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Who Signs Up for and Engages in a Peer Support Heart Failure Self-Management Intervention

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Abstract

Background—Many programs for patients with heart failure (HF) fail to improve clinical outcomes in part due to low rates of patient enrollment and engagement. A better understanding of patient characteristics associated with willingness to enroll and then engage in HF self-management programs will improve the design and targeting of programs.

Methods and Results—Analyses of screening, baseline and engagement data from a randomized controlled effectiveness trial of a HF peer self-management support program. The median age of the 266 recently hospitalized HF patients who enrolled in the study was 69 years, 51% were female, and 26% were minorities (primarily African American). Of 135 randomized to the peer support intervention, only 39% engaged in either the group sessions or telephone peer support calls. Older white women who reported higher baseline health status, functioning, social support, confidence in their ability to manage, and less difficulty with the physical and emotional aspects of living with heart failure were the most likely to engage in program activities. Minority status and reporting a need for social support were both correlated with higher enrollment but lower engagement in the intervention.

Conclusions—Although minority patients with poorer reported health status and social support were most likely to consent to participate in the study, participants who engaged in program activities were more likely to have higher baseline health status, functioning, and social support. Developing HF interventions that successfully engage participants most in need of HF self-management support remains a difficult challenge.

INTRODUCTION

The Challenge of Heart Failure Self-Management

Patients with Heart Failure (HF) face many self-management challenges. HF medications are effective in improving symptoms and reducing hospitalizations and morbidity,^{1, 2} yet side effects and treatment complexity contribute to poor adherence to medication regimens resulting in health complications.^{3, 4} HF patients are directed by their physicians to engage in a range of additional self-management behaviors, but adherence to these recommendations is also often poor.^{5, 6} Social support has been shown to improve HF patients' self-management and outcomes, yet reaching out for support when feeling ill can be a difficult challenge.⁷ A variety of intervention approaches have been developed to help HF patients better manage their HF, but to date little is known about which patients are most likely to agree to participate and then engage in these programs. In order to design more effective HF programs, it is important to understand factors that influence whether or not HF patients are willing to enroll in a HF self-management program and, if they do join, the extent to which they engage in intervention activities.

The Challenge of Heart Failure Research

To best help HF patients improve their HF self-management, evidence is needed to design effective strategies for reaching diverse populations of HF patients and assisting them with their complex self-management tasks. It is not possible to evaluate the usefulness of health behavior interventions or translate them into evidence-based practice without significant participation in research activities by these patients. Unfortunately, many HF studies have enrolled subjects that fail to represent the population affected by HF,⁸⁻¹⁰ failed to meet recruitment targets,¹¹ and failed to retain a sufficient number of participants to have enough power to allow for the fine-tuned analyses necessary to form meaningful conclusions.¹² Minority representation in Heart Failure clinical trials is an especially problematic issue, with low rates of initial agreement to participate and high rates of attrition.¹³⁻¹⁵

The Challenge of Heart Failure Patient Engagement

Once participants are enrolled in Heart Failure Self-management research studies, levels of engagement are often low.¹⁶ Poor participant engagement in HF interventions has been a persistent challenge, often contributing to negative findings.¹⁰ Identifying who participates and benefits from Heart Failure interventions will support the best use of the limited health-care resources available for improving outcomes and reducing health disparities. Furthermore, identifying methods to engage this population in behavior change and social support interventions is important. Therefore, especially as it pertains to minority patients disproportionately burdened by HF, investigations must address whether the problem is outreach, unwillingness, or other barriers to participation and engagement in research efforts.¹⁷

Aim of This Paper

This research was designed to learn whether telephone peer support between patients facing similar HF challenges supplemented with optional Nurse Practitioner-led group sessions

might mitigate barriers to engagement among patients with a high illness burden. However, in this randomized controlled study, nearly two thirds of participants randomized to the peer support arm had minimal phone contacts with their peer partner and did not attend the optional group sessions.¹⁸ Accordingly, this paper seeks to define and describe various types of participation in our trial: 1) Who agreed to participate and enroll in this Heart Failure peer support study? 2) Who engaged in the peer support interventions offered (face-to-face group sessions and/or peer telephone calls)? and, 3) Were there differences between those who engaged in one type of support over the other?

METHODS: Design and Process of Recruitment of Parent RCT

Eligibility

Participation and engagement in this randomized controlled trial was examined according to the RE-AIM framework.¹⁹ Details on the study design and outcomes have been described elsewhere.¹⁸ Briefly, patients were recruited from both the inpatient unit and the specialty outpatient heart failure clinic of a community hospital in Southeast Michigan. 85% of enrolled patients had been hospitalized at least one time for HF in the prior twelve months, reflecting a high level of HF disease severity.

