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Title

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Abstract

Background—The use of remote monitoring systems (RMSs) in healthcare has grown exponentially and has improved the accessibility to and ability of patients to engage in treatment intensification. However, research describing the effects of RMSs on activation, self-care, and quality of life (QOL) in older patients with heart failure (HF) is limited.

Objective—The aim of this study was to compare the effects of a 3-month RMS intervention on activation, self-care, and QOL of older patients versus a reference group matched on age, gender, race, and functional status (ie, New York Heart Association classification) who received standard discharge instructions after an acute episode of HF exacerbation requiring hospitalization.

Methods—A total of 21 patients (mean age, 72.7 ± 8.9 years; range, 58–83 years; 52.4% women) provided consent and were trained to measure their weight, blood pressure, and heart rate

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at home with an RMS device and transmit this information every day for 3 months to a centralized information system. The system gathered all data and dispatched alerts when certain clinical conditions were met.

Results—The baseline sociodemographic and clinical characteristics of the 2 groups were comparable. Over time, participants in the RMS group showed greater improvements in activation, self-care, and QOL compared with their counterparts. Data showed moderately strong associations between increased activation, self-care, and QOL.

Conclusion—Our preliminary data show that the use of an RMS is feasible and effective in promoting activation, self-care, and QOL. A larger-scale randomized clinical trial is warranted to show that the RMS is a new and effective method for improving clinical management of older adults with chronic HF.

Keywords

activation; heart failure; quality of life; remote monitoring systems; self-care

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Chronic heart failure (HF) is a healthcare epidemic characterized by progressive decline of cardiac performance and functional status with frequent decompensation of the chronic state resulting in recurrent hospitalizations.[1] Despite tremendous advances achieved in medical management, HF continues to present patients with challenges that lead to marked physical, psychological, social, and existential distress; furthermore, diverse symptoms are common and result in feelings of loss of control over their own health outcomes or in adequate self-care knowledge, skills, and self-efficacy, which are expressed by the composite construct of patient activation (ie, activation).[2] Likewise, there is ample research to show that older adults with chronic HF also experience an inability to engage in self-care, defined as the ability to deal with symptoms, treatment, complications, and lifestyle changes and processes that enhance self-advocacy, improve self-efficacy, and support application of knowledge to maintain a satisfactory quality of life (QOL).[3] Because patient self-care is so critical to health outcomes, greater attention to activation and advocating for interventions that promote self-care and enhance QOL may potentially reduce suffering from both physical and psychological symptoms and lessen the distress associated with this incurable condition.[3]

Initiatives that increase accessibility of healthcare information and support individual decision making have therefore been developed. One such initiative is the use of remote monitoring systems (RMSs), defined as an external stand-alone platform designed to collect clinical data and electronically transfer these between the patient and the healthcare professional.[4] These systems are usually composed of wireless sensors that measure the physiological status of the patients, such as blood pressure, weight, and heart rate, and transmit the data through a gateway (eg, a smartphone) to a server computer on the Internet. The data are displayed to the clinicians through a computer application such as a Web application or an application developed for tablet computers. Such systems support patient monitoring at a distance and support patient-provider communication and care at a time and place convenient for the patient. However, research that focuses on the impact of RMSs on activation, self-care, and QOL in HF is still in its infancy. Likewise, although there is

increasing advocacy for the use of wireless technologies in patients with HF, few studies have examined the efficacy of RMSs on activation and self-care.[5]

The primary objective of the current study was to assess prospectively the feasibility and efficacy of implementing an RMS intervention with standard HF care on activation, self-care, and QOL outcomes in a cohort of older patients hospitalized for acute HF exacerbation and compare them to an age-, gender-, race-, and functional class–matched comparison group receiving standard care alone. The specific aims of this study were to (1) assess the feasibility of the planned study protocol of referring patients recently hospitalized for HF decompensation to an RMS intervention along with standard HF care with follow-up of outcomes planned at 3 months; (2) compare the impact of an RMS with standard HF care versus standard HF care alone on activation, self-care, and QOL (physical health, emotional health, overall QOL) at baseline and 3 months; and (3) examine the relationships between sociodemographic and clinical variables and activation, self-care, and QOL at follow-up (3 months) in older adults with chronic HF recently discharged from the hospital for symptom exacerbation.

