Bipolar Disorders 2008: 10: 672–683

BIPOLAR DISORDERS

Original Article

Service delivery in older patients with bipolar disorder: a review and development of a medical care model

Kilbourne AM, Post EP, Nossek A, Sonel E, Drill LJ, Cooley S, Bauer MS. Service delivery in older patients with bipolar disorder: a review and development of a medical care model.
Bipolar Disord 2008: 10: 672–683. © Blackwell Munksgaard, 2008

Objectives: Medical comorbidities, especially cardiovascular disease (CVD), occur disproportionately in older patients with bipolar disorder. We describe the development, implementation, and feasibility/tolerability results of a manual-based medical care model (BCM) designed to improve medical outcomes in older patients with bipolar disorder.

Methods: The BCM consisted of (i) self-management sessions focused on bipolar disorder symptom control, healthy habits, and provider engagement, (ii) telephone care management to coordinate care and reinforce self-management goals, and (iii) guideline dissemination focused on medical issues in bipolar disorder. Older patients with bipolar disorder and a CVD-related risk factor (n = 58) were consented, enrolled, and randomized to receive BCM or usual care.

Results: Baseline assessment (mean age = 55, 9% female, 9% African American) revealed a vulnerable population: 21% were substance users, 31% relied on public transportation, and 22% reported problems accessing medical care. Evaluation of BCM feasibility revealed high overall patient satisfaction with the intervention, high fidelity (e.g., majority of self-management sessions and follow-up contacts completed), and good tolerability (dropout rate < 5%). Use of telephone contacts may have mitigated barriers to medical care (e.g., transportation).

Conclusions: The BCM is a feasible model for older, medically ill patients with bipolar disorder, and could be an alternative to more costly treatment models that involve co-location and/or additional hiring of medical providers in mental health clinics. Future research directions pertinent to the development of the BCM and other medical care models for older patients with bipolar disorder include assessment of their long-term effects on physical health and their cost-effectiveness across different treatment settings.

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Key words: bipolar disorder – medical comorbidity – randomized controlled trial

Received 26 May 2007, revised and accepted for publication 25 October 2007

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Background

Bipolar disorder is one of the world's ten most disabling conditions (1) and is associated with substantial functional limitation, premature mortality, and significant personal and societal costs (2–5). Up to 40–70% of these costs have been attributed to co-occurring general medical conditions (4–7).

There has been an increased awareness of the burden of general medical comorbidity in patients with bipolar disorder, especially among older patients with this illness (8–14). Cardiovascular

The authors of this manuscript warrant that they have no actual or perceived conflicts of interest, financial or non-financial, in the procedures described in this manuscript.

disease (CVD) is the leading cause of morbidity and mortality among older patients with bipolar disorder (12, 13). Some of the most common medical conditions (diabetes, hypertension, hyperlipidemia, and obesity) observed in older patients with bipolar disorder are also the leading risk factors for CVD (14), and often occur at a younger age among patients with bipolar disorder compared to those without bipolar disorder (8, 9).

Nonetheless, compared to those without bipolar disorder, patients with this illness are less likely to receive adequate care for CVD-related conditions (15–18). Only half receive adequate CVD risk monitoring related to atypical antipsychotic use (e.g., cholesterol screening) (17), and a substantial proportion have reported barriers to medical care (18).

Hence, interventions that improve quality of medical care for older persons with bipolar disorder are sorely needed. This paper describes the development and implementation of a medical treatment model for patients with bipolar disorder, the Bipolar Disorder Medical Care Model (BCM). We discuss the need for a new treatment approach for older patients with bipolar and medical disorders, how the BCM evolved from previously developed treatment models, the development of the BCM, and key issues regarding its implementation.

