Mental Health Collaborative Care and its Role in Primary Care Settings

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SMI Life Goals: Description of a Randomized Trial of a Collaborative Care Model to Improve Outcomes for Persons with Serious Mental Illness

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Abstract

Background—Persons with serious mental illnesses (SMI) are more likely to die earlier than the general population, primarily due to increased medical burden, particularly from cardiovascular disease (CVD). Life Goals Collaborative Care (LG-CC) is designed to improve health outcomes in SMI through self-management, care management, and provider support. This single-blind

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randomized controlled effectiveness study will determine whether patients with SMI receiving LG-CC compared to usual care (UC) experience improved physical health in 12 months.

Methods—Patients diagnosed with SMI and at least one CVD risk factor receiving care at a VA mental health clinic were randomized to LG-CC or UC. LG-CC included five self-management sessions covering mental health symptom management reinforced through healthy behavior change; care coordination and health monitoring via a registry, and provider feedback. The primary outcome is change in physical health-related quality of life score (VR-12) from baseline to 12 months. Secondary outcomes include changes in mental health-related quality of life, CVD risk factors (blood pressure, BMI), and physical activity from baseline to 12 months later.

Results—Out of 304 enrolled, 139 were randomized to LG-CC and 145 to UC. Among patients completing baseline assessments (N=284); the mean age was 55.2 (SD=10.9; range 28-75 years), 15.6% were women, the majority (62%) were diagnosed with depression, and the majority (63%) were diagnosed with hypertension or were overweight (BMI mean±SD=33.3±6.3). Baseline VR-12 physical health component score was below population norms (50.0±SD=10) at 33.4±11.0.

Conclusions—Findings from this trial may inform initiatives to improve physical health for SMI patient populations.

Keywords

care management; self-management; mood disorders; schizophrenia

INTRODUCTION

Serious mental illness (SMI-including schizophrenia, bipolar disorder, and recurrent major depressive disorder)[1] is associated with substantial functional impairment, morbidity, economic burden, and mortality [1-3]. Persons with SMI receiving care die on average 8-25 years younger than the U.S. general population [1, 4], and a key driver of this premature mortality is increased burden from medical conditions, particularly cardiovascular disease (CVD) [1, 5, 6]. Some of the most common medical conditions (e.g., hypertension, hyperlipidemia) that disproportionately burden patients with SMI [5] are also the leading risk factors for CVD.

While there has been much attention concerning CVD risk factors associated with second generation antipsychotics, unhealthy behaviors, notably lack of physical activity, can

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HbA1C	hemoglobin A1C
ICD-9-CM	International Statistical Classification of Diseases, 9th Revision, Clinical Modification
LG-CC	Life Goals Collaborative Care
MHICM	mental health intensive case management
SMI	serious mental illness
VR-12	Veterans short form survey

contribute up to 60% increased CVD mortality risk in patients with SMI compared to those without these disorders [6]. Moreover, patients with SMI are often managed in specialty mental healthcare settings, and may experience gaps in quality of medical care [7] for services that require coordination between mental health and general medical providers [8]. Psychiatric symptoms can further exacerbate CVD risk. For example, mood symptoms can decrease motivation to seek medical care when needed and increase sedentary lifestyle, leading to subsequent weight gain [9]. Psychotic symptoms can also impede healthy behaviors and increase the risk of substance use [10].

Interventions for persons with SMI need to address multiple barriers to reduce CVD risk and improve outcomes by incorporating behavioral change and collaborative care strategies. Collaborative Care Models (CCMs) [11], which provide proactive care for patients through self-management education, coordination of services, and ongoing follow-up with patients and communications with providers by a care manager have been shown to improve medical and psychiatric outcomes, primarily for patients with depression [12]. More recently, Life Goals Collaborative Care (LG-CC), a CCM-based intervention developed to address physical health and CVD risk in patients with bipolar disorder, led to improved mental health physical health outcomes [13-16]. LG-CC adds components of health behavior change to the CCM components, notably by linking symptom management with healthy behavior goal-setting, as well as follow-up on physical and mental health symptoms and care. However, to date LG-CC has not been tested in a broader SMI patient population, including those with chronic major depression or schizophrenia, which represent the majority of persons seeking care in mental health outpatient clinics.

The goal of this single-blind randomized controlled trial (SMI Life Goals) is to determine whether LG-CC compared to usual care improves physical and mental health outcomes in 12 months among patients with SMI. Our primary hypothesis is, within 12 months, patients randomized to receive LG-CC compared to those randomized to receive usual care will have improved physical health-related quality of life (VR-12) scores from baseline to 12 months later. Our secondary hypotheses are that compared to those enrolled in UC, patients in the LG-CC group will have reductions in CVD risk factors, notably 1) improved mental health-related quality of life scores, 2) lower systolic blood pressure, 3) lower diastolic blood pressure , 4) lower body mass index (BMI), and 5) increased physical activity in 12 months. Exploratory outcomes include psychiatric symptoms and intermediate and long-term CVD risk factors.

MATERIALS and METHODS

This is a prospective, randomized, controlled, single-blind, effectiveness intervention trial designed to determine whether the LG-CC compared to usual care improved outcomes in 12 months among adult patients diagnosed with serious mental illness with at least one CVD risk factor who received care in a large urban VA outpatient mental health clinic. Patients were randomized following the completion of a baseline survey and clinical assessment by the study outcomes assessor. LG-CC was delivered be the study interventionist (health specialist). The study outcomes assessor is blinded to the treatment arm the patients were assigned, but the interventionist (health specialist) and patients enrolled were not blinded.

