SOCIAL, BEHAVIORAL, and NON-CLINICAL RESEARCH PLAN

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Comparing Integrated Illness Management and Recovery to the Stanford Chronic Disease Self-Management Program in People with Serious Mental Illness

1. Introduction and Background

People with serious mental illness (SMI), including schizophrenia, schizoaffective disorder, bipolar disorder and chronic depression comprise up to 4-6% of the population[1] and experience one of the nation's greatest health disparities with a life expectancy that is 11-30 years shorter than the general population.[2-5] This alarming health disparity is largely due to disproportionately high rates of cardiovascular disease, diabetes, chronic obstructive pulmonary disease, obesity, and tobacco use.[6] In 2007, consumer advocates, federal agencies, provider organizations, and researchers (including Stephen Bartels, Co-PI for this proposal) came together to launch the "10x10 Campaign", with the goal to "*increase the life expectancy of people with serious mental illness by 10 years in 10 years.*"[7] *A decade later it is tragically clear that we have collectively failed to deliver on this commitment to consumers and their families*. Although substantial progress has been made in developing evidence-based practices to improve health outcomes for people with SMI[8-15], *there has been little change in the high rates of chronic health conditions, excess disability, and early mortality*.[16-19] In response to this major health disparity, a national demonstration program by the Substance Abuse and Mental Health Administration (SAMHSA) supported broad dissemination of "behavioral health homes" for people with SMI. This initiative has resulted in increased rates of screening and treatment of chronic disease, but has not significantly improved key health outcomes [16,18,20]. It has become clear that improving screening and access to primary care is necessary, *but not sufficient* to substantively improve health outcomes and the life expectancy of people with SMI. Consumer advocates, provider organizations, policymakers, and researchers now concur that **illness self-management** programs are essential to improving health outcomes and in reducing early mortality risk for people with SMI. As a reflection of this clear consensus on the critical role of self-management, SAMHSA now requires that mental health providers offer self-management programs as a core component of all behavioral health homes.

The proposed study will be the first to compare two commonly used but substantially different, evidence-based self-management interventions. **Integrated Illness Management and Recovery (I-IMR)**[9,11] is an individually-tailored, 16-session, integrated program combining **both *physical and mental health self-management*** specifically developed for people with SMI. In contrast, the **Stanford Chronic Disease Self-Management Program (CDSMP)**[21,22] is a group-based, 6-session, chronic

disease self-management program largely focused on ***physical health self-management*** **alone**. I-IMR is delivered by community mental health providers or by community outreach workers, while CDSMP is co-delivered by two peers or by a health professional and a peer. Both programs have been widely recommended, disseminated, and used.

While life expectancy for the general population has increased each decade since the 1970s, numerous studies across the US have shown that it has *decreased* for those with SMI,[19] standing at an alarming **11 to 30 years less for people with SMI** such as schizophrenia, bipolar disorder, or chronic depression.[3-5] This represents one of the greatest health disparities in the nation. The prevalence of chronic illness in people with SMI dramatically exceeds that of the general population, including cardiovascular disease,[4,6,23] diabetes, chronic obstructive pulmonary disease, and other diseases.[6,24-30] Cardiovascular disease is the major cause of early mortality for this high-risk group, due to high rates of obesity, diabetes, hypertension, sedentary behavior, poor nutrition, and smoking. SMI is not only devastating for individuals and families, through its impact on functioning, productivity, and early mortality, it also exerts considerable burden on the US population and economy. People with SMI and medical comorbidity have costs that are 2-3 times greater than those of people with medical illness alone.[31,32] The greater incidence of medical comorbidity,[4,6,23-30,33] early mortality,[2-5] and disproportionately high costs among people with SMI make this group a major priority for developing and disseminating effective and sustainable models of integrated Illness self-management. Knowledge generated from studies of people with SMI may also inform initiatives directed at other challenging, health disparity populations.

This population and their social vulnerabilities also place them at disproportionate risk for COVID-19 acquisition, morbidity, and mortality.[117-118] Many social vulnerabilities[119] also increase risk of negative COVID-19 outcomes, including poverty, homelessness, and residence in congregate and transitional group homes, emergency shelters, and long-term care facilities where viral transmission has happened rapidly. Without specific training on COVID-19, these vulnerabilities will continue to be a source of unchecked community transmission that will have larger societal impacts.

We received funding to develop and evaluate the effectiveness of a 3-session I-IMR module to provide specific training on how to prevent contracting and spreading COVID-19 and other acute viral infectious diseases that may arise in the future and will similarly require: 1) knowledge and enactment of measures to maximize personal and societal safety (e.g., safely acquiring food, paying bills, accessing healthcare and COVID-related resources), 2) use of illness self-management behaviors to reduce risk of contracting and spreading illness, and 3) methods for addressing social determinants of health (e.g., maintaining social connection while ensuring physical distancing).

This component of the project will involve: 1) an initial needs assessment that will inform the refinement and specification of the training materials in the 3-session I-IMR COVID-19 and viral infectious disease module, 2) delivery of the module in phone or video-based sessions with a clinician trained in I-IMR, and 3) evaluation of the impact of the module on key outcomes. I-IMR participants will receive this 3-session module, which will be individually-delivered by phone or video (e.g., secure Zoom) to 75 participants (current and future participants assigned to I-IMR). We are not at liberty to add training on infectious viral diseases to CDSMP because this is not our intervention. The CDSMP participants are essential to the study as they serve as the comparison group, preserving the comparative effectiveness design, as required by PCORI.