A bipolar medical treatment model is needed

Older patients with bipolar disorder are more prone to the adverse effects of medical comorbidity than their younger counterparts because of aging combined with the cumulative burden of mania and depression over the life span and use of multiple medications (19–21). These characteristics can contribute to poor adherence and unstable treatment course, ultimately resulting in suboptimal outcomes (19, 20). The use of atypical antipsychotic medications as mood stabilizers has also increased the risk of diabetes and subsequent CVD in older patients with bipolar disorder (21), and the adverse effects of these medications will become more apparent as the U.S. population ages. Furthermore, unlike other mental disorders, the alternating manic and depressive symptoms associated with bipolar disorder can lead to long periods when the patient has little or no contact with friends or providers (e.g., during a manic episode). Manic episodes may also be associated with binge eating and nonadherence, while depressive episodes can be associated with sedentary lifestyle (8, 19, 20), all of which can increase the risk of CVD and other medical conditions.

The fragmentation of mental health and general medical care is another substantial barrier faced by older patients with bipolar disorder. Bipolar disorder is primarily managed in the mental health setting (22), and as the primary focal point of their care revolves around the mental disorder, other conditions are given less attention (23). Among older patients in particular, medical conditions may also be missed because they often present with milder physical symptoms than in younger individuals and older patients may fail to recall medical symptoms or conditions, or their medical illnesses may be overlooked (23). Many of these patients have health care needs that span several locations (e.g., medicine, rehabilitation), and they often have trouble accessing medical care at a different location due to functional limitations and transportation barriers (e.g., reliance on public transportation) (24, 25).

Evolution of medical treatment models

Few treatment models have been developed to address gaps in quality and outcomes of medical care for individuals with mental disorders, and none has been developed for bipolar disorder. Early treatment models designed to improve medical outcomes for patients with mental disorders involved enhancing access through co-location of general medical clinicians within mental health facilities (26) or establishment of treatment teams (27). However, these approaches may be too costly for smaller sites to implement and sustain over time.

Alternatively, 'manual-based' treatment models, such as the Chronic Care Model (CCM) (28), that focus on enhancing existing services within a treatment setting have been shown to improve management of chronic medical illness in primary care patients (29, 30) and depression in older primary care patients (31). The CCM promotes coordination of care across different providers via a care manager, patient self-management education, and guideline implementation. This multifaceted approach is necessary for improving quality and outcomes because guideline dissemination alone is ineffective in improving quality and outcomes of care (30). Moreover, patient-focused behavioral interventions that constitute self-management approaches are most likely sustainable if coupled with ongoing care management (30, 31). Care managers, who are usually nurses or social workers, can also assist older patients in navigating across multiple (i.e., medical and psychiatric) providers.

However, no published CCM-based models exist to manage *general medical* conditions (e.g., CVD) in older patients with bipolar or other mental

disorders. The Bipolar Collaborative Chronic Care Model was recently developed based on the CCM to improve *mental health outcomes* in patients with bipolar disorder (32–34). However, this model was not designed to address medical issues, as no linkages were established with medical care providers.

Methods

The BCM was adapted from the Bipolar Disorder Collaborative Chronic Care Model developed by Bauer et al. (32, 33) and Simon et al. (34) to emphasize behavioral change and facilitated medical care access for reducing the risk of CVD in patients with bipolar disorder. The BCM intervention study was developed in late 2005 and implemented beginning March 2006. The BCM included three components: patient self-management support, care management, and guideline dissemination focused on medical treatment in bipolar disorder (Table 1). The overarching premise of these BCM components is that optimal health outcomes and CVD risk reduction cannot be achieved without effective strategies for controlling symptoms (e.g., manic, depressive), and that effective symptom control is essential for maximizing treatment adherence and health behavior change (e.g., improving diet, exercise). In addition, symptom control is maintained through patient self-management education combined with ongoing, anticipatory support through care management.

BCM intervention components

Each BCM component is described briefly below. Further details regarding the BCM components are available from the authors.

Self-management. The BCM self-management program was adapted from the Life Goals Program, a group-based psychoeducational program for bipolar disorder (35). Additional material added to the program included CVD risk in the context of bipolar disorder (36), strategies for improving diet and exercise habits (37), and tips for engaging general medical providers for older and/or medically ill patients. The self-management program included four two-hour sessions led by the study care manager (Table 2). Sessions were held on a weekly basis and patients were given workbooks with additional information covered in the sessions. While self-management sessions were delivered in group sessions, patients were allowed to make up sessions over the phone as long as they attended at least one of the sessions in person.