This study received IRB approval and all patients provided informed consent. No changes to the trial design were made.

Setting, Recruitment, and Participants

The study is being conducted at an outpatient mental health clinic at a large Midwestern U.S. Department of Veterans Affairs medical center. Using VA electronic medical records, the study data analyst and outcomes assessor would first use the VA electronic medical record system to identify all potentially eligible patients based on the following **<u>inclusion criteria:</u>**

1. Age 18 years or older with a diagnosis of serious mental illness in the medical record based on the presence of at least one inpatient or outpatient ICD-9-CM [17] diagnosis of schizophrenia, bipolar disorder, or major depressive disorder within the past year from the study recruitment start date (February 15, 2010). These SMI ICD-9 CM diagnoses were chosen because they were considered the most chronic and debilitating mental health diagnoses that are primarily seen in VA mental health specialty [18].

2. Having at least one of the following risk factors for CVD (cardiovascular disease) recorded in the medical record:

    a. Body mass index (BMI) >28 or waist circumference of >35 (women) or >40 (men) inches OR

    b. Documentation of a diagnosis of or treatment for hypertension (defined as documented diagnosis or blood pressure of >140/90 on 2 occasions or prescription for an antihypertensive medication), dyslipidemia (documented diagnosis or LDL>160 or prescription for a lipid-lowering medication) or diabetes mellitus (documented diagnosis or HbA1C >7% or current prescription for oral hypoglycemic therapy)

All potentially eligible participants based on medical record review were then approached by the study outcomes assessor, who then confirmed eligibility and offered enrollment in the study. At the time of study enrollment, the outcomes assessor excluded potential participants if any of the following **<u>exclusion criteria</u>** were met:

1. Unresolved substance intoxication or withdrawal, such as appearing to be intoxicated (e.g., incoherent, slurred speech), or experiencing withdrawal symptoms from substance abuse at the time of enrollment.

2. Unwilling or unable to provide informed consent or comply with study requirements at the time of enrollment (e.g., unable to complete forms or attend sessions due to substantial functional limitations).

3. Expression of active suicidal ideation at time of enrollment

Enrollment and Randomization Procedures

Enrollment procedures included confirmation of eligibility, documentation of informed consent, and completion of a baseline questionnaire, and brief clinical assessment (physical

exam) by the study outcomes assessor. Those eligible and consenting to be in the study are given a baseline survey and brief clinical assessment to assess systolic and diastolic blood pressure, weight, and waist circumference, described in detail below.

Patients are then randomized by the study data analyst to receive LG-CC or usual care (UC; Table 1). Patients were randomized when at least 16 but no more than 20 patients at a time were recruited and enrolled into the study, in order to ensure sufficient numbers of patients for the intervention group sessions and avoid delays between the baseline assessment and intervention initiation. Randomization was stratified by gender, age, race, and presence/absence of diabetes diagnosis. Participants received $20 gift card as remuneration at each outcome assessment wave.

LG-CC Intervention

Patients randomized to receive Life Goals Collaborative Care (LG-CC) are then contacted by the health specialist to conduct an initial assessment, and then are scheduled for group self-management sessions. In addition to the self-management sessions patients randomized to receive LG-CC also receive care management, and their principle primary care and mental health providers also receive support from the health specialist (Table 1). LG-CC is based on the Collaborative Care Model that was customized to address unique barriers to optimal medical outcomes, particularly around CVD risk factors, faced by persons with SMI (Figure 1) [19].

Interventionist training and background—The health specialist is responsible for direct encounters for each of the LG-CC components described below, including group sessions, post-group follow-up phone contacts, and communications with providers. The health specialist has a master's in health education and a background in mental health care and mental health psychoeducation. The Health Specialist was trained by the Study PI, Co-Investigators, as well as a Life Goals training specialist. The health specialist training program was developed from prior LG-CC studies [13-16] and was customized by study co-investigators to address broader symptom issues related to SMI. The health specialist training consisted of a 2-day course that included: 1) background on the LG program, review of the program's clinical evidence, and overview of the three components (self-management, care management, and provider support) (Day 1), and 2) role plays to practice the specific components and training across SMI diagnoses (Day 2). The health specialist also has access to a hardcopy of the intervention manual as well as access to all handouts in electronic format and hardcopy for group sessions

Self-management—The LG-CC self-management component includes five separate group weekly sessions delivered by the health specialist in a guided, semi-structured format that last approximately 90 minutes each that were focused on reducing psychiatric symptoms by promoting healthy behaviors. Derived from social cognitive theory [20] and health belief model [21], the central tenet of the LG-CC self-management program is reducing both CVD risk factors and psychiatric symptom burden through the use of healthy behavior change goal-setting through increased physical activity and healthier eating choices [22, 23]. Specifically, the self-management program assumes patients make decisions about

behavior change based on their own analysis of potential costs and benefits [24] , and the health specialist, using motivational enhancement techniques, helps them build self-efficacy for change [25]. Through ongoing monitoring, the health specialist also promotes maintenance to the health behavior changes as well as provider engagement to reinforce behavior change [16]. Where appropriate, the health specialist also provides patients information on community organizations or groups that support health behavior change or recovery (e.g., 12-step addiction groups).

Care management—LG-CC care management includes six monthly contacts lasting approximately 20 minutes made to each patient by the health specialist that are tracked using a Microsoft Access registry. The purpose of the care manager calls is to discuss progress on achieving health behavior goals (physical activity, dietary changes) that were selected by patients in the self-management sessions, as well as to monitor health status and disseminate information on linkages to community resources where appropriate (Table 1). The health specialist also contacts the patient's primary care and mental health providers each month. These provider contacts are made either through the VA electronic medical record in the form of a view alert sent to the provider about a specific patient, or in person if the provider is available.