2. Objectives and Hypotheses

This study will compare two commonly used but substantially different, evidence-based self-management interventions. **Integrated Illness Management and Recovery (I-IMR)**[9,11] is an individually-tailored, 16-session, integrated program combining **both *physical and mental health self-management*** specifically developed for people with SMI. In contrast, the **Stanford Chronic Disease Self-Management Program (CDSMP)**[21,22] is a group-based, 6-session, chronic disease self-management program largely focused on ***physical health self-management*** **alone**. I-IMR is delivered by community mental health providers or by community outreach workers, while CDSMP is co-delivered by two peers or by a health professional and a peer.

In response to the COVID 19 pandemic, starting on March 13, 2020, we pivoted in-person delivery of all study group interventions and assessments to phone or video conference (Zoom). Beginning in July 2021, one of our sites (TN) will resume in-person services, so groups will revert to in-person (with remote assessments continuing for the time being). The other site has no established timeline for resuming in-person services, but we anticipate this happening at some point in the future, before the end of the study period. Given the unpredictable nature of the pandemic and our established experience and procedures for delivering the groups and assessments in-person or remotely, we plan to include language in the consent form explaining that the mode of delivery will depend on the status of the pandemic and whether services are being provided remotely or in-person. This will allow us to nimbly shift between remote and in-person as needed when and if abrupt changes related to the pandemic occur at the study sites, thus minimizing any interruption in delivery of study activities. For remote groups, participants will receive the intervention handouts in advance by mail so that they can read from and refer to them as they would during an in-person session. They will also receive a handout with instructions for successfully participating in research assessments and joining groups remotely. The same group leaders trained to deliver the interventions in person will deliver them remotely. Supervisors at Dartmouth will review video-recordings of remote groups whereas in-person groups will be audiotaped only for fidelity monitoring purposes.

The proposed study will randomize people with serious mental illness to I-IMR (n=300) and CDSMP (n=300) to address the following four specific aims and hypotheses**:**

Aim 1: Compare the effectiveness of I-IMR to CDSMP with respect to our primary ***physical health self-management outcomes***.

Hypothesis 1: I-IMR compared to CDSMP will be associated with greater improvements in **physical health self-management *abilities*** (Self-Rated Abilities for Health Practices scale; SRAHP, and a qualitative interview) and ***physical health consumer activation*** (Patient Activation Measure; PAM); and (secondary hypothesis) greater improvement in self-reported physical health functioning (PROMIS Global Health measure).

Aim 2: Compare the effectiveness of I-IMR to CDSMP with respect to our primary ***mental health self-management outcomes***.

Hypothesis 2: I-IMR compared to CDSMP will be associated with greater improvements in **mental health self-management *abilities*** (Illness Management and Recovery Scale; IMRS, and a qualitative interview); and ***mental health consumer activation*** (PAM-MH); and (secondary hypothesis) greater improvement in self-reported mental health (PROMIS Global Health measure).

Aim 3: Compare the effectiveness of I-IMR to CDSMP with respect to ***emergency room and acute care hospital days,*** and risk of ***10-year cardiovascular mortality***.

Hypothesis 3: Participation in I-IMR compared to CDSMP will be associated with fewer emergency room admissions and acute care hospital days over 12 months compared to the 12 months before participation; and greater reduction in 10-year cardiovascular risk score (ACC/AHA Cardiovascular Risk Score) from baseline to 12 months.

Aim 4: Compare I-IMR to CDSMP with respect to subgroup differences in self-management outcomes by ***mental illness subgroup*** (schizophrenia-spectrum vs. mood disorders) and by ***age group*** (18-49 vs. 50+).
Hypothesis 4: Comparing I-IMR and CDSMP, the difference in treatment effects will be greater for people with schizophrenia spectrum disorders compared to mood disorders; and greater for older (age 50+) compared to younger (18-49) participants with respect to: ***physical health*** **self-management** ***abilities and activation*** (SRAHP; PAM); ***mental health*** **self-management** ***abilities and activation*** (IMRS; PAM-MH); and 10-year ***cardiovascular risk reduction*** (ACC/AHA Cardiovascular Risk Score).

COVID-19 Enhancement Primary Aim: After co-design of the 3-session I-IMR module, we will evaluate the impact of the module by comparing participants assigned to I-IMR (n=75) to participants assigned to CDSMP (n=75) on the primary and secondary outcomes (**primary**: knowledge and use of measures to prevent contracting and spreading COVID-19; **secondary**: use of healthcare services for COVID-related concerns; perceived isolation and social disconnectedness).

Primary Hypothesis: I-IMR participants will demonstrate greater improvements in their scores on the primary outcome measure (a measure of knowledge and behaviors to prevent contracting and spreading COVID-19 developed for this project) compared to CDSMP participants.

Secondary Hypothesis: I-IMR compared to CDSMP participants will demonstrate less COVID-related health care service use and greater improvements in social connectedness.

Exploratory Aim: Explore differential response with respect to race/ethnicity (Black versus White adults); age (older versus younger adults); and psychiatric diagnosis (schizophrenia-spectrum vs. mood disorders).
Exploratory Hypothesis: Effect sizes for the I-IMR module versus generic support calls alone will be even greater among Blacks v. Whites, older (55+) v. younger adults, and people with schizophrenia-spectrum v. mood disorders.