Care management. The care management component was implemented at the completion of the

Table 1. Synopsis of the Bipolar Disorder Medical Care Model (BCM) intervention and comparison to usual care

Domain	BCM intervention	Enhanced usual care for bipolar disorder
Self-management	Psychoeducation: self-management behavioral education (group sessions on coping strategies for symptoms, adherence, diet and exercise, building self-efficacy via active discussions of coping strategies) based on the Life Goals Program	Current care under patient's mental health and general medical providers (no formal program)
Care management	Nurse care manager (CM): Scheduled contacts with patient that foster lessons from self-management sessions, address symptoms and side effects and facilitate provider communication Directly contact medical/mental health/geriatric providers regarding urgent health concerns based on patient communication or medical record information CM outreach/crisis management after critical service encounters or missed appointments	Typical access/continuity (no CM): Scheduled care with providers No formal care management program
Guidelines	Continuing medical education (CME) sessions and materials addressing cardiovascular disease (CVD) risk in older patients with bipolar disorder and management based on guidelines from the American Diabetes Association and guidelines for managing bipolar disorder from the American Psychiatric Association	CME sessions and materials addressing CVD risk in older patients with bipolar disorder and management based on guidelines from the American Diabetes Association

Table 2. Self-management sessions based on the Life Goals Program modified to address medical care and cardiovascular disease (CVD) risk

Session	Topics of Life Goals session	Added topics for current intervention
Session 1: Orientation	Therapeutic relationship Bipolar symptoms and psychosis Causes of bipolar disorder, prevalence, stigma, substance use	Causes of CVD and diabetes, risk factors among patients with bipolar disorder Bipolar symptoms—impact on functioning in older patients Introduce tips to promote healthy habits (sleep, diet, exercise) for older patients
Session 2: Mania	Recognizing manic symptoms Personal manic symptom profile Identify triggers of mania (e.g., substance use) Cost-benefits of coping strategies	Medical consequences of mania Behavioral consequences of manic symptoms related to CVD risk (e.g., binge eating) Coping with manic symptoms in the context of CVD risk Setting diet and exercise goals
Session 3: Depression	Recognizing depressive symptoms Personal depressive symptom profile Identify triggers of depression Cost-benefits of coping strategies Substance abuse, suicide risk	Medical consequences of depression Behavioral consequences of depressive symptoms (overeating, sedentary lifestyle) Coping with depressive symptoms in the context of CVD risk Maintaining diet/exercise goals: exercise regimens, walking, portion control, and reduced fat intake
Session 4: Treatments for bipolar disorder, CVD-related risk	Provider engagement focused on collaborative treatment Medications Psychosocial therapies Personal care plan Adherence	Common treatments for CVD-related conditions Provider engagement: facilitating communication with general medical providers (e.g., setting goals for blood pressure, cholesterol, etc., listing concerns, side effects) Adherence guides (reminders)

self-management program, and was based on approaches to chronic care management outlined in the Chronic Care Model. Specifically, a nurse care manager served as a liaison between patients and providers regarding ongoing care and encouraged adherence to patient self-management goals for up to six months. Through regular phone calls, the care manager addressed patients' health concerns, referred urgent matters to medical and mental health providers, and promoted lessons learned from the self-management sessions. Care management also involved documenting patient progress over time, and outreach/crisis management after critical service encounters or missed appointments.

Guideline implementation. A series of one-hour continuing medical education (CME) in-services were held that addressed CVD risk in older patients with bipolar disorder for all primary care and mental health providers. Sessions were based on the American Diabetes Association (38) and American Heart Association guidelines for managing diabetes and CVD risk factors (36), and managing psychotropic drug toxicity effects in older patients with bipolar disorder based on American Psychiatric Association guidelines (39). Pocket cards summarizing these recommendations for metabolic syndrome risk monitoring, psychotropic drug toxicity monitoring, and reminders to promote diet and exercise with patients were also handed out as part of the educational sessions (Table 3).