The health specialist uses the registry primarily to record contacts from the care management component of LG-CC, but also to record information from the initial contact made to patients prior to scheduling the self-management sessions (e.g., to record principle care providers for future contact), and during the self-management sessions to record patient-specific health behavior goals. The registry tracks patients' health behavior change progress (e.g., progress on physical activity or dietary changes), ongoing medical and psychiatric symptoms, and current treatments (e.g., medications, health status, and if applicable, no-shows and rescheduled appointments for reminder purposes). The health specialist uses this information to relay any potential health concerns to patients' primary care and/or mental health providers, especially if symptoms were not improving or there is a need to follow up on other treatment issues (e.g., medication refills, new symptoms requiring attention). As the registry is customized to help track clinical care related to LG-CC, it is not embedded in the VA electronic medical record system and providers do not have access to this registry.

Provider support—In addition to the regular contacts with the providers, the health specialist also disseminates a care plan that includes patients' health status and behavior goals to their primary care and mental health providers after the last care management contact. The goal of this care plan is to facilitate provider decision-making regarding ongoing clinical management by their assigned primary care and mental health provider once the LG-CC program is over. The health specialist also disseminates at staff meetings on a quarterly basis summaries of the LG-CC program as well as the VA guidelines for CVD risk factor monitoring, which cover cardiometabolic assessments recommended for individuals prescribed atypical antipsychotic medications. [26]

LG-CC Fidelity Monitoring

Fidelity to patient receipt of LG-CC components include observations of 50% of groups and monitoring of patient and provider contacts based on the registry. Adequate fidelity to LG-CC will be defined as: mean percentage of self-management sessions attended by patients is 80% (average of 4 out of 5 sessions attended), mean percentage of session topics covered in lessons is 80%, and mean percentage of completed number of care management contacts to patients is 65% (mean number of 4 out of 6 required contacts).

Usual Care

Patients randomized to the usual care group receive their routine VA care (Table 1), but there are no ongoing contacts by the health specialist to patients or their providers or any registry tracking provided. Usual care in the mental health clinic includes on-site psychiatrists who provide routine medication management, as well as psychologists and social workers who provide individual or group psychotherapy sessions on an ad-hoc basis for specific diagnosis (e.g., PTSD) or treatment modalities (e.g., cognitive behavioral therapy). However, the psychotherapy sessions do not provide specific guidance in managing psychiatric symptoms or their relationship to CVD risk factors. Case management is also available in the mental health clinic. Routine medical care is provided by general practitioners who resided on a different floor of the same facility, both without any contacts or information on patient care preferences or needs by the health specialist.

Outcomes

Patient outcome assessments include a self-completed survey and a clinical exam administered at baseline, six, and twelve months later by the outcomes assessor. The survey includes questions for the primary, secondary, and exploratory outcomes (quality of life, symptoms, and health behaviors), as well as covariates. The clinical exam was completed in-person in a private room in the mental health clinic and includes clinical measures for secondary and exploratory outcomes related to CVD risk. Additional CVD risk factors (e.g., lab values) and covariates (e.g., medical diagnoses) are ascertained from the VA electronic medical record.

Primary Outcome Measure—The primary outcome is changes in physical health-related quality of life between baseline and 12 months later. This outcome was chosen because physical health-related quality of life is thought to be directly affected by the LG-CC intervention based on prior studies [15, 16] [22, 23], regardless of mental health diagnosis or specific CVD risk factors. Self-reported poor physical HRQOL was also shown to be significantly associated with a 2 to 3-fold increased risk in CVD-related mortality [28].Physical health-related quality of life is assessed using the patient survey based on the Veterans Short-Form (VR)-12 [27]. The VR-12 is a widely used and validated instrument that generates two composite scores: physical health (PCS) and mental health (MCS) composite scores. Both the PCS and MCS were scored 0-100 (higher scores represent better health-related quality of life) and normalized so that 50 ±10 represented the mean ± standard deviation for the general population.

Secondary Outcomes—The five secondary (exploratory) outcomes include 1) mental health-related quality of life based on the aforementioned MCS score, 2) systolic blood pressure, 3) diastolic blood pressure, 4) body mass index (BMI), and 5) physical activity; variables though to directly affect CVD risk [15, 16]. Blood pressure is ascertained from a clinical exam that included averaging the two separate readings of the patients' blood pressure sitting down. BMI is assessed during the same clinical exam by measuring the patients' weight and recording height from the medical record. Physical activity is assessed via the patient survey using the Physical Activity Questionnaire-Short Form (IPAQ-SF), a self-reported four-item measure of habitual physical activity over the past 7 days. IPAQ-SF ascertains information on time spent walking in moderate intensity, in vigorous-intensity, and sitting, on weekdays and weekend days. An average number of minutes of activity is generated and multiplied by body weight and a caloric value (based on intensity) to yield total energy expenditure using a standard protocol (http://www.ipaq.ki.se/ipaq.htm). The IPAQ-SF has good reliability and validity in large population-based surveys and among mental health populations [29].

Exploratory Outcomes—Additional exploratory outcomes to be assessed in this study include psychiatric symptoms and intermediate and long-term (10-year) CVD risk factors [30]. Psychiatric symptoms are ascertained from the patient survey and include mood and psychotic symptoms, considered the most common symptoms experienced among persons with SMI [31]. Mood symptoms are assessed using the Patient Health Questionnaire (PHQ-9) and the Internal State Scale (ISS). The PHQ-9 is a previously validated measures for depressive symptoms used across chronically ill patient populations [32]. The ISS is an 8-item brief self-reported symptom assessment that assesses activation (mania) and well-being, and was strongly correlated with clinician ratings of mania [33, 34]. Psychotic symptoms are assessed using the 5-item revised Behavior Symptom Identification Scale (BASIS©)[35], a self-reported scale that assesses relationship difficulty, self-harm, and emotions.

Intermediate CVD risk factors include waist circumference, assessed via the clinical exam at baseline, six, and twelve months. In addition, long-term CVD risk factors will be assessed based on the Framingham Risk Score [36]. The Framingham Score is designed to estimate 10-year risk of acquiring CVD based on a weighted score, and will be derived from key CVD risk factors from the clinical exam (blood pressure), electronic medical records (diabetes diagnosis, lipid levels), and patient survey (age, sex, and current smoking status). Lipid levels including fasting total cholesterol, low-density lipoprotein, and high-density lipoprotein in mg/dL are ascertained from the electronic medical record review using lab results recorded nearest to the patient's assessment dates at baseline, 6 and 12 months.

Covariates—Covariates that might influence LG-CC response and outcomes are also ascertained, including demographics [13] and clinical factors from the patient survey and medical record review, including substance use, medical, and psychiatric comorbidities [37]. Substance use included self-reported alcohol use based on the Alcohol Use Disorders Identification Test [38, 39] as well as smoking status. Medical comorbidity diagnoses and

medications were ascertained from the medical records [37, 40] using a previously established chart review tool [41, 42].

Assessment and management of suicidal ideation

Once enrolled, suicidal ideation is ascertained from survey responses, and whether patients articular at any time thoughts of suicide or death during LG-CC sessions or contacts. During the baseline assessment, suicidal ideation is ascertained based on responses to one of two questions from the baseline and follow-up surveys: 1) "thoughts that you would be better off dead or of hurting yourself in some way" (several days more frequently) from the PHQ-9, or 2) "think about ending your life" (at least sometimes) from the BASIS© [35] psychosis symptom assessment. If patients answer in the affirmative to one of those two questions, or articulate suicidal ideation at the time of enrollment or assessment or during any of the group sessions or contacts, study staff members (outcomes assessor, health specialist) employ a procedure developed with Study Investigators and the VA mental health staff that involves asking patients additional questions about the suicidal ideation, including whether there is an active plan. If patients respond in the affirmative to these follow-up questions, then the patient will be immediately referred to their mental health clinician, or if the clinician was not available, the VA Suicide Prevention Coordinator if the encounter was in person. If the encounter was over the phone, then the study staff member will keep them on the line and made a direct referral to either a crisis line or emergency room, and would follow up with the patient's mental health provider to develop a suicide prevention plan when appropriate.

Analyses Plans

Bivariate baseline analyses will first be conducted to see if randomization was successful by comparing patient demographics, clinical covariates, and baseline outcome values between randomization groups. If there is a lack of equal distribution across groups, we will adjust for the imbalance by adding these baseline variables as covariates to our outcomes analyses or use propensity scoring. We will compare baseline characteristics and time-varying measures among those enrolled but dropped out over time to those who remained in the study. Missing data will be addressed using multiple imputation methods, where each missing value is replaced with a set of plausible values generated from the non-missing data.

The primary and secondary outcome variables (health-related quality of life, blood pressure, BMI, and psychiatric symptoms) will be treated as continuous variables, and analyses will focus on changes over the 6- and 12-month period between LG-CC and usual care groups in each outcome. For continuous outcome variables, mixed-effects models will be run to assess the intervention effects. An intent-to-treat analysis will be performed for all analyses, adjusting for all baseline covariates in the stratified randomization. A subgroup analysis by psychiatric diagnosis will be conducted in order to explore whether the effect of LG-CC versus UC varied by specific diagnosis (major depression, bipolar disorder, schizophrenia).

Sample Size

The sample size for this study was determined based on the comparison of LG-CC vs UC for the primary outcome: physical health-related quality of life score based on the VR-12.

Specifically, the calculation was based on a small to moderate effect size for changes in the physical health VR-12 component score (e.g., Cohen's D =.31) between baseline and 12 months later comparing the LG-CC and UC groups *[15, 16]*. Participant refusal rates were anticipated to be 5% and long-term attrition rates are expected to be 10% based on similar studies of the LG-CC intervention in patients with bipolar disorder [15]. Sample size was determined by estimating the smallest detectable difference in physical health-related quality of life score between the population mean over time, at a significance level of .05 (using a two-tailed statistical test) and a minimum power of .80. Hence, recruitment called for enrolling 300 subjects in total in order to have at least 240 subjects complete the study which would account for a 20% attrition rate, assuming 0.5 within-person correlation coefficient, and adjustment for multiple comparisons.

RESULTS

Participants

Study staff began recruiting and enrolling patients on February 24, 2010 and all baseline assessments were completed by February 15, 2014 (See Figure 2 for the Consort diagram describing recruitment flow and losses/exclusions). Out of the 3,732 eligible patients screened for study participation, 2,897 were not approached due to ineligibility or inability to contact. Of the 835 approached, 304 were enrolled, or which 20 dropped out prior to randomization, resulting in a final sample size of 284. Overall, 139 were randomized to LG-CC and 145 to usual care.

The total caseload provided by the health specialist was 139 patients over the 2-year enrollment and intervention period. This caseload is comparable to prior studies of LG-CC, in which the yearly caseload for a full-time health specialist ranged from 60-80 patients per year [13-16].

