Improving Physical Health in Patients With Chronic Mental Disorders: Twelve-Month Results From a Randomized Controlled Collaborative Care Trial

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ABSTRACT

Objective: Persons with chronic mental disorders are disproportionately burdened with physical health conditions. We determined whether Life Goals Collaborative Care compared to usual care improves physical health in patients with mental disorders within 12 months.

Methods: This single-blind randomized controlled effectiveness study of a collaborative care model was conducted at a midwestern Veterans Affairs urban outpatient mental health clinic. Patients (N = 293 out of 474 eligible approached) with an *ICD-9-CM* diagnosis of schizophrenia, bipolar disorder, or major depressive disorder and at least 1 cardiovascular disease risk factor provided informed consent and were randomized (February 24, 2010, to April 29, 2015) to Life Goals (n = 146) or usual care (n = 147). A total of 287 completed baseline assessments, and 245 completed 12-month follow-up assessments. Life Goals included 5 weekly sessions that provided semistructured guidance on managing physical and mental health symptoms through healthy behavior changes, augmented by ongoing care coordination. The primary outcome was change in physical health-related quality of life score (Veterans RAND 12-item Short Form Health Survey [VR-12] physical health component score). Secondary outcomes included control of cardiovascular risk factors from baseline to 12 months (blood pressure, lipids, weight), mental health-related quality of life, and mental health symptoms.

Results: Among patients completing baseline and 12-month outcomes assessments (N = 245), the mean age was 55.3 years (SD = 10.8; range, 25–78 years), and 15.4% were female. Intent-to-treat analysis revealed that compared to those in usual care, patients randomized to Life Goals had slightly increased VR-12 physical health scores (coefficient = 3.21; $P = .01$).

Conclusions: Patients with chronic mental disorders and cardiovascular disease risk who received Life Goals had improved physical health-related quality of life.

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Chronic mental disorders including schizophrenia, bipolar disorder, and major depressive disorder[1] are associated with worse physical health[2,3] and premature mortality.[2,4,5] A key driver is cardiovascular disease (CVD),[2,6,7] and common physical health conditions, such as hypertension and obesity, disproportionately burden these patients with mental disorders[6] and are also leading risk factors for CVD.

Poor self-management and unhealthy behaviors contribute up to 60% increased CVD-related mortality risk in this group.[7] Lack of coordinated physical and mental health care, as well as limited dissemination of self-management strategies to support patients with mental health symptoms, can also further exacerbate morbidity and mortality risk.[8–11]

Treatment models for persons with chronic mental disorders need to address barriers to self-management and care coordination. Collaborative Care Models (CCMs),[12] which provide proactive care for patients through self-management and care coordination, have been shown to improve health outcomes, primarily for patients with depression.[13,14] Life Goals Collaborative Care (LG-CC), a CCM-based intervention, was shown to improve physical health-related quality of life and reduce CVD risk factors in patients with bipolar disorder.[15–18] However, to date LG-CC has not been tested in a broader psychiatric patient population, beyond single diagnoses.[7]

The goal of this single-blind randomized controlled trial was to determine whether LG-CC compared to usual care (UC) improved physical and mental health outcomes in 12 months among patients with chronic mental disorders who are at risk for CVD. Our primary hypothesis was that patients randomized to receive LG-CC compared to those randomized to receive usual care would have improved physical health-related quality of life (Veterans RAND 12-item Short Form Health Survey [VR-12][19,20]) scores from baseline to 12 months later. Commonly used in several clinical trials,[21,22] improved health-related quality of life scores have been linked to improvements in CVD symptom–specific measures,[23] and lower physical health-related quality of life scores were associated with a 2- to 3-fold increased risk in CVD-related mortality.[24]

Our secondary and exploratory hypotheses were that, compared to those enrolled in UC, patients in the LG-CC group would have improved mental health-related quality of life scores, increased physical activity in 12 months, decreased psychiatric symptoms, and changes in intermediate and long-term CVD risk factors (Framingham Score[25]).

Clinical Points

- Collaborative Care Models (CCMs) provide proactive care for patients through self-management education and ongoing care coordination with providers, but have not been evaluated in a diverse patient population with mental disorders.
- CCMs may improve health-related quality of life for persons with chronic mental disorders, but more support might be needed to reduce risk of cardiovascular disease.

METHODS

This randomized controlled effectiveness intervention trial was conducted between February 24, 2010, and February 15, 2014 (with the last assessment completed April 29, 2015) among adult patients diagnosed with chronic mental disorders with at least 1 CVD risk factor who received care in a large urban Veterans Affairs (VA) outpatient mental health clinic.[26] This study received approval from the VA Ann Arbor Institutional Review Board. All patients provided informed consent, and the trial has been registered in ClinicalTrials.gov (NCT01487668 and NCT01244854).

