IRB#00047631

Peer-Led, Medical Disease Self-Management Program for Mental Health Consumers

The Health Access and Recovery Peer Program (HARP)

NCT01725815

Protocol Dated: 10/26/2010

I. INTRODUCTION TO THE REVISED APPLICATION

We greatly appreciate the thoughtful comments by the reviewers, as well as the reviewers' enthusiasm about the high public health significance of the proposed project. Extensive modifications were made in response to these comments, which we believe considerably strengthen the application and will add to the study's scientific and public health impact. The following section briefly summarizes those changes:

1. Representativeness of group participants and peer educators: "*The study will take place in the context of an organization of consumers who have sought group-based peer-led services…raising questions as to the generalizability to routine community mental health center settings."* In response to this important concern, the application now proposes a multisite study that would recruit subjects across four diverse community mental health clinics throughout metro Atlanta rather than from the Georgia Mental Health Consumer Network. (IIIC4)

"*Given the requirements listed for the peer specialists to be trained and retain their position, there is some doubt that the individuals qualifying for this role will in fact have the same severity of mental illness as the treatment participants."* We have dropped the requirement that the interventionists be certified peer specialists at the time they are recruited. Instead, peer educators will be chosen using the identical selection criteria as subjects participating in the groups. As part of the initial training, the Georgia Mental Health Consumer Network will provide additional instruction to allow the interventionists to become certified peer specialists, (IIIC6f) which will allow them to bill for services during the dissemination phase (IV).

2. Peer relapse: "*A plan is not evident for when peer specialists relapse."* We now describe strategies for addressing this possibility in the text (IIIC6f) and in the human subjects section (VIID3b).

3. More detailed description of pilot data:"*The pilot study is not adequately described."* We now more fully describe the initial pilot study, whose results have recently been published in *Schizophrenia Research,*[1] (IIIC1d). We also conducted a second pilot study since the last submission to test a recruitment strategy designed to enhance engagement and retention in the program (IIIC1e). Together, these studies demonstrated high rates of engagement, retention, fidelity, and the potential for improving improved clinical outcomes to as great or greater an extent than in general medical populations. We believe these data provide a strong foundation and rationale for the full-scale study proposed in this application.

4. Study outcomes and power calculations: *"Better rationale for study outcomes, as well as power analysis for a broader set of outcomes… it is not likely the [physical fitness outcomes] would change...*" We have better clarified the rationale for choosing the study outcomes; the number of outcome measures has been streamlined and the fitness outcomes have been removed. (IIID3). Power calculations are now provided for a broader range of outcomes (IIID4d); based on these new calculations and the proposed sample size has been increased from 300 to 400.

5. Optimizing engagement and retention in the intervention group: "*Participants in the intervention group will be paid $20 for attending five of the six sessions of the intervention, raising questions of…generalizability..."* We have dropped the plan to pay consumers to attend sessions (subjects were not paid for attending sessions in either of the pilot studies). Instead we are proposing a strategy that couples an initial informational session coupled with reminders from the peer educator prior to each group (section IIIC5a). In the second pilot, this approach resulted in high rates of participation, engagement, and retention in groups.

6. Other methodological clarifications: *"Several issues in the methods…randomization procedures, masking or retention (particularly for control group). Data collection/data collectors."* We have now more clearly specified details around each of these important methodological considerations (IIIC5, IIID2). "*More detail needed about supports and contacts between sessions, how many people will be in each group, how long individuals will have to wait for groups to start…"*We now provide greater detail about the contacts between sessions with other peers (IIIC6b2) the numbers of participants in each group (8-12 members; see section IIIC6a), and the use of rolling recruitment to minimize wait times for enrollment (anticipated to be less than three weeks: section IIIC5a).

7. Qualitative substudy: "*The qualitative analysis plan …is less well-specified than other parts of the application."* We agree that this was underspecified and have removed it from the modified proposal to allow more attention to the expanded quantitative study.

Because of these major changes, as well as the move to a shorter format, nearly the whole application has been rewritten and thus revisions are not highlighted in the text.

II. SPECIFIC AIMS

IIA. Introduction

Persons with serious mental illnesses (SMI) face elevated rates of chronic medical illnesses, and a more than twofold elevation in preventable mortality caused by those medical conditions. Despite growing alarm in the mental health consumer community about these statistics, persons with SMI currently have few tools available to help them to effectively manage their medical conditions.

In general populations, peer-led disease self-management interventions have been demonstrated to lead to sustained improvements in self-management and health outcomes. The most widely tested and used management program is the Chronic Disease Self-Management Program (CDSMP) developed at the Stanford Patient Center by Kate Lorig and colleagues. With funding from an R34 intervention development grant from NIMH, the study team has developed and piloted a modified version of the CDSMP, called the Health and Recovery Peer Program (HARP), to be delivered by mental health consumers to mental health consumers. The theoretical model underlying the intervention, the Information-Motivation-Behavior Model, suggests that gaps in health knowledge, motivation, and behavioral activation make it necessary to modify the CDSMP to use it in persons with SMI --both group members and group leaders), and guided the adaptation process.

Two pilot tests of the HARP program demonstrated that the program can be implemented with high engagement, retention, and program fidelity, and can result in improvements across a range of outcomes comparable to or greater than those seen in general medical populations. This application now proposes to perform a fully powered, multisite trial of HARP. This new study will make it possible to establish this new intervention as an evidence-based practice, while providing an understanding of the settings and populations where it may provide the greatest benefits.

A total of 400 individuals with serious mental illnesses and one or more chronic medical condition (hypertension; heart disease; arthritis; diabetes; or asthma/COPD) will be recruited from four diverse community mental health clinics in the Atlanta metro region and randomized to HARP or usual care. For individuals in HARP, two peer educators with SMI and one or more medical comorbid condition will implement a six-session manualized intervention over six consecutive weeks (one session per week). Peer educators will receive training through the Stanford CDSMP and through the Georgia Consumer Mental Health Consumer Network, which will provide additional instruction to allow peers to become certified mental health peer specialists. Follow-up interviews and chart reviews at 3 months, 6 months (primary endpoint) and one-year post-intervention will assess clinical outcomes, improvement in generic and disease-specific measures of illness self-management, and quality of care.

During the final year of the study, group participants will be trained to lead HARP groups, which will lay the groundwork for dissemination efforts. These efforts will build on the nationwide CDSMP infrastructure. Peer-led services can be reimbursed under Medicaid in a large and growing number of states, providing a potential funding mechanism for these efforts.

IIB: Study Aims and Hypotheses:

Study Aim 1: To study the impact of HARP on health outcomes
H1. As compared with participants referred to usual care, participants in HARP will show greater improvement on validated measures of physical health-related quality of life, disability, and recovery.
Study Aim 2: To study the impact of HARP on quality of disease management and medical care.
H2: As compared with participants referred to usual care, participants in HARP will show greater improvement on validated measures of behavioral activation, generic and disease-specific self-management, and quality of medical care.
Study Aim 3: To understand subpopulations in which the intervention is most and least useful (moderation) and to understand the mechanisms underlying the effectiveness of the intervention (mediation).
H3: Persons with medical and social vulnerability will show differentially greater improvement from HARP than non-vulnerable populations; information and motivation will mediate the impact of the intervention on disease self-management.

There is an urgent need to develop effective, scalable interventions to address the high rates of medical co-morbidity and premature mortality among persons with serious mental illnesses. If successful, this study will establish and lay the groundwork for disseminating the first evidence-based, fully peer-led intervention for improving physical self-management in this vulnerable population.

III. RESEARCH STRATEGY

IIIA. Significance

A literature extending back more than 70 years has demonstrated the high rates of medical morbidity and excess mortality in persons with serious mental disorders.[2] Mental disorders are risk factors for elevated rates for nearly every type of medical illness,[3, 4] including cardiovascular disease, diabetes, and pulmonary conditions[5-11] Mortality due to general medical conditions is elevated by two to three times in persons with serious mental disorders,[12, 13] and this differential mortality gap appears to be increasing over time.[14.15]

There has been a growing sense of urgency among mental health consumer leaders about this epidemic of medical morbidity and premature mortality.[16] However, to date, consumers have not had the tools available to address physical health and healthcare as part of their broader efforts to promote mental health recovery.[17] Mental health consumers are becoming playing an increasingly important role in the mental health workforce, and 26 state Medicaid programs directly reimburse consumers as service providers.[16] Given the low cost of these services, states' growing interest in recovery-based approaches to care, and the expansion of Medicaid under health reform, these trends are likely to accelerate in coming years.