Baseline data

Of the 284 participants who began the study, 139 were randomized to receive LG-CC group and 145 to UC. The mean age was 55.2 (SD=10.9; range 28-75 years), 15.6 were women, 17.5% were Black, reflecting similar demographics in this VA mental health clinic (mean age = 55, 6% female, 11% African-American). Among participants, the majority (62%) were diagnosed with depression (Table 3).

At baseline, VR-12 scores were markedly below population norms (50.0±SD=10) for both physical and mental health-related quality of life (respectively mean±SD = 33.4±11.0 and 34.3±11.9). The majority had a diagnosis of hypertension and the mean BMI was 33.3 (SD=6.3). In addition, the majority had a moderate to high 10-year risk for an acute cardiovascular event according to Framingham Risk Scores. Self-reported measures revealed substantial burden of depressive symptoms as well (Table 4).

There were no significant differences in baseline demographic/clinical factors or baseline primary or secondary outcome measures with the exception of BMI (Table 4). By chance alone, it is expected that at least 1-2 differences will be significant at the 5% level ($1.8 = 0.05 \times 36$ comparisons in Tables 3 and 4). To be conservative, however, sensitivity analyses

for the primary and secondary outcomes will adjust for BMI; results will be reported with and without adjustment.

DISCUSSION

We described the design, rationale, and baseline results of a randomized controlled trial that seeks to determine whether a Collaborative Care Model (LG-CC) tailored for individuals with SMI improves physical and mental health outcomes, notably health-related quality of life and CVD risk factor control. Despite ongoing access to medical care experienced by this VA patient cohort, a substantial number had elevated risk factors for CVD, notably hypertension and high BMI, which can also impact overall health. Moreover, health-related quality of life scores were substantially lower than the general U.S. population, reflecting a particularly vulnerable group.

Interventions to date that are designed to reduce CVD risk factors in persons with SMI have typically involved multiple provider teams [43-46], closely supervised diet or exercise regimens [47, 48], or were limited to a single diagnosis, thus precluding their potential generalizability in routine care settings [49, 50]. In contrast, LG-CC includes components that can be potentially taught to existing providers via a manual and training program. Moreover, LG-CC provides support in coping with mental health as well as physical health symptoms (beyond CVD risk factors), thus having the potential for increased generalizability by impacting overall health status. In addition, LG-CC emphasizes self-management, care coordination, and setting personal goals, providing patients with a number of tools to potentially reduce CVD risk factors that extend outside the clinic walls.

The SMI Life Goals study has several strengths, notably the use of a randomized design and clinical exams to assess outcomes. Nonetheless, this study is not without limits. First, it is possible that LG-CC could be less effective for VA patients with psychotic disorders, such as schizophrenia, which is often associated with cognitive limitations. Nonetheless, there is growing realization that similar psychosocial programs such as cognitive-behavioral therapy can be delivered effectively for patients with schizophrenia [51]. This study will closely track program adherence as well as changes in key outcomes stratified by patient diagnosis to determine whether further adaptations to LG-CC are necessary. Second, key components of LG-CC are currently not integrated with existing VA services, notably the patient registry with the VA electronic medical record or the group self-management sessions in the mental health clinic.

The additional time involved in implementing LG-CC self-management group sessions, care management, and follow-up with providers would be challenging for one person to perform without protected clinical time. If the intervention is found to be effective, study investigators will plan an implementation initiative to incorporate LG-CC components into routine VA care, notably by identifying existing VA infrastructures (e.g., electronic medical record fields) and providers (e.g., social workers) that could be deliver the LG-CC components. Third, there is potential that the usual care group will be exposed to some of the LG-CC components, notably through contacts by the health specialist with providers who are also treating patients in the usual care group. However, LG-CC components are

tailored by the health specialist for patients based on their unique needs, so it is unlikely that the interactions between the health specialist and providers will directly impact patients in the usual care group. Fourth, cost considerations precluded us from including measures that involved direct observation of health behaviors such as physical activity. Finally, the generalizability of the sample is limited by the focus on a VA patient population, as VA's medical and mental health services [52]. Still, the persistent level of CVD risk factors has been observed elsewhere in non-VA settings [53].

Despite these potential limitations, this study represents an important step forward in addressing an often unmet treatment need among patients with SMI regardless of their psychiatric diagnosis. CVD remains the number one cause of morbidity and mortality among persons with SMI, and despite the dissemination of guidelines to manage CVD risk factors [54], outcomes remain suboptimal for this group. Furthermore, Veterans are a vulnerable group that is characterized by lower socioeconomic status, greater medical morbidity, and a higher probability of having comorbid psychiatric disorders. The VA is a significant provider of mental health services to patients with SMI across the U.S. and thus results will have implications for improving care to this patient population.

Overall, the SMI Life Goals Study will potentially add to the much-needed literature on studies addressing medical and psychiatric needs of patients with SMI. Current baseline findings show that patients with SMI are burdened with multiple CVD risk factors while displaying a propensity for poor health behaviors and lower health-related quality of life. Results from this trial will inform efforts to improve health outcomes and reduce CVD risk for persons with SMI.

