge is a necessary but not sufficient factor for changing self-care behaviors. Patients need to link the knowledge to their personal experiences so that they can apply this knowledge into their daily lives [29]. Therefore, the education session provided to both intervention groups in our study included not only information about HF but also a discussion of the importance of self-care and signs and symptoms of fluid overload, as well as supportive coaching to identify barriers to seeking care and to develop action plans for worsening symptoms. Our findings indicate that these strategies were effective in improving both HF knowledge and self-care and that educational sessions reinforcing these strategies may need to be repeated at least yearly or upon major changes in their health status to maintain and enhance the effects of the intervention over a longer period.

Our findings are especially noteworthy because the simple educational intervention used in our study does not require specialized HF care or providers with advanced training, which is often difficult to be obtained in rural areas [12]. Rural patients with HF tend to have poorer health outcomes than their counterparts in urban areas, which are likely to be attributable to decreased supply of health care providers, limited resource availability, and greater distance to health care facilities in rural areas [12, 30]. In previous studies testing different approaches to improve HF self-care, favorable effects have been reported on HF knowledge [8, 10] or self-care [6–9, 11]. However, some of these approaches may not be suitable in rural areas. Multiple group self-management sessions [9] may not be feasible in remote areas, and programs led by advance practice nurses [7, 9] cannot be readily implemented in areas with limited resources. Although simple technologies, such as an interactive CD-ROM and a video, can be utilized in rural settings, an intervention delivered via an interactive CD-ROM was not effective on HF self-care [10]. Also, the effect of video education on HF self-care is yet to be tested beyond 3 months [6]. Similar to the one tested in our study, interventions with telephone contacts have been reported to be effective. Improvement in HF self-care was observed in two studies that provided 6–7 telephone contacts over a 3–6 month period [8, 11]. In our study, the two intervention groups with different doses showed a comparable effect on self-care, meaning that the low dose intervention (i.e., a single session education with two phone calls) was as effective as the high dose intervention (i.e., a single session education with additional telephone calls and an audiotape of the educational session). Therefore, it is promising that a simple intervention such as the low dose intervention in our study can improve knowledge about HF and self-care in rural patients with HF, and therefore, may contribute to reducing health disparities between urban and rural areas.

In the subgroup analyses conducted to examine whether the intervention effects were similar in patients with and without depressive symptoms, we found intervention effects on HF knowledge and self-care among patients who were not depressed. But, such effects were not observed in patients who had depressive symptoms. In a cross-sectional analysis of baseline data from this trial, we previously found that having knowledge about HF and its management was not sufficient in carrying out HF self-care, especially for patients with psychological distress, including depression [31]. And the findings from this subgroup analysis add evidence for the longitudinal effect of depression on HF self-care. In a recent randomized trial of cognitive behavior therapy (CBT) for HF patients with comorbid depression, the CBT intervention was effective for depression, but not for HF self-care [32].

Self-care is critical for individuals with chronic illnesses such as HF. It is complex and influenced by multiple factors, including psychosocial status (i.e., depression, anxiety, perceived control, socioeconomic status, and social support), aging status, health literacy, current and prior symptom experiences, and prior experiences with the healthcare system [17]. Therefore, future studies need to focus on developing and testing interventions that include multiple strategies aimed at promoting self-care, and at the same time, reducing depression. One potential strategy may be to provide additional educational sessions as depression improves. Because individuals with depression often experience inattention, lack of motivation, loss of energy, and even psychomotor retardation [26], all of which contribute to difficulties in learning about their chronic illness and self-care strategies as well as

performing self-care, the intervention effect can be enhanced by reinforcing their learning and encouraging motivation when their depressive symptoms are in remission. Depressive symptoms in HF patients change over time and the changes in depressive symptoms are significantly associated with patients' clinical outcomes [33]. Therefore, routine and frequent screening for depression can help clinicians not only determine the best timing for self-care education but also prevent adverse outcomes in HF patients.

Social support may be another potential key factor to improve self-care in HF patients with comorbid depression. Lack of social support has been reported to contribute to both depression and poor self-care [34, 35]. As family caregivers are a major source of social support for patients with HF, involving family caregivers in educational interventions can be an effective strategy to potentiate intervention effects. However, family caregivers' involvement in the care of patients with chronic illness is still limited. In a recent national survey of 703 family caregivers of patients with chronic illness, 40% reported having insufficient knowledge about their family members' health condition [36]. Furthermore, less than a half of the caregivers had communicated with their family members' health care providers in person or via phone, and only a half of those reported that health care providers involved them in health care decisions or suggested ways that they could help. Almost a third of the family caregivers even felt that health care providers were not willing to share information about their loved ones' health care [36]. These findings indicate that more effort is needed from health care providers to engage family members in the care of patients with chronic illness. Family caregivers should be included in conversations and be invited to any education opportunities about the care. Also, technology-based interventions can be effective for family caregivers in rural areas because it can be provided and accessed regardless of geographic location [37].