Methods

Study Design, Setting, and Participants

This prospective, quasi-experimental study was conducted at a single, university-affiliated medical center. Participants were recruited from the inpatient setting during an episode of acute HF exacerbation through HF provider referrals; patients who agreed to participate in the study were given instructions on how to use the RMS device using a demonstration–return demonstration approach before discharge.

Study Participants

A convenience sample was drawn from hospitalized patients receiving care for worsening symptoms of HF at a single tertiary care center in Southern California. Eligible participants were at least 18 years old; were able to read, write, and speak English or Spanish; and were willing to be trained on how to use the RMS platform. Patients were precluded from study participation if they (1) had dementia, which would impact adherence with the study protocol; (2) had irreversible conditions likely to affect 6-month survival (eg, malignant cancer, liver cirrhosis) or ability to participate in the study protocol; (3) were unable to use the RMS platform (eg, severe visual impairment, unwillingness to use the device, no 3G mobile network coverage); and (4) were homeless or living in a long-term care facility.

Because the patient sample was small (N = 21), we randomly selected 21 patients hospitalized for HF exacerbation from a larger pool of approximately 157 participants enrolled in another randomized controlled trial conducted by our group before the 3-month window of the present intervention and assessed them after 3 months, similar to the interval used for patients assigned to the RMS intervention. The goal of the matching was to include subjects in the comparison group, balanced on gender, age, race, and functional class, to increase our ability to compare them with intervention subjects on study measures. The

success of the matching is evidenced by the lack of large or statistically significant differences on the matching variables or other demographic variables (Table 1).

Procedures

The study protocol was approved by the appropriate institutional review board; all participants provided informed consent. Participants completed survey instruments during a 20- to 30-minute telephone interview before and 3 months after hospital discharge. Medical chart reviews were conducted to verify self-reported data.

The Remote Monitoring System Intervention

Before discharge, the research nurse showed the participants in the intervention arm how to use the RMS platform and instructed them to take their weight, heart rate, and blood pressure daily for 3 months. A simplified step-by-step guide summarizing these instructions was included with the RMS equipment that was sent out to the patients 24 hours after they were discharged. Participants were also given a toll-free number that was available 24/7 for them to access for any technical issues related to the use of the device. The study nurse contacted each patient 24 to 48 hours after discharge to ensure that patients received the device and to answer any questions about using the device.

The RMS provided alerts and feedback if there were worrisome responses to a question or if vital signs were outside preset limits. The research nurse communicated with the patient via teleconferencing and collaborated with the participant's primary care provider to facilitate a plan of action, which included 1 or a combination of the following: (1) limited advice, (2) reset thresholds, (3) timely provider outpatient visit, or (4) emergency department evaluation.

Comparison Group

Participants in the comparison group received usual care for HF follow-up, including primary care and specialty office practice visits, as required. It also included home healthcare, posthospital outpatient visits, a nurse-generated telephone call within 1 business day of hospital discharge to assess patient status after discharge, and standard clinic telephone triage during business hours.

Measures

Participants were asked to provide sociodemographic data (eg, age, gender, race/ethnicity, marital status, education); clinical information (eg, HF etiology and duration, ejection fraction, and medication regimen) was abstracted from participants' electronic medical records. To measure activation, participants were asked to complete the Patient Activation Measure, a 13-item tool that assesses patient's self-rated ability to take preventive actions, manage symptoms, access medical care, and work with healthcare providers to make decisions about care.[2] A 4-point Likert scale that ranges from 1 (strongly agree) to 4 (strongly disagree) is used for each item, and scores are added to derive a single score previously shown to be reliable and valid.[6] Higher scores indicate greater activation and correlate with better chronic disease self-care and greater engagement in healthy behaviors.[7] The Cronbach's a for the Patient Activation Measure for the current study was .88.