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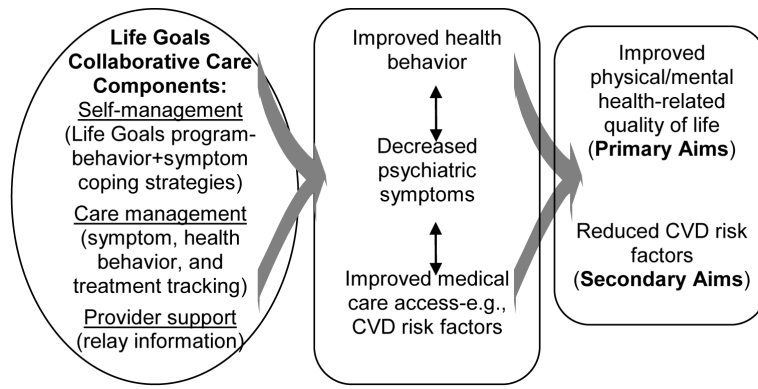
Figure 1.
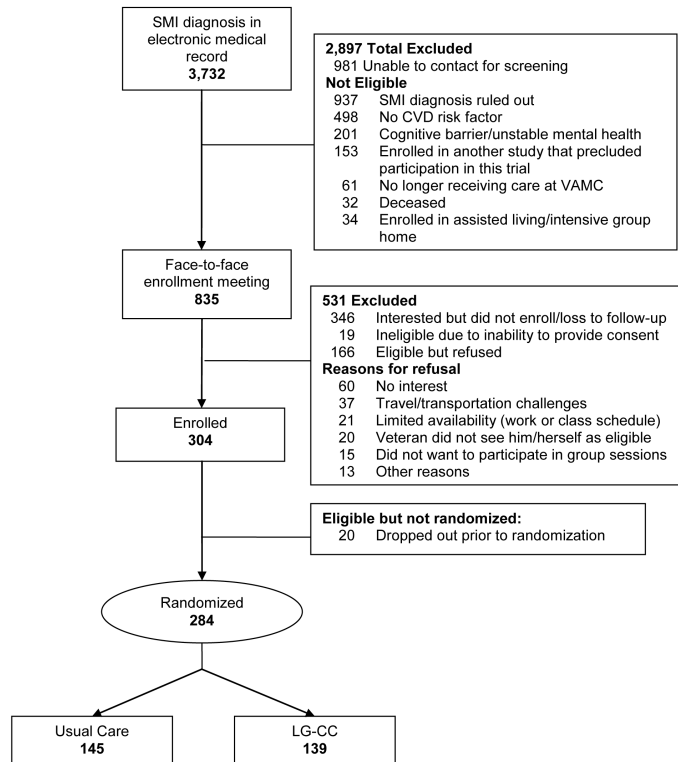LG-CC Components and Outcomes Related to SMI

Figure 2.
CONSORT: Participant Recruitment and Enrollment Flow Diagram

Table 1

Life Goals Collaborative Care (LG-CC) and Usual Care (UC): Timeline and Core Components:

Timeline	LG-CC Components	Usual Care
Baseline	• Baseline survey and clinical exam • Initial contact by health specialist	• Baseline survey and clinical exam • No contact by health specialist
Months 1-2	**Five weekly self-management sessions by health specialist** Five group sessions (90 minutes, approx. 8-10 individuals per group cohort) covering: • SMI facts • Understanding personal and behavioral risk factors for CVD • Setting personal goals • Active discussions of coping with psychiatric symptoms and strategies to manage psychiatric/ medical risks factors • Provider engagement and communication tips	No self-management sessions or follow-up contacts by health specialist
Months 3-8	**Care management by health specialist:** • Conduct ongoing patient contacts monthly for 6 months to reinforce lessons from self-management, track progress on patient-specific physical activity and dietary goals made during self-management sessions, and identify symptoms or other health issues to relay to providers Provides links to community resources where applicable. • Health specialist contacts patient's principle primary care and mental health provider on a monthly basis using electronic medical record view alerts or in-person curbside consultations to relay potential issues brought up when contacting patients, including physical or mental health symptoms, medication side effects, symptoms, or urgent health concerns • Health specialist uses the registry for recording information from initial contact made to patients prior to scheduling the self-management sessions, during the self-management sessions, and for care management contacts. Uses registry to monitor contacts, patient progress in health behavior change, mental health symptoms, and care needs over time **(6 month survey and clinical exams conducted 6 months after patient's enrollment date)**	No ongoing contacts to patients by the health specialist or registry tracking Standard services available in the mental health clinic include ongoing clinical management by patients' assigned primary care and mental health providers, case management, group psychotherapy, and individual psychotherapy on an ad-hoc basis. **(6 month survey and clinical exams conducted 6 months after patient's enrollment date)**
	Provider support • Health specialist provides care plan to primary care and mental health providers on mental health treatment and health issues after last care management contact to facilitate ongoing clinical management • Health specialist disseminates information on LG-CC program and VA guidelines for CVD risk monitoring to primary care and mental health providers at staff meetings	No ongoing contacts to providers or care plan provided by the health specialist Health specialist disseminates information on LG-CC program and VA guidelines for CVD risk monitoring to primary care and mental health providers at staff meetings
Month 12	• 12-month survey and clinical exam	• 12-month survey and clinical exam