There is now an opportunity to directly engage mental health consumers in improving physical health and well-being. The Health and Recovery Peer program (HARP), developed in close collaboration with the creator of the nation's leading disease self-management program and mental health consumer leaders, has the potential to improve medical illness self-management among a group of hard-to-reach individuals who are commonly underserved by the formal healthcare system. The values of wellness and self-management promoted by the program are highly compatible with the recovery-based orientation of the mental health consumer movement. [17]

The public health significance of the application and its centrality to NIMH's goals are underscored by the introduction to the NIMH strategic plan. "NIMH must measure success by 'outcomes': how well the research we support provides the evidence base…to enhance recovery for those affected, serve diverse and previously under-served populations, and reduce premature mortality among persons with mental illness." [18] It addresses Goal 3 of the Strategic Plan, "Strategic Objective 3: Develop New and Better Interventions for Mental Disorders that Incorporate the Diverse Needs and Circumstances of People with Mental Illness," and also Goal 4, "Strengthen the Public Health Impact of NIMH-Supported Research."

IIIB. Innovation

Although there is a growing literature on the use of peer-led models to address recovery and mental health symptoms among individuals with serious mental disorders, [19-22] we are not aware of any peer-led interventions that address management of physical illnesses in this vulnerable population. The current study will establish a new evidence-based program for improving management of chronic medical conditions that is delivered by mental health consumers to fellow consumers. This approach has the potential to change the paradigm of healthcare delivery for this population, shifting from a professionally-driven approach to one that more actively engages consumers in their own health and wellbeing.

The dissemination plan (section IV), which uses a pyramidal approach in which graduates of the program train leaders to run groups, will provide an innovative model for disseminating the intervention, and further enhance its public health impact.

IIIC. Approach

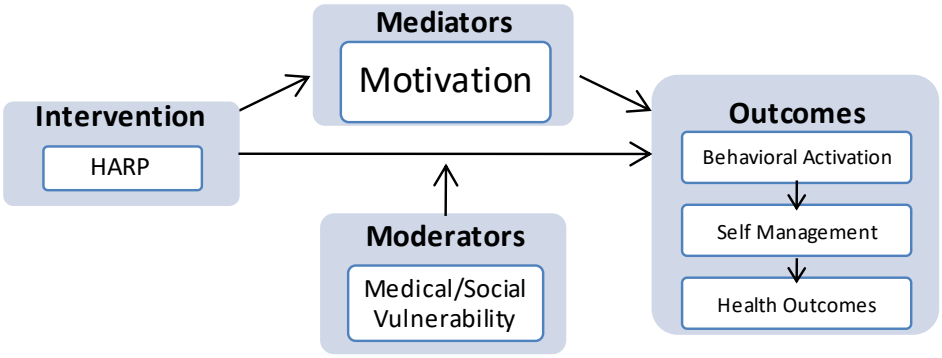
IIIC1. Overview of the Chronic Disease Self-Management Program, Adaptation, and Preliminary Data

IIIC1a. The Chronic Disease Self-Management Program (CDSMP): Overview and Evidence of Effectiveness in General Populations The intervention builds on the Chronic Disease Self Management Program (CDSMP), the most widely established peer-led program for improving chronic illness self-management in general medical populations. [23, 24] CDSMP groups are led by two peer educators with chronic medical conditions; any given group includes participants with a range of chronic conditions such as diabetes and arthritis. A series of six group sessions delivered over 6 weeks addresses self-management tasks found to be common across chronic health conditions. [25-27] The CDSMP has shown to improve disease self management, health service use, and clinical outcomes. [28-31]

IIIC1b. Theoretical Model Underlying the Development of the Health And Recovery Peer Program (HARP): The Health And Recovery Peer (HARP) program was modified from the CDSMP using the Information Motivation Behavior Model (IMB). The IMB, originally developed for understanding HIV, has been extended to a variety of settings for understanding use of preventive[32,33] and chronic care services.[34] This approach is

increasingly being used as a model both for understanding and improving chronic illness self-management.[35, 36] This model suggested that that while the CDSMP held potential for persons with SMI, it would also require adaptation to address the unique issues faced by this population --both group participants and peer educators.

The IMB framework asserts that information, motivation, and behavioral activation are the fundamental determinants of successful illness self-management. Information reflects knowledge about the condition that is directly relevant to the particular behavior. Information, however, must be coupled with motivation for behavior change. [37, 38] Together, information and motivation make it possible to improve behavioral activation, which comprises an individual's capacity to manage his or her own illness and work effectively within the formal health system. [26, 27, 39] Behavioral activation is the key patient-level precursor to improving self-management and health seeking behaviors.



Previous studies in general populations have suggested a series of moderating factors that might be expected to identify populations in whom improving self-management may be particularly important. Social vulnerability factors include lack of an adequate support network; medical vulnerability factors represent problems in obtaining and maintaining appropriate medical services. [40, 41] Persons in these groups might be expected to have more to gain from a program designed to enhance self-management skills.

IIIC1c. Adaptation Process With funding from an NIMH intervention development grant, 5R34MH078583, we modified the CDSMP for this population using an iterative, theory-driven approach. [42] Initial focus groups were followed by a prepilot of the program, and a redrafting of the CDSMP manual in close collaboration and input of the developer of the CDSMP and mental health consumers. The process identified and retained the active ingredients of the CDSMP while making needed modifications to allow it to be able to be delivered by, and to, mental health consumers.

Modifications to the program were specifically targeted to the deficits in information, motivation, and behavioral activation that have been demonstrated for persons with SMI. Limitations in cognition[43] and health literacy [44, 45] among persons with SMI might be expected to affect ability to understand and retain information. To address these problems, the manual was simplified to a sixth-grade reading level, and a self-management record was added to help consumers track disease-specific self-management activities (e.g. measuring blood sugar), updated medications, and a list of upcoming appointments, dietary intake, and physical activity. Deficits in motivation for persons with SMI may be related in part to limited social networks, and high rates of adverse health behaviors within those networks. [46] Thus, each participant was paired with a partner from the group, with the two meeting between sessions to work toward accomplishing action plans and goals.

Comorbidity and complexity of conditions may limit these individuals' behavioral activation both in illness self-management,[47, 48] and in their capacity to serve as effective patients.[49-51] Sections were added to the curriculum emphasizing the connection between physical and mental health, and on coordinating information between primary care providers and mental health providers. A section on medical advance directives was expanded to include mental health advance directives, which specify preferences if a client is unable to make decisions due to psychiatric symptoms.[52] Finally, the CDSMP was developed and has largely been tested in middle-class populations. Persons with mental disorders are largely poor and economically disadvantaged, making it challenging to afford healthy food or find safe places for physical activity. [53] Thus the diet section provided strategies for purchasing healthy food on a budget (including using food stamps) and strategies were provided to allow participants to safely exercise in their own homes.

IIIC1d.Randomized Pilot Trial**:** Subsequently, we conducted a small randomized trial comparing the HARP program to usual care for a sample of subjects in the DeKalb County Community Mental Health Center, an urban CMHC.[1] The purpose of this pilot trial was to establish feasibility, effectiveness, and to inform the development of a full-scale randomized trial. The program was led by two mental health consumers with serious mental illnesses and medical comorbidities. One peer has diagnoses of schizophrenia and congestive heart failure; the second has bipolar disorder and diabetes.

1. Recruitment and retention: A total of 80 individuals were enrolled in the study. Among the individuals randomized to the intervention (n=41), a total of 33 (80.5%) attended at least one session; 29 (70.7%) attended three or more sessions; 26 (63.4%) attended at least 4 sessions, and 22 (53.7%) attended 5 or 6 sessions. A second pilot using a modified recruitment strategy resulted in considerably higher rates of engagement and retention (IIIC1e).
2. Sample characteristics: The mean age was 48; most (82.5%) were African American, and most were poor (mean annual income $7,704 ($2,520, $12,306). The most common mental diagnoses were bipolar disorder (32.5%), schizophrenia (28.8%), major depression (26.3%) and PTSD (11.3%). The most common medical comorbidities were hypertension (62.5%), arthritis (48.8%), asthma/COPD (22.5%), and heart disease (22.5%).
3. 6-month Outcomes: All outcome analyses were conducted as intent-to-treat, and thus provide a relatively conservative estimate of potential intervention effect sizes. At six month follow-up substantial relative improvements in outcome measures were observed for the HARP group relative to usual care, although several did not achieve statistical significance due to the small sample size. The table below shows the baseline (BL) and six-month measures for the primary outcomes of interest. The table shows the p-value and t-statistic for the group*time interaction to quantify difference in outcomes over time between the intervention versus usual care (UC) groups. We also present the Cohen's d effect size (ES), a standardized measure that incorporates both difference in change and variance.