Setting, Recruitment, and Participants

A clinical assessor, who was blinded to treatment allocation, screened for eligibility using electronic medical records per the following inclusion criteria:

1. Age of 18 years or older with a diagnosis of schizophrenia, bipolar disorder, or major depressive disorder (single or recurrent) among patients receiving care in the mental health clinic. Mental disorder diagnosis was based on the presence of at least 1 inpatient or outpatient *ICD-9-CM*[27] diagnosis of within the past year from the study recruitment start date (February 15, 2010). These diagnoses were chosen because they were considered the most chronic and debilitating mental health diagnoses that are primarily seen in VA mental health specialty.[28] Previous research suggests that a single *ICD-9* encounter code is sufficient for case ascertainment in studies in mental health clinics.[29] We used the following previously established diagnosis hierarchy to categorize patients: (*a*) schizophrenia, (*b*) bipolar disorder (but no presence of schizophrenia diagnosis), and (*c*) major depressive disorder diagnosis (without presence of schizophrenia or bipolar disorder diagnosis).[30]
2. At least 1 of the following CVD risk factors recorded in the medical record: (*a*) body mass index (BMI) > 28 or waist circumference > 35 (women)/ > 40 (men) inches; and (*b*) diagnosis of or treatment for hypertension (diagnosis or blood pressure of > 140/90 on 2 occasions or prescription for an antihypertensive medication),[31] dyslipidemia (diagnosis or LDL > 160 or prescription for a lipid-lowering medication), or diabetes mellitus (diagnosis or hemoglobin A_{1c} > 7% or current prescription for oral hypoglycemic therapy).

All potentially eligible participants based on medical record review were approached by the clinical assessor, who then confirmed eligibility and excluded potential participants based on the following criteria: (1) unresolved substance intoxication or withdrawal (eg, incoherent, slurred speech), (2) unwilling or unable to provide informed consent or comply with study requirements at the time of enrollment, or (3) expressing active suicidal ideation at time of enrollment (these patients were immediately referred to their mental health provider).

Those eligible and who consented to participate completed a baseline survey and underwent a clinical assessment that included systolic/diastolic blood pressure (2 readings) and weight/height/waist circumference.

Treatment Assignment and Intervention

After confirmation of eligibility, documentation of informed consent, and completion of a baseline questionnaire and brief clinical assessment, participants were randomized to LG-CC or UC by a separate data analyst. Randomization was stratified by gender, age, race, and diabetes diagnosis (given that patients with diabetes may already be receiving health education and nutrition counseling through the VA).

LG-CC Intervention

Participants randomized to receive LG-CC were contacted by a study interventionist to schedule the first group self-management session. The interventionist (masters-level in health education) was trained over a 2-day period in LG-CC by study investigators using a previously established protocol.[28,32–34] LG-CC, described in detail elsewhere,[26] consisted of 5 group sessions lasting 90 minutes each session (with an average of 10 participants per group), and subsequent care management contacts lasting on average 20 minutes per contact that were delivered by the interventionist for up to 6 months after the group sessions ended (Table 1). LG-CC is based on the Collaborative Care Model but customized to include use of symptom coping strategies that targeted CVD risk factors among persons with chronic mental disorders.[35–39] LG-CC group sessions focused on helping patients manage mental health symptoms by promoting healthy behaviors that also addressed physical health issues, notably CVD risk, especially healthy eating and physical activity.

Monthly care management calls included monitoring of progress on achieving healthy behavior goals and additional guidance on symptom coping strategies. The interventionist also shared with providers the patients' care plans, health

Table 1. Life Goals Collaborative Care (LG-CC) Intervention and Usual Care Components

Component	LG-CC Group	Usual Care Group
Self-management (months 1–2)	**Five weekly self-management sessions by health specialist** Five group sessions (90 min, approximately 8–10 individuals per group cohort) covering the following: Mood/psychotic symptoms and stigma issues Understanding behavioral risk factors for CVD Setting health behavior goals focused on diet and/or physical activity Active discussions with group members on identifying effective symptom coping strategies that are also healthy behaviors (eg, increased physical activity, decrease stress eating) Tips for patients in communicating with providers regarding symptoms and health care needs	No LG-CC group sessions focused on symptom coping strategies and CVD risk
Care coordination (months 1–12)	**Care management** Conduct ongoing patient contacts monthly for 6 mo to reinforce lessons from self-management Use registry to track progress on physical activity and dietary goals made during self-management sessions Interventionist identifies symptoms or other health issues to relay to providers when appropriate Interventionist provides care plan to patient's providers Interventionist provides information on LG-CC program and VA guidelines for CVD risk monitoring to primary care and mental health providers at staff meetings	No follow-up phone calls to patients or contacts with providers by LC-GG interventionist No ongoing contacts to providers or care plan provided by the interventionist 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
Mental health clinic resources (months 1–12)	Providers given guidelines on how to manage CVD risk in patients with chronic mental disorders, including the VA MIAMI cardiometabolic monitoring guidelines[32] Psychotropic medications provided by psychiatrists; ad hoc individual or group therapy provided by psychologists or clinical social workers Routine medical care available at facility	Psychotropic medications provided by psychiatrists; ad hoc individual or group therapy provided by psychologists or clinical social workers Routine medical care available at facility

