Peer-Led Self-Management of General Medical Conditions for Patients With Serious Mental Illnesses: A Randomized Trial

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Objective: Individuals with serious mental illnesses have high rates of general medical comorbidity and challenges in managing these conditions. A growing workforce of certified peer specialists is available to help these individuals more effectively manage their health and health care. However, few studies have examined the effectiveness of peer-led programs for self-management of general medical conditions for this population.

Methods: This randomized study enrolled 400 participants with a serious mental illness and one or more chronic general medical conditions across three community mental health clinics. Participants were randomly assigned to the Health and Recovery Peer (HARP) program, a self-management program for general medical conditions led by certified peer specialists (N=198), or to usual care (N=202). Assessments were conducted at baseline and three and six months.

Results: At six months, participants in the intervention group demonstrated a significant differential improvement in the primary study outcome, health-related quality of life. Specifically, compared with the usual care group, intervention participants had greater improvement in the Short-Form Health Survey physical component summary (an increase of 2.7 versus 1.4 points, p=.046) and mental component summary (4.6 versus 2.5 points, p=.039). Significantly greater six-month improvements in mental health recovery were seen for the intervention group (p=.02), but no other between-group differences in secondary outcome measures were significant.

Conclusions: The HARP program was associated with improved physical health– and mental health–related quality of life among individuals with serious mental illness and comorbid general medical conditions, suggesting the potential benefits of more widespread dissemination of peer-led disease self-management in this population.

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Individuals with serious mental illness are at elevated risk of comorbid general medical conditions (1–3). These illnesses, individually and in combination, are the most prevalent etiologies of excess morbidity and premature mortality in this population (4–6). Particularly in vulnerable populations, such as those with serious mental illness, addressing chronic general medical conditions requires not only high-quality medical care but also effective self-management of these illnesses outside provider visits (7,8). However, many of the same risk factors that place individuals with serious mental illness at risk of developing chronic general medical conditions, including psychiatric symptoms (9), limited health literacy (10,11), and poverty (12), may also raise challenges for effective disease self-management (13).

An emerging strategy for improving disease self-management among patients with serious mental illness is the use of wellness groups led by certified peer specialists (14,15). Certified peer specialists are self-identified mental health care consumers who receive specialized training to provide support to consumers in their recovery process (16–19). A total of 38 state Medicaid programs recognize and reimburse mental health services delivered by certified peer specialists (20,21), and a growing number of state programs have begun to reimburse peer delivery of physical wellness services (22). However, only a handful of studies have tested the effectiveness of these interventions for patients with serious mental illness (23–26). Small samples and variability in methodological quality have limited the ability to draw definitive results about the impact of these models on health outcomes for patients with serious mental illness (27–30).

This article presents findings from a multisite, randomized trial of a peer-led intervention grounded in an evidence-based chronic disease model and adapted to the specific needs of patients with serious mental illness. The findings can inform future efforts to improve the well-being of patients with serious mental illnesses.

METHODS

The study tested the Health and Recovery Peer (HARP) program, a six-session general medical disease management program developed for patients with serious mental illness and general medical comorbidity. A pilot study found that the program was feasible and acceptable to implement; however, that study was not designed to assess the program's impact on distal clinical outcomes (23). The study reported here was a fully powered, randomized trial of this intervention. The study was approved by the Emory University Institutional Review Board (Clinicaltrials.gov registry number NCT01725815).

Recruitment, Eligibility, and Randomization

The study was conducted at one urban and two suburban community mental health center (CMHC) clinics. Potential participants were identified from a list of active patients at each CMHC or referred by mental health providers. Inclusion criteria were presence of a serious mental illness (schizophrenia, schizoaffective disorder, bipolar disorder, major depression, obsessive-compulsive disorder, or posttraumatic stress disorder, with or without a comorbid substance use disorder) (31) and one or more of the following chronic general medical illnesses: diabetes, heart disease, hyperlipidemia, hypertension, arthritis, hepatitis, asthma or chronic obstructive pulmonary disorder (COPD), or HIV. The exclusion criterion was cognitive impairment as measured by a score of ≥3 on a six-item, validated screener (32). Individuals who met eligibility criteria and provided informed consent to participate were randomly assigned at the patient level to either the intervention group or usual care. Block randomization was used to ensure an equal distribution of participants between the urban clinic (N=200) and the two suburban clinics (N=200 total).