Despite the significant improvements in HF knowledge and self-care in both intervention groups, we did not find any significant difference in HRQOL among the three groups at 3, 12, and 24 months. In fact, significant improvements in HRQOL were observed in all three groups, and the change was sustained throughout the 24-month period. A similar finding was reported previously. In a recent randomized trial of HF self-management intervention, Grady et al. [38] reported improvements in HRQOL in both intervention and control groups and no difference between the groups. In this study, the intervention group received 18 sessions of group counseling with HF education and the control group received written education materials per mail with follow-up telephone calls. The investigators concluded that the care provided to the control group in addition to their usual care may have contributed to the improvement in HRQOL. Similarly, in our study, patients in the control group received written educational materials. In addition, patients in all three groups (including the control group) were encouraged to document their contacts with physicians, ED visits, and hospitalizations and to return the logs monthly to the research team. Although the healthcare log was provided to collect data on healthcare usage, it may have served as an intervention in itself. In addition, the non-significant intervention effect on HRQOL in our study is in line with findings from a recent systematic review, which reported consistently non-significant association between HRQOL and HF self-care [15]. In another meta-analysis focusing on randomized controlled trials of psychological interventions, a short-term effect was found with psychological interventions on HRQOL of patients with HF [39].

Considering these findings together, we suggest combining psychological strategies (i.e., CBT, motivational interviewing) with educational interventions in future studies aimed at improving both HF self-care and HRQOL.

The findings of this study need to be interpreted with caution in light of its limitations. Because the patients in our study were recruited from rural areas with limited access to health care and resources, the generalizability of the findings is limited to similar settings. In the subgroup analyses, we found no significant intervention effect among depressed patients. However, we cannot rule out the possibility of lack of power to detect significant effects in this subgroup. For future research with similar aims, we recommend a stratified randomization design with the strata defined by depression to ensure sufficient representation in each subgroup.

4.2. Conclusion

The simple educational intervention was effective in improving HF knowledge and self-care. To ensure long-term effects of the intervention, yearly booster sessions may be helpful. The intervention effects were not observed in patients with clinical depression. Both intervention groups as well as the control group showed significant improvements in HRQOL from baseline to 3 months with no significant difference among groups.

4.3. Practice implications

For HF patients living in rural areas where resources are limited, a simple educational intervention delivered by nurses can be a promising approach to improve HF knowledge and self-care. Additional psychological strategies may be needed to improve HRQOL. Future research is needed to identify effective strategies to improve HF knowledge and self-care among HF patients with clinical depression.

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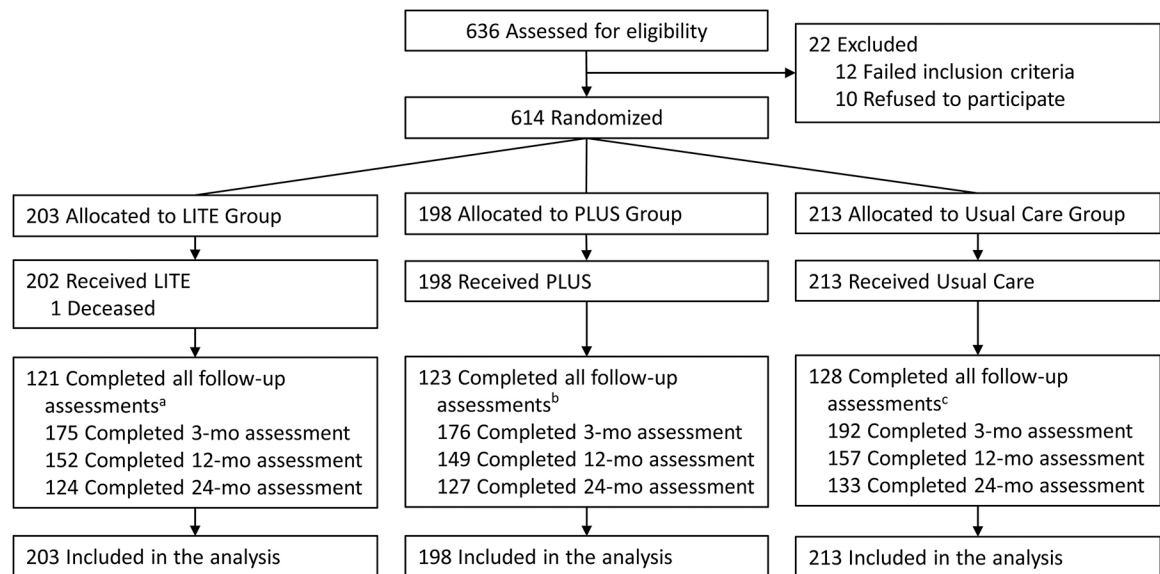
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Highlights