Self-care was measured using the 22-item Self-care of HF Index, which is made up of 3 scales that comprise the components of HF self-care: maintenance, management, and confidence.[8] The self-care maintenance scale has 10 items that measure symptom monitoring and adherence behaviors performed to prevent HF decompensation (eg, daily weights, low-sodium diet, and medication adherence). The self-care management scale has 6 items to measure patients' abilities to recognize symptoms when they occur and ability to respond appropriately in response to symptoms (eg, call healthcare provider, reduce fluid intake, and take an extra water pill) and treatment evaluation. The self-care confidence scale uses 6 items to evaluate patients' perceptions related to their ability to engage in self-care behaviors (eg, preventing symptom onset and recognizing symptom changes). Each scale uses a 4-point self-report response format (1, never or rarely; 2, sometimes; 3, frequently; and 4, always or daily) and can be transformed to yield a standardized score from 0 to 100; higher scores indicate better self-care.[9] The management, maintenance, and confidence scales had a Cronbach's α of .70, .56, and .82, respectively, in a sample of 760 HF patients. Cronbach's α for the 3 scales for the current study was .74, .66, and .88, respectively. Construct validity was demonstrated through factor analysis.[10–12]

Quality of life was measured using the Minnesota Living With Heart Failure Questionnaire (MLHFQ), a 21-item disease-specific tool that measures various HF symptoms experienced by participants in the previous month that prevented them from living as they wanted to.[13] The tool was designed to assess HF and HF treatment impact on physical, emotional, and overall QOL; a lower score on the MLHFQ indicates better QOL.[13] Cronbach's α for the overall, emotional, and physical subscales of the MLHFQ for the current study were .74, .84, and .82, respectively.

Data Analysis

Preestablished criteria were used to assess the feasibility of implementing an RMS intervention with disease-directed care for HF with follow-up of outcomes planned at 3 months (aim 1). The study protocol was deemed feasible if the recruitment rate and target completion of measures at 3 months were at least 60% for each time interval.[14]

To analyze aim 2, descriptive statistics including means, ranges, standard deviations and χ^2 statistics were used to characterize the study population. Activation, self-care, and QOL were compared between participants who had access to the RMS and their counterparts using the analysis of covariance statistic. First, we determined whether there were significant group differences in mean outcome scores over time. Then, to account for the possibility that similar group means might be found only because outcomes improved over time for 1 group while worsening for the other, we conducted analyses of group × time interactions. To control for the baseline group differences, we controlled for time 1 values by entering them as covariates in the analysis of covariance equation. The adjusted means presented herein account for the influence of time 1 value.

For aim 3, Pearson product-moment or Spearman ρ correlations were calculated depending on level of measurement to identify variables that significantly correlated with activation, self-care, and QOL at 3 months. All statistical analyses were carried out using SPSS for

Windows (version 18, 1.0; SPSS, Inc, Chicago, Illinois); statistical significance was set at $P < .05$ for all analyses.

Results

Study Participants and Study Feasibility

Between June 1, 2010, and December 31, 2010 (6 months), 32 patients with symptomatic HF were approached, of whom 24 consented (75% recruitment); 3 patients (12.5%) were dropped (ie, 2 transferred to a long-term care facility and 1 was not available to start study participation because of an unplanned out-of-state visit). Of the 24 patients who signed informed consent, 21 (87.5%) completed the baseline and 3-month follow-up measures. The sociodemographic and clinical characteristics of participants in the RMS group versus the comparison group were comparable (Table 1).

Participants were, on average, 72.7 ± 8.9 years old; were predominantly women (52.4%), white (52.4%), and married (61.9%); and had NYHA class II HF (69%), with a mean left ventricular ejection fraction of 26.5% ± 6.4%. The most common comorbidities were coronary artery disease (52.4%), diabetes mellitus (50%), and hypertension (45.2%); the proportion of participants with a history of smoking was moderately high (52.4%), but none of the participants in either group reported being current smokers. Most participants were prescribed diuretics (88.1%), angiotensin converting enzyme inhibitors (83.5%), β-blockers (73.8%), and digoxin (59.5%).

Comparative Data

Table 2 illustrates the baseline and 3-month data on variables of interest. Participants in both groups demonstrated significantly higher levels of activation, self-care management, and self-care confidence over time; however, improvements in the RMS group were more marked (all P values < 0.001). Self-care maintenance improved in participants in the RMS group but got worse in the comparison group. Physical QOL scores improved in both groups over time. Although similar improvements were observed in the emotional and overall QOL scores of participants in the RMS group, there were no changes in these QOL variables among participants in the comparison group.