Recruitment

Inpatients approved for the study were approached in their hospital rooms by study staff. This often required multiple attempts to find a suitable time for discussing the study and completing the required paperwork. Additionally, this type of recruiting required strong support from the hospital leadership and carefully cultivated relationships with the professionals staffing the inpatient units. The study recruiters were trained in Motivational Interviewing and made use of these skills when interacting with patients, family members and staff. Informed consent was secured and baseline surveys were administered while these patients were hospitalized, with follow-up after discharge when necessary.

The clinic patients were initially approached by their HF nurse practitioner to determine interest in learning about the study. If agreeable, the study recruiters would approach the patient at the time of their clinic visit or make a follow-up outreach call. It was not possible to gather sociodemographic data for those clinic patients that declined, but numbers were carefully tracked for inclusion in our overall consent rate. Again, strong commitment to the study and good communication and working relationships with the clinic nurse practitioners was essential. The study staff shared office space in this clinic so maintained frequent formal and informal communication with clinic staff.

Enrollment and Randomization

Enrollment began in May 2007 and concluded in October 2010. 266 patients were enrolled in a total of 31 cohorts over a period of two years and five months. The initial design required both a minimum three-week waiting period after discharge and attendance in an initial face-to-face group session as conditions of enrollment/randomization. This requirement produced a sizeable group of patients who consented to participate, but were never randomized (n=111). After 8 months of significant enrollment losses due to the barrier

that the group attendance presented to many patients, our IRBs approved a protocol change allowing telephone orientation for all patients not able to attend the initial session. The three-week delay remained in effect for hospitalized recruits because our program was not intended to address immediate post-discharge re-hospitalizations or deaths. Therefore, the sample size calculation did not account for those immediate post-discharge events that usually occur within three weeks. No such delay was necessary when recruiting Heart Failure Clinic outpatients. Because of this delay for inpatient recruits, the group of patients who gave informed consent but were never randomized continued to grow over the course of the study.

Enrolled patients were randomly assigned to either enhanced usual care which offered a one-time group class led by the HF Nurse Practitioner or a 6 month peer support intervention consisting of 4 group classes and weekly telephone calls with an assigned peer partner who was a fellow HF patient participant. These pairs were matched first by gender (male, female), then by similar age and level of risk for readmission (high risk, low risk). The Intervention classes took place on the hospital campus. Participants were offered free taxi rides if they reported transportation difficulties to bring them to and from intervention sessions.

MEASURES

Rates

Enrollment and consent rates were determined by review of participation at each step of the recruiting process (see Figure 1). Wide variation exists in the literature in how eligibility rates were calculated, with recent attention directed to the sometimes high percentage of “all people not contacted” or “unable to assess” that are not counted in enrollment rates.¹⁷ Therefore, an actual and a presumed rate of participation were established and are described below.

Screening Characteristics (Pre-Enrollment)

In addition to sociodemographic information and eligibility criteria, self-reports of social support, general health and heart failure self-management were captured at screening. (Appendix 1) Eligible patients who consented to participate were compared with eligible patients who declined to participate. 313 (38%) of those patients who declined agreed to provide both screening and demographic information as well as their reason(s) for declining to participate. 111 eligible patients who consented were never enrolled in the study, and 104 of these (94%) provided screening and demographic information. These non-enrollers were compared to the 266 subjects who were enrolled in the study. Participation was then evaluated by looking at the self-reported characteristics of those who did and did not consent and those consented patients who did or did not enroll.

Measures of Engagement (Post-Enrollment)

Screening and baseline survey measures for 135 subjects randomized to the intervention were evaluated to determine whether and how these measures were associated with engagement with the intervention. The baseline survey measures included the Minnesota

Living with Heart Failure scale measuring functioning,²⁰ the Euroqol EQ 5D measuring self-reported health status,²¹ the TSRQ measuring autonomous motivation to engage in healthy behaviors,²² a health literacy scale measuring ability to perform basic reading and numerical tasks,²³ and the PHQ-9 measuring depression.²⁴ Engagement was measured by a count of group sessions attended and the number of peer telephone calls completed. The interactive voice response telephone system was able to collect detailed utilization information on the dates and duration of all intervention participants' telephone calls.