- (maximum 85 characters, including spaces, per bullet point)
- The educational intervention improved heart failure (HF) knowledge and self-care.
- The effect of the intervention on HF self-care was sustained up to 12 months.
- Intervention effects were not observed among patients with clinical depression.
- The intervention requires little resource, thus is promising for rural HF patients.

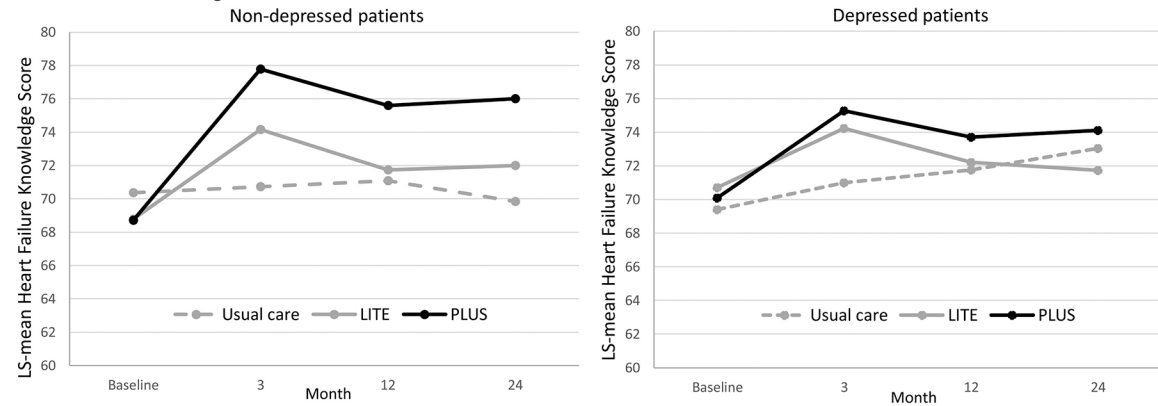
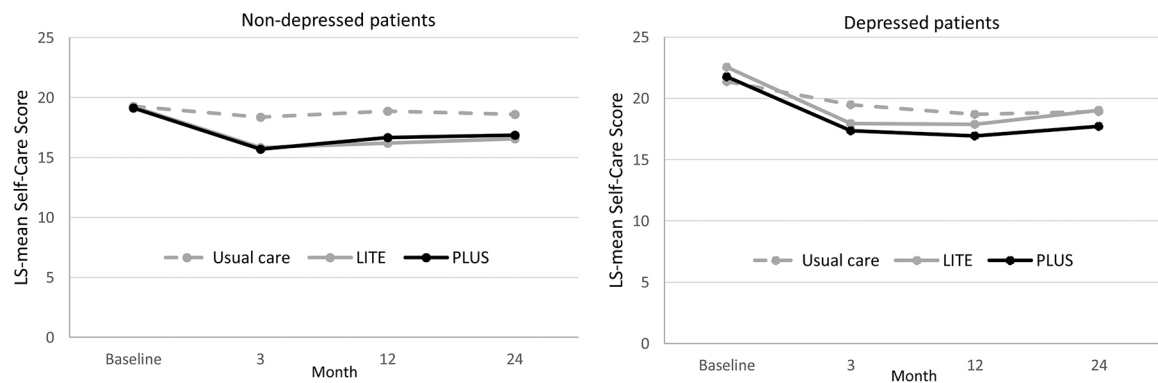


^a Reasons for non-completion of 1 or more assessments (LITE group): death (n=36), dropped out (n=31), unable to contact (n=15).

^b Reasons for non-completion of 1 or more assessments (PLUS group): death (n=37), dropped out (n=18), unable to contact (n=20).

^c Reasons for non-completion of 1 or more assessments (Usual care group): death (n=52), dropped out (n=19), unable to contact (n=14).