Abbreviations: CVD = cardiovascular disease, MIAMI = MIRECC Initiative on Antipsychotic Management Improvement, VA = Veterans Affairs.

goals, and guidelines for cardiometabolic risk management for key psychotropic medications where appropriate.[40] Taking provider contact time into consideration (5 minutes per encounter), the overall time the interventionist spent delivering LG-CC was 952 hours (average 6.5 hours per participant).

Fidelity to the LG-CC intervention was tracked using in-person monitoring of group sessions to ensure core topic areas of the self-management program were completed. Session attendance and contact completion were also tracked for each participant. Using a previous definition that was associated with improved outcomes from LG-CC,[41] adequate attendance was defined as participating in 4 out of 5 self-management sessions and completing at least 4 care management contacts.[42]

Usual Care

Patients who were randomized to usual care received routine VA care (Table 1), but were not provided LG-CC self-management sessions or ongoing contacts by the interventionist. UC included routine medication management provided by psychiatrists, as well as psychotherapy for specific diagnoses (eg, cognitive-behavioral therapy) provided by mental health clinicians, but was not focused on CVD risk factors.

Data Collection and Measures

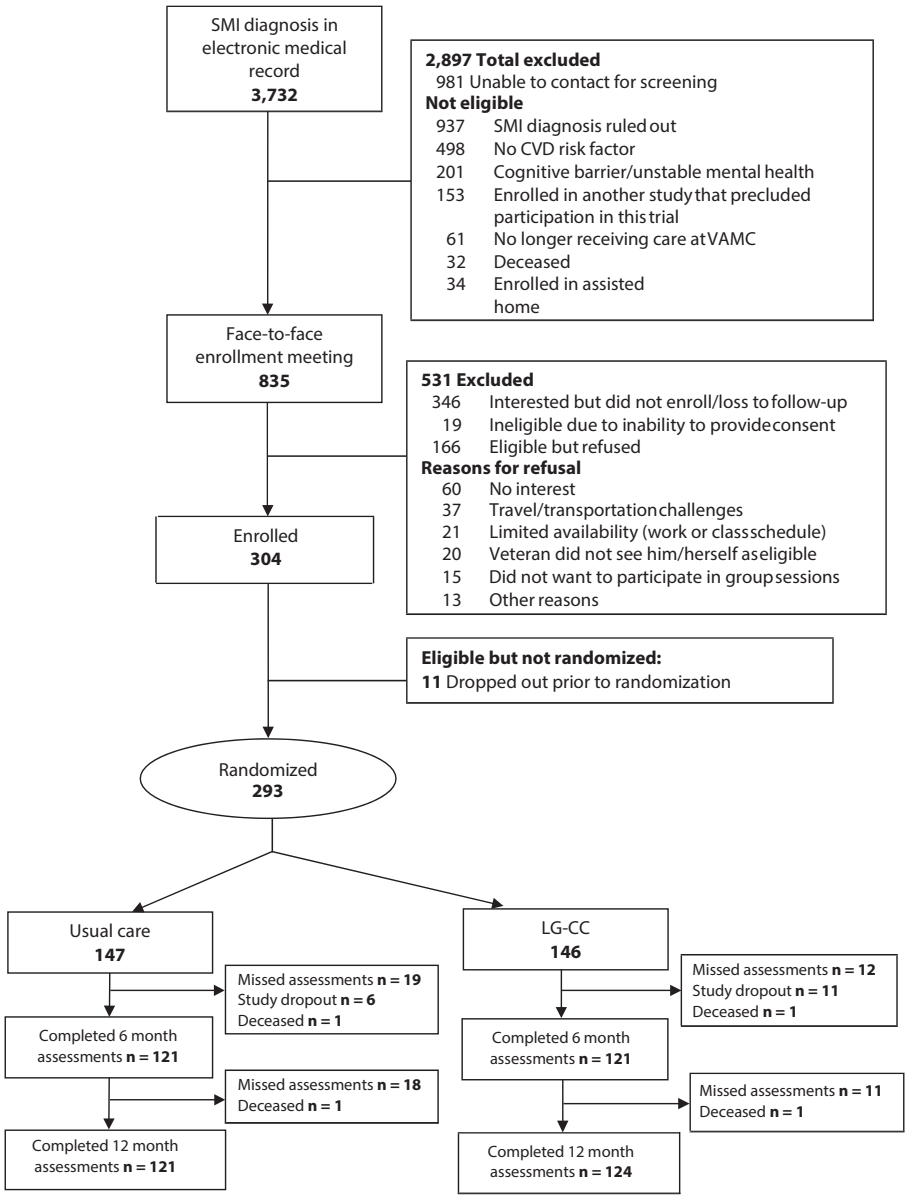
All study participants completed a survey and clinical examination that were administered at baseline and at 6 and 12 months by the clinical assessor. Survey questions covered the primary (physical health-related quality of life), secondary (mental health-related quality of life, measures of cardiovascular risk), and exploratory outcomes (symptoms and other health behaviors), as well as covariates. The clinical examination was completed in person in a private room in the mental health clinic and included CVD risk indicators including blood pressure (average of 2 readings of systolic and diastolic blood pressure ascertained when the patient was sitting down), and height/weight to calculate BMI. Additional CVD risk factors including lipids were ordered as fasting laboratories through the VA medical record, and the results were extracted by the outcomes assessor nearest to the baseline and 6 and 12 month survey dates.