Univariate Findings

Table 3 illustrates the relationships between sociodemographic variables, activation, self-care, and QOL at 3 months. None of the sociodemographic variables were associated with activation, self-care, and QOL at 3 months; the same findings applied to clinical variables (not illustrated in the table). Data showed that group assignments (RMS vs comparison group) were strongly correlated with activation levels ($r = 0.658$, $P < .001$) and emotional QOL ($r = -0.403$, $P < .001$) at 3 months and were moderately associated with improvements in all self-care components (all P values < .05) and overall QOL ($r = -0.329$, $P < .35$); participants in the RMS group had greater improvements than the comparison group did in all variables of interest, except physical QOL. Activation at 3 months was also moderately associated with self-care maintenance ($r = 0.335$, $P = .033$) and self-care confidence (r = 0.382, P = .028) at 3 months. The association between activation and self-care management

was trending in the right direction but did not meet statistical significance. However, we did observe a strong association between self-care maintenance and self-care management ($r = 0.594$, $P < .001$) that supports the premise that as self-care maintenance increased, self-care management also improved. Finally, we observed a strong negative association between self-care confidence and emotional QOL ($r = -0.467$, $P < .001$); improvements in self-care confidence were related to greater reductions in emotional symptoms (ie, better QOL).

Discussion

Our study shows that integrating an RMS intervention with standard HF care after discharge from the hospital for acute symptoms of HF decompensation is feasible. In addition, patients in the RMS group who were able to self-monitor and transmit data using the RMS over 3 months reported higher levels of self-care knowledge, skills, and self-efficacy and greater improvements in activation levels over time compared with the comparison group.[15] Participants in the RMS group also reported greater improvements in self-care maintenance, or their ability to adhere to healthier behaviors known to prevent HF decompensation, and self-care confidence, or better perceptions related to their ability to engage in self-care behaviors.[9] Data also showed that exposure to the RMS over 3 months was associated with improvements in emotional and overall QOL. Our findings confirm that the use of RMS-based platform enhanced perceptions of self-efficacy and empowerment in our sample and support the notion that RMSs can potentially promote adherence and self-care of patients with chronic HF as posited by the Theory of Planned Behavior.[16]

Our findings also showed moderately low levels of activation in our patient sample at baseline, which is consistent with earlier research in older adults with chronic illness.[17] Likewise, patients in both groups reported moderately low levels of self-care (ie, maintenance, management, and confidence), which reflects patients' low confidence in their ability to take control of their health. Access to self-monitoring that was made possible through the RMS platform and accessories helped patients achieve greater self-efficacy and enhanced their confidence to become increasingly active in self-managing their health, as reflected in patients achieving higher levels of self-care during the 3-month follow-up. Studies have shown that as individuals achieve higher levels of activation, they develop the knowledge and skills to become actively involved in self-managing their condition.[2] Likewise, patients who believe that they can impact their own health are more likely to play a role in making decisions about their health and are more likely to adhere to behaviors that promote symptom control.[16] We speculate that this argument explains why patients who were exposed to RMS had greater reductions in symptom distress and greater improvements in emotional and overall QOL and supports the premise that RMSs can potentially enhance problem solving skills that enable the individual to confidently engage in decision making and actions to effectively manage their chronic health condition.[17]

As the concept of patient-centered care gains momentum, healthcare providers need to be proactive in providing patients with the tools necessary to make informed decisions about their healthcare and to solve problems encountered daily from living with a chronic condition. Remote monitoring systems have been shown to enhance patient-provider communication and early recognition of worsening symptoms of HF decompensation, which

have led to reductions in disability and healthcare resource utilization.[18–20] The current study provides researchers and clinicians with a better understanding of the potential role of RMSs in enhancing activation and self-care and promoting patients' readiness, willingness, and ability to manage their own care.