3. Study Design

The proposed study is to compare I-IMR and CDSMP in improving outcomes of importance to the target population of people with SMI: optimizing personal physical and mental health, being an active agent in determining personal physical and mental health wellness goals, decreasing risk of early mortality, and minimizing use of the ER and hospitals. A secondary objective is to learn whether psychiatric diagnosis and/or age interacts with treatment, specifically, whether treatment effects vary more for participants with schizophrenia or older age. Consistent with a truly pragmatic trial, inclusion criteria are broad and exclusion criteria are limited. Participants will be randomized, stratified by diagnosis (schizophrenia spectrum vs. mood disorder) and age group (age 18-49 vs. age 50+). Intervention fidelity will be measured but not controlled; likewise, participant engagement will be measured but not required. The interventions will be delivered by community providers as part of routine services at Centerstone TN and Seven Counties Services in Kentucky to maximize generalizability of findings. Mixed quantitative and qualitative methods will be used to assess outcomes. Trained raters will administer in-person assessments at baseline, 4, 8, and 12 months. A sub-sample of participants will be invited to participate in a qualitative interview to describe their treatment experience. Temporarily, during the COVID-19 pandemic, the assessments will be conducted by telephone instead of in person. Participants due for assessments will receive a packet of the response options that are normally presented to them during the assessments and instructions for phone-based interviews. Research staff will mail them a gift card (instead of cash) when they complete their assessments.

Study participants will be 600 adults age 18+ with SMI (diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, chronic depression with moderate impairment in functioning, PTSD, and/or other serious anxiety disorders (e.g., Generalized Anxiety Disorder, OCD, Panic Disorder, Agoraphobia, etc.) receiving services at Centerstone (TN) and Seven Counties Services (KY) who reflect the racial, cultural, linguistic, and ethnic diversity of people with SMI in this agency. The race/ethnicity of consumers is as follows: White: 61%, Black: 30%, Hispanic: 3%, Other: 6%; 95% English speaking; and 52% Female. Eligibility for the study also includes: diagnosis of a chronic medical condition increasing risk of early mortality from cardiovascular or respiratory disease or diabetes, hyperlipidemia, hypertension, COPD [including emphysema], asthma, coronary artery disease, heart failure, tobacco dependence, obesity), chronic pain, and at least 1 ER visit or hospitalization within the past year (and/or 3 or more unscheduled outpatient visits) or judgment by the treatment team of substantial need for illness self-management training. Consumers who do not speak English will be excluded for logistical reasons. Consumers with either no, or a well-controlled medical condition will not be included. Individuals residing in a nursing home or other institution will be excluded given the focus on independent management of illness. Because I-IMR and CDSMP involve learning new skills, individuals with a chart diagnosis of dementia, or evidence of significant cognitive impairment as indicated by the Saint Louis University Mental Status Examination[73] score <20, will be excluded. Temporarily, during the COVID-19 pandemic, we will use the Telephone Interview for Cognitive Status (TICS)[120] because the SLUMS cannot be administered over the phone.

In addition we will conduct an implementation assessment using the Consolidated Framework for Implementation Research (CFIR) to specify types of determinants that influence implementation outcomes of program acceptance, fidelity, adherence, and sustainability. The CFIR is composed of five major domains: Intervention Characteristics, Outer Setting, Inner Setting, Characteristics of Individuals, and Process.[116] Our research team will conduct semi-structured interviews with stakeholders critical to the implementation of the CDSMP and I-IMR interventions in order to understand factors influencing implementation. These interviews will be either by phone or in-person at baseline, close to the beginning of the implementation of the study interventions. The baseline assessment in KY occurred in November 2019. The baseline assessment in TN was scheduled to occur in late January or early February, 2020, but IRB delays have prevented scheduling until April or May 2020. Subsequent assessments will be at six month intervals.

Since a highly novel aspect of our CER proposal is the comparison of two evidence-based interventions delivered by either peers (i.e., CDSMP) or providers (I-IMR), our assessment will explore differences in implementation that may be influenced by these intervention characteristics. For example, we will inquire about interventionists' knowledge and beliefs about the intervention, belief in their ability to deliver the intervention protocol, and the interventionists' identification within the organization. The CFIR evaluation will also examine the agency's capacity for and implementation of training and ongoing supervision in the implementation of the intervention for peers and providers.

We will also explore potential differences in the extent to which participants form positive peer networks with other participants by intervention type (peer delivered vs. professional delivered programs). Dr. Kelly Aschbrenner, an experienced implementation scientist and long-time collaborator with both study PIs, will lead a mixed methods evaluation of potential determinants of implementation outcomes with data collected through telephone interviews and online survey assessments with program staff and agency leadership every 6 months while the interventions are being delivered as part of the study. The CFIR-based analysis will examine the relationship between factors in a number of domains and implementation outcomes. She will be assisted by a half-time research assistant, who will help with administration of surveys and will take copious notes critical to

the evaluation and coding of information provided in semi-structured interviews.

The Needs Assessment required as part of the COVID-related component of the project involves qualitative interviews by research staff with 10 clinical staff who work directly with clients, and 20 participants who have already enrolled in I'M Well. The Site Coordinators and Site PIs at each site will meet to select staff who work most closely with service users and therefore are in the best position to comment on how they are handling the COVID-19 pandemic and what they need at this time. The Site Coordinators will identify participants for the needs assessment, which will be conducted by members of the PI's research team (including review of an information sheet describing the interview and process), and will coordinate the appointments and arrange for them to be audiotaped to permit evaluation of themes. We could have used an approach in which each person would have an equal chance to participate using randomly generated numbers. However, this could have resulted in an imbalanced group (for example, mostly white males). We felt it was essential to hear a wide range of perspectives, from participants who reflect the characteristics of the broader study population. For example, we wanted to be sure to include equal numbers of males and females, equal numbers of CDSMP and I-IMR participants, participants from a diverse set of racial and ethnic backgrounds, older and younger people. Therefore, the Study Coordinators will work to ensure that the individuals who will be invited are a diverse group. Site Coordinators will also provide the compensation for the interviews ($50 VISA card for participants, $25 restaurant gift card for staff).