Primary and Secondary Outcomes

The primary outcome was changes in physical health-related quality of life between baseline and 12 months later. Physical health-related quality of life was found to be directly affected by LG-CC based on prior studies.[15,17,18,24] The Veterans Short-Form (VR)-12,[19,20] a widely used and validated instrument, was the source of data on physical health-related quality of life. The VR-12 generated a physical health (PCS) and mental health (MCS) composite score, in which each component score ranged from 0 to 100, whereas a higher score represented better health-related quality of life.

Secondary outcomes included mental health-related quality of life based on the aforementioned MCS score, as well as measures of CVD risk including systolic blood pressure, diastolic blood pressure, BMI, and physical activity.[17,18] Physical activity was ascertained from the patient survey using the Physical Activity Questionnaire-Short Form (IPAQ-SF),[43] a self-reported 4-item measure of habitual physical activity over the past 7 days. IPAQ-SF ascertains information on time spent in moderate-intensity

Figure 1. CONSORT: Participant Recruitment and Enrollment Flow Diagram



Abbreviations: CVD = cardiovascular disease, LG-CC = Life Goals Collaborative Care, VAMC = Veterans Affairs Medical Center.

activity (such as walking), in vigorous-intensity activity, and sitting, on weekdays and weekend days.

Other exploratory outcomes included psychiatric symptoms, 10-year CVD risk based on the Framingham score,[25] and waist circumference. Psychiatric symptoms are ascertained from the patient survey and include mood, psychosis, anxiety, and posttraumatic stress disorder (PTSD) symptoms.[44] Mood symptoms were assessed using the Patient Health Questionnaire (PHQ-9)[45] and the Internal State Scale (ISS).[46,47] Psychotic symptoms were ascertained 5-item Behavior and Symptom Identification Scale (BASIS).[48] Anxiety symptoms were measured using the GAD-7, a 7-item self-report tool designed to screen for the *DSM-IV* diagnostic criteria of Generalized Anxiety Disorder (GAD). The GAD-7 measure is recognized for its reliability and validity for assessing anxiety.[49] PTSD symptoms were assessed based on the PTSD Checklist—Civilian Version (PCL-C) 17-item measure, which includes key symptoms of PTSD.[50,51]

The Framingham Risk Score[25] estimated 10-year risk of acquiring CVD based on a weighted score derived from blood pressure data, diabetes diagnosis (VA electronic medical record diagnoses at baseline), patient age, sex, and current smoking status (from the baseline survey), and fasting low-density lipoprotein levels in mg/dL ascertained from the VA electronic medical record review[52–55] based on laboratory results recorded nearest to the patient's assessment dates at baseline, 6 and 12 months. Finally, socio-demographics and other health behaviors were ascertained from the participant survey.[56,57]

Sample Size and Power

The sample size for the study (N = 240) enabled a minimum power of 0.80 to detect a small to moderate effect (Cohen $d > 0.30$),[17,18] at a significance level of .05 (using a 2-tailed statistical test) on our primary outcome.[58]

Analysis

Repeated measures analyses were used to assess the intervention effects on changes in outcomes, adjusting for LG-CC, time (6 and 12 months using dummy indicators), and the interaction between LG-CC and time, as well as baseline variables that were significantly different between in the intervention and control groups. All analyses were conducted using SAS 9.4 (Cary, North Carolina) and included the 245 individuals with complete baseline and 12-month data. The coefficients reported represent main effects of the difference in LG-CC scores compared to differences in the usual care scores over the baseline and 12-month period. Primary and secondary outcomes were changes over the baseline and 12-month period between LG-CC and usual care groups.