Usual care. Patients assigned to the usual-care arm continued to receive their care through their usual providers but did not receive the BCM self-management program or care management (Table 1). However, both the intervention and usual-care providers received the guidelines. No monitoring of usual care occurred in order to avoid the Hawthorne effect; however, we collected information from patient chart reviews on utilization in order to monitor potential contamination (if any) across treatment arms.

Model fidelity. Fidelity to the intervention was promoted using an effectiveness-oriented approach. That is, instead of tightly controlled treatment team meetings that are infeasible in routine care settings, we used the following techniques to maintain and monitor fidelity to the BCM without burdening staff. First, the care manager was trained by study staff over a three-day period in August 2005. Second, we implemented fidelity measures based on data from care manager logs and chart review,

Table 3. Guideline implementation: provider pocket card

FRONT SIDE

Bipolar disorder: common medications, follow-up tests

Medication	Common side effects	Labs (at least every 6 months)
Lithium	Diarrhea, vomiting, nausea, tremor, weight gain, polyuria, acne/psoriasis and thyroid dysfunction. RARE: kidney failure	• Electrolytes: CBC, differential, EKG (>40 years or cardiac risk), urinalysis, bun, creatinine • Thyroid panel (TSH, t4, t3 uptake) • Anti-thyroid antibodies • Pregnancy test • Lithium level
Divalproex/valproic acid	Nausea, diarrhea, sedation, alopecia, LFT elevation. RARE: liver failure, pancreatitis	CBC and LFT, lipase, pregnancy test, divalproex level
Carbamazepine	Nausea, dizziness, rash, blurred vision, ataxia	Carbamazepine level, CBC, liver profile
Lamotrigine	Headache, ataxia, nausea, insomnia, tremor	Pregnancy test
Risperidone	Akathisia, orthostatic hypotension, agitation	Pregnancy test. Also see reverse side
Quetiapine	Weight gain, headache, drowsiness, dizziness	Pregnancy test, ophthalmic exam (slit lamp)

BACK SIDE

Bipolar disorder treatment: risk of metabolic syndrome

Atypical antipsychotics:
Risks: weight gain, hyperglycemia, dyslipidemia
Greatest risks: Clozapine, Olanzapine
Lesser risks: Quetiapine, Risperidone
Lowest risks: Ziprasidone, Aripiprazole

Baseline case
- Height, weight (BMI) and waist circumference
- Personal and family history: obesity, DM, dyslipidemia, HTN, CVD
- Blood pressure
- Fasting glucose
- Lipid profile
- Physical exam

Follow-up care
- **Height, weight (BMI) waist circumference:** 4, 8, 12 weeks, quarterly. If weight gain ≥5% of initial weight, consider switching atypical
- Blood pressure
- Fasting glucose
- Lipid profile
- Additional tests if CVD: EKG, electrolytes (Ca and Mg), Holter, if indicated

- **Counsel on diet, exercise:** Reduce fat, sugar intake; physical activity, smoking cessation

Improving Care for Veterans with Bipolar Study (care manager contact information)

CBC = complete blood cell count; EKG = electrocardiogram; LFT = liver function test; TSH = thyroid stimulating hormone; BMI = body mass index; CVD = cardiovascular disease; DM = diabetes mellitus; HTN = hypertension; Ca = calcium; Mg = magnesium.

including number of self-management sessions completed, number of calls, and degree to which the registry was completed for each encounter.

Pilot study setting

We chose to adapt and test the BCM within Veterans Affairs (VA) because it serves a disproportionate number of older patients compared to the general population, with the majority experiencing co-occurring conditions that often exclude them from participating in clinical trials (39). Although still serving a predominantly white male population, the VA also serves increasing numbers of minority and female individuals, notably with the number of women veterans now exceeding 1.6 million (>6%) (24, 25). Given that the VA patient population is on average 10 years older than the general population, this patient population may reflect the U.S. general population of the future.

The VA can also inform the implementation of integrated care models such as the BCM because the organizational barriers to integrated care observed in the VA (e.g., administrative, professional separation) can also exist outside this system (40). Not all VA mental health clinics provide general medical services, and many patients with serious mental illness still live a considerable distance away from specialty mental health services (41).