These interviews will inform development of the curriculum for the 3-session I-IMR module on COVID-19 and other viral diseases. This component of the project will also involve development of the primary outcome measure, given that no appropriate measure of COVID-19 knowledge and use of behaviors to avoid catching and spreading disease was available. After finalizing the curriculum for the 3-session I-IMR module, interventionists will be trained to deliver it by phone or video. We will record the sessions to permit supervision and fidelity assessment by the co-developers of I-IMR. All participants have already consented to audiotaping or videotaping of IIMR sessions. Research staff will conduct baseline, 6- and 12-week assessments by phone with all participants (75 I-IMR and 75 CDSMP participants). (Site Coordinators will first complete informed consent to participate in this project, by phone using the procedure described below). We will work with the statisticians from the I'M Well project to complete data analyses.

Site Coordinators will contact individuals who have been randomized to I-IMR and CDSMP to invite them to participate in this component of the project. I-IMR group participants will be offered the 3 session I-IMR module and asked to participate in a phone-based assessment no more than one week prior to receiving the intervention (baseline), a second assessment no more than two weeks after completing the 3 sessions (6 week assessment), and a third assessment approximately 12 weeks after receiving the last session of the module (12 week assessment). CDSMP group participants are receiving usual care, which includes generic supportive telephone calls from agency staff. They will be asked to participate in phone-based assessments on the same schedule as the I-IMR participants. For both groups (I-IMR & CDSMP), Site Coordinators will call participants to review a description of the project in the consent form. Consent to participate will be obtained by phone.

Interventions to be Compared

IIMR (Integrated Illness Management and Recovery vs. CDSMP (Stanford Chronic Disease Self-Management Program)

Overview of Integrated Illness Management and Recovery (I-IMR): I-IMR combines 4 evidence-based psychosocial interventions for SMI: (1) *psychoeducation*, which improves knowledge about

mental illness management,[43-45] (2) *behavioral tailoring*, which improves medication adherence,[46-49] (3) *relapse prevention training*, which decreases relapses and rehospitalizations,[50-55] and (4) *coping skills training*, which reduces distress related to symptoms.[56-61] **Integrated Illness Management and Recovery** (I-IMR) was developed by integrating *chronic medical illness self-management* with psychiatric illness self-management.[9,11] Currently, I-IMR is available in mental health agencies in New York, Massachusetts, New Hampshire, Minnesota, Maryland, Illinois, California, and Indiana.

The I-IMR curriculum topics are shown in Table 1 below.

Table 1: Integrated Illness Self-Management and Recovery Curriculum

Module Topics	Description of Content
Module 1: Recovery Strategies	Developing personal recovery goals and strategies
Module 2: The Brain-Body Connection	Understanding the relationship between physical and mental health
Module 3: Practical Facts About Mental and Physical Health Conditions	Fact sheets with education about the cause and course of illnesses
Module 4: Healthy Lifestyles	The impact of exercise, eating, sleep, and tobacco smoking on mental and physical health
Module 5: Using Medications Effectively	Education on medical and psychiatric medications (side effects, adherence strategies, etc.)
Module 6: Social Support for Illness Self-Management	Engaging significant others for medical and psychiatric illness self-management support
Module 7: Managing Stress	Learning strategies to manage stress to reduce its impact on medical and mental health
Module 8: Managing Persistent Physical and Mental Health Symptoms	The interaction of persistent physical and mental health symptoms and how to cope
Module 9: Relapse Prevention Planning	Identifying early warning signs of physical and mental illness and making an action plan
Module 10: Getting Your Needs Met in the Health Care System	Finding and communicating with health care providers, responding to health emergencies
Supplemental Module: Alcohol and Substance Use	The impact of alcohol and illicit substances on medical and psychiatric illness management

Overview of the Stanford Chronic Disease Self-Management Program (CDSMP): CDSMP is a 6-session group-based educational program co-delivered by two peers (lay people who have successfully managed a chronic illness) or a peer and a medical professional.[21,22] This 6-week program covers techniques for dealing with problems such as: frustration, fatigue, pain and isolation; appropriate exercise for maintaining and improving strength, flexibility and endurance; appropriate use of medications; communicating effectively with family, friends and health professionals; nutrition; and evaluating new treatments (see Table 2). A meta-analysis of 23 studies of the CDSMP program *in general populations* conducted by the Centers for Disease Control and Prevention in 2013 found 4-6 month improvements in energy, fatigue, self-rated health, aerobic exercise, cognitive symptom management, psychological health, communication with physicians, and health care utilization.[62] CDSMP is currently offered in over 45 states and over 19 countries.

-Identifying Common Problems	-Problem Solving	-Making Informed Treatment Decisions
-Differences between Acute and Chronic Illnesses	-Better Breathing	-Depression Management
	-Pain and Fatigue Management	-Positive Thinking
-Using Your Mind to Manage Symptoms	-Endurance Activities	-Guided Imagery
-Making an Action Plan	-Future Plans for Health Care	-Working with Your Health Care Professional
-Dealing with Difficult Emotions	-Healthy Eating Communications Skills	-Looking Back and Planning for the Future
-Intro to Physical Activity and Exercise	-Medication Usage	

Table 2: The Stanford Chronic Disease Self-Management (CDSMP) Curriculum

4. Analysis

Evaluation of Group Equivalence.