Figure1.
Flow of enrollment, randomization, and follow-up

A Heart Failure Knowledge**B Heart Failure Self-Care****Figure2.**

Levels of heart failure knowledge and self-care behaviors during the 24-month study period among depressed and non-depressed patients

Panel A. Higher scores indicate higher levels of knowledge about heart failure; Panel B. Lower scores indicate better self-care.

Table1.

Baseline characteristics of the study population

	Total sample (N = 614)	Study Group			p-value
		Usual Care (N = 213)	LITE group (N = 203)	PLUS group (N = 198)	
Sociodemographic characteristics					
Age (in years)	65.92 ± 12.94	65.98 ± 13.20	65.87 ± 12.75	65.90 ± 12.93	.99
Female	253 (41.2)	82 (38.5)	85 (41.9)	86 (43.4)	.58
Non-Hispanic white	525 (85.5)	177 (83.1)	178 (87.7)	170 (85.9)	.41
Education < High school	117 (19.1)	47 (22.1)	36 (17.7)	34 (17.2)	.52
S-TOFHLA health literacy, % correct	70.92 ± 24.49	69.51 ± 24.72	70.34 ± 23.32	73.03 ± 25.41	.34
Household income < \$20,000/year	218 (35.5)	74 (34.7)	79 (38.9)	65 (32.8)	.46
Employed	90 (14.7)	26 (12.2)	26 (12.8)	38 (19.2)	.09
Currently married/cohabitating	347 (56.5)	122 (57.3)	111 (54.7)	114 (57.6)	.81
Living alone	142 (23.1)	48 (22.5)	50 (24.6)	44 (22.2)	.82
Clinical characteristics					
Cause of heart failure					.82
Ischemic/MI/CAD	292 (47.7)	104 (49.1)	101 (50.0)	87 (43.9)	
Hypertension	148 (24.2)	51 (24.1)	48 (23.8)	49 (24.7)	
Cardiomyopathy	111 (18.1)	34 (16.0)	35 (17.3)	42 (21.2)	
Idiopathic/viral/other	61 (10.0)	23 (10.8)	18 (8.9)	20 (10.1)	
Ejection fraction < 40%	298 (49.3)	97 (47.1)	99 (49.3)	102 (51.8)	.64
NYHA class III or IV	217 (35.4)	77 (36.3)	75 (36.9)	65 (32.8)	.65
Charlson comorbidity index score	3.36 ± 1.79	3.58 ± 1.91	3.29 ± 1.70	3.19 ± 1.72	.07
Risk factors					
Current smoker	81 (13.2)	29 (13.6)	24 (11.8)	28 (14.1)	.77
High cholesterol	410 (66.8)	145 (68.1)	136 (67.0)	129 (65.2)	.82
High blood pressure	495 (80.6)	182 (85.4)	147 (72.4)	166 (83.8)	.001
Sedentary	298 (48.7)	111 (52.6)	99 (48.8)	88 (44.4)	.26
Body mass index > 25 Kg/m ²	455 (74.5)	155 (73.1)	155 (77.1)	145 (73.2)	.58
Cardiac medications					
ACE inhibitor	342 (56.1)	110 (52.1)	117 (58.2)	115 (58.1)	.36
Angiotensin II receptor blocker	116 (18.9)	47 (22.1)	33 (16.3)	36 (18.2)	.31
Beta blocker	491 (80.1)	167 (78.4)	157 (77.7)	167 (84.3)	.19
Aldosterone inhibitor	144 (23.5)	58 (27.4)	42 (20.8)	44 (22.2)	.25
Diuretic	517 (84.3)	186 (87.3)	171 (84.7)	160 (80.8)	.19
Digitalis	139 (22.7)	46 (21.6)	54 (26.9)	39 (19.7)	.21
Anticoagulant	486 (79.3)	174 (81.7)	157 (77.7)	155 (78.3)	.56
Depressive symptoms					
PHQ-9 score	7.41 ± 6.44	7.80 ± 6.62	7.41 ± 6.35	7.00 ± 6.33	.46
PHQ-9 score ≥ 10	186 (30.9)	68 (32.5)	60 (30.0)	58 (30.1)	.82
Outcomes					

	Total sample (N = 614)	Study Group			<i>p</i> -value
		Usual Care (N = 213)	LITE group (N = 203)	PLUS group (N = 198)	
Heart failure knowledge score, % correct	69.51 ± 12.93	70.05 ± 12.74	69.31 ± 13.07	69.14 ± 13.04	.75
EHFScB-9 self-care behavior score	20.06 ± 6.99	19.98 ± 6.83	20.23 ± 7.34	19.97 ± 6.83	.92
MLHFQ score	46.77 ± 27.82	48.08 ± 27.59	45.43 ± 28.66	46.72 ± 27.28	.63

Note. Data on some characteristics were not available for all subjects. Due to rounding, not all percentages total 100. Continuous variables are reported as mean ± SD. Categorical variables are reported as number (percentage) of patients.