52 of the 135 intervention subjects engaged in either the group sessions or peer telephone calls, as defined by participation in 9 or more calls or 2 or more groups. The characteristics of the subjects who engaged in the different components of the intervention were compared to those who did not engage. The characteristics of those 30 participants who took advantage of the option to have a telephone orientation were also examined to learn more about whether this requirement had been a barrier to any sub-set of patients.

RESULTS

Analysis

This section presents rates of consent, refusal, enrollment and engagement, and the statistics (percent and mean) of screening variables and key baseline measures. We provided p-values in the attached tables after testing group difference for each of the screening variables and key baseline measures. We used Pearson's chi-square test for categorical variables and t test for continuous measures.

Consent

As shown in Figure 1, the actual rate of consent was 31% (378/1204). For the presumed rate of consent, 45% of those who were unable to be reached were included in the eligibility denominator, as this is the eligibility rate of those who were able to be assessed ($785 \times .45 = 353$). By doing this the presumption is that all of these patients would have declined participation. This is a conservative approach, given that in the overwhelming majority of these cases it was not possible to access any data or attempt any contact. Using the total number of patients who completed informed consent divided by the total number of patients presumed eligible, a conservative measure of consent is established at 24% ($378 / 1204 + 353$).

Refusal

Those patients who declined participation gave their reasons for not wanting to enroll in the program (Appendix 2). The majority said that they didn't need or want the services, due to time, disliking phone calls or not needing the "kind" of program offered. Of these patients who declined, 38% completed screening questions that gave sociodemographic information and brief self-reported functioning, health and social support details. Of those who completed the pre-enrollment questions, those who refused were older, white, less educated, not employed, and reported greater satisfaction with their social support, better HF self-management and better general health status. (Table 1)

Enrollment

Patients who were in the youngest third of the sample, of minority status, still actively employed, of higher educational status, and reporting less social support than they wished were significantly more likely to enroll in the study. (Table 2) Those who initially consented but did not follow through with enrollment had lower levels of formal education and lower incomes and were less likely to be living with a spouse. (Table 3) HF patients who were male, younger, living with a spouse and reported poorer general health status and more depressive symptoms were the most likely of all intervention participants to make use of the option of telephone enrollment rather than attending a face-to-face session. (Table 4)

Engagement

Older women who reported better self-reported health status, sufficient social support, greater confidence in their ability to manage and less difficulty with the physical and emotional aspects of living with heart failure made most use of the services offered in the program, both by telephone and in person group visits. (Table 5) Participants who engaged in the groups, regardless of whether they engaged in the calls, appeared to be the highest functioning because they shared all the characteristics noted above and reported fewer depressive symptoms ($p=0.04$), scored higher on a measure of health literacy ($p=0.04$) and showed greater autonomous motivation as measured by the TSRQ ($p=0.006$). Those who engaged in the calls, regardless of whether they engaged in the groups, were as likely to be male as female.

DISCUSSION

In assessing this intervention study's reach and levels of engagement the characteristics associated with consent were found to be different from those associated with enrollment, which in turn were different from those associated with engagement. Although initially indicating willingness to enroll, those with lower socioeconomic status, educational level and confidence in their HF self-care were most likely not to complete enrollment.

Participants who did enroll in this study shared important demographic similarities to the general HF population as quantified in a recent review of the available data from the National Center for Health Statistics: men and women were nearly equally represented (49/51% of our sample compared to 51/49% of NHANES); minority patients were overrepresented, as is the case with the diagnosis of HF (26% in our sample compared to 24% in NHANES); and, the age of 69 years in our sample is just slightly older than the NHANES mean age of 67.7.²⁵ These similarities support the generalizability of our findings

The study was successful in enrolling minority patients who have traditionally been underserved, younger patients and patients who had lower social support. However, the patients who made most use of the intervention were not younger, minority patients in need of social support. The highly engaged subjects were older women with sufficient social support who were already functioning at a higher level than those who did not engage in the program.

Variable outcomes in HF research are challenging to interpret. Studies of Heart Failure self-management interventions have often recruited different populations.^{8–12} Some types of interventions do appear to work for some patients.^{1, 2} As with this study, many prior carefully designed programs showed little to no improvement in clinical outcomes.^{10, 26–28}

Despite the fact that adherence to HF self-management recommendations is low,⁶ patients report that they want support and self-management programs. We found that ethnic minorities and patients with low social support were indeed willing to participate in our intervention, as they consented to enroll in the study. Because social support is associated with improved HF self-management and outcomes,⁷ learning that it is possible to recruit HF patients who acknowledge the need for social support is important.

The minority patients approached also clearly reported wanting HF programs. African Americans struggle with heavier HF illness burden yet the literature shows a lack of minority recruitment for clinical trials and lack of minority enrollment in HF RCTs prior to 2002.^{8, 29} Increased awareness of this failure of representation is evident in recent studies that have achieved greater minority enrollment.^{9, 10, 26, 30, 31}

Engagement Findings in Context

The majority of subjects randomized to the intervention did not make use of the groups or peer calls. Older women with good social support who also reported better functioning on the survey measures were most likely to engage in the group sessions or the peer telephone calls. In contrast to the findings on patient characteristics associated with willingness to enroll, younger patients and racial/ethnic minorities were significantly less likely to engage in the intervention activities than older patients. Depression was not associated with engagement in intervention activities.

The preference of men and more depressed patients for the telephone orientation session over a face to face group meeting was also reflected in these groups' lower rates of engagement in all of the face-to-face sessions. These characteristics were not associated with lower rates of engagement in the peer telephone calls. Because depression is associated with poorer HF self-care,³² this possible barrier to group attendance is important to consider when designing interventions.

Limitations

Although the sample of refusers who provided screening and sociodemographic information is larger than the sample of enrolled patients, it still represents only 38% of all who declined to join the research study. This may mean that specific groups of patients were under-represented. Also, we were often unable to reach those who consented and did not enroll; therefore we may be missing important information about their reasons for not enrolling. There are also limits to the strength of any of these findings because the sample of patients who engaged in the intervention activities was so small. Finally, since this study was conducted in only one health system, any findings may not generalize to other sites and settings.

IMPLICATIONS

The engaged subjects in this study were higher functioning at baseline than those who did not engage and this may partially explain the lack of positive intervention effect in this study. In order to engage those at greater risk due to depression, stated lack of confidence in their HF self-care, or need for social support, identifying and relaxing any barriers to participation must be a high priority. This can be accomplished by designing interventions more likely to engage men, minorities, younger patients, those wanting more support and those who are more depressed. Some patients may be more likely to engage when others in the programs share significant non-illness aspects of identity with them, as in successful VA peer support and Church-based interventions in African American communities.^{33, 34} Depressed patients may benefit from programs that incorporate remote participation tools such as telephone, internet chat rooms and the like.^{35, 36} For patients of lower socioeconomic status, educational level and HF self-care confidence, it may be important to have services that are able to accept them without any delays. In general, these results suggest that the patients who are struggling more with their HF will find it more difficult to be actively engaged in the kinds of interventions offered by this research study. Programs targeting these patients likely should provide more proactive outreach and more intensive assistance that does not require the degree of activation and motivation entailed in a reciprocal peer support program.

What still needs to be done

Further investigation into the characteristics associated with differential engagement in other types of HF interventions should be undertaken. It may also be useful to convene a group of Heart Failure patients who share the characteristics of those patients who did not engage in the services of this study for a more in-depth focus group investigation or individual semi-structured interviews. These qualitative processes could be designed to elicit the feelings and opinions of HF patients necessary for designing attractive and effective interventions. To further build on the understanding of our findings, future research could examine the extent to which the characteristics we found are also associated with differential engagement in other HF interventions and what these patients describe to be the best ways to meet their needs.

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Appendix 1

Screening (pre-enrollment) variables

1. Age
2. Gender

3. Highest level of education
4. Marital status
5. Racial/Ethnic background
6. Household income
7. How well are you able to manage your heart failure?
8. How satisfied are you with your current level of support from friends and family to help you manage your heart failure?
9. In general, would you say your health is?

Appendix 2

Reasons for Refusing to Participate

1. Don't need this kind of help 39%
2. Time involved/Too busy 22%
3. Receiving phone calls is a hassle 13%
4. No reason 11%
5. Too ill 9%
6. Doesn't like to participate in research 3%
7. Other 3%

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Figure 1.
Flow Diagram

Table 1

RECRUITMENT	Refused (N=313)		Consented (N=371)		p value
Pre-Enrollment SCREENING: Characteristic	N	%	N	%	
Age:	310		370		<0.001
younger	85	27%	161	44%	
middle	95	31%	124	34%	
older	130	42%	85	23%	
Gender: % Female	295	48%	370	52%	0.345
Race: % Minority	292	13%	370	24%	0.001
Education: % Some College or more	293	44%	369	52%	0.048
Living: % Lives with Spouse	296	51%	368	50%	0.863
Employment: % Employed	219	10%	362	15%	0.043
Income: % Less than 19K	216	32%	322	29%	0.402
Social Support: % Not satisfied	261	7%	270	20%	<0.001
HF Self-Management: % Fair/Poor	250	15%	258	22%	0.044
Self-Reported Health Status: % Fair/Poor	287	40%	301	50%	0.022