At six month follow-up the HARP group scored higher on the SF-36 Physical Component Summary (PCS) than the usual care group. The effect size is larger than those reported in studies implementing the CDSMP in general medical populations.[54] [55] This 3-point relative difference observed in the PCS has been found to predict a 15% reduction in inpatient medical hospitalization, and a 20% decrease in 2-year mortality.[56]

Change in patient activation over time was clinically and statistically significantly higher in the HARP intervention than in usual care. As with HRQOL, the effect size was larger than those seen when the CDSMP was implemented in general clinical populations.[26] Changes of these magnitude have been found to predict significant reductions in inpatient hospitalization, higher rates of diabetes and lipid testing, and improvements in Hemoglobin A1C control among diabetics.[57] There was also a significantly higher difference in improvement over time for the HARP group in the proportion of the sample reporting one or more visit to a primary care provider, regarded as a critical element of care provision for individuals with chronic conditions.[58] HARP participants had an additional 40 minutes per week spent in moderate/vigorous exercise compared to usual care. While not statistically significant, the difference in exercise (d=0.19) was nearly identical to the six month effect size for the six month follow-up on the original CDSMP study in a general community sample (111 vs. 91 minutes) (Lorig et al. 1999). The Morisky scale for medication adherence has a possible range from zero (no problems) to four (more problems). The mean change over time for the HARP group was lower (better) than the mean change for the usual care group (d=0.31).

Table 1: HARP Pilot Study Outcomes

		HARP (n=41)	UC (n=39)	group*time		
				P	T	ES
Physical Component Summary of SF-36	BL	36.9	37.0	.252	1.16	.30
	6mos	42.9	40.0			
Patient Activation	BL	48.3	47.6	.030	2.21	.56
	6mos	52.0	44.9			
>1 Primary Care Visit	BL	58.5%	61.1%	.046	2.03	.51
	6mos	68.4%	51.9%			
Medication Adherence	BL	1.5	1.5	.220	1.24	.31
	6mos	1.3	1.6			

IIIC1e. Open-Label Pilot Study of Modified Recruitment and Retention Strategy: To address the modest initial engagement rate in the first study, we tested a modified recruitment approach using a strategy that is being used in current dissemination efforts for the CDSMP.[59] Participants were recruited at the Fulton County CMHC, an urban CMHC, via posted flyers and clinician referrals for an open-label trial to assess subject engagement, retention, and fidelity. The same peers who led the initial trial led this series of groups.

The recruitment strategy and eligibility criteria were identical to the strategy proposed for use in the full trial which is described in greater detail in IIIC5a. Potential subjects were invited to attend an initial informational session to more fully describe the program and optimize the informed consent process. Attendees at this session who were interested in participating and met study eligibility criteria were offered informed consent immediately following the informational session. To optimize retention, peer educators called participants 1-2 days prior to each group session as a reminder and to troubleshoot any potential barriers to

attendance. Aside from bus tokens for those taking public transportation, no financial incentives were provided for attending meetings.
1. Engagement and participation in groups in the second pilot trial was high. Of 13 individuals attending the informational session, 8 were eligible and consented to participate in the pilot. Among those consenting to participate (n=8), a total of 4 attended all 6 sessions and the remaining 4 attended 5 out of the 6 sessions, resulting in attendance at a mean of 5.5 (SD=0.53) out of 6 possible sessions.
2. Sample characteristics were similar to the sample for the first pilot study (IIIC1d), and reflective of the clinic population (IIIC4) with regards to sociodemographic characteristics (mean age 44; 87.5% African American; mean income $5,120), primary mental health diagnoses (37.5% depression; 37.5% schizophrenia; 25% bipolar d/o), and medical comorbidities (hypertension 50%; arthritis 37.5%; diabetes 25%; asthma/COPD 25%).
3. Fidelity was assessed by audiotaping the groups, and using the quantitative fidelity measure described in IIIC6e. All audiotapes were rated by the health educator. Each of the 44 content/activity sections was rated using a Likert scale, with 5 being "completely adhered to the written curriculum guide" to 1 being "did not adhere to the written curriculum guide at all." Totals for two summary categories indicated of 14 out of a possible 15 for patient activation enhancing techniques (making an action plan; sharing and feedback; modeling and persuasion), and 23.5 out of a possible 25 score on training techniques (lecture with discussion; brainstorming; demonstration; feedback; problem solving).

IIIC2. Summary and Rationale for a full trial: The R34 grant allowed us to develop and manualize HARP. Two pilot studies demonstrated potential for high rates of engagement, retention, and fidelity, and promise for improving improved key clinical outcomes. However, these were intended to inform a larger trial and not powered to assess statistical significance. An adequately powered trial is needed to assess whether HARP can lead to improved self-management and outcomes. Second, the pilot study's outcomes were limited to a relatively small number of self-reported measures. A more diverse set of measures from multiple data sources is essential to definitively test HARP's effectiveness. Third, the pilot study was conducted in a single urban community mental health center, which limits generalizability and the ability to compare impact across different types of settings or patient subgroups. Recruitment from multiple settings will make it possible to establish whether the program is effective across a broad population of persons with SMI and also to understand in what subpopulations the program works best. If successful, this study will establish the first evidence-based, fully peer-led program to improve physical health and well-being among mental health consumers.

IIIC3. Overview of the Proposed Research Project: We propose a multisite, randomized trial of the HARP program, an adaptation of the Chronic Disease Self Management Program delivered by, and to, mental health consumers. A total of 400 participants will be randomized to either HARP or usual care. Interviews and chart reviews at 3 months, 6 months (primary endpoint), and 1-year after the completion of the groups will assess the impact of the program on clinical and functional outcomes and disease self-management skills.

IIIC4. Study Setting: Metro Atlanta CMHCs: The study will recruit from four diverse safety net mental health clinics throughout the greater Atlanta region, with two urban and two suburban clinics. The Fulton County Department of Health and Wellness is a public health clinic that serves the mental health needs of Fulton County, a poor, inner-city County in Atlanta. The Fulton County CMHC also serves adults with serious mental illness in Fulton County. Two community mental health centers operated by the Georgia Regional Network (GRN) provide care within Gwinnett County, a suburban county located 30 minutes north of downtown Atlanta.

Table 2: Characteristics of Study Sites

Characteristics of Clients FY 2009	**Fulton County Department of Health and Wellness**	**Fulton County CMHC**	**GRN CMHC Lawrenceville Clinic**	**GRN CMHC Norcross Clinic**
# of Adults with SMI served	4,986	3,400	2,029	921
Location	Urban/Inner City	Urban/Inner City	Suburban	Suburban
Gender Female	52.0%	51.2%	57.1%	66.3%
Race/Ethnicity				
Caucasian	8.7%	20.0%	65.7%	55.1%
African American	89.9%	77.7%	23.4%	25.9%
Hispanic/Latino	1.0%	2.0%	6.0%	9.5%
Income below Federal Poverty Line	89.7%	93.6%	73.5%	62.4%

IIIC5. Recruitment and Randomization

IIIC5a. Recruitment Strategy: We will recruit and randomize 100 participants sequentially from each site, with each site conducting 6 consecutive weekly group meetings of 8-12 participants over a one-year period (1 group session per week) and then follow-up over a second year. Rolling recruitment throughout the year will be used to minimize waiting time between recruitment and beginning a group program. Based on recruitment projections, clients should have to wait no longer than three weeks between recruitment and entry into a group.

To optimize the balance between internal validity and generalizability to community settings, we will use the strategy developed for CDSMP dissemination efforts. [59] In our second pilot study (IIIC1e), this approach resulted in high rates of engagement, retention, and representativeness of the sample. Flyers will be posted and clinicians encouraged to refer subjects to a one-hour weekly informational meeting scheduled at the CMHC. At this meeting, the project director will provide a one-hour description of the HARP intervention and the broader study. The session will describe the intervention, explain random assignment, review the study protocol, detail the informed consent process and confidentiality, and answer any questions. At the end of this session, participants who wish to enroll in the study will provide brief written consent for the screening process, then be assessed for eligibility via a review of CMHC administrative records and a brief screening interview.

Inclusion criteria will include: 1. On CMHC roster of active patients. 2. Presence of a serious mental illness (schizophrenia, schizoaffective disorder, bipolar disorder, major depression, obsessive-compulsive disorder, or post-traumatic stress disorder, with or without comorbid substance use),[60] either via CMHC chart or the MINI, a brief diagnostic psychiatric interview designed for use in clinical trials. [61] 3. Chronic Medical Condition as noted in the CMHC chart or via self-report: (hypertension; arthritis; heart disease; diabetes; and asthma/COPD), the most common comorbid conditions seen in the pilot work and other studies in this population.[62] The exclusion criterion will be cognitive impairment based on a score of $\geq$ 3 on a 6-item, validated screener developed for clinical research. [63]

IIIC5b. Randomization: One fourth of the sample, or 100 individuals, will be randomized at each site. A block randomization strategy will be employed, to ensure balance across each site. Participants who meet eligibility criteria and provide informed consent will be randomly assigned using a computer-generated algorithm and concealment of allocation techniques to minimize assignment bias, to either the HARP or usual care.