RESULTS

A total of 3,732 eligible patients were screened for study participation, of which 2,897 were not found to be eligible (Figure 1). Of the 835 approached, 474 were found to be

Table 2. Participant Demographic and Clinical Characteristics[a,b]

	Total (N = 287)	LG-CC (n = 141)	Usual Care (n = 146)	*t*	*P* Value
Demographics					
Age, mean ± SD, y (range, 25–78 y)	55.3 ± 10.8	55.3 ± 10.7	55.4 ± 11.0	.08	.93
Age group					
< 50 y	25.7	24.3	27.1		.86
50–59 y	31.3	32.1	30.6		
≥ 60 y	42.9	43.6	42.4		
Female	15.4	15.6	15.3		.93
Black (vs nonblack)	18.1	22.1	14.2		.08
Some college education	72.9	73.8	72.2		.77
Lives alone	32.2	29.6	34.8		.35
Clinical factors					
Current diagnosis[c]					
Schizophrenia	7.3	5.7	8.9		.67
Bipolar disorder	24.0	23.4	24.7		
Major depressive disorder	57.5	60.3	54.8		
Other SMI diagnosis	11.2	10.6	11.6		
Current substance use					
Current smoker	26.1	23.5	28.6		.33
Alcohol misuse					
AUDIT-C score, median (IQR)[d]	0 (0, 3)	0 (0, 3)	0 (0, 3)		.88
Hazardous drinking	12.3	11.8	12.9		.78
Current CVD diagnosis[e]					
Hypertension	63.8	65.3	62.3		.60
Hyperlipidemia	62.0	62.4	61.6		.89
Diabetes mellitus	31.4	34.0	28.8		.33
Medications[f]					
Antipsychotics	38.0	33.1	42.8		.09
Antidepressants	83.5	85.6	81.4		.33
Mood stabilizers	52.1	49.6	54.5		.41
Statins	51.2	52.5	50.0		.67

[a]Values expressed as percentages unless otherwise noted.
[b]Statistical method: χ^2 test for categorical variables (% reported); 2 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.
[c]Mental disorder diagnosis based on medical record review and delineated based on the following diagnosis hierarchy: (1) schizophrenia, (2) bipolar disorder but no presence of schizophrenia diagnosis, and (3) major depressive disorder diagnosis (without diagnosis of schizophrenia or bipolar disorder).
[d]Current hazardous drinking is based on the score of 1 item of the AUDIT-C defined as having 6 or more drinks on 1 occasion in the past month (yes/no). AUDIT-C scores are defined on a 0–12 scale and based on 3 items, with higher scores indicating more serious drinking. Wilcoxon-Mann-Whitney test is used for this variable.
[e]CVD-related diagnoses based on medical record review.
[f]Medication use ascertained from the medical record include any current use of antipsychotic medications, antidepressants, or mood stabilizing medications.
Abbreviations: AUDIT-C = Alcohol Use Disorders Identification Test Consumption, CVD = cardiovascular disease, IQR = interquartile range, LG-CC = Life Goals Collaborative Care, SMI = serious mental illness.

eligible, and of those, 304 agreed to participate and were enrolled. Of the 304, a total of 11 dropped out prior to randomization, resulting in a final baseline sample size of 293, and 245 of the 293 completed baseline and 12 month assessments. The mean age was 55.3 years (SD = 10.8; range, 25–78 years), 44 (15.4%) were women, and 50 (18.1%) were African-American, reflecting similar demographics in this VA mental health clinic (mean age = 55 years, 6% female, 11% African-American). The majority, 165 (57.5%), were diagnosed with depression (Table 2).

At baseline (Table 3), overall health-related quality of life scores were on average substantially lower (17 points) than the national norms (50 points) for the VR-12 component scores, Furthermore, the mean BMI was 33, in which a BMI > 30 is the definition of obesity. There were no statistically significant differences in baseline demographic characteristics (age, gender, race, college education, living alone) between participants who remained in the analysis at 12 months compared with those who did not complete a 12 month follow-up survey.

Comparisons on baseline (pretreatment) outcomes revealed significant differences in BMI, waist circumference, and physical activity between the intervention and control groups (Table 3), so these variables were included in the repeated measures analyses.

Table 4 presents repeated measures results, which were estimates in the differences of changes from baseline to 12 months between patients randomized to either LG-CC or usual care. Overall, patients randomized to LG-CC compared to those randomized to usual care had a greater improvement, or difference in 12-month health-related quality of life VR-12 physical health component scores ($\beta = 3.21$, $P = .01$, Cohen $d = 0.39$). There was a statistically significant reduction in low-density lipoprotein (LDL) levels for the LG-CC group compared to those from the usual care group ($\beta = -8.77$, $P = .04$, Cohen $d = -0.30$).