Intervention design, selection, and eligibility criteria

We conducted a prospective, randomized, single-site, single-blind intervention pilot study at a large VA mental health facility in Pittsburgh, PA, USA, to determine if BCM, compared to usual care, improved quality and outcomes related to general

medical care for patients with bipolar disorder. This facility serves as the primary source of mental health care for the vast majority of veterans in the Western Pennsylvania region. The nearest VA general medical clinic is located at a facility that is approximately seven miles from the mental health clinic.

Patient inclusion criteria were: (i) adult patients in the Continuous Improvement for Veterans in Care–Mood Disorders cohort who had an active diagnosis or treatment plan for bipolar disorder [I, II, or not otherwise specified (NOS)] from a clinician; (ii) assigned a primary care provider in the VA; and (iii) diagnosis of or receiving treatment for at least one of the following medical conditions most strongly related to CVD risk: hypertension, hyperlipidemia, diabetes mellitus, or obesity [or body mass index (BMI) > 25]. We chose to include patients with bipolar II disorder or bipolar disorder NOS because of evidence suggesting that these patients experience a similar level of functional decline and medical comorbidity compared to those with bipolar I disorder (11).

Patients were excluded if they (i) had unresolved substance intoxication or withdrawal, such as appearing to be intoxicated (e.g., incoherent, slurred speech); (ii) were already enrolled in a mental health program with a mobile outreach component in which clinical caregivers deliver services to the patient in the community (e.g., assertive community treatment or intensive case management); or (iii) were unwilling or unable to provide informed consent or comply with study requirements at the time of enrollment. Eligible patients were consented, enrolled, and randomized to receive either the BCM or 'enhanced' usual VA care (guideline implementation only).

Eligible patients were then randomly selected by the data analyst and contacted via telephone by a survey coordinator, and completed a baseline assessment over the phone and subsequent assessments at three and six months. Enrolled patients were then randomized by the study data analyst to receive the BCM or usual care. This randomized controlled trial was reviewed and approved by local institutional review boards.

Assessments and selection of outcomes

Assessments were completed over the phone by a survey coordinator who was blinded to randomization assignment. These 30-minute assessments included questions on key outcomes and other patient factors, including demographics, behaviors, and treatment perspectives. Additional information on utilization, comorbidities, lab values representing CVD risk factors, and other clinical variables was collected from a chart review conducted by the survey coordinator at baseline and six months.

Our primary outcomes included physical and mental health-related quality of life, and secondary outcomes included global functioning and bipolar disorder symptoms. Health-related quality of life was assessed using the 12-item Short Form Health Survey (SF-12), which generates a physical and mental health summary score (range: 0–100) (42). The SF-12 was found to be highly correlated with the SF-36 on the mental health ($r = 0.91$) and physical health ($r = 0.92$) summary scores (42). Global functioning was measured using the World Health Organization Disability Assessment Scale (WHO-DAS) (43), a 12-item assessment of the degree of functional impairment experienced within the past month regarding self-care (e.g., bathing, dressing), mobility (e.g., standing, walking), cognition (e.g., remembering), social functioning (e.g., conversing), and role functioning. Bipolar disorder symptoms were assessed using the Internal State Scale (ISS), a 15-item self-completed instrument that generates subscales reflecting depressive, manic, or euthymic symptoms. The ISS has high test-retest reliability, and the symptom subscales are highly correlated with clinician ratings of current episode (44).

We also assessed patient demographics, socioeconomic status, support, and health behaviors (substance use and adherence), and treatment characteristics thought to potentially influence the effect of the BCM on outcomes. Alcohol use was measured using one question that reflects hazardous, or 'binge' drinking (defined as five or more drinks on a single occasion) from the Alcohol Use Disorders Identification Test (45). Illicit drug use and smoking were assessed using the Composite International Diagnostic Interview Survey short form survey (46). Adherence was assessed based on the number of missed doses within the past week, which was strongly correlated with other valid measures of adherence (e.g., electronic monitoring) (47).

Treatment characteristics such as access to medical care and self-efficacy in managing chronic illness were also included in the patient survey. We included questions from the Cunningham Access to Care Survey (48), which asks about perceived barriers to needed medical care using a five-point Likert scale. Patients also completