Life Goals Collaborative Care for Patients With Bipolar Disorder and Cardiovascular Disease Risk

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Objective: This pilot study compared Life Goals Collaborative Care (LGCC) with enhanced treatment as usual in reducing cardiometabolic risk factors and improving outcomes for persons with bipolar disorder. Methods: Participants were randomly assigned to LGCC (N=34) or enhanced treatment as usual (N=34). LGCC included four weekly self-management sessions and monthly telephone contacts for six months thereafter. Enhanced treatment as usual included wellness mailings. Outcomes were blood pressure, body mass index (BMI), quality of life, functioning, and symptoms. Results: Compared with enhanced treatment as usual, LGCC was not associated with reductions in cardiometabolic risk factors in 12month repeated-measures analyses. Among patients with a BMI of ≥30 or systolic blood pressure of ≥140, LGCC was associated with improvements in functioning (beta=

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-2.2 and beta=-3.8, respectively, p=.04) and reduced depressive symptoms (beta=-2.0 and -3.5, respectively, p=.04). <u>Conclusions:</u> Further research is needed to determine whether LGCC improves outcomes for patients with elevated cardiometabolic risk. (*Psychiatric Services* 63: 1234-1238, 2012; doi: 10.1176/appi.ps.201100528)

M ental disorders are associated with premature mortality, primarily from cardiovascular disease (1). Cardiovascular disease or cardiometabolic risk can be exacerbated by psychiatric symptoms and unhealthy behaviors, including physical inactivity, overeating, and tobacco use (2).

Bipolar disorder is one of the most expensive mental disorders in the United States (3). It affects 1%–6% of the U.S. population (4) and is characterized by alternating manic and depressive episodes that lead to disrupted continuity of care and elevated cardiometabolic risk (5). Many persons with bipolar disorder receive care in community-based mental health programs, where they have limited access to general medical care (6).

Most programs that target cardiometabolic risk factors among persons with mental disorders have been implemented for those with unipolar depression (7) or have involved intensive behavioral interventions (8). With the increasing focus on value-based care, practical interventions that address multiple risk factors and can be taught to existing providers are desired.

Collaborative models for persons with chronic conditions (9) might be used to address cardiometabolic risk factors among patients with mental disorders (7). These models consist of patient education on disease selfmanagement, coordination of medical and mental health care by a nonphysician interventionist, and ongoing symptom monitoring and represent a core component of the emerging medical home models. However, implementation of chronic care models in community-based mental health programs has been limited, and none has focused on bipolar disorder.

The goal of this pilot study was to compare the effectiveness of a chronic care model, Life Goals Collaborative Care (LGCC), and of enhanced treatment as usual in reducing cardiometabolic risk factors and improving outcomes for patients with bipolar disorder.

Methods

Patients were receiving care from two community-based mental health outpatient programs in southeastern Michigan. Eligible patients were age 18 and older and had a diagnosis of bipolar disorder (type I or II or not otherwise specified) and one or more diagnoses that indicate a cardiometabolic risk factor (hypertension, hyperlipidemia, diabetes, or a body mass index [BMI] >25) as recorded in medical records. Patients were recruited in 2009 and randomly assigned to receive LGCC or enhanced treatment as usual. Patients were excluded if they had severe cognitive impairment or were unable to give informed consent. The study was reviewed and approved by the University of Michigan Institutional Review Board.

After a survey coordinator confirmed eligibility, patients provided informed consent, underwent a clinical exam (weight, height, and two blood pressure measures), and completed a survey. Participants were compensated \$10 for each assessment. The survey coordinator also conducted chart reviews to ascertain service utilization data. The data analyst then randomly assigned participants to LGCC or enhanced treatment as usual in blocks of 16 to 20 stratified by age, race, and diabetes diagnosis in order to ensure balance of these characteristics. The survey coordinator was blind to patient assignment. Patients randomly assigned to LGCC were contacted by the study interventionist within two weeks to schedule intervention sessions.

The LGCC intervention is described in detail elsewhere (10). In brief, an interventionist with a master's degree in social work provided four two-hour weekly group self-management sessions to LGCC patients, followed by brief care management contacts for up to six months. Each group session included approximately eight to ten participants and featured guided discussions and exercises designed to help patients set personal self-management goals. These discussions draw heavily on social cognitive theory (11) and employ a mixture of motivational interviewing and cognitive-behavioral techniques (12) to help participants develop the behavioral capability to effectively selfmanage or cope with chronic health conditions such as bipolar disorder and cardiometabolic risk factors. Discussions were also guided to cover key topics focused on setting diet or exercise goals that could be used to minimize the burden of psychiatric

symptoms and reduce cardiovascular disease risk. Specific topics covered in the four sessions included bipolar disorder and the link to cardiovascular disease risk, stigma issues, diet and exercise within the context of strategies to cope with psychiatric symptoms, and collaborative care management. Each session included focus on recognition of symptom and behavior patterns, with an emphasis on early warning signs; triggers to maladaptive coping or health behaviors (for example, depressive symptoms and overeating); substitution of more adaptive coping and behaviors (for example, taking a walk); and tracking and reinforcing health behaviors in follow-up contacts (for example, walking goals).

When the four group sessions were over, the interventionist made one brief (20-minute), individualized telephone or in-person contacts with patients each month over a sixmonth period to track symptoms as well as progress toward wellness goals. For care management, the interventionist also alerted providers about patients' general medical or mental health care needs as documented in the follow-up contacts and tracked health goals and care by using an electronic registry over the six-month period.

The interventionist completed a training program (10,13) and followed a standardized set of protocols and an intervention manual. Fidelity was measured on the basis of direct observation of a random sample of LGCC group sessions and reviews of interventionist logs. Fidelity indicators included number of group sessions and follow-up contacts completed by patients and number of topics covered in sessions.

Enhanced treatment as usual included monthly receipt of mailings on wellness topics over six months in addition to available mental health care and referral to off-site primary care services.

Outcomes included cardiometabolic risk (BMI and systolic and diastolic blood pressure), health-related quality of life as measured by the 12-item Short-Form Health Survey, functioning as measured by the World Health Organization Disability Assessment Scale (14), and psychiatric symptoms as measured by the Internal State Scale (15).

Because this was a pilot study, statistical analyses ascertaining the effect of LGCC versus enhanced treatment as usual were considered exploratory. Repeated-measures analyses were used to determine the effect on outcomes and utilization of the two treatment conditions, and the Bonferroni method was used to adjust for multiple comparisons.

Results

Of 118 patients who were approached to participate, 12 were ineligible because they did not have a confirmed diagnosis of bipolar disorder, 13 were ineligible because they had no cardiometabolic risk factors, and 25 declined to participate. No significant differences were found between those who declined and those who were enrolled. Of the 68 enrolled patients, 34 were randomly assigned to LGCC and 34 to enhanced treatment as usual. Overall, 65 patients completed the six- and 12-month assessments. The mean± SD age of the 68 patients was 45 ± 13 ; 61% were women, and 19% were African American (Table 1). Most participants had at least one elevated cardiometabolic risk factor at baseline. Twenty-six percent had a current prescription for a mood stabilizer, and 11% had a prescription for a second-generation antipsychotic (Table 1).

In the LGCC group, 26 (79%) completed at least three self-management sessions in which the interventionist covered more than 80% of session topics. The mean number of followup contacts completed for the LGCC patients was 4.5 ± 1.5 out of six. The mean number of contacts to providers made by interventionists for each patient was 2.2 ± 1.8 during the sixmonth follow-up period.

Repeated-measures analyses indicated that LGCC participants did not experience reductions in cardiometabolic risk factors or improvements in health-related quality of life compared with participants in enhanced treatment as usual (Table 2). For the LGCC participants, the difference in improvements approached significance for only two measures—impaired functioning

Table 1
Baseline characteristics of patients receiving Life Goals Collaborative Care (LGCC) or enhanced treatment as usual

p				Enhanced trea as usual (N=3	2)	LGCC (N=3	5)	Total (N=65	
	df	Test statistic ^a	%	N	%	N	%	N	Characteristic
									Demographic
.24	63	-1.20		43.4 ± 13.6		47.2 ± 11.8		45.3 ± 12.8	$Age(M\pm SD)$
.44	1	.59	66	21	56	18	61	39	Female
									Race-ethnicity
.56	1	.34	16	5	22	7	19	12	African American
			79	26	78	25	78	51	White
			6	2	3	1	5	3	Other
.26	1	1.25	58	19	71	22	64	41	Some college education
									Substance use
.90	1	.02	28	9	27	8	27	17	Current illicit substance use
.53	1	.40	58	18	50	15	54	33	Current smoker
									Medication and health services use
.36	1	.85	21	7	31	10	26	17	Any mood stabilizer prescription ^b
.72	1	.13	12	4	9	3	11	7	
.06	3	7.67	22	5	33	8	28	13	Medicaid
			26	6	25	6	26	12	Medicare
			26	6	42	10	34	16	Medicaid and Medicare
			26	6	—	0	13	6	Other insurance
									Outcome measure
.03	63	2.28		37.2 ± 7.9		33.2 ± 6.2		35.2 ± 7.3	Body mass index (kg/m ²)
.01	63	3.33		47.3 ± 5.8		42.7 ± 5.4		45.0 ± 6.0	Waist circumference (inches)
.13	63	1.52		137.5 ± 24.1		130.2 ± 13.3		133.9 ± 1.7	Systolic blood pressure (mmHg)
.44	63	.78		86.2 ± 12.1		84.0 ± 10.0		85.1 ± 11.1	
									Quality of life ^d
.84	63	20		29.7 ± 6.4		30.1 ± 7.4		29.9 ± 6.9	MCS score
.38	63	.89		36.8 ± 8.7		34.8 ± 7.7		35.8 ± 8.2	PCS score
.06	63	1.96		20.9 ± 7.4		16.7 ± 9.6		18.8 ± 8.7	Functioning ^e
									Symptoms ^f
.17	63	1.40		9.9 ± 6.0		7.8 ± 6.5		8.8 ± 6.3	Depressive
.16	63	1.43		21.0 ± 10.9		16.4 ± 14.3		18.7 ± 12.8	Manic
1 1 1 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	6. 6. 6. 6. 6. 6.	2.28 3.33 1.52 .78 -20 .89 1.96	58 21 12 22 26 26 26	18 7 4 5 6 6 6 6 37.2±7.9 47.3±5.8 137.5±24.1 86.2±12.1 29.7±6.4 36.8±8.7 20.9±7.4 9.9±6.0	50 31 9 33 25	15 10 3 8 6 10 0 33.2±6.2 42.7±5.4 130.2±13.3 84.0±10.0 30.1±7.4 34.8±7.7 16.7±9.6 7.8±6.5	54 26 11 28 26 34	33 17 7 13 12 16 6 35.2±7.3 45.0±6.0 133.9±1.7 85.1±11.1 29.9±6.9 35.8±8.2 18.8±8.7 8.8±6.3	Current smoker Medication and health services use Any mood stabilizer prescription ^b Any second-generation antipsychotic prescription ^c Insurance type Medicaid Medicare Medicaid and Medicare Other insurance Outcome measure Body mass index (kg/m²) Waist circumference (inches) Systolic blood pressure (mmHg) Diastolic blood pressure (mmHg) Quality of life ^d MCS score PCS score Functioning ^e Symptoms ^f Depressive

^a Chi square test values, except for age, for which a t test was used

and depressive symptoms—with effect sizes of .20 (p=.11) and .23 (p=.15), respectively.