Subgroup analysis for treatment effects (i.e., estimate of the treatment effect for each subgroup) is a common approach for HTE analysis. However, this approach is susceptible to the issue of multiple post hoc analyses. We have a total of 20 subgroup analyses (5 outcome measures by 4 subgroups), thus we will adjust the p-value to account for multiple tests for each subgroup analysis and use the false discovery rate method[90] implemented in SAS software.[91] Subgroup analysis may increase the

likelihood of Type II error due to small sample sizes. Therefore, we will not rely on statistical tests and p-values alone to evaluate HTE; we will rely on estimated effect sizes (estimate divided by the standard deviation) and compute confidence intervals around these effect sizes.

Evaluation of Attrition

We will recruit 600 participants and randomly assign them to two arms with equal allocation (300 per arm). Based on previous experience, we assumed 20% attrition by 12 months. In addition to enhancing the process of full informed consent, these procedures are designed to decrease the likelihood of study attrition due to inadequate appreciation of the time, effort, and component activities involved in participating in the intervention program, or in the study protocol.

Analyses for Primary Study Aims and Hypotheses

Analysis for Aim 1: All analysis will be conducted on the full sample regardless of exposure to treatment (intent to treat). Our **primary hypothesis** in **Aim 1** is that I-IMR compared to CDSMP will be associated with greater improvements in physical health self-management abilities (Self-Rated Abilities for Health Practices) and physical health consumer activation (Patient Activation Measure). To test this hypothesis, we will fit generalized linear mixed-effects linear models (GLMM) with identity link functions and normal distribution specification. Treatment arm (I-IMR and vs. CDSMP), time (baseline, 4-, 8- and 12-month), and arm-by-time interactions will be specified as fixed effects. Intercept and time will be specified as random effects to take the correlated nature of the data resulting from repeated measures into account. The primary hypothesis of interest will be examined by testing if the arm-by-time interaction effect (difference in rate of improvement over 12 month) is significantly different from zero. Our **secondary hypothesis** is that I-IMR compared to CDSMP will have greater improvement in self-reported physical health functioning (PROMIS Global Health Measure). The same GLMM model will be used to test this hypothesis. Qualitative data for Aims 1 and 2 will be audio-recorded, de-identified and transcribed, and analyzed with ATLAS.ti using the "grounded theory" approach.[85] The Research Support Team will read data and develop operational definitions from transcript coding, a validated approach which allows for multiple perspectives.[85] Codes will be assigned to text, grouped, and checked for themes. The codebook will consist of *a priori* researcher-driven codes, derived from interviews and inductively derived codes from qualitative data.[85] Analyses will assess within group consensus or disagreement. Member checking will be employed to validate qualitative results and resolve any incongruent findings.

Analysis for Aim 2: Our **primary hypothesis for Aim 2 is that** I-IMR compared to CDSMP will be associated with greater improvements in **mental health self-management *abilities*** (Illness Management and Recovery Scale[80]); and ***mental health consumer activation*** (Patient-Activation Measure-MH[81]); and our **secondary hypothesis** is that I-IMR compared to CDSMP will be associated with greater improvements in self-reported mental health functioning (PROMIS Global Health Measure[79]). We will use the same GLMM approach to test primary and secondary hypotheses for Aim 2.

Analysis for Aim 3: We hypothesized that (1) participation in I-IMR compared to CDSMP will result in greater reductions in emergency room (ER) visits and acute care hospital days compared to the 12 months before participation; and (2) greater reduction in 10-year cardiovascular mortality risk (ACC/AHA Cardiovascular Risk Score[82]) over 12 months. To test **Aim 3** (1), we will compute the total number of ER visits and hospital days 12-months before intervention, and 12-months after intervention, and fit the same generalized linear mixed model (GLMM) but with log link function and Poisson, or negative binomial or zero-inflated distribution (depending on model fit) because the

outcomes are counts and are likely to be skewed with a cluster of zero values.[86] The arm, time (before vs. after) and arm*time interaction will be included as fixed effects, and the superiority hypothesis of I-IMR compared to CDSMP will be tested with the significance of the interaction term. For this analysis, because we cannot ensure covariates are balanced between two arms 12-months before randomization, we will test group (arm) balance with respect to demographic and clinical covariates. Depending on the number of imbalances we find, we will either include covariates in the model or use propensity score adjustment with inverse probability weighting to balance the groups.

The same GLMM model will be used to test **Aim 3** (2), and the same fixed effects, intervention arm, time and arm*time interaction will be included in the model, but the time variable has four assessment points (baseline, 4-, 8- and 12-month), not two points. Thus, the outcome, 10-year cardiovascular mortality risk (ACC/AHA Cardiovascular Risk Score[82]) is a proportion/percent, which is a continuous variable with limited range. The identity link function and normal distribution will be specified for this outcome. However, if outcome data does not include the lower and upper limits (0 and 1), the logit link function and beta distribution[87] will be specified because beta regression is more appropriate for percent and proportion outcomes within the 0-1 range.