Study Limitations and Future Work

There are several important limitations to our findings. First, our patient cohorts were small, allowing for the possibility of type II errors. In addition, participants were not individually randomized but rather matched on sociodemographic variables and functional class to optimize our ability to compare the effects of providing RMS devices to patients with chronic HF. Although nearly all baseline characteristics in the 2 groups were similar, we cannot be sure that the differences in activation, self-care, and QOL at follow-up were indeed related to the RMS. For example, in the case of emotional and overall QOL, participants in the RMS group improved, whereas participants in the comparative group either got worse or remained unchanged; intuitively, we can argue that the RMS intervention may have the added benefit of improving QOL by enhancing activation and self-care, thus supporting the argument that an RMS intervention for patients with symptomatic HF may be beneficial. However, the quasi-experimental design of the study limits our ability to say that the RMS improved health outcomes. Our findings merely support the association between the RMS intervention, activation, self-care, and QOL. Second, although we purposely selected a fairly heterogeneous sample of patients receiving optimized medical treatment for their HF through a single tertiary care center, our findings may not be generalized to the general population of HF patients. Finally, we simply report the short-term outcomes of implementing an RMS intervention; clearly, additional studies that assess the long-term outcomes of an RMS and standard HF care are warranted. Nevertheless, our findings justify a larger randomized controlled trial to test the effectiveness of using an RMS intervention with disease-specific HF care on patient outcomes. Research trials that evaluate the impact of RMSs on patient and family satisfaction, clinical outcomes (eg, hospital readmissions, mortality), and resource utilization (emergency department and urgent care visits, length of hospital stay, utilization of home health services, cost-effectiveness), as well as healthcare providers' attitudes and perceptions, are needed to better explicate the role of RMSs on overall outcomes of care.

Conclusion

Our findings suggest that the use of RMSs is feasible and shows promise in being able to enhance activation, self-care, and QOL in older adults with symptomatic HF and open the possibility for planning larger studies to assess the effect of RMSs on these variables as possible mediators to improvements in clinical outcomes and healthcare resource utilization in this subgroup of older adults with HF. Measuring activation and self-care and using the information to improve RMS platforms and processes that support patient self-care could be an important key to enhancing QOL and improving outcomes of care in patients with symptomatic HF.[3,4] Thus, developing RMS programs to promote activation and self-care and determining the mechanisms by which they influence outcomes warrant additional investigation.

Acknowledgments

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What's New and Important

■ The use of RMSs is feasible and effective in promoting activation, self-care, and QOL in patients with chronic HF.

■ Over time, participants in the RMS group showed greater improvements in activation, self-care, and QOL compared with their counterparts.

■ Data showed moderately strong associations between increased activation, self-care, and QOL.

TABLE 1

Baseline Sociodemographic and Clinical Characteristics (N = 42)

	All Participants (N = 42)	RMS Group (n = 21)	Comparison Group (n = 21)	*P*
Age, y	72.7 ± 8.9	73.1 ± 9.2	72.3 ± 8.8	.772
Male	20 (47.6)	10 (47.6)	10 (47.6)	1.000
Race				1.000
Hispanic	8 (19.0)	4 (19.0)	4 (19.0)	
White	22 (52.4)	11 (52.4)	11 (52.4)	
African American	12 (28.6)	6 (28.6)	6 (28.6)	
Married	26 (61.9)	12 (57.1)	14 (66.7)	.525
Education				.786
High school	17 (40.5)	6 (28.5)	11(52.4)	.077
Some college	15 (35.7)	7 (33.3)	8 (38.1)	
Completed college	10 (23.8)	8 (35.7)	2 (9.5)	
Ejection fraction, %	26.5 ± 6.4	27.3 ± 6.7	25.7 ± 6.2	.407
Peak V·o_2, mg/kg/min	13.2 ± 3.0	12.6 ± 3.2	13.8 ± 2.7	.191
Body mass index, kg/m^2	27.2 ± 3.7	27.1 ± 4.0	27.3 ± 3.4	.877
Charlson comorbidity index	3.5 ± 1.4	3.7 ± 1.5	3.3 ± 1.3	.220
NYHA class				.795
Class 2	29 (69.0)	14 (66.7)	15 (71.4)	
Class 3	13 (30.9)	7 (33.3)	6 (28.6)	
Hypertension	19 (45.2)	10 (47.6)	9 (42.9)	.757
Coronary artery disease	22 (52.4)	10 (47.6)	12 (57.1)	.537
Type 2 diabetes mellitus	21 (50.0)	12 (33.3)	9 (25.0)	.254
Overweight or obese	12 (28.6)	7 (33.3)	5 (23.8)	.533
History smoking (previous smoker)	22 (52.4)	10 (47.6)	12 (57.1)	.448
Medication use				
ACE inhibitors	35 (83.5)	17 (81.0)	18 (85.7)	.789
Angiotensin receptor blockers	7 (16.7)	4 (19.0)	3 (14.3)	.802
β-Blockers	31 (73.8)	16 (76.2)	15 (71.4)	.830
Diuretics	37 (88.1)	18 (85.7)	19 (90.5)	.929
Digoxin	25 (59.5)	12 (57.1)	13 (61.9)	.946