Study Arms

The intervention group received the HARP intervention, a peer-led program for self-management of general medical diseases among individuals with mental disorders (23). The program builds on the Chronic Disease Self-Management Program (CDSMP), the most widely tested program for self-management of chronic general medical conditions (33). The CDSMP is a six-session health education program developed to address common needs seen across patients with chronic illnesses. The CDSMP supports participants by providing skills that help them become more effective self-managers by applying strategies that include modeling of healthy behaviors, problem solving, reinterpretation of symptoms, and training in specific disease management techniques (34). At each session, patients identify and commit to action plans—concrete, achievable health targets that help develop self-efficacy and build toward longer-term health goals (35,36).

The HARP intervention retains the six-session, group-based structure of the CDSMP while adapting the program to address issues specific to individuals with serious mental illnesses. A total of six to ten participants were included in each cohort, and each group session was led by two certified peer specialists. The program comprises six sessions of two-and-a-half hours each that address the following: information about chronic general medical conditions, use of action planning, healthy diet and exercise on a budget, communicating with health care providers, medication and other treatments, and working across the health system. One-on-one peer coaching meetings were held between group sessions to reinforce messages and skills taught at each group session. A structured manual and worksheets were provided to all participants to support development of key competencies and skills. No compensation was provided for attending the intervention sessions; bus tokens were provided to assist with transportation to and from the meetings.

Modifications of the CDSMP for the HARP intervention addressed specific patient-, provider-, and community-level determinants of health among patients with comorbid general medical conditions and serious mental disorders (37). For patients, materials were added about addressing the mental health impact of chronic conditions and dealing with social isolation. To address limitations in health literacy, all materials were simplified to a sixth-grade reading level.

For certified peer specialist providers, greater flexibility was added to the teaching format to build on their training and to support the broader goal of mental health recovery. To address community factors, including social disadvantage, training was provided in buying and preparing food on a limited budget, including interactive cooking demonstrations. The physical activity section incorporated a training session for exercises that could be done at home without special equipment. Participants were encouraged to exchange contact information to develop social networks and provide support in meeting their health goals.

To optimize generalizability and relevance to real-world community settings, four trained certified peer specialists subcontracted through the state's mental health consumer network served as the study interventionists. Certification as a peer specialist involves a two-week training program addressing core competencies, including fundamentals of peer support, strategies for supporting mental health recovery, understanding and navigating the health and mental health care systems, chart documentation and billing, developing therapeutic relationships, supporting mental health self-management, advocacy, and professionalism and ethics (38,39).

Each interventionist received a one-week training program in the HARP intervention and study protocol. The program included didactic training and role playing for core intervention and teaching components, including techniques for enhancing patient activation (making an action plan, sharing and feedback, and modeling and persuasion) and health education techniques (lecture with discussion, brainstorming, demonstration, feedback, and problem solving). A leader's manual provided structured guidance for each session. The principal investigator (BGD) and the director of

the mental health consumer network (SJT) led weekly supervision sessions for the peer leaders.

Participants assigned to the control group received all usual medical and mental health care. None of the participating clinics had formal wellness or general medical self-management programs.