Table 2

LG-CC: Summary of Self-management Session Content

Session	Focus points (core behaviors addressed)	Topics covered
Motivational enhancement principles used throughout all sessions	Interactions with patients characterized by a non-judgmental approach to elicit change in self-management behaviors through patient interactions using opened-ended questions, active listening, affirmations of desired behaviors and statements, and developing discrepancy between present actions to self-manage psychiatric and health concerns with core patient values to develop intrinsically-based action plans for self-management.	
Session 1: Program orientation, self-management	• Patient perspective of collaborative care and provider engagement • Establish association between mental and physical health • Explain biopsychosocial model of self-care • Values identification exercise to motivate health behavior goal setting • Establish understanding of mental health and CVD risk factors on physical health • Exercise: goal prioritization	• Patient-centered collaborative care • Causes of mental health disorders; prevalence, stigma, behavioral comorbidity • Psychiatric symptoms and behaviors contributing to CVD risk • Impact of mental illness symptoms on functioning and role with physical health • Treatments for CVD risk prevention • Values clarification exercise • Prioritizing areas for change • Small change approach for health
Session 2: Managing mental health symptoms	• Impact of mental symptoms on personal functioning • Symptom management and lifestyle change • Exercise: personal symptom profile and +/- coping behaviors • Identify triggers to psychiatric symptoms (e.g., substance use) • Exercise: decisional balance of choices to manage symptoms • Personal assessment of health behaviors for initial action plan for symptom management and physical health behavior change	• Recognizing psychiatric symptoms and impact on physical health • Personal psychiatric symptom profile; • Medical and behavioral consequences of psychiatric symptoms (overeating, sedentary lifestyle) • Triggers to serious psychiatric episodes • Proactive, positive coping plans for coping with psychiatric symptoms • Cost-benefit analysis of various self-management strategies for psychiatric symptoms and relation to overall health
Session 3: Overcoming thoughts that get in the way of wellness	• Recognizing how thoughts, feelings & perceptions affect behavior responses • Exercise: the Observing Self • Reflecting on thoughts and actions that promote positive health behaviors • Incorporating mindfulness into managing health behaviors • Reviewing the priority of health behavior change goals	• Recognizing how affective/psychosis symptoms impact perceptions of events • Developing insight into the cognitive behavioral approach to symptom management • Contingency planning and problem-solving environment triggers/cues to identify positive coping responses • Adopting nonjudgmental reactions to stressors • Benefits of coping with affective symptoms in the context of CVD risk • Eliciting examples of small steps towards setting diet & exercise goals
Session 4: Motivational enhancement-based wellness goals	• Reviewing the interrelationship between physical & mental health • Understanding personal risks for metabolic syndrome (lab values, vitals, cholesterol monitoring) • Making healthy nutritional choices	• Association between nutrition and CVD risk factors, weight gain, impact on mental illness symptoms and functioning (energy, fatigue, self-esteem) • Components of healthy diet; portion control; identifying healthy foods (low fat, lower salt and sugar content)

Session	Focus points (core behaviors addressed)	Topics covered
	• Benefits of physical activity for mind and body • Exercise for anxiety/stress reduction • Monitoring sleep patterns	• Triggers for unhealthy eating. • Risks of an inactive lifestyle; attaining desirable levels of physical activity for health; identifying personal and environmental barriers to activity • Making a personal action plan for physical activity using small steps approach; recognizing safety concerns, physical limitations. • Importance of establishing good sleep hygiene
Session 5:	• Building and strengthening collaborative care, • Preparation for effective visit communication with providers • Anticipating barriers and facilitators to long-term self-management • Understanding treatment strategies to manage risks • Medication adherence (CVD) • Identifying and linking to community resources. • Relapse Prevention • Developing a personalized wellness plan (diet, exercise tips) • Preparing for small change goal follow-up contacts	• Optimizing patient and provider engagement at care visits • Facilitating communication with medical providers (e.g., setting goals for blood pressure and cholesterol, listing personal concerns, discussing medication side effects) • Reviewing psychosocial therapies • Reviewing medication treatments • Identifying community and personal resources for long-term change • Personal care planning; treatment adherence: problem solving strategies and contingency planning to overcome relapses to wellness and mental health goals

Table 3

Participant Demographic and Clinical Characteristics

	Total (N =284)		LG-CC (N=139)		Usual care (N =145)			
	mean±sd or median (IQR)	%	mean±sd or median (IQR)	%	mean±sd or median (IQR)	%	t	p-value
Demographics								
Age;Range:28-75 yrs	55.2 ± 10.9		55.1±10.7		55.3 ± 11.0		−.13	.90
Age breakdown								
<50 years		26.0		24.6		27.3		.87
50-59 years		31.7		32.6		30.8		
60 years		42.4		42.8		42.0		
Female		15.6		15.8		15.4		.92
Black (vs. non-Black)		17.5		20.9		14.3		.15
Some college education		29.1		32.4		25.9		.23
Lives alone		32.2		30.0		34.3		.45
Clinical Factors								
Current SMI Diagnosis[a]								
Schizophrenia		7.0		5.0		9.0		
Bipolar disorder		24.3		23.7		24.8		
Major depression		57.4		60.4		54.5		.56
Other SMI		11.3		10.8		11.7		
Current Substance Use								
Current Smoker		25.7		22.3		28.8		.22
Alcohol misuse								
AUDIT-C Score[b]	0 (0,2)		0 (0,2)		0 (0,2)			.77
% Hazardous Drinking[c]		12.1		11.2		13.0		.66
Current CVD Diagnosis[d]								
Hypertension		63.7		64.8		62.8		.73
Hyperlipidemia		61.6		61.9		61.4		.93
Diabetes mellitus		31.0		33.1		29.0		.45
Medications[e]								
Antipsychotics		38.0		33.1		42.8		.09
Antidepressants		83.5		85.6		81.4		.34
Mood Stabilizers		52.1		49.6		55.5		.41

Statistical method: Chi-squared test for categorical variables (% reported); Two independent samples t-test for numeric variables (mean±sd reported); Wilcoxon-Mann-Whitney test for the variables with a highly skewed distribution (median (IQR) reported).