Data are provided as mean ± SD or n (%).

Abbreviations: ACE, angiotensin converting enzyme; NYHA, New York Heart Association; RMS, remote monitoring system.

TABLE 2

Patient Activation, Self-management, and Quality of Life at Baseline and 3 Months (N = 42)

Variable	Remote Monitoring Group (n = 21)		Standard HF Care Group (n = 21)		*P* (Time)	*P* (Time × Group)
	Baseline	3 Mo	Baseline	3 Mo		
Patient activation (PAM)	37.8 ± 7.1	54.4 ± 9.2	37.7 ± 7.1	42.8 ± 6.8	<.001	<.001
Self-care maintenance (SCHFI)	59.5 ± 14.8	65.9 ± 13.1	58.9 ± 12.6	57.9 ± 14.6	<.001	<.001
Self-care management (SCHFI)	49.0 ± 10.3	55.4 ± 12.1	51.2 ± 11.9	50.2 ± 10.3	<.001	.015
Self-care confidence (SCHFI)	68.2 ± 13.1	75.2 ± 13.6	69.1 ± 10.9	71.7 ± 11.3	<.001	.027
Quality of life (MLHFQ)[a]						
Physical	19.5 ± 9.8	15.9 ± 8.1	18.9 ± 7.6	16.9 ± 6.6	<.001	.035
Emotional	21.0 ± 4.3	14.4 ± 6.1	21.2 ± 5.9	21.1 ± 6.3	.002	.003
Overall	38.2 ± 13.1	31.2 ± 13.6	39.1 ± 10.9	39.7 ± 11.3	<.001	<.001

Data are presented as mean ± SD.

Abbreviations: HF, heart failure; MLHFQ, Minnesota Living With Heart Failure Questionnaire; PAM, Patient Activation Measure; SCHFI, Self-care of Heart Failure Index Version 6.2.

[a] Higher scores indicate greater symptom interference and lower health-related quality of life.

TABLE 3

Correlational Matrix of Key Variables at 3 Months (N = 42)

	1	2	3	4	5	6	7	8	9	10
1. Group (RMS)	1.000									
2. Age	0.046	1.000								
3. Gender	1.000	−0.017	1.000							
4. Patient activation (PAM) (3 mo)	0.658^a	−0.101	0.071	1.000						
5. Maintenance (SCHFI) (3 mo)	0.325^b	0.020	0.162	0.335^b	1.000					
6. Management (SCHFI) (3 mo)	0.333^b	0.147	0.152	0.295	0.594^a	1.000				
7. Confidence (SCHFI) (3 mo)	0.345^b	0.091	0.072	0.382^b	0.140	0.192	1.000			
8. Physical QOL (MLHFQ)^c (3 mo)	−0.066	−0.750	0.103	−0.122	0.141	0.288	−0.107	1.000		
9. Emotional QOL (MLHFQ)^c (3 mo)	$−0.403^a$	−0.009	0.143	0.493^a	0.022	0.109	$−0.467^a$	0.115	1.000	
10. Overall QOL (MLHFQ)^c (3 mo)	$−0.329^b$	−0.052	0.113	0.215	0.158	0.396^a	−0.172	0.587^a	0.437^a	1.000

Abbreviations: MLHFQ, Minnesota Living With Heart Failure Questionnaire; PAM, Patient Activation Measure; QOL, quality of life; RMS, remote monitoring system; SCHFI, Self-care of Heart Failure Index Version 6.2.

$^a P$ .001.

$^b P$ .05.

^{c}Higher scores indicate greater symptom interference and lower health-related quality of life.