DISCUSSION

Patients with chronic mental disorders and at least 1 CVD risk factor receiving LG-CC had a greater improvement in physical health-related quality of life after 12 months compared to those receiving usual care. These findings reflect similar results elsewhere in which Life Goals Collaborative Care compared to usual care improved physical health-related quality of life among patients with bipolar disorder.[15–18] While this finding was statistically significant, the effect size was moderate (Cohen $d = 0.39$), and the actual change in points based on the Physical Health Component score was small. Previous studies[23,24] based on the physical health-related quality of life measure found that a 7-point improvement in the physical health component score was strongly correlated with improvements in cardiovascular disease symptom-specific measures.[23] Nonetheless, the substantially low physical health-related quality of life scores in this patient population (eg, 33–34 points on average, when the population norm is 50 points) was found in previous research to be associated with a clinically significant increased risk in cardiovascular disease– related mortality (2- to 3-fold increased risk).[24]

We did not find observed improvement in secondary outcomes, notably CVD risk factors. In a recent review, evidence suggests that more intensive interventions for a longer duration might be needed to achieve weight loss in persons with mental disorders (eg, direct physical activity involvement, direct provision of healthier food).[59] Life

Table 3. Differences in Baseline Primary and Secondary Outcomes Comparing Intervention (LG-CC) and Usual Care Groups[a,b]

	Total (N = 287)	LG-CC (n = 141)	Usual Care (n = 146)	*t*	*P* Value
Primary outcome					
HRQOL physical health score (VR-12)[c]	33.3 ± 10.9	32.8 ± 10.9	33.9 ± 11.0	0.86	.39
Secondary outcomes					
HRQOL mental health score (VR-12)[c]	34.6 ± 12.1	35.5 ± 12.4	33.8 ± 11.8	−1.23	.21
Systolic BP, mm Hg[d]	135.3 ± 14.5	135.7 ± 14.5	134.9 ± 14.5	−0.47	.63
Diastolic BP, mm Hg[d]	77.4 ± 9.8	76.8 ± 9.7	77.9 ± 9.9	0.92	.35
BMI (kg/m^2)[e]	33.3 ± 6.2	34.3 ± 7.1	32.3 ± 5.2	−2.71	.007
Physical activity (min/wk)[f]	270.9 ± 287.1	167.5 ± 225.1	344.6 ± 305.5	2.78	.006
Psychiatric symptoms					
Depression: PHQ-9[g]	11.9 ± 5.9	11.5 ± 5.8	12.4 ± 6.0	1.34	.18
% with score < 10	36.4	40.7	32.2		.31
% with score 10–14	38.1	35.0	41.1		
% with score ≥ 15	25.5	24.3	26.7		
Psychosis, median (IQR)[h]	0.8 (0.1, 1.7)	0.7 (0.1, 1.5)	0.8 (0.1, 1.8)		.24
Manic (activation)[i]	20.4 ± 11.2	19.8 ± 11.1	20.9 ± 11.3	0.89	.37
Well-being[h]	16.5 ± 6.7	16.5 ± 6.7	16.4 ± 6.7	−0.07	.94
GAD	9.4 ± 5.9	8.9 ± 5.8	9.7 ± 5.9	1.02	.30
PCL	46.7 ± 16.5	45.2 ± 16.9	48.2 ± 16.0	1.48	.14
Framingham (FH) score[j]	12.5 ± 7.8	12.6 ± 7.7	12.3 ± 7.9	−0.36	.72
% with FH < 10%	36.2	35.7	36.8		.97
% with FH 10%–20%	54.7	55.0	54.4		
% with FH > 20%	9.1	9.3	8.8		
Lipids					
LDL	11.3 ± 35.5	112.0 ± 36.5	110.6 ± 34.7	−0.34	.73
HDL	41.5 ± 11.1	40.7 ± 10.3	42.3 ± 11.8	1.25	.21
Total cholesterol	184.2 ± 43.9	182.1 ± 43.6	186.2 ± 44.2	0.78	.43
Waist circumference, in[k]	45.2 ± 6.1	45.9 ± 6.6	44.4 ± 5.4	−2.13	.03

[a]Values expressed as mean ± SD unless otherwise noted.
[b]Statistical method: χ^2 test for categorical variables (% reported); 2 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].
[c]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.
[d]Systolic and diastolic blood pressure were ascertained from a clinical assessment: based on the average of 2 blood pressure readings sitting down.
[e]Height and weight measurements to calculate body mass index (BMI) were ascertained from medical records and the clinical assessment, respectively.
[f]Physical activity was assessed via the International Physical Activity Questionnaire (IPAQ), which defines physical activity in number of minutes per week based on 7-day self-report.
[g]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.
[h]Psychosis was assessed using a 5-item subscale of Behavior and Symptom Identification Scale (BASIS) measure; as a weighted sum of 4 items (scores from 0–4), with a higher score indicating more severe symptoms. Wilcoxon-Mann-Whitney test is used for this variable.
[i]Manic symptoms and well-being 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 greater well-being).
[j]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%). The score was calculated based on the following variables: sex, age, diabetic status, smoking status, total cholesterol, HDL, systolic blood pressure, and diastolic blood pressure.
[k]Waist circumference was ascertained from the patient clinical assessment.
Abbreviations: BP = blood pressure, HDL = high-density lipoprotein, IQR = interquartile range, LDL = low-density lipoprotein, LG-CC = Life Goals Collaborative Care.