Analysis for Aim 4: In **Aim 4,** we compare I-IMR to CDSMP with respect to subgroup differences in self-management outcomes by ***mental illness subgroup*** (schizophrenia-spectrum vs. mood disorders) and by ***age*** (18-49 vs. 50+) based on our belief that greater cognitive limitations and comorbid health conditions may require more intensive and specialized self-management training consistent with I-IMR. We hypothesize that when comparing I-IMR and CDSMP, the difference in treatment effects will be greater for schizophrenia spectrum disorders compared to mood disorders; and greater for older (age 50+) compared to younger (age 18-49) participants with respect to: ***physical health*** **self-management** ***abilities and activation***; ***mental health*** **self-management** ***abilities and activation*** and 10-year ***cardiovascular mortality risk reduction***. In this aim, we examine heterogeneity of treatment effects (HTE) using subgroup analyses. Because we pre-specified the 2 subgroups (diagnosis and age) and hypothesized the differential treatment effect between subgroups based on the literature, our approach is confirmatory (hypothesis driven) HTE analysis. To test HTE, we will use the same analytic models, GLMM for **Aim 1**, **Aim 2** and **Aim 3**, but we will include 3-way interaction terms (arm*time*group) in each model. A significant 3-way interaction effect will indicate the existence of the heterogeneity of treatment effects between subgroups. Following this step, we will conduct simple effect analysis to estimate treatment effect differences (a difference in slopes by time effect between arms) within each subgroup. Although our HTE analysis is hypothesis driven, we will report p-values for hypothesis testing for all subgroup analyses. We will also evaluate HTE by examining the magnitude of treatment effects with standard errors (clinically meaningful effect sizes) as outlined in PCORI Methodology Standards[88] and recommended by statisticians.[89]

COVID Component Analyses: The primary outcome is a measure we will create, based in part on a large (n=6000) online survey of knowledge and use of measures to prevent contracting and spreading COVID-19 that was conducted in April in both the US and the UK. This will be measured at baseline, 6- and 12-weeks. Covariance pattern modelling will be used for the analysis, with group (intervention vs. comparison), time (baseline, 6- and 12 weeks) and group*time interaction included in the model, and variance-covariance parameters fully estimated to account for within-subject correlation over time. A significant group*time interaction will indicate superiority of I-IMR over CDSMP. In addition to the measures used to evaluate the primary and secondary aims, we will also administer the PHQ-9,[121] the GAD-7,[122] and the Fear of COVID Scale[123] to assess depression, anxiety, and fear of COVID as potential co-variates in the analyses.

Power analysis: The primary outcome is continuous, thus power analysis will be based on a linear mixed model. With n=150 (75 per arm), 3 assessments, assuming 10% attrition, within-subject correlation of 0.05, 2-tailed test with alpha = 0.05, the study has 80% power to detect an effect size of 0.46, between small (0.2) and medium (0.5).

Quantitative Assessment Measures

Table 1. Study Measures

Aim 1: Physical Illness Self- Management and Activation	**Instrument**	Baseline	8 wks	4 mo.	8 mo.	12 mo.
Medical Illness Self- Management	Self-Rated Abilities for Health Practices[77]	✓		✓	✓	✓
Consumer Activation	Patient Activation Measure (PAM)[78]	✓		✓	✓	✓
Self-Reported Physical Health Functioning	PROMIS Global Health measure[79]	✓		✓	✓	✓
Social Functioning Scale	Social Functioning Scale[114]	✓		✓	✓	✓
Aim 2: Mental Health Self-Management and Activation						
Psychiatric Illness Self- Management	Illness Management and Recovery Scale[80]	✓		✓	✓	✓
Consumer Activation	Patient Activation Measure - Mental Health[81]	✓		✓	✓	✓
Self-Reported Mental Health Functioning	PROMIS Global Health measure[79]	✓		✓	✓	✓
Aim 3: Service Use and Mortality Risk						
Mortality Risk	ACC/AHA Cardiovascular Risk Score[82]	✓		✓	✓	✓
Service Use	Number of Hospital Days and ER visits and Cornell Service Index	✓		✓	✓	✓
Carbon Monoxide Level	CO Analyzer PICO+[115]	✓		✓	✓	✓
Satisfaction Survey			✓			

Table 2. COVID-Related Component Assessment Schedule

Aim 1:	**Instrument**	Baseline		6 wk	12 wk
Knowledge and use of measures to prevent catching and spreading virus	Measure to be developed as part of project	✓		✓	✓
Aim 2:					
Use of healthcare for COVID-related issues	Self-reported service use and record review	✓		✓	✓
Social determinants of health	UCLA Loneliness Scale[124]	✓		✓	✓
	Lubben Social Network Scale-6[125]	✓		✓	✓
	Social Connectedness (items developed for this project)	✓	✓	✓	✓

5. Study Progress Monitoring

Upon completion of trainings, promotion and recruitment will begin at both Seven Counties Kentucky and Centerstone Tennessee. Theresa Watson and Ruchita Agrawal, the site PIs in Kentucky, will facilitate the research team's access to the clinical treatment teams at Seven Counties Kentucky to identify potentially eligible participants and Dr. Schut will facilitate access at Centerstone Tennessee. In addition, the Site PIs will ensure that the research staff have access to information needed in the electronic medical record to efficiently screen potential participants. Both Site PIs will participate in the weekly project meetings with Dartmouth to discuss pre-implementation and implementation tasks as well as dissemination of outcomes for the project. Dr. Agrawal, Theresa Watson, and Dr. Schut will provide the administrative supervision to the site research staff and will periodically attend meetings of the Key Stakeholder Advisory Group and Consumer Advisory Group.

In addition to enrolling participants, the research staff hired for this project will be responsible for all data collection required for this project. The Research Coordinators and Research Interviewers will conduct baseline assessments with participants; while only the blinded Research Interviewer will conduct research assessments at 4, 8, and 12 months follow-up. The Research Coordinators will conduct the 8-week phone call to assess satisfaction with the study interventions. The Research Coordinators will manage an account to provide reimbursement to participants for completing research interviews. They will also assist in coordination of the Consumer Advisory Group meetings and the Key Stakeholder Advisory Group quarterly meetings.