TABLE 1. Characteristics of participants with serious mental illness and chronic general medical conditions, by study arm

Characteristic	Intervention (N=198)		Control (N=202)		p
	N	%	N	%	
Age (M±SD)	49.74±8.72		49.69±9.51		.95
Male	66	33	79	39	.23
Single	79	40	67	33	.17
Race					
White	60	30	60	30	.9
Black	131	66	133	66	.95
Other	7	4	8	4	.82
Education (M±SD years)	12.73±2.29		12.87±2.48		.55
Total annual income					
$0–$4,999	96	48	87	43	.28
$5,000–$9,999	53	27	60	30	.51
$10,000–$14,999	26	13	27	13	.94
≥$15,000	21	11	24	12	.69
Insurance					
Medicaid	56	28	60	30	.75
Medicare	38	19	47	23	.32
Private	6	3	14	7	.07
General medical diagnosis					
Diabetes	51	26	65	32	.16
Heart disease, coronary artery disease, or coronary heart disease	25	13	20	10	.39
Hyperlipidemia	81	41	82	41	.95
Hypertension	133	67	142	70	.5
Arthritis	93	47	79	39	.11
Hepatitis	19	10	25	12	.37
Asthma or chronic obstructive pulmonary disorder	65	33	72	36	.55
HIV	6	3	12	6	.16
Primary psychiatric diagnosis					
Schizophrenia or schizoaffective disorder	52	26	62	31	.33
Bipolar disorder	74	37	80	40	.65
Depression	141	71	139	69	.6
Obsessive-compulsive disorder	12	6	18	9	.28
Posttraumatic stress disorder	43	22	58	29	.11

Outcome Measures

Structured interviews were administered by trained interviewers at baseline and at three- and six-month follow-up assessments. The primary outcome for the study was health-related quality of life as measured by the Short-Form Health Survey (SF-36) (40–42). The physical component summary (PCS) and mental component summary (MCS) scores are summary measures of physical and mental health–related quality of life that are derived from this instrument (40–42). These scores have been found to have strong reliability, discriminant validity (43–45), and sensitivity to change in studies of patients with serious mental illness (46,47).

Several secondary outcomes were assessed to better understand the potential impact of the intervention on intermediate measures of self-management and other relevant outcomes. The intervention was hypothesized to improve health-related quality of life through improved general medical self-management, which was assessed with the Patient Activation Measure (48), a measure of patients' perceived ability to manage their illnesses and their health care visits. Improved self-management has been found to be associated with improvements in healthy eating (24,49) and medication adherence (50,51). We assessed diet by using the Block Fat-Sugar-Fruit-Vegetable Screener (52,53) and medication adherence by using the Morisky scale (54–56). Because self-management can also facilitate improved linkage to primary care, we asked participants at each time point whether they had a usual source of medical care. Finally, because certified peer specialists are specifically trained to support mental health recovery, we examined changes in this outcome by using the 41-item Recovery Assessment Scale (RAS) (57–59). The RAS has been demonstrated to have strong reliability, internal consistency, test-retest reliability, interrater reliability, and construct validity (57,60,61).

Data Analysis

All analyses were conducted as intent to treat. Analyses were conducted using SAS STAT software, version 9.4. Mixed methods were used to account for the longitudinal nature of the data and to handle missing data. SAS PROC MIXED procedure was used for continuous variables and incorporated a compound symmetric covariance structure. PROC GLIMMIX was used for the categorical variables, approximated by using an adaptive Gauss-Hermite quadrature. For each outcome measure, the model assessed the outcome as a function of randomization, time since randomization, and group × time interaction. The group × time interaction, which reflects the relative difference in change in the parameters over time, was the primary measure of statistical significance. All models adjusted for study site as a fixed effect (62).

Hypotheses were two-sided and tested at a .05 significance level. We prespecified a primary outcome (health-related quality of life) to minimize type I error and used a p value of .05 for exploratory analyses of secondary outcomes in order to minimize the potential for type II error (63–65).

The intervention and research interviews were conducted between September 2011 and August 2016.