Goals was designed as a briefer intervention that primarily focused on implementing collaborative care model components, notably self-management skills, among patients with chronic mental disorders among existing teams of providers. In contrast, more intensive weight loss programs for persons with chronic mental disorders[60,61] typically involved added investments in new provider teams[62–65] or deployment of closely supervised diet or exercise regimens.[66–68] Nonetheless, LG-CC did have an observed impact on physical health-related quality of life, which in turn can be an important functional milestone toward the adoption of healthier lifestyles.[18]

In addition, we did not find any impact of LG-CC on mental health outcomes. The lack of findings on mental health effects might have been due to the fact that patients in both the intervention and control groups not only were enrolled in outpatient mental health services but also had access to psychotherapies in a VA clinic, including individual and group therapy. Moreover, the LG-CC intervention was focused mainly on mitigating physical health risk.

There are limitations to this study that warrant consideration. The intervention was evaluated in a single VA site so generalizability may not extend to sites beyond midwestern VA mental health clinics.[69] The inclusion criteria were broad (with the inclusion of different CVD risk factors) in order to closely resemble a real-world clinic population, which may have also led to heterogeneity in the sample and limited impact on outcomes or significance in findings. Still, the persistent level of CVD risk factors has been observed elsewhere in non-VA settings.[70] In addition, the study relied on a single interventionist with a health education background. While consistent results were found in previous LG-CC studies utilizing interventionists with nursing, psychology, and other medical backgrounds,[12,16,17,32] it is possible that the study results were influenced by the individual characteristics of the interventionist. There was insufficient information on diet and medication use to determine the mechanisms by which LG-CC might have contributed to changes in LDL levels. There were also questions regarding whether the usual care group received any of the LG-CC components, notably through patients' providers who might have had another patient in the LG-CC group. Diagnoses based on *ICD-9* codes to identify those with mental disorder were not confirmed by clinician diagnostic confirmation. Finally, only self-completed physical activity measures were included, with no direct observation of health behaviors such as physical activity.

Overall, LG-CC compared to usual care produced modest improvements in physical health-related quality

Table 4. Twelve-Month Changes in Primary and Secondary Outcomes Comparing Participants Randomized to Life Goals Collaborative Care (LG-CC) or Usual Care (UC)[a]