IIIC6. Intervention: Health and Recovery Peer (HARP) program

IIIC6a. Overview: The HARP intervention is a 6-week, 6-session, group format intervention to improve self-management of chronic medical diseases. Each group lasts 90 minutes and has 8-12 attendees. Between groups, participants work with partners from the group to troubleshoot problems and accomplish action plans identified during the session. The intervention will be scheduled at a time and location that is convenient to participants and does not interfere with work or homemaking activities, typically in the evening. When feasible, meetings will be held in the Wellness Center, a home-like, nonclinical setting run by the Georgia Mental Health Consumer Network in downtown Decatur that provides recovery classes as well as a respite program. Where this option is not feasible, classes will be held at the mental health centers. At the end of the program, monthly alumni groups meet for six months to reinforce lessons from the intervention, monitor progress, and maintain peer support.

IIIC6b. Optimizing Information, Motivation and Behavioral Activation:

1. Optimizing Information: Charts and handouts are used throughout the sessions to help convey and reinforce key concepts. Each attendee is given a copy of the CDSMP workbook titled “Living a Healthy Life With Chronic Conditions” which combines information and interactive exercises for self-management of chronic illnesses.[64] The book is used as a reference and to reinforce information provided in the groups. Information about specific chronic conditions is provided in the form of handouts and through chapters in the CDSMP workbook. Handouts are provided for preventive services, [65] hypertension, [66] arthritis, [30] diabetes, [67] heart disease, [68] and COPD. [69-71] Each participant is provided with a self-management health record that includes fields for each of the key targets of the intervention: 1. Disease-specific self-management activities (e.g. measuring blood sugar); 2. Updated Medication List 3. List of upcoming appointments 4. Dietary intake and 5. Physical Activity. This is used to track improvement in self-management activities through the study period. All materials are targeted to a 6th grade reading level to address limited health literacy.

2. Optimizing Motivation: Peer support helps improve motivation by solidifying intentions, modeling appropriate intensions, and reinforcing positive social norms for self-management, appropriate use of health services, and health behaviors. [37, 38] During the first session, each participant is paired with a partner from the group. Between sessions, participants are encouraged to meet at least once per week with the partner to accomplish

a specific action plan outlined during the session. For instance, the participant and their partner might set a plan in which they will shop together for healthy groceries prior to the next session.
3. Optimizing Behavioral Activation: Each session, clients develop a short term "action plan" related to the topic of the session.[23] This involves identifying a problem that is of particular concern, listing ideas for solving the problem, and then developing a plan outlining specific, short-term goals for improvement. For instance, the plan might be "This week I will walk around the block before lunch on Monday, Wednesday, and Friday for 30 minutes." Action plans should be specific and realistic, proposing behavior that the client is confident he or she can accomplish. The client is asked about his or her level of confidence, on a scale of 0-10, that the specific goal can be accomplished. If confidence is 6 or less then goals are modified accordingly and a new action plan is developed.

IIIC6c. Individual Sessions (see manual in Appendix for detailed overview of each session):
1. Session One: introduces the concept of disease self management to attendees. Topics include: understanding chronic disease, the basic principles for self management, and an introduction to action planning. At the end of the class, each attendee develops a short-term action plan to help them more actively manage their chronic medical illness and obtain appropriate preventive services.
2. Session Two: provides an overview of problem solving and an introduction to exercise and physical activity. The group begins by brainstorming about the potential benefits of exercise and physical activity, with an overview of flexibility, strengthening, and aerobic forms of exercise. This session includes a "hands-on" exercise training session including an easy to perform a chair workout covering major muscle groups. This workout includes both strength exercises and some stretching exercises.
3. Session Three: provides an overview of pain and fatigue management as well as a continuation of the exercise program. Members learn the potential factors causing or exacerbating pain and fatigue, and strategies for addressing them, including good diet, exercise, social contact, and relaxation techniques. Breathing strategies are developed and the group is instructed in performing progressive muscle relaxation techniques. Participants develop a personal exercise program using the FIT acronym (Frequency, Intensity, and Time spent each session) for a successful exercise program.
4. Session Four: provides an introduction to healthy eating, including food variety; eating smaller and more, regular meals; increasing fruit and vegetable intake; reducing fat and cholesterol intake; reducing carbohydrate and salt intake; and increasing water intake. Sections on reading nutritional labels and weight loss are included. A module covers how to shop for healthy, culturally appropriate foods on a limited budget. A "hands on" nutrition session consists of a thirty minute cooking demonstration.
5. Session Five: Peer educators provide an overview of the purposes, benefits, and side effects of common medications. The importance of taking medications as prescribed, even when a patient is asymptomatic, is discussed. A section about combining medications for medical and mental conditions, along with the importance of sharing information across different physicians, was added from the CDSMP to HARP.
6. Session Six: provides an overview of finding and working with a regular doctor. Peer leaders present strategies for working effectively with a primary care provider, including the following acronym (PART): 1. Prepare for the appointment in advance, and bring a list of the most important concerns or questions to the visit. 2. Ask about diagnosis, tests, treatments, and follow-up. 3. Repeat back to the provider the key points discussed during the visit. 4. Take Action: Let the provider know if there are any potential barriers to following through with the recommendations. A final section reviews the highlights from each of the section and asks participants to share goals for the coming months.

IIIC6d. Graduation and Alumni Group: At the final session, participants have a graduation ceremony in which they receive a certificate from the program. This certificate indicates both that they have graduated from the HARP program and that they are eligible to participate in a training program to lead groups in HARP. Participants are encouraged to continue to meet with the peer partner to set new action plans. An alumni group conducted by the peer educators meets monthly for six months after HARP is completed to track progress and help participants retain gains made during the program.

IIIC6e: Assessing Fidelity: Fidelity, or the degree to which the intervention follows the program model,[72, 73] will be optimized and assessed using standards from the NIH behavior change consortium.[74] We have developed and pilot tested a fidelity measure (IIIC1e) that will be used in the larger study.

All groups will be audiotaped. The health educator (Sterling) will review a randomly selected session from each group. Sessions will be assessed in terms of overall accuracy and how closely the facilitator

adhered to the written curriculum guide. Each of the 44 content/activity sections are rated using a Likert scale, with 5 being "completely adhered to the written curriculum guide" to 1 being "did not adhere to the written curriculum guide at all." These sections are then grouped into two categories: 1. Patient activation enhancing techniques, comprising (a) making an action plan (b). sharing and feedback and (c). modeling and persuasion and 2. Training techniques, comprising (a). lecture with discussion (b). brainstorming (c). demonstration, (d). feedback and (e). problem solving. These are key "active ingredients" of the CDSMP model identified by its developers, and have been recommended for use in assessing fidelity of the model. [59, 75]

IIIC6f. Selection, Training and Supervision of Peer Leaders: The Georgia Mental Health Consumer Network (GMHCN), will identify, hire, and supervise three part-time peer educators who will lead groups across all 4 sites. The identical criteria will be used for selecting group leaders as selecting group members; active treatment at a CMHC; a serious mental disorder; and a chronic medical condition. Positions will be advertised through postings at the four CMHCs, local newspapers, and listservs.

Peer educators will attend a 4 ½-day workshop at the Stanford Patient Education Research Center. This program is led by the developers of the CDSMP and certifies graduates to lead groups. Each trainee will receive a detailed Leader's Manual (see Appendix). After the Stanford training workshop, members of the study team, including the Principal Investigator (Druss), Health Educator (Sterling), Diet and Nutrition expert (Frediani), Disease Self-Management Expert (Dunbar) Director of the Georgia Mental Health Consumer Network (Jenkins-Tucker), and peer-intervention expert (Fricks) will provide a two-day orientation to the peer educators including instruction in the HARP manual and study design.

Next, peers will role play two workshop sessions with mock participants, under the supervision of the health educator (Sterling) and peer-intervention expert (Fricks). The health educator and peer-intervention expert will provide real-time feedback on all activities. Sherry Jenkins Tucker, the director of the Georgia Mental Health Consumer network, who is a master trainer in the CDSMP, and helped develop the HARP curriculum, will attend all six sessions in the first workshop. She will provide structured feedback to the educators after each of these sessions. If she has any remaining concerns about the peer educators' ability to effectively lead the groups, she will continue to attend these sessions until the concerns have been resolved.