TABLE 2. Change in primary outcome measures between baseline and six months, by study arm

Measure and time point[a]	Intervention (N=198)		Control (N=202)			
	M	SD	M	SD	F[b]	p
PCS					3.09	.046
Baseline	32.73	10.92	32.74	11.29		
3 months	34.49	11.15	33.89	10.41		
6 months	35.42	11.02	34.15	11.52		
MCS					3.25	.039
Baseline	32.05	11.79	32.04	11.36		
3 months	34.49	11.15	34.25	11.97		
6 months	36.64	12.28	34.54	11.82		

[a] Possible scores on the physical component summary (PCS) and mental component summary (MCS) of the Short-Form Health Survey range from 0 to 100, with higher scores indicating greater levels of physical or mental functioning, respectively.
[b] df=2 and 697

RESULTS

A total of 400 participants were enrolled and randomly assigned to the study arms. [A CONSORT diagram showing recruitment flow is available in an online supplement to this article.] Most of those assessed (N=701) were eligible, and the vast majority of those who were eligible (N=458) consented to participate in the study.

A majority of participants were female, African American, and poor; nearly all were uninsured or covered by public insurance (Table 1). The most common psychiatric diagnoses as assessed by CMHC charts were major depression, bipolar disorder, and schizophrenia, and the most common chronic general medical conditions as assessed by CMHC charts and confirmed by medical charts ordered for each participant were hypertension, hyperlipidemia, asthma or COPD, and diabetes. No statistically significant differences between the intervention and control groups were found in any baseline characteristics, suggesting that randomization was successful.

Of the 198 participants in the intervention group, 139 (70%) attended at least four of six sessions. Of these, 132 (67%) attended at least five sessions, and 109 (55%) attended all six sessions.

At baseline, participants fell well below the standardized population mean of 50 for the SF-36 PCS score (mean=32.7) and MCS score (mean=32.1) (Table 2). At six-month follow up, the intervention group improved by a total of 2.7 percentage points on the PCS, significantly greater than the gain of 1.4 percentage points in the usual care group (p=.046). For the MCS score, an improvement of 4.6 points was seen in the intervention group, significantly greater than the gain of 2.5 points in the usual care group (p=.039). Cohen's d for the PCS (d=.11) and MCS (d=.17) represented small effect sizes.

For secondary outcomes, a significantly greater improvement was noted at six months on the RAS for the intervention group versus usual care (.15 points versus .08 points, p=.02) (Table 3). At six months, patient activation increased significantly in the intervention group (increase of 3.1 points, t=2.35, p=.01), but the increase in the usual care group was not significant (increase of 1.5 points). The group × time interaction for patient activation was statistically significant at three months (F=4.26, df=2 and 352, p=.04; data not shown), however, at the six-month follow-up the difference was not statistically significant.

None of the other secondary outcomes (diet, medication adherence, or usual source of medical care) differed statistically between the intervention and control groups over time.

DISCUSSION AND CONCLUSIONS

We found that the HARP intervention, a disease self-management program for individuals with serious mental illness and general medical comorbidity, led to improved physical and mental health–related quality of life. This study builds on smaller and uncontrolled studies that have demonstrated the feasibility and potential benefits of peer-led programs addressing chronic general medical conditions among patients with serious mental illness. As the largest and first fully powered randomized trial of a peer-led intervention to address self-management of general medical conditions among patients with serious mental illness, this study provides evidence that these programs hold the potential to improve the health and well-being of patients with serious mental illnesses.

Compared with participants in the usual care group, participants in the intervention group experienced greater improvement on the SF-36 PCS (difference in improvement of 1.3 points) and on the SF-36 MCS (difference of 2.1 points). Although these effect sizes were small, previous research suggests that for health-related quality of life, small effects can have clinically meaningful impacts (66,67). For instance, among patients with diabetes in the Medical Outcomes Study sample, a 1-point improvement in PCS score was associated with a 9% reduction in relative risk of seven-year mortality, and a 1-point improvement in MCS score was associated with a 5% decrease in the likelihood of inability to work (67).