	LG-CC (n = 124)			Usual Care (n = 121)			Estimate of 12 Month Changes Between LG-CC and Usual Care Groups, β (95% CI)	Cohen *d*	*t* Value	*P* Value
	Baseline Mean (SD)	6 Month Mean (SD)	12 Month Mean (SD)	Baseline Mean (SD)	6 Month Mean (SD)	12 Month Mean (SD)				
HRQOL physical health score (VR-12)[b]	32.41 (10.59)	32.76 (11.89)	33.61 (11.36)	34.31 (10.92)	33.54 (11.31)	34.00 (11.49)	3.21 (0.55 to 5.86)	0.39	2.37	.01
HRQOL mental health score (VR-12)[c]	35.42 (12.23)	38.25 (12.87)	38.13 (12.41)	34.49 (11.41)	35.69 (10.97)	36.36 (12.11)	−0.004 (−3.38 to 3.37)	0.00	−0.00	.99
Systolic BP, mm Hg[b]	135.39 (14.36)	137.18 (17.74)	135.95 (17.23)	135.07 (14.58)	136.37 (15.44)	137.42 (16.95)	−1.82 (−6.26 to 2.62)	−0.12	−0.80	.42
Diastolic BP, mm Hg[b]	76.44 (8.74)	76.14 (10.28)	75.46 (9.05)	77.71 (9.69)	77.61 (9.83)	77.43 (9.32)	−1.07 (−3.75 to 1.62)	−0.11	−0.78	.43
BMI, kg/m^2[d]	34.01 (6.74)	34.38 (6.56)	34.07 (6.98)	32.48 (5.26)	32.79 (5.66)	32.76 (5.55)	−0.50 (−1.05 to 0.05)	−0.27	−1.80	.07
Physical activity (min/wk)[e]	1,212.61 (1,776.04)	1,583.09 (2,222.08)	1,494.50 (1,927.02)	1,294.25 (1,538.96)	1,492.99 (1,943.34)	1,230.77 (1,617.59)	364.54 (−240.9 to 970.1)	0.18	1.18	.23
Depressive symptoms (PHQ-9 score)[f]	11.39 (5.67)	9.99 (6.33)	9.53 (6.19)	12.06 (5.78)	10.74 (5.44)	11.26 (6.04)	−0.73 (−2.35 to 0.89)	−0.13	−0.88	.37
ISS Activation score[g]	19.53 (10.86)	20.37 (11.70)	19.83 (11.65)	21.05 (11.26)	21.22 (11.59)	21.51 (11.67)	−0.73 (−4.13 to 2.66)	−0.07	−0.42	.67
ISS Well-being score[g]	16.52 (6.53)	17.18 (6.71)	18.19 (6.51)	16.73 (6.81)	17.39 (6.31)	17.45 (6.47)	−0.29 (−2.29 to 1.71)	−0.04	−0.29	.77
GAD score[h]	8.93 (5.84)	7.55 (5.48)	6.35 (5.39)	9.42 (5.78)	9.16 (5.75)	8.86 (5.51)	−1.48 (−3.10 to 0.15)	−0.28	−1.78	.07
PTSD score[i]	45.42 (16.63)	41.80 (16.52)	39.85 (16.51)	47.45 (15.48)	44.95 (14.12)	45.00 (14.12)	−0.59 (−3.92 to 2.74)	−0.05	−0.35	.72
Overall BASIS-24 Symptom score[j]	1.63 (0.56)	1.43 (0.60)	1.38 (0.61)	1.63 (0.64)	1.56 (0.54)	1.53 (0.57)	−0.05 (−0.21 to 0.11)	−0.09	−0.60	.55
Framingham Risk score (%)[k]	12.59 (7.73)	14.69 (10.19)	12.84 (8.69)	12.29 (7.95)	13.13 (8.24)	13.86 (9.88)	−1.79 (−4.23 to 0.66)	−0.26	−1.43	.15
LDL (mg/dL)	112.24 (35.52)	112.13 (35.13)	107.71 (34.18)	110.57 (34.31)	115.15 (38.10)	112.84 (37.72)	−8.77 (−17.25 to −0.29)	−0.30	−2.03	.04
HDL (mg/dL)	40.90 (10.49)	41.75 (10.69)	42.24 (10.56)	41.86 (11.73)	41.45 (10.48)	42.81 (11.15)	0.72 (−1.54 to 2.98)	0.09	0.62	.53
Total cholesterol (mg/dL)	182.65 (42.32)	185.71 (42.11)	179.47 (41.70)	186.31 (45.50)	187.99 (46.68)	187.08 (46.52)	−6.53 (−17.0 to 3.99)	−0.18	−1.22	.22
Waist circumference[l]	45.68 (6.37)	45.96 (6.31)	45.34 (6.91)	44.59 (5.51)	44.63 (5.74)	44.38 (5.55)	−0.02 (−0.78 to 0.74)	−0.01	−0.06	.95

[a]All models used repeated measures analyses, adjusting for time (6 and 12 months), the LG-CC intervention, interaction term LG-CC × time, baseline IPAQ minutes per week, and waist circumference.
[b]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.
[c]Systolic and diastolic blood pressure were ascertained from a clinical assessment: based on the average of 2 blood pressure readings sitting down.
[d]Height and weight measurements to calculate body mass index (BMI) were ascertained from medical records and the clinical assessment, respectively.
[e]Physical activity was assessed via the International Physical Activity Questionnaire (IPAQ), which defines physical activity in number of minutes per week based on 7-day self-report.
[f]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.
[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]GAD is a 7-item self-report tool designed to screen for the *DSM-IV* diagnostic criteria of generalized anxiety disorder (GAD). Higher scores represent greater symptom intensity.
[i]The PTSD PCL assesses posttraumatic stress disorder symptoms via a 17-item self-reported measure, where higher score is equivalent to more symptoms.
[j]Psychosis was assessed using a 5-item subscale of BASIS measure; as a weighted sum of 4 items (scores range from 0 to 4), with a higher score indicating more severe symptoms. Wilcoxon-Mann-Whitney test is used for this variable.
[k]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%). The score was calculated based on the following variables: sex, age, diabetic status, smoking status, total cholesterol, HDL, systolic blood pressure, and diastolic blood pressure.
[l]Waist circumference was ascertained from the patient clinical assessment.
Abbreviations: BP = blood pressure, HDL = high-density lipoprotein, LDL = low-density lipoprotein.

of life and had no effect on specific CVD-related outcomes with the exception of LDL levels. Despite the dissemination of guidelines to manage CVD risk factors,[40] outcomes remain suboptimal for persons with chronic mental disorders. Moreover, the consistently low health-related quality of life scores suggest that this population is particularly vulnerable to poor CVD-related outcomes. The VA is one of the largest providers of care for patients with chronic mental disorders across the United States, and thus results will have implications for improving care for this group. Interventions such as Life Goals Collaborative Care that are driven by patient self-management approaches may improve overall health in this group. Further studies are needed to determine whether changes in quality of life lead to long-term effects on morbidity or mortality.

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