Abbreviations: ACE, angiotensin-converting enzyme; CAD, coronary artery disease; EHFScB-9, European HF Self-care Behavior Scale; MI, myocardial infarction; MLHFQ, Minnesota Living with Heart Failure Questionnaire; NYHA, New York Heart Association; PHQ-9, Patient Health Questionnaire 9-items; S-TOFHLA, Short-form Test of Functional Health Literacy in Adults.

Table2.

Heart failure knowledge, self-care behaviors, and health-related quality of life during the 24-month study period

	Usual care	LITE	PLUS	LITE vs. Usual care	PLUS vs. Usual care	PLUS vs. LITE	
	Mean (SD) ^a	Mean (SD) ^a	Mean (SD) ^a	Difference (95% CI) ^b	Difference (95% CI) ^b	Difference (95% CI) ^b	p-value ^c
Heart failure knowledge[*] ($p < .001$)^d							
Baseline	70.05 (0.89)	69.34 (0.91)	69.12 (0.92)	-0.71 (-3.20 to 1.79)	-0.93 (-3.44 to 1.58)	-0.23 (-2.77 to 2.31)	.86
3 mo	70.80 (0.79)	74.24 (0.83)	77.05 (0.83)	3.45 (1.19 to 5.70)	6.25 (4.0 to 8.50)	2.81 (0.51 to 5.1)	.017
12 mo	71.31 (0.85)	71.85 (0.87)	75.04 (0.88)	0.54 (-1.85 to 2.93)	3.73 (1.33 to 6.13)	3.19 (0.77 to 5.61)	.01
24 mo	70.78 (0.92)	71.85 (0.95)	75.48 (0.95)	1.07 (-1.53 to 3.68)	4.70 (2.11 to 7.29)	3.63 (0.99 to 6.26)	.007
Self-care behaviors[†] ($p < .001$)^d							
Baseline	19.98 (0.48)	20.23 (0.49)	19.97 (0.50)	0.25 (-1.10 to 1.60)	-0.01 (-1.37 to 1.34)	-0.26 (-1.64 to 1.11)	.71
3 mo	18.75 (0.42)	16.48 (0.44)	16.20 (0.44)	-2.28 (-3.46 to -1.09)	-2.55 (-3.74 to -1.37)	-0.28 (-1.49 to 0.93)	.65
12 mo	18.85 (0.45)	16.70 (0.46)	16.80 (0.47)	-2.15 (-3.43 to -0.88)	-2.05 (-3.33 to -0.77)	0.10 (-1.2 to 1.39)	.88
24 mo	18.76 (0.49)	17.23 (0.50)	17.15 (0.50)	-1.53 (-2.9 to -0.15)	-1.61 (-2.98 to -0.24)	-0.08 (-1.48 to 1.31)	.91
Health-related quality of life[‡] ($p = .294$)^d							
Baseline	48.04 (1.91)	45.51 (1.96)	46.73 (1.98)	-2.53 (-7.90 to 2.84)	-1.31 (-6.71 to 4.09)	1.22 (-4.25 to 6.68)	.66
3 mo	41.23 (1.87)	39.78 (1.94)	37.59 (1.95)	-1.46 (-6.76 to 3.84)	-3.64 (-8.95 to 1.66)	-2.19 (-7.59 to 3.22)	.43
12 mo	41.73 (2.02)	38.62 (2.07)	33.53 (2.09)	-3.12 (-8.80 to 2.58)	-8.19 (-13.90 to -2.48)	-5.09 (-10.86 to 0.69)	.08
24 mo	41.31 (2.12)	39.09 (2.19)	35.20 (2.17)	-2.22 (-8.20 to 3.76)	-6.11 (-12.07 to -0.14)	-3.89 (-9.95 to 2.18)	.21

^aScores are least-square means (SD) from linear mixed models.^bDifference scores were computed by subtracting the scores in the latter group from the scores in the former group: i.e., LITE – Usual care; PLUS – Usual care; PLUS – LITE.^cP-values are for pairwise comparisons and compared to the adjusted alpha level of 0.0167 ($= 0.05/3$).^dP-values are for the time by study group interaction from the linear mixed models.^{*}Higher scores indicate higher levels of knowledge about heart failure;[†]Lower scores indicate better self-care;[‡]Lower scores indicate better health-related quality of life.