The Georgia Mental Health Consumer network will also provide standardized training to allow the group leaders to become certified mental health peer specialists; a standardized 2-week training program focuses on teaching skills such as person-centered planning, recovery-based group leadership skills, and Medicaid note writing and billing protocols,. The certification process includes both a written and oral test covering these core skills. This will provide added training for the peer educators in leadership and recovery-oriented skills, as well as make them eligible to bill Medicaid for services during the dissemination of the intervention.

Subsequently, weekly supervision will be provided to the peer leaders from Ms. Jenkins-Tucker and the Principal Investigator. These sessions will involve reinforcement of core elements of the program, address issues and challenges that arise during the sessions, and allow sharing of success stories.

Should peer leaders face difficulties or suffer a relapse, Sherry Jenkins-Tucker and Dr. Druss will work with the peer leader to develop a treatment plan with their clinician. One of the other peer leaders will lead groups until the consumer is ready to resume leading groups.

IIIC7. Usual Care: Participants in usual care will continue to obtain any mental health or peer-support services that they would otherwise be receiving. While we considered using an active or attention-control comparison group, we chose a usual care group, using principles from the NIH consensus panel on the use of usual care in study design. [76] Most importantly, that there is no current evidence-based standard of medical disease self-management that would otherwise be delivered to the control group.[77]

IIID. Evaluation

IIID1. Overview: The study will use interview and chart review data to examine the intervention's impact on clinical outcomes, self-management, and quality of medical care at three months, six months, and one year after the groups are completed. As with the CDSMP, [28] six-month analyses will be used as the primary timeframe. Three-month assessment will be used to assess shorter term gains after the group sessions and one-year assessment will be used to measure the longer-term sustainability of any changes resulting from the program.

IIID2. Training, study procedures, and quality control for research interviewers: Research interviewers will receive a one-week training program covering the study protocol, interviewing and chart abstraction

techniques, and ethical issues including privacy protection, and subsequently will receive weekly supervision from the Principal Investigator and project director. The project director will oversee three mock interviews to ensure that the interviewer has adequately mastered the materials.

Follow-up interviews and chart reviews will be conducted with the interviewer blinded to participants' randomization status. Interviewers will be asked to note any instances of "unblinding." Sensitivity analyses will be conducted including and not including such unblinded information to assess for the possibility of bias. We have used this approach successfully in our other studies.[62]

Interviewers will receive training and supervision to ensure close tracking of patients after study entry. In the event that a subject cannot be located at follow-up, a range of search strategies will be used including: 1) Social security death index 2) inmate information for local county jails, and prisons along with lists of parolees. 3) White pages reverse address look up 4) County property tax information and 5) paid internet person-search sites (e.g. Choicepoint).

Interview and chart data will be entered in a secured, web-based form with a SQL-based server located at Emory University. A 5% sample of chart reviews will be audited to check on accuracy and completeness.

IIID3. Dependent Variables

IIID3a. Health, Disability and Recovery Outcomes

1. Physical Health Related Quality of Life (HRQOL): The SF-36 is a measure of HRQOL constructed for use in the Medical Outcomes Study. [78, 79] The Physical Component Summary Score is an aggregate measure that combines subscales for physical functioning (both actual activities and ability to perform in roles such as work and school), bodily pain, and general self-reported health. [80] This will be used as the primary study outcome because it is able to capture multiple domains of health and functioning targeted by disease management programs, and is predictive of other distal health outcomes including hospitalization and mortality. In other populations, the 3-point difference in change found in the pilot study, and targeted in the current study, has been associated with a 15% reduction in medical hospitalization, and a 20% increase in 2-year mortality. [56]

It is possible that the intervention will have particular benefits for specific domains of physical HRQOL, and also that it might have benefits for mental health and functioning. Therefore we will also examine the intervention's impact on each of the four subscales that make up the Physical Component Summary Score, the four mental health subscales, and the Mental Component Summary.

2. Disability: The World Health Organization Disability Assessment Schedule II (WHODAS II) assesses day to day functioning in six activity domains. Results provide a profile of functioning across the domains, as well as an overall disability score. [81-84]

3. Recovery: The goals of wellness and health promoted by medical self-management programs are closely related to the notion of recovery, the "ability to live a meaningful life …while striving to achieve his or her full potential." [85, 86] To assess whether this chronic disease program also promotes mental health recovery, we will use the 41-item Recovery Assessment Scale, a well-tested measure of this construct. [87, 88]

IIID3b. Behavioral Activation and Self-Management: The IMB model suggests that the intervention may improve behavioral activation, which will facilitate improved generic and disease-specific self management.

1. Behavioral Activation will be measured using the Patient Activation Measure (PAM), an instrument which has been found to be reliable and valid across a wide range of patient populations.[39] As a secondary measure, we will also include assess mental health-related behavioral activation using a separate survey, the PAM-MH, developed for persons with serious mental disorders. [89]

2. Health behaviors: *Dietary intake* will be Kristal Fat and Fiber Behavior (FFB) scale, a validated 20-item scale assessing behavior related to low-fat eating, [90-92] and the Block Fat-Sugar-Fruit-Vegetable Screener which assesses both frequency and quantity of food intake based on typical eating habits. [93, 94] *Physical Activity* will be assessed with the International Physical Activity Questionnaire (IPAQ), a one-week recall measure of physical activity that includes domains for job-related, transportation, housework and family care, recreation domains, as well as time spent sitting, [95] and the Paffenbarger questionnaire, which quantifies the number of calories people expend per week in sports, leisure, and recreational activities.[96,97]

3. Medication Adherence will be assessed using the Morisky scale, a 4-item questionnaire that has been shown to have strong content and predictive validity in hypertension,[98] cardiovascular disease,[99] and diabetes.[100] Separate indicators will be calculated for each class of medications used to treat hypertension, cardiovascular disease, arthritis, asthma, and with an average value across the three cardiometabolic conditions used as an aggregate measure of adherence.

4. Disease-Specific Self-Management Behaviors: This variable will be calculated as the proportion of disease-specific activities performed for which an individual was eligible. For instance, if a subject has both diabetes and hypertension, the variable would be calculated as the sum of the total number of self-management activities for both conditions performed by that individual. [101] Established measures will be used for measuring arthritis self-management, [102, 103] diabetes self-management, [104 104] hypertension self-management, [105] heart disease self-management, [106] and asthma and [107] COPD self-management.[108] This approach towards aggregating measures is similar to that used for measures of physician-delivered quality of care (see IIID3c).

IIID3c. Quality of Medical Care: Chronic disease self-management programs have been demonstrated to have the potential to improve use of appropriate medical services and decrease use of unnecessary emergency and inpatient services.[109] A self-reported measure of service use developed for the CATIE trial, the Service Utilization and Resources Form (SURF), will be used to track the number of medical and mental emergency room visits, outpatient visits, and hospital days. [110, 111] ER admissions for ambulatory-sensitive conditions, which can be used as a marker for overuse of medical services, [114-117] will be drawn from the list developed by the UCSF-Stanford Evidence-based Practice Center (EPC) for AHRQ. [118]

With subject consent, charts will be requested for all sites in which patients received outpatient services. In previous studies we have been able to obtain approximately 85% of medical and mental health charts for patients in CMHCs.[112] Using these charts, quality for the individual study diseases will be measured using indicators from the RAND Community Quality Index (CQI) study.[101, 113, 114, 115] The quality score for each condition is generated by dividing all instances in which recommended care is delivered by the number of times a participant is eligible for indicator. Quality of preventive care will be assessed indicators from the US Preventive Services Taskforce Guidelines.[65]

IIID3d. Moderators, Mediators, and Confounders

1: Moderator Variables: In general populations, two groups of factors have been found to place populations at risk of poor self-management and health outcomes: social vulnerability factors including lack of an adequate support network and low SES, and medical vulnerability factors, such as problems in obtaining and maintaining appropriate medical services.[40, 41] In keeping with those previous definitions, medical vulnerability will be defined as lack of a report of a usual source of care, and social vulnerability as report of living alone. Second, we will examine cross-site differences in outcomes, comparing the two clinics in poorer, inner-city neighborhoods with those in the middle class, suburban settings.

2. Mediator Variables: The Information Motivation Behavior Model proposes that information and motivation will each be mediators of behavioral activation, which in turn mediates better outcomes. Information will be assessed using a chronic disease knowledge survey that includes questions about diabetes, hypertension, heart disease, and asthma,[116] and a 15-item arthritis knowledge questionnaire. [117] Motivation will be assessed using items from a questionnaire developed and validated in a large community sample which operationalizes this construct using the Theory of Planned Behavior. [37, 38]

3. Confounding Variables: These are variables that are not hypothesized to have a major impact on the intervention effect, but which are important to measure to ensure adequacy of randomization and the generalizability of the sample. These will include sociodemographic characteristics: (age, race, gender), medical comorbidity: measured using the Total Illness Burden Index (TIBI),[118],[119] mental diagnosis using the Mini-International Neuropsychiatric Interview (MINI), [61,120] and substance use using the Alcohol and Drug Composite Problem Indices from the Addiction Severity Index (ASI).[121, 122]

Table 3: Summary of Study Measures and Data Collection

	Screen	Baseline	3-month	6-Month	1-year	Source
Eligibility Measures						
Active patient in CMHC	X					Chart review
Serious Mental Illness	X					Chart review, interview
Chronic Medical Condition	X					Chart review, interview
No Cognitive Impairment (Callahan)	X					Interview
Health Outcomes						
Health Related Quality of Life (SF-36)		X	X	X	X	Interview
Disability (WHODAS)		X	X	X	X	Interview
Recovery (Recovery Assessment Scale)		X	X	X	X	Interview
Behavioral Activation (PAM)		X	X	X	X	Interview
Self-Management						

Disease-Specific Self-Management		X	X	X	X	Interview
Mental Health Activation (PAM-MH)						
Diet (Kristal FFB, Block Screener)		X	X	X	X	Interview
Physical Activity (IPAQ, Paffenbarger)		X	X	X	X	Interview
Medication Adherence (Morisky)		X	X	X	X	Interview
Quality of Medical Care						
Disease-Specific Quality Indicators (CQI)		X	X	X	X	Chart review
Quality of Preventive Services (USPTF)		X	X	X	X	Chart review
Ambulatory Sensitive ER/Hospitalizations		X	X	X	X	Chart Review
Potential Mediating Variables						
Information		X	X	X	X	Interview
Motivation		X	X	X	X	Interview
Potential Moderating Variables						
Medical/Social Vulnerability		X	X	X	X	Interview
Study site		X				Chart Review
Potential Confounding Variables						
Sociodemographics		X				Interview
Medical comorbidity (TIBI)		X				Interview
Mental diagnosis (MINI)		X				Interview
Substance Use (ASI)		X	X	X	X	Interview

PAM=Patient Activation Measure; FFB=Fat and Fiber Behavior; SURF=Services Utilization and Resources Form; MINI=Mini-International Neuropsychiatric Interview; WHODAS World Health Organization Disability Assessment Schedule; ASI= Addiction Severity Index

IIID4. Data Analytic Strategy

IIID4a. Overall analytic strategy: All analyses will be conducted as intent-to-treat. Six-month outcomes will be the primary study endpoints, consistent with previous work using the CDSMP. 3-month outcomes will be used to examine short-term intervention impact and 1-year endpoints will assess the longer-term impact of HARP. The primary analytic technique for assessing differences between the study groups will be random regression (repeated measures GLM), [123] comparing the difference in change between groups over time. Analyses will adjust for site as a random effect, given the goal to generalize to other clinics. These will be conducted using the SAS MIXED procedure for continuous variables and PROC GLIMMIX, which is the preferred procedure for binary and ordinal variables when there are relatively few observations per subject.[124]

IIID4b. Departures from Randomization, Noncompliance, and Loss to Follow-Up:

1. Baseline departures from randomization: Potential confounding variables that differ significantly between the groups at baseline will be included as covariates in subsequent analytic models.

2. Noncompliance/Dropout from Treatment: Although the primary analyses will be conducted as intention-to-treat, we will also conduct a series of analyses to model incomplete group attendance. Partial attendance will be modeled using method-of-moments estimators, which are extensions of econometric instrumental variables techniques.[125, 126] This procedure accounts for compliance status and correlation between compliance status and nonresponse. Treatment assignment is used as an instrument, and analyses are conducted to estimate causal effects.[127] Dr. Peng has experience in using this methodology.

3. Loss to Study Follow-Up/Missing Data: In addition to the strategies described in section IIID2 for optimizing study retention, appropriate analytic techniques will be used to adjust for loss to follow-up. Multiple imputation techniques[128,129] will be used as the initial strategy for handling missing data. In the case that there is evidence that these data do not satisfy the missing-at-random assumption, they will be supplemented with selection models and pattern-mixture models that relax this assumption.[128,130,131]

IIID4c. Hypotheses and Methods for Each of the Specific Aims

H1. As compared with participants referred to usual care, participants in HARP will have greater improvement in physical health-related quality of life, disability, and recovery-based outcomes. The Physical Component Summary (PCS) is scored between 0 (poor health) to 100 (perfect health). The oblique method, which is the preferred approach when examining persons with comorbid physical and mental conditions, [133, 134] will be used to calculate summary scores.[135] Other subscales of the SF-36, the WHODAS, and the Recovery Assessment Scale are also scored as continuous outcomes. Random regression analyses will examine the group*time interaction term for each of these continuous variables to assess statistical significance, adjusted means, and confidence intervals.

H2. As compared with participants referred to usual care, participants in HARP will show greater improvement on validated measures of behavioral activation, and generic and disease-specific self-management and quality of medical care. Patient activation, aggregate disease management, medication compliance, and quality of care are scored as continuous measures; random regression analyses will examine the group*time interaction term for each of these variables to assess statistical significance, adjusted means, and confidence intervals.
H3. Medical or social vulnerability will be associated with greater improvements from HARP in health related quality of life: Moderator analyses make it possible to identify what types of clients benefit most from a given intervention. The approach will follow Kenny et al's method for analyzing moderator effects in randomized trials using random regression. [136] For each moderator of interest we will use the models in H1 and H2 with a group*time*moderator interaction term, the statistical significance of which will allow us to assess the presence of moderation. All appropriate lower-order interactions will also be included in the model.
H4. Information and motivation will each mediate the impact of the intervention on patient activation. Patient activation, will, in turn, mediate the impact of the intervention on health related quality of life Mediation analyses will use adaptations of structural mean models developed by Ten Have. [137, 138] Models will be constructed to examine the relationship between the independent variable (study arm), the outcome (either patient activation or health related quality of life) and each putative mediator (information, motivation or patient activation). Models will determine whether 1. Intervention status is associated with the hypothesized outcome at six months. 2. Intervention status is associated with the hypothesized mediator at three months. 3. Adding the hypothesized mediator at three months in a multivariate model significantly reduces the magnitude of the association between intervention status and the outcome variable. All models will include covariates that are significantly correlated with randomization status, mediating variables, or outcomes at baseline. The Sobel Test, as specified by MacKinnon and Dwyer, [139] will be used to test the statistical significance of the separate impact of each hypothesized mediator on the direct effect of the baseline intervention by comparing adjusted and unadjusted effects of the intervention relative to their standard errors.

IIID4d. Sample Size Calculation: Sample size calculations were conducted using the Power Analysis Statistical Software (PASS). Our goal is to have 80% power to detect a statistically significant difference in the change in outcome over time between the intervention and usual care groups. We assume alpha=.05, two-tailed tests, and a 20% attrition rate over the follow-up period. A final sample of 320 (160 in each treatment arm) will provide 80% power to detect the group*time interaction for the primary study outcome, and for other effect sizes of Cohen's d=0.30.
1.Physical Component Summary Score of the SF-36 (Primary Study Outcome): A final sample of 320 (160 in each treatment arm) will provide 80% power to detect a statistically significant group*time interaction for the effect size seen in the pilot study (Cohen's d=0.30). This equates with an improvement of 3 points on the PCS and is regarded by the developers of the survey as the threshold for a clinically significant effect size.[56]
2. Other Study Outcomes: 1. For patient activation, a sample size of 320 will provide an adequate power to detect a 3-point differential change, found to be associated with significant beneficial changes in screening behaviors and health outcomes.[57] 2. For medication adherence, we anticipate having adequate power to detect a 0.3 difference (Cohen's d of 0.3). 3. For the quality of medical care and quality of self-management we anticipate having 80% power to detect a 10% relative change difference. [112]
3. Mediator analyses: Using methods developed by Fritz and MacKinnon,[140] a final sample of 320 will provide 80% power to detect a significant mediation effect if there is a moderate effect size in the relationship between the intervention and the outcome (e.g. health related quality of life) and a small (t'=.11) remaining direct effect after controlling for patient activation (i.e. partial mediation). This sample size is sufficient to detect the mediated relationship when the association between the intervention and the mediator, and the mediator and outcome are both in the small to moderate range (r^2 =0.14-0.26).
4. Moderator analyses: According to Kenny the estimate of the moderator effects can be viewed as a comparison of Cohen's d across levels of the moderator.[141] This difference is itself a Cohen's d. Our final sample size of 320 will provide power of 80% to detect a moderate effect, or a difference in Cohen's d of d=.3 between levels of the moderator (i.e. d=.2 for group*time on the outcome in the high medical vulnerability group and d=.5 for group*time on the outcome in the low medical vulnerability group).