A schedule of weekly calls will be scheduled with the Dartmouth team for supervision of the research staff and for fidelity assurance of the I-IMR and CDSMP models. The Research Coordinators and the Research Interviewers will participate in these weekly meetings and the intervention facilitators will participate in weekly fidelity assurance calls. Intervention facilitators will audio or video record (mode will depend on whether the sessions are being delivered remotely or in-person) CDSMP and I-IMR sessions and submit recordings to the Dartmouth team for review and feedback each week.

Joy Varney, Director of Peer Support Services at Centerstone Kentucky, will be an integral member of the project team. She will participate in the weekly project management meetings with the Dartmouth team and will also facilitate monthly phone meetings of the Consumer Advisory group with Dr. Fortuna. Ms. Varney and the other 2 Peer Advisors from Kentucky will travel annually to Tennessee with Karen Fortuna, PhD for an in-person meeting with the 2 Peer Advisors from Centerstone Tennessee.

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

The risks associated with participation in the study are deemed to be minimal and are outweighed by the potential benefits. Participation in an illness self-management group, like CDSMP or I-IMR, is no greater than participating in similar skills training groups as part of usual mental health care. Anxiety, boredom, or related discomfort could occur during self-management sessions or during research interviews. There is also a risk of loss of confidentiality from participating in a group, participating in research assessments, and using the mobile app (associated with I-IMR).

b. Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:

Anxiety or discomfort during illness self-management groups and during interviews will be handled by trained facilitators/interviews who will work individually with participants to develop and enact strategies to cope and reduce distress during the groups. Breaks will be offered during both groups and interviews as needed as well. Risks regarding breach of confidentiality with respect to the study data will be minimized in several ways. First, we will use using code numbers instead of names on the data.

The data collected using codes will be electronically captured on REDCap, a secure data collection program. The code will be unavailable to anyone outside of the research team, and it will be destroyed at the conclusion of the project. With respect to the data that is collected by the smartphone application, data are transmitted to ZCO (software development company for the smartphone application) server via secure, HIPAA-compliant security protocol over secure cellular connection. The data transmitted during sessions do not include participant identifiers.

c. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

The risk to participants is minimal and outweighed by the potential benefit of improving self-management of illness prompting to engage in illness management and positive coping behaviors,

7. Unexpected Events or Incidental Findings

Describe potential events and provide a plan of action:

Serious, unexpected adverse events (SAE) related to study participation are rare in our research groups' studies. If an SAE occurs, the Co-PIs will report the event to the Dartmouth CPHS and to the DSMB. The Co-PIs, in consultation with Co-Is and others as needed, will review the adverse event report and gather other information as needed to investigate the event and determine the need for subsequent action. Any subsequent action will be documented and reported to the Dartmouth CPHS.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☐ **Yes** ☒ **No**

If Yes, provide an explanation which addresses the following:

- A description of the deception being used
- Why the deception is necessary
- A plan for debriefing, or providing subjects with the pertinent information after participation

9. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

600 Adults 18+ and 150 of consented participants will also participate in the COVID-19 enhancement.

b. Provide a justification of the proposed sample size

The sample size is based on maintaining an adequate sample for data analyses with consideration to retention based on previous studies. Retention in our previous studies and in our IIMR studies has been very high. We conservatively estimate a loss of 20% over the 12-month study, resulting in full follow-up data on $n = 480$.

c. Define the target population:

The target population are individuals diagnosed with a SMI (diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, chronic depression with moderate impairment in functioning, PTSD, or other serious anxiety disorders) with co-morbid chronic medical problems receiving services at Seven Counties Services (KY) and Centerstone (TN) who reflect the racial, cultural, linguistic, and ethnic diversity of people with SMI in this agency.

Inclusion and Exclusion Criteria: Eligibility for the study also includes: diagnosis of a chronic medical condition increasing risk of early mortality from cardiovascular or respiratory disease or diabetes, hyperlipidemia, hypertension, COPD [including emphysema], asthma, coronary artery disease, heart failure, tobacco dependence, obesity), chronic pain, and at least 1 ER visit or hospitalization within the past year (and/or 3 or more unscheduled outpatient visits) or judgment by the treatment team of substantial need for illness self-management training. Consumers who do not speak English will be excluded for logistical reasons. Consumers with either no, or a well-controlled medical condition will not be included. Individuals residing in a nursing home or other institution will be excluded given the focus on independent management of illness. Because I-IMR and CDSMP involve learning new skills, individuals with a chart diagnosis of dementia, or evidence of significant cognitive impairment as indicated by the Saint Louis University Mental Status Examination[73] score <20, will be excluded. Temporarily during the COVID-19 pandemic, participants who score <20 on the TICS will be excluded.

d. Vulnerable populations

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☒ Pregnant Women, Fetuses and Neonates
☐ Children
☒ People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

10. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

We will use several approaches that have had proven effectiveness in prior studies with similar populations to ensure that all potentially eligible consumers are aware of the opportunity to participate in the project and that enrolled participants are retained. Potentially eligible consumers will be identified initially through a review by the site research staff of the electronic health record (EHR) and elicitation of referrals from the mental health treatment teams. Posters and pamphlets describing the project will also be distributed in the waiting rooms at the study sites. Letters will be sent to potentially eligible participants to ensure that all consumers who may qualify are aware of the study. Potential participants will be invited to group events to hear descriptions of the study. Email blasts and social media venues will be used to stimulate self- and clinical referrals to the study, and a description of the study will be included on the websites at the study sites. Following referral, the research staff will review eligibility criteria. Potentially eligible participants will be invited to meet with one of the research staff for an in-person verification of eligibility and an introductory description of the project and study requirements, including description of the study interventions, review of the study protocols, randomization, and required research assessments. Research introduction meetings have been successfully used by our research group to assure that study participants fully understand clinical and research procedures. In addition to enhancing the process of full informed consent, these procedures are designed to decrease the likelihood of study attrition due to inadequate appreciation of the time, effort, and component activities involved in participating in the intervention program, or in the study protocol.