[a] SMI diagnosis based on medical record review and confirmed by patients' mental health care professional

[b]AUDIT-C scores are defined on 0-12 scale and based on 3 items with higher scores indicating more serious drinking. Wilcoxon-Mann-Whitney test is used for this variable.

[c]Current hazardous drinking is based on the score of one item of AUDIT-C defined as having 6 or more drinks on one occasion in the past month (yes/no).

[d]CVD-related diagnoses based on medical record review

[e]Medication use ascertained from the medical record include any current use of antipsychotic medications, antidepressants, or mood stabilizing medications

Table 4

Baseline Assessment Results of Participants: Primary and Secondary Outcomes

	Total (N =284)		LG-CC (N=139)		Usual care (N =145)			
	mean ± sd or median (IQR)	%	mean ± sd or median (IQR)	%	mean ± sd or median (IQR)	%	*t*	*p-value*
Primary outcome								
HRQOL physical health Score (VR-12)[a]	33.4 ± 11.0		32.8 ± 10.9		33.9 ± 11.0		−.92	.36
Secondary outcomes								
HRQOL mental health Score (VR-12)[a]	34.3 ± 11.9		35.2 ± 12.2		33.4 ± 11.6		1.30	.20
Systolic BP, mmHg[b]	135.4 ± 14.4		135.8 ± 14.5		135.1 ± 14.4		.44	.66
Diastolic BP, mmHg[b]	77.5 ± 9.8		76.9 ± 9.7		78.0 ± 9.9		−.88	.38
BMI, kg/m2[c]	33.3 ± 6.3		34.3 ± 7.11		32.3 ± 5.2		2.66	.008
<25		5.3		5.0		5.5		
25-29.9		27.5		25.9		29.0		
30-34.9		31.7		29.5		33.8		
35-39.9		21.5		19.4		23.5		
40		14.1		20.1		8.3		.08
Physical activity (min/wk)[d]	113.8 ± 159.0		104.3 ± 141.5		123.7 ± 175.5		−.87	.39
Walking (min/wk)	82.0 ± 134.8		70.8 ± 125.7		92.8 ± 142.8		−1.24	.22
Moderate (min/wk)	18.4 ± 44.4		19.7 ± 46.6		17.1 ± 42.3		.43	.66
Vigorous (min/wk)	15.6 ± 42.6		15.8 ± 43.4		15.3 ± 42.1		.09	.93
Exploratory outcomes								
Psychiatric Symptoms								
Depression: PHQ-9[e]	12.0 ± 5.9		11.6 ± 5.7		12.4 ± 6.0		−1.17	.24
<10		36.0		39.9		32.4		.42
10-14		38.2		35.5		40.7		
>=15		25.8		24.6		26.9		
Psychosis[f]	.8 (.1, 1.7)		.7 (.0, 1.5)		.8 (.1, 1.8)			.23
Manic (activation) [g]	20.4 ± 11.1		19.8 ± 11.1		20.9 ± 11.2		−.82	.41
Well-being[g]	16.5 ± 6.7		16.5 ± 6.7		16.4 ± 6.7		.02	.99

	Total (N =284)		LG-CC (N=139)		Usual care (N =145)			
	mean ± sd or median (IQR)	%	mean ± sd or median (IQR)	%	mean ± sd or median (IQR)	%	t	p-value
Framingham (FH) Score[h]	12.4 ± 7.6		12.4 ± 7.4		12.3 ± 7.9		.87	.39
FH < 10%		36.3		36.2		36.3		
FH 10-20%		55.0		55.1		54.8		
FH > 20%		8.8		8.7		8.9		.99
Waist Circumference, in.[i]	45.2 ± 6.1		45.9 ± 6.1		44.4 ± 5.4		2.0	.04

Statistical method: Chi-squared test for categorical variables (% reported); Two independent samples t-test for numeric variables (mean±sd reported); Wilcoxon-Mann-Whitney test for the variables with a highly skewed distribution (median (IQR) reported).

[a]Health-related quality of life (HRQOL) was assessed from the patient survey using the 12-item Veterans Short-Form Health Survey (VR-12). Mental health (MCS) and physical health (PCS) component scores each ranged from 0 to 100, with higher scores indicating better health.

[b]Systolic and diastolic blood pressure were ascertained from a clinical assessment: based on the average of two blood pressure readings sitting down

[c]Height and weight measurements to calculate body mass index (BMI) were ascertained from medical records and the clinical assessment, respectively

[d]Physical activity was assessed via the International Physical Activity Questionnaire (IPAQ), which defines physical activity in # minutes per week based on 7-day self-report.

[e]The Patient Health Questionnaire (PHQ-9) depression symptom scale is a 9-item measure scored 0 to 27, with higher scores indicating more depressive symptoms. Scores <10 represent minimal symptoms, 10–14: dysthymia or mild depression, and >=15: moderate-severe depressive symptoms.

[f]Psychosis was assessed using a 5-item subscale of BASIS® measure; as a weighted sum of 4 items (scores range from 0-4), with a higher score indicating more severe symptoms. Wilcoxon-Mann-Whitney test is used for this variable.

[g]Manic and well-being symptoms were assessed using the Internal State Scale (ISS), which includes scales for manic symptoms (scores range from 0 to 50, with higher score indicating more severe manic symptoms) and well-being (scores range from 0 to 30, with higher scores indicating great well-being).

[h]Framingham Risk Scores: 3 risk categories estimate 10-year risk for coronary heart disease: high risk (>20%), moderately high risk (10%-20%), or lower to moderate risk (10-year risk <10%)

[i]Waist circumference was ascertained from the patient clinical assessment