IV. Dissemination Phase: The final year of the study will be spent on piloting a dissemination strategy that would build on the approach and infrastructure used in the CDSMP. The CDSMP approach is built on a pyramidal workforce approach in which peer educators can become certified as "master trainers," who train other peers as group leaders. This strategy has made it possible to disseminate the CDSMP to 510 different

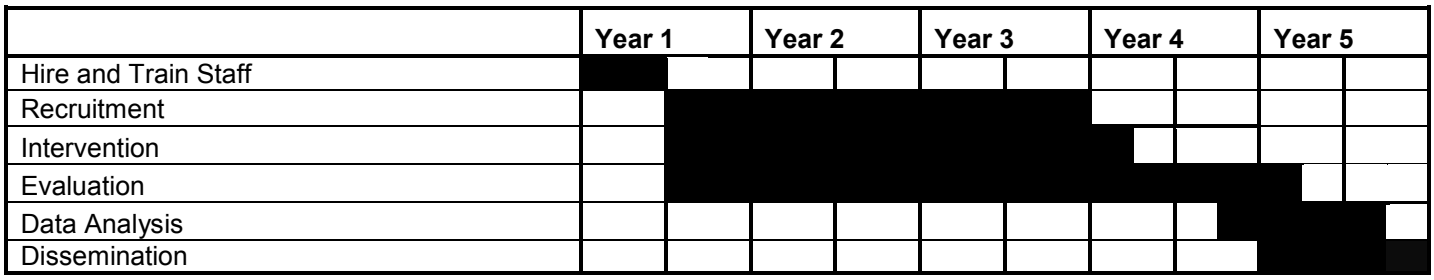
sites in every state of the US and 32 countries across the globe. [59] Because HARP has been designated as an official derivative of the CDSMP, it will be possible to build on the broader CDSMP infrastructure for these dissemination efforts.

During the final year of the project, the three peers who have been administering the intervention will become master trainers through the Stanford CDSMP training program as well as supplemental instruction through the HARP team. The Stanford master training program includes instruction in identifying appropriate peer leaders, core programmatic elements, and maintaining program fidelity. It provides training, direct observation, and feedback on the process of teaching peer educators how to lead groups. This program will be followed by a three-day inservice training program led by the principal investigator and Sherry Jenkins-Tucker, which will focus specifically on helping these new master trainers develop skills to instruct other mental consumer peer educators.

Three subjects who participated in the intervention program will be recontacted by these new master trainers and invited to become peer educators in the dissemination phase. Peers will keep a log of number of groups led and number of members attending each group; sessions will be audiotaped. Data will be collected on engagement, retention, and fidelity to the HARP protocol. Peers will bill for these services through Medicaid or the Department of Mental Health for uninsured clients. Coupled with the effectiveness data from the current study, information on this dissemination pilot will help establish the feasibility of a larger strategy to disseminate HARP broadly within a group mental health peers.

V. Potential Limitations: While we believe the proposed study has a number of strengths, including building on an evidence-based self-management approach, and the potential for sustainability and generalizability, we also recognize several limitations: 1. Diversity of chronic conditions and health behaviors: The proposed program, like the CDSMP, will treat patients with a variety of medical conditions. We recognize that this may reduce the ability to track specific disease-based outcomes. However, this strategy may increase generalizability to public mental health settings. If successful, this may increase the program's reach and adoption more broadly. 2. Focus on Self-Management Rather than Provider or System-Based Approaches: Approaches such as the Chronic Care Model primarily focus on change at the provider/practice level as a strategy for improving illness outcomes.[142] In contrast, the CDSMP and HARP programs focus on improving the determinants of health outcomes that are under a patient's control, including those that occur outside of the formal health system. This latter approach is particularly applicable to programs implemented in community settings and within the peer workforce. These two types of approaches are each critical, and potentially complementary strategies for addressing morbidity and mortality in mental health consumers. 3. Challenges in implementing the program as a fully consumer-based approach: We recognize that having the HARP groups led by mental health consumers is more logistically complex than if groups were led by professional staff such as nurses or dieticians. However, our initial work suggests that this approach is not only feasible, but extremely empowering for participants, and may provide unique benefits in improving activation and self-management.

VI. Timeline: We anticipate that approximately 6 months will be required to hire and train research and peers prior to starting recruitment. The intervention will be sequentially implemented at each of the four study locations. At a rate of 13 participants per month (derived from our experience on the pilot study), recruitment is anticipated to last 30 months, with the interview data complete approximately one-year afterwards. Dissemination activities will occur during the final year of the study.



VII. HUMAN SUBJECTS

This study tests a randomized trial of a medical disease self-management program for mental health consumers. A total of 400 individuals with serious mental illnesses and one or more chronic medical condition (hypertension; heart disease; arthritis; diabetes; or asthma/COPD) will be recruited at four community mental health centers and randomized to HARP or usual care. For individuals in HARP, peer leaders will lead six group sessions focusing on improving medical self-management. Outcome data will be collected at 3-months, 6-months and 12-month intervals after the group program is completed.

VIIA. Protection of Human Subjects

VIIA1. Sources of research material:

VIIA1a. Interviews: Interviews will be conducted at baseline, 3 months, and 12 months after the completion of the intervention. Interviews will be conducted in private rooms where peer groups are led.

VIIA1b. Chart Reviews: After initial consent, CMHC charts and interview will be used for establishing study eligibility. For study participants, medical charts will be obtained for all mental health and medical visits for all study participants. These will be reviewed at baseline and 12-month follow-up, with data entered into a standardized abstraction form.

VIIA2. Plans for Recruitment of Subjects*:* Recruitment for the groups will rotate across the four study sites, with separate sets of groups for subjects at each CMHC. At each study site, weekly one-hour informational sessions will be held at the CMHC. Participants will be notified about these sessions via clinician referrals and waiting room flyers. At these sessions, the project director will outline the overall purpose of the study, and the fact that if they choose to participate they will be assigned randomly to either the intervention or control group. The project director will describe the group format and content of the intervention, as well as the importance of being able to attend the full program to achieve its benefits. Among those interested in participating, subjects will be offered informed consent to participate in the study by the research interviewer on a one-to-one basis.

VIIB. Informed Consent:

A two-stage informed consent process will be used for the randomized trial and the dissemination phase of the study. First, brief written consent will be obtained to participate in the eligibility process, which includes checking the CMHC records for assessing that the subject is on the roster of established patients, and establishing presence of mental (SMI) and medical diagnosis. Potential subjects will be administered a cognitive screener. Next, after eligibility has been established, study participants will be given a full written informed consent for the research study. The senior research interviewer will review the content of the informed consent and emphasize that the study is voluntary and confidential. The senior research interviewer will then ask the study participant to briefly describe what the study is about to establish understanding, and ask if she has any questions prior to asking the study participant to sign the informed consent form.

Informed consent will only occur if and only if a subject with substantial understanding and in absence of control by others. The research staff will be trained to ensure that the individual is competent to act, receives full disclosure, understands the disclosure, acts voluntarily and consents to the intervention. If there are questions with regards to the individual's competence, the research interviewers will contact the PI for guidance.

The informed consent process for the randomized study will include the following: notification that participants will be interviewed four times (baseline, three-month, six-month, and 1-year follow-up); that half of participants (selected at random) will participate in a medical disease self-management program; that groups may be audiotaped; that agreement to participate in the study does not obligate participants to accept any particular treatments; and that participants are free to withdraw from any part of the study (either the intervention program or the follow-up assessments) at any time. After study entry, a separate informed consent form will be administered to obtain permission to obtain chart records. For the dissemination pilot, the informed consent will contain information about the program, but not include the sections about randomization, interviews, or chart reviews.

VIIC. Potential Risks

VIIC1. Acute medical or mental health crisis: It is possible that patients will be found to be in a medical or mental health crisis at the time of screening or that a new problem will emerge sometime during the study. The

exercise class is both extremely low-impact and designed for use in chronically ill populations. However, it is possible that that it could induce discomfort or medical complications. It is also possible that the peer leaders may have a relapse or face other challenges during the study. Mechanisms for addressing these risks are described below in section VIID3a.

VIIC2. Incorrect Medical Information or Advice Given to Participants by Peers: Although no formal medical treatment or medical advice will be provided in the study, it is possible that either peer leaders or fellow group members would give incorrect information to group members. Mechanisms for addressing that potential concern are described in section VIID3b.

VIIC3. Breach of confidentiality: It is essential to monitor and minimize the possibility that the research staff, peer leaders, or other group members might reveal personal or sensitive patient information to medical providers or family members. Section VIID1 describes the training and supervision process and VIID3c discusses methods for keeping such breaches from occurring in either the focus group or the randomized trial.

VIIC4. Subject Burden: Study assessments will always result in an expenditure of time and inconvenience for subjects, as well as the potential for discomfort or embarrassment related to the content of the interview. Section VIID3d discusses mechanisms for minimizing subject burden.

VIID. Adequacy of Protection against Risks:

VIID1. Hiring, Training and supervision of peer leaders

Group leaders will be selected using the same inclusion criteria as group members: 1. History of SMI[60] 2. Current treatment in a community mental health center and 3. one or more chronic medical condition. The Georgia Mental Health Consumer Network, which oversees the training and certification program, will then hire and supervise three part-time peer educators who will lead groups across all 4 sites.

Peer educators will attend a 4 ½-day workshop at the Stanford Patient Education Research Center. After the Stanford training workshop, members of the study team will provide a two-day orientation and training program. The GMHCN will provide additional training in recovery-based treatments and help peers obtain certification and allow them to bill for services. Subsequently, weekly supervision will be provided by the principal investigator and Sherry Jenkins Tucker, the director of the GMHCN, to the peer leaders reinforcing core elements of the program, address issues and challenges that arise during the sessions, and allowing sharing of success stories.

For the dissemination phase of the study, group participants will be invited to train as peer leaders. They will receive training from the CDSMP program, the GMHCN (Sherry Jenkins-Tucker) and the former peer educators (who will have been retrained as master trainers).

VIID2. Training and supervision of the research assistants:

The Principal Investigator will organize a training program including a) an overview of research and ethical issues involved in randomized clinical trials; b) administration of informed consent and c) patient confidentiality (with a focus on recent HIPAA regulations). Classes will be supplemented with the NIH Human Subjects Assurance training and self-test program. The project manager will provide training in chart abstraction and administration of each of the structured interviews, accompanied by reference manuals. The project manager will provide basic training in data entry, data backup, and maintaining patient confidentiality in all entry and storage of data.

The principal investigator and/or project manager will observe the first three instances of each activity conducted by the research assistants: screening interviews and informed consent processes, interviews, and chart reviews. If there are continuing issues at the end of this period, they will continue to observe and provide oversight until they are resolved. Subsequently, weekly supervision meetings will be held with the research assistants, presenting statistics on rates of recruitment, follow-up, and any problems that arise, with periodic in-service lectures about topics such as confidentiality.

VIID3. Protection Against Specific Risks:

VIID3a. Protocol for addressing acute medical or mental health crisis:

In the case that a subject describes any potentially serious symptoms (e.g. chest pain, shortness of breath) in either a group or a study interview, the research assistant or peer leader will immediately contact the principal investigator or project manager. Based on the clinical situation, acuity, and patient preferences, a

decision will be made whether to a. Contact the patient's primary care provider or mental health clinician or b. Call 911 for immediate assistance.

The study subjects are not directly asked about suicidal ideation. However, should subjects raise this concern to one of the research assistants or in a peer group, they will ask the patient to remain onsite after the interview and immediately call Dr. Druss who will establish a plan for follow-up. The plan will typically involve an urgent referral to the client's mental health clinician for further assessment and care, and obtaining consent for the study investigator to speak with that clinician.

VIID3b. Addressing possible relapse of peer leaders:

The peer educators will be closely supervised throughout the study by Dr. Druss and Sherry-Jenkins Tucker, who is the Director of the Georgia Mental Health Consumer Network and the Principal Investigator. Should peer leaders face difficulties or suffer a relapse, Sherry Jenkins-Tucker and Dr. Druss will work with the peer leader to develop a treatment plan with their clinician. One of the other peer leaders will lead groups until the peer is ready to resume work.

VIID3c. Minimizing Risk of Incorrect Medical Information or Advice Given to Participants by Peers: Within the HARP group settings, all information and activities will be given in a highly structured, manualized format. For both these group settings and any contacts with peer leaders or fellow group members outside of the classes, it will be made clear to all participants and group leaders that they that the role of this program is to provide support in disease self-management, but in no way to substitute for clinical care. Should subjects have medical symptoms or questions, they will be encouraged to contact their primary care physicians, since neither peer leaders nor fellow participants are not qualified to provide formal medical advice. This will be specified to all subjects as part of the informed consent process, and in training and supervision of the peer leaders.

VIID3d. Protecting against breach of confidentiality:

VIID3di. Protecting against breach of confidentiality by peer leaders or other group members: All peer leaders will be trained in protection of confidentiality. Each session will begin with a statement that whatever is said during the group session is confidential and not to be discussed outside of the group. Similar instructions will be included for all focus groups.

VIID3dii. Preserving privacy and integrity of data: A web-based, password-protected SQL database will be created and housed on a protected drive on the Emory server. Data will be directly entered into this central database during data collection. Unique identifiers will be generated for all study subjects; these will be the only identifiers used in files used for data entry and analysis. The file linking these identifiers to patient names and addresses will be stored in a separate locked file that will be available only to the principal investigator and project manager.

VIID3e. Minimizing subject burden:

Interviews will be scheduled at a time and location that is as convenient as possible for patients – when possible, prior to or directly after a mental health appointment. Interviews will be conducted in a private, comfortable setting. If a subject appears tired or anxious, the subject will be asked if he or she wishes to rest, take a break, or terminate the interview. Subjects will be paid $20 for each interview to help compensate for time and effort.

The intervention will be scheduled at a time and location that is convenient to participants and does not interfere with work or homemaking activities, typically in the evening. When feasible, group meetings and interviews will be held in the Wellness Center, a home-like, nonclinical setting run by the Georgia Mental Health Consumer network in downtown Decatur that provides recovery classes as well as a respite program. Where this option is not feasible, classes will be held at the mental health center where patients receive their care. Bus and/or subway tokens will be provided to facilitate transportation to the meetings, and refreshments will be provided.

VIIE. Potential Benefits of the Proposed Research Project to the Subjects and Others:

VIIE1. For subjects in the usual care group: During the study period the usual care group will not receive any benefits from the program other than compensation for time completing interviews. After the initial study period and during the dissemination phase, they may have the opportunity to participate in the intervention.
VIIE2. For subjects in the intervention group: Subjects participating in the intervention group are expected

to directly benefit from the intervention. As described in the body of the proposal, we anticipate that the intervention may improve medical self-management and health outcomes.
VIIE3. For other persons treated in public safety net settings: The study's results are hoped to inform the development of peer-based medical disease management strategies. Strategies described in section V will be used to disseminate the results of the study to help obtain the broadest possible reach.
VIIE4. Risk-Benefit Ratio: Given the protections to ensure confidentiality, ensure high quality of the intervention, and minimize subject burden, and the benefits for patients in the active treatment group, we anticipate a favorable risk-benefit ratio for the project.

VIIF. Data Safety and Monitoring Plan:
VIIF1. Responsibility, Frequency, and Content of Data Safety Monitoring: The Principal Investigator will be involved in all aspects of the research and will be responsible for monitoring all data. The PI will review safety data on a monthly basis during the course of the study.
VIIF2. Adverse Event Reporting: Adverse events data will come from two sources: 1) Patient reports to study staff and 2) Chart reviews. Any deaths will be reported upon discovery to the IRB. All other study-related serious adverse events will be reported immediately to the Emory IRB.

VIIG: Women and Minority Inclusion

TARGETED/PLANNED ENROLLMENT FOR RANDOMIZED TRIAL: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	5	5	10
Not Hispanic or Latino	201	189	390
Ethnic Category Total of all Subjects	206	194	400
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	3	2	5
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	163	153	316
Hispanic or Latino	5	5	10
White	35	34	69
Other	0	0	0
Racial Categories: Total of All Subjects	206	194	400

VIIG1. Inclusion of Women Women will be included in the enrollment process and we expect them to be well-represented based on the characteristics of the CMHCs from which they are recruited.

VIIG2. Inclusion of Minorities Minority groups are well-represented in the mental health centers, and will be included based on their representation in that population.

VIIG3. Inclusion of Children
Because children under age 18 have different health problems and needs from adults, they would not easily be integrated into the broader intervention, and hence will not be included in intervention. Approximately 5% of patients at the four CMHCs are between the ages of 18 and 20, and thus are considered children under NIH guidelines. The CDSMP intervention and study instruments have been validated in the age group (i.e. age

18 and older). Therefore, individuals age 18-20 will be included in the study, and there is no reason to expect that special accommodations will be needed for the group.

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