11. Informed Consent, Assent, and Authorization

Interested individuals who have had an introduction meeting will then meet with a member of the research staff to review the informed consent form. Research staff will read the consent form word-for-word, stopping to check understanding after each paragraph. Competence to provide informed consent will be confirmed with a review of personal history and functioning and completion of an informed consent evaluation tool that will be designed for the study. If all goes well and the individual has a full understanding of the form, they will be asked to sign the consent agreeing to participate. Individuals with guardians will be able to participate as long as they are able to understand what the study involves. In these instances, assent will be obtained from the client and consent will be obtained from the legally designated guardian. Participants (and guardians) will be provided a signed copy of the consent form with contact telephone numbers if they have additional questions.

During the COVID-19 pandemic, we plan to consent new participants remotely. The staff providing services at Centerstone TN and Seven Counties have continued to make referrals of potentially eligible service users and the research staff have continued to chart screen potential participants for eligibility.

Following confirmation of eligibility, research staff will call potential participants to describe the details of the program and the research in the same way that is was presented to potential participants in person before the pandemic. Staff will mail a copy of the consent form to eligible and interested participants and schedule a time to review it, word-for-word, in a phone meeting, exactly as it would be reviewed in person, including administration of the consent evaluation. The research staff will obtain verbal consent, documenting this on REDCap, and requesting return of a signed copy of the consent form in a self-addressed, stamped envelope that will be provided to the participant.

a. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.
Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

☐ For the informed consent *process*
☐ For the *documentation* of informed consent
☐ For the HIPAA Authorization to use and/or disclose PHI
☐ For a waiver of the requirement for medical record documentation

12. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

All consented participants who are eligible will be paid $50 each after completing the baseline and the 4 and 8 month study visits. Participants will receive $25 for completing a satisfaction survey at 8 weeks and $75 for completing an assessment at 12 months, for a total of $250 per participant. Participants will not be taxed on any money received from this study since it is under the $600 dollars per year minimum.

Individuals participating in the COVID-related needs assessment will receive $50 for a one-hour qualitative interview. Research staff at Centerstone and Seven Counties will send a $50 gift card by certified mail to the needs assessment participants. They will also send gift cards for completed research assessments for the COVID-related component ($25 baseline, $50 for 6 weeks, and $75 for the 12 week) by certified mail.

13. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

The research staff will be trained by Centerstone and Seven Counties Services in privacy standards such as the HIPAA privacy rule. Our research team is experienced in training, instrument

construction, editing, and data management at remote sites. We will use the same procedures for data acquisition and management used in prior studies, including: (1) a common core of initial and refresher training for staff collecting data; (2) continuous team feedback approach at the sites; and (3) final data editing and management at our facility in Concord, NH. Regular conference calls, including weekly assessment supervision, will also help ensure standardization of research procedures across sites, and identify quality control issues early, allowing consensus solutions to be reached. Weekly meetings of the research team provide an environment where quality assurance issues can be quickly identified.

14. Confidentiality of Data

Note: Any person engaged in research collecting information about illegal conduct may apply for a Certificate of Confidentiality from the National Institute of Health.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☐ **No** ☒ **Yes**

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

In order to participate in this study protocol, the participants must be receiving services at one of the community mental health centers. Although participation in mental health services and information related to receipt of services, such as mental health diagnosis, may be considered "sensitive," we will not apply for a Certificate of Confidentiality as this would suggest that having a mental illness is akin to using illegal substances in that it could leave a person vulnerable to undesirable consequences related to employability, financial, legal status, etc. The suggestion that having a mental illness is something that requires protection from a Certificate of Confidentiality serves to further stigmatize individuals with mental illness, who should not be made to feel ashamed or compelled to hide the fact that they have a mental health diagnosis.

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

Risks regarding breach of confidentiality with respect to the study data will be minimized in several ways. First, we will use using code numbers instead of names on the data. The data collected using codes will be electronically captured on REDCap, a secure data collection program. The code will be unavailable to anyone outside of the research team, and it will be destroyed at the conclusion of the project. No medical records or protected health information shall be re-disclosed. A Certificate of Confidentiality will not be required. Other confidentiality protections include confidentiality training for all new staff and refresher seminars annually for all staff; removing or obscuring names from data forms; using an acronym in return addresses on correspondence to participants; and password-protected computer databases. The risks to participants will also be minimized by reporting on all findings in an aggregate, anonymous manner. In addition, data access will be restricted to members of

the evaluation team only and the data will be stored on a password protected computer and kept in a locked filing cabinets at the research sites.

c. Describe the plan for storage or destruction of data upon study completion:

Data will be stored for up to ten years following the end of the study. Electronic files will be stored on password protected computers and backed up by a remote online server that encrypts the data and is also password protected. If the data is no longer being used, we will systematically delete all electronic files. Paper files will be kept in a locked filing cabinet in a locked office. In the future, if data is no longer being used, all files will be shredded and discarded.

REFERENCES CITED

For detailed instructions, refer to the Application Guidelines for this PFA. Do not exceed 10 pages.

Follow scholarly citation practice and list the source material cited in your Research Plan. PCORI suggests using American Medical Association citation style, but other citation styles are accepted.

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