A post-hoc exploratory analysis limited the sample to participants with elevated cardiometabolic risk. Among those whose BMI was ≥30 or whose systolic blood pressure was ≥140, LGCC patients showed greater improvements than those receiving enhanced treatment as usual in impaired functioning (beta=-2.2 and -3.8, respectively, p=.04 for both) and depressive symptom scores (beta=-2.0 and -3.5, respectively, p=.04 for

both). [Tables presenting these and other data from repeated-measures analyses are available as an online data supplement to this report.] However, after post-hoc Bonferroni adjustment for multiple comparisons, these findings were not statistically significant.

Furthermore, we conducted a multifactorial analysis that included treatment and groups as factors in the repeated-measures multivariate regression models, and we tested the interactions between treatment and groups. Results showed that for patients whose systolic blood pressure

was \geq 140, there was a significant interaction with treatment (beta for the interaction=-4.1, p=.02), indicating that LGCC decreased impaired functioning to a greater extent among those whose systolic blood pressure was \geq 140 than among those whose systolic blood pressure was <140. Because these post-hoc analyses were exploratory, the significant interactions between LGCC and systolic blood pressure \geq 140 warrant further investigations in regard to which risk factor subgroups may benefit most from the intervention.

^b Lithium, valproate, carbamazepine, or lamotrigine

^c Olanzapine, ziprasidone, aripiprazole, quetiapine, or clozapine

^d Possible scores on the mental component summary (MCS) and physical component summary (PCS) of the 12-item Short-Form Health Survey range from 0 to 100, with higher scores indicating better health-related quality of life. For both, the population mean±SD is 50±10.

^e Assessed using the 12-item World Health Organization Disability Assessment Scale, which measures past-month impairment in self-care, mobility, cognition, social functioning, and role functioning. Possible scores range from 0 to 48, with higher scores indicating worse functioning.

f Assessed using the Internal State Scale, an 8-item measure of depressive and manic symptoms. For depressive symptoms, possible scores range from 0 to 20. For manic symptoms, possible scores range from 0 to 50. Higher scores indicate more severe symptoms.

Repeated-measures analysis of 12-month outcomes of patients receiving Life Goals Collaborative Care (LGCC) or enhanced treatment as usual **Table**

TRIC SI	TCCC						Enhanc	ed treatr	Enhanced treatment as usual	aal								
ERVICE	Baseline	е	6 months	.hs	12 mont	ths	Baseline	6	6 months	St	12 months	ths	Repeated	Repeated-measures analysis ^a	lysis ^a			
Variable	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	Beta	95% CI	t	Эþ	Ъ	$q_{\rm p}$
$\overline{\mathrm{BMI}}$ (kg/m ²) ^c	33.2	6.1	32.8	6.7	32.6	5.5	37.2	7.9	36.6	9.2	36.5	10.4	03	e. of to .9	1	62	.95	04
Wai	42.7	5.4	43.9	7.1	43.0	6.2	47.3	5.8	48.7	7.3	46.7	6.3	29	-1.4 to .9	ا. تن	62	.61	05
Blood pressure (mmHg)																		
Systolic	130.2	13.3	134.9	13.1	134.5	17.5	137.5	24.1	132.8	15.8	135.3	19.0	54	-4.7 to 3.6	 3	62	.79	02
Diastolic	84.0	10.0	84.9	12.3	83.2	12.7	86.2	12.1	84.6	13.2	84.1	11.7	84	-3.9 to 2.2	9.–	62	55	07
Quality of life ^d																		
ı	30.1	7.4	32.5	7.4	33.2	5.5	29.7	6.4	31.5	7.9	31.0	9.9	.03	-1.9 to 1.9	.03	51	86.	.01
PCS	34.8	7.7	34.8	7.0	36.0	8.8	36.8	8.7	35.5	7.2	34.3	7.1	35	-1.1 to 2.8	6.	51	.38	.12
${ m Functioning}^{ m e}$	17.3	9.5	16.8	8.0	15.7	11.8	20.9	7.4	19.9	6.1	21.2	7.5	-1.35	-3.0 to .3	-1.6	59	.11	20
Symptoms																		
Depressive	7.8	6.5	6.4	0.9	5.4	5.1	6.6	0.9	9.0	6.3	8.8	6.7	-1.15	-2.7 to .4	-1.5	61	.15	23
Manic	17.5	14.1	17.0	14.7	16.6	16.0	21.5	9.01	20.6	12.2	18.0	10.1	64	-3.7 to 2.5	4.–	59	89.	07

The analysis adjusted for the baseline value of the outcome, effect of LGCC, time (6 and 12 months), and the interaction of time and LGCC effect.

A Cohen's d > .3 indicates a small to moderate effect. Body mass index range from 0 to 48, with higher scores indicating worse functioning

Possible scores on the mental component summary (MCS) and physical component summary (PCS) of the 12-item Short-Form Health Survey range from 0 to 100, with higher scores indicating better health-related Assessed using the 12-item World Health Organization Disability Assessment Scale, which measures past-month impairment in self-care, mobility, cognition, social functioning, and role functioning. Possible scores quality of life. For both, the population mean \pm SD is 50 ± 10

Scale, an 8-item measure of depressive and manic symptoms. For depressive symptoms, possible scores range from 0 to 20. For manic symptoms, possible scores range from 0 to 50. Higher scores indicate more severe symptoms.

In the 12 months after study entry, no significant differences were found in service utilization between the LGCC participants and those receiving enhanced treatment as usual; 40% of the overall sample received diet and wellness group sessions apart from LGCC. [A table presenting utilization data is available in the online data supplement.]

Discussion

Compared with enhanced treatment as usual, LGCC was not associated with reductions in cardiometabolic risk factors or with other patient outcomes. However, among patients with elevated cardiometabolic risk, LGCC may have reduced patients' impaired functioning.

LGCC was designed to be costefficient, emphasizing patient selfmanagement. LGCC care management was limited to communication with clinicians—that is, it did not involve medication management. General medical care was available off site, which may have impeded access to cardiometabolic risk factor management. Katon and colleagues (7) found that for patients with substantial medical burden, the chronic care model led to reduced cardiometabolic risk primarily through management of general medical care. In contrast, LGCC involved four twohour self-management sessions and limited follow-up contacts with providers, which may have had limited impact on behavior change and cardiometabolic risk. Our target population included those with a wider range of cardiometabolic risk factors than in the study by Katon and colleagues, and thus there may have been little room for improvement in outcomes. Moreover, in our community mental health programs, "usual care" included wellness sessions, which may have mitigated differences in cardiometabolic risk in the LGCC group.

Nonetheless, LGCC may have improved outcomes for patients with elevated cardiometabolic risk, notably by reducing dysfunction. Perhaps LGCC's focus on symptom coping strategies had a positive effect on functioning. Reducing functional impairment might also be an initial step toward ultimately reducing cardiometabolic risk by mitigating barriers to self-management strategies such as exercise. Interventions that focus on improved functioning are also important because they help with recovery-oriented goals such as employment and relationships.

Although the elevated risk of mortality from cardiovascular disease has been well recognized among persons with mental disorders (2), few effective interventions have been developed that improve outcomes in this group and that are also practical to implement in community-based settings. Recognizing the mortality gap due to cardiovascular disease among persons with mental disorders, communitybased mental health programs have advocated for integrated general medical services. The Substance Abuse and Mental Health Services Administration has funded several demonstration programs focused on improving general medical outcomes among patients seen in community mental health programs. Provisions in the Affordable Care Act create health home models that reimburse general medical care for persons with mental disorders. However, these initiatives have not specified the types of services that should be provided or how to integrate and reimburse for components of the chronic care model, such as selfmanagement.

Limitations of this study included the relatively small sample and the lack of formal diagnostic assessment for bipolar disorder. Moreover, improvements among participants with elevated cardiometabolic risk may have been due to regression to the mean. The brevity of the selfmanagement program, limited use of care management, and limited use of specific cardiometabolic educational content in the follow-up contacts may account for the limited impact of LGCC on long-term cardiometabolic risk. Only a fraction of participants had complete laboratory data, which may have reflected

inadequate access to medical care. Because some mental health providers were likely treating patients from both study conditions, the contacts they received from the interventionist may have also affected the likelihood that the providers would more carefully monitor cardiometabolic risk factors among those receiving enhanced treatment as usual.

Conclusions

A more definitive study of LGCC is needed to determine whether patients with elevated cardiometabolic risk can benefit from this relatively brief intervention. Psychosocial interventions such as LGCC have the potential to be acceptable to this group because these interventions are consistent with recovery-oriented care, and the recovery focus on selfmanagement and personal goals may complement disease management. Investigating whether LGCC can be used to improve cardiometabolic outcomes in other treatment settings, such as primary care, would help to further tailor these programs for the most vulnerable groups.

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References

- Kilbourne AM, Morden NE, Austin K, et al: Excess heart-disease-related mortality in a national study of patients with mental disorders: identifying modifiable risk factors. General Hospital Psychiatry 31:555–563, 2009
- Katon WJ: Clinical and health services relationships between major depression, depressive symptoms, and general medical illness. Biological Psychiatry 54: 216–226, 2003
- 3. Bryant-Comstock L, Stender M, Devercelli G: Health care utilization and costs among

- privately insured patients with bipolar I disorder. Bipolar Disorders 4:398–405, 2002
- Judd LL, Akiskal HS: The prevalence and disability of bipolar spectrum disorders in the US population: re-analysis of the ECA database taking into account subthreshold cases. Journal of Affective Disorders 73: 123–131, 2003
- Wildes JE, Marcus MD, Fagiolini A: Obesity in patients with bipolar disorder: a biopsychosocial-behavioral model. Journal of Clinical Psychiatry 67:904–915, 2006
- Druss BG, Marcus SC, Campbell J, et al: Medical services for clients in community mental health centers: results from a national survey. Psychiatric Services 59: 917–920, 2008
- Katon WJ, Lin EH, Von Korff M, et al: Collaborative care for patients with depression and chronic illnesses. New England Journal of Medicine 363:2611–2620, 2010
- Daumit GL, Dalcin AT, Jerome GJ, et al: A behavioral weight-loss intervention for persons with serious mental illness in psychiatric rehabilitation centers. International Journal of Obesity 35:1114–1123, 2011
- Gilbody S, Bower P, Fletcher J, et al: Collaborative care for depression: a cumulative meta-analysis and review of longerterm outcomes. Archives of Internal Medicine 166:2314–2321, 2006
- Kilbourne AM, Post EP, Nossek A, et al: Service delivery in older patients with bipolar disorder: a review and development of a medical care model. Bipolar Disorders 10:672–683, 2008
- Goodrich DE, Kilbourne AM, Lai Z, et al: Design and rationale of a randomized controlled trial to reduce cardiovascular disease risk for patients with bipolar disorder. Contemporary Clinical Trials 33: 666–678, 2012
- Bandura A: Social Foundations of Thought and Action: A Social Cognitive Theory. Englewood Cliffs, NJ, Prentice Hall, 1996
- Bauer MS, McBride L, Williford WO, et al: Collaborative care for bipolar disorder: part I. intervention and implementation in a randomized effectiveness trial. Psychiatric Services 57: 927–936, 2006
- Ustün TB, Chisholm D: Global "burden of disease"-study for psychiatric disorders. Psychiatrische Praxis 28(suppl 1):S7–S11, 2001
- Bauer MS, Vojta C, Kinosian B, et al: The Internal State Scale: replication of its discriminating abilities in a multisite, public sector sample. Bipolar Disorders 2: 340–346, 2000