Table 2

ENROLLMENT	Refused (N=313)		Enrolled (N=266)		p value
Pre-Enrollment SCREENING: Characteristic	N	%	N	%	
Age:	310		266		<0.001
younger	85	27%	118	44%	
middle	95	31%	86	32%	
older	130	42%	62	23%	
Gender: % Female	295	48%	266	52%	0.474
Race: % Minority	292	13%	266	26%	<0.001
Education: % Some College or more	293	44%	265	57%	0.003
Living: % Lives with Spouse	296	51%	264	53%	0.518
Employment: % Employed	219	10%	264	17%	0.023
Income: % Less than 19K	216	32%	235	26%	0.132
Social Support: % Not satisfied	261	7%	211	19%	<0.001
HF Self-Management: % Fair/Poor	250	15%	202	19%	0.203
Self-Reported Health Status: % Fair/Poor	287	40%	231	47%	0.104

Table 3

THOSE WHO CONSENT	Did Not Enroll (N=104)		Enrolled (N=266)		p value
	N	%	N	%	
Pre-Enrollment SCREENING: Characteristic					
Age:	104		266		0.742
younger	43	41%	118	44%	
middle	38	37%	86	32%	
older	23	22%	62	23%	
Gender: % Female	104	54%	266	52%	0.685
Race: % Minority	104	17%	266	26%	0.078
Education: % Some College or more	104	39%	265	57%	0.003
Living: % Lives with Spouse	104	41%	264	53%	0.037
Employment: % Employed	98	12%	264	17%	0.301
Income: % Less than 19K	87	37%	235	26%	0.047
Social Support: % Not satisfied	59	22%	211	19%	0.599
HF Self-Management: % Fair/Poor	56	30%	202	19%	0.076
Self-Reported Health Status: % Fair/Poor	70	57%	231	47%	0.144

Table 4

TELEPHONE ORIENTATION	In-Person Enrollment (N=105)		Telephone Enrollment (N=30)		p value
	N	%	N	%	
Pre-Enrollment SCREENING Characteristic					
Age:	105		30		0.028
younger	39	37%	16	53%	
middle	34	32%	12	34%	
older	32	30%	2	7%	
Gender: % Female	105	56%	30	33%	0.027
Race: % Minority	105	25%	30	17%	0.353
Education: % Some College or more	104	56%	30	63%	0.460
Living: % Lives with Spouse	104	48%	30	70%	0.034
Employment: % Employed	104	13%	30	17%	0.658
Income: % Less than 19K	95	29%	28	18%	0.223
Social Support: % Not satisfied	82	20%	25	20%	0.957
HF Self-Management: % Fair/Poor	78	13%	23	22%	0.291
Self-Reported Health Status: % Fair/Poor	94	37%	28	61%	0.027
BASELINE Survey Measures	N	mean	N	mean	p value
Depression (higher score means more depression)	100	6.22	26	8.5	0.0361

Table 5

ENGAGEMENT	Engaged in Intervention (N=52)		Not Engaged in Intervention (N=83)		p value
	N	%	N	%	
Pre-Enrollment SCREENING Characteristics					
Age:	52		83		0.010
younger	13	25%	42	51%	
middle	24	46%	22	27%	
older	15	29%	19	23%	
Gender: % Female	52	63%	83	43%	0.023
Race: % Minority	52	17%	83	27%	0.216
Education: % Some College or more	51	65%	83	53%	0.184
Living: % Lives with Spouse	52	46%	82	57%	0.207
Employment: % Employed	51	10%	83	17%	0.255
Income: % Less than 19K	44	30%	79	25%	0.612
Social Support: % Satisfied	37	86%	70	77%	0.025
HF Self-Management: % Fair/Poor	36	3%	65	22%	0.011
Self-Reported Health Status: % Fair/Poor	46	39%	76	45%	0.544
BASELINE Survey Measures	N	mean	N	mean	p value
Minnesota Living with HF Composite Score (lower score means fewer problems)	51	40.08	79	49.01	0.0392
Euroqol 5D (higher score means fewer problems in functioning)	51	0.742	81	.654	0.0349
Depression					
Health Literacy					