Patient activation, which reflects an individual's confidence in managing his or her medical conditions, improved significantly more for the intervention group than for the control group at three months; however, the effect diminished and was no longer statistically significant at six months. It is possible that shorter-term improvements in self-management may lead to longer-lasting improvements in distal health outcomes. However, the finding also suggests the broader need to optimize the sustainability and longer-term benefits of time-limited self-management programs for patients with chronic conditions (68).

The program demonstrated a benefit for mental health recovery, a construct that reflects "a way of living a satisfying, hopeful, and contributing life even with the limitations

caused by illness" (69). Although recovery is not an explicit target of the HARP program, it is a focus of training for the certified peer specialists who delivered the intervention. The findings indicate that there may be particular benefits to programs led by trained peers who can help place general medical self-management in the broader context of participants' recovery goals.

Other secondary outcomes, including diet, medication adherence, and report of a usual source of care, did not differ significantly between the groups. This may be due to the fact that these behaviors were not the primary focus of the HARP intervention. Programs directly addressing diet, physical activity, and quality of medical care may be important adjuncts to disease self-management interventions for patients with serious mental illnesses and general medical comorbidity (70).

TABLE 3. Change in secondary outcome measures between baseline and six months, by study arm

Measure and time point	Intervention (N=198)		Control (N=202)				
	N	%	N	%	F	df	p
Patient Activation Measure (M±SD score)[a]					2.14	2, 704	.12
Baseline	57.4±16.6		55.7±14.9				
3 months	61.6±15.9		56.4±16.5				
6 months	60.5±16.7		57.2±16.3				
Block Fat-Sugar-Fruit-Vegetable Screener (M±SD score)[b]					.3	2, 704	.72
Baseline	10.1±5.1		9.8±5.6				
3 months	10.1±5.0		9.3±5.3				
6 months	10.2±5.6		9.4±5.3				
Morisky scale (M±SD score)[c]					1.27	2, 693	.28
Baseline	.92 ±.94		.94±1.02				
3 months	.79±.92		.97±.96				
6 months	.84±.92		.89±.96				
Recovery Assessment Scale (M±SD score)[d]					3.79	2, 704	.02
Baseline	3.72±.62		3.66±.57				
3 months	3.89±.55		3.70±.68				
6 months	3.87±.61		3.74±.59				
Usual source of medical care					.62	2, 704	.54
Baseline	177	89	170	84			
3 months	173	87	181	87			
6 months	176	97	178	87			

[a] Possible scores range from 0 to 100, with higher scores indicating greater patient activation.
[b] Possible scores range from 0 to 68, with higher scores indicating greater consumption of fat.
[c] A measure of medication adherence. Possible scores range from 0 to 4, with lower scores indicating greater adherence.
[d] Possible scores range from 0 to 5, with higher scores indicating greater recovery.

Several study limitations should be noted. First, the study was conducted in only three CMHC clinics in one geographic region. Although the clinic populations are similar to those of other CMHCs nationwide (71), replication is needed for samples in other regions. Second, the outcomes were all self-reported; future studies should examine whether and how these programs affect distal clinical outcomes, such as cardiovascular risk factors. Third, although the usual care comparator made it possible to understand the potential benefits of this program under real-world conditions, it limited the ability to assess the impact of the specific features of the program over and above nonspecific effects of contact with peer leaders. It has been argued that usual care is often the most useful comparator for assessing the overall effectiveness of interventions under real-world conditions (72). Similarly, many participants did not attend all the intervention sessions. Although this may have reduced the effect sizes in the study, it also made it possible to estimate the program's effectiveness as implemented in community settings.

These limitations notwithstanding, the findings suggest that the HARP program can improve physical and mental health–related quality of life of individuals with serious mental illness and comorbid general medical conditions. The findings suggest the potential benefits of more widespread dissemination of peer-led general medical disease self-management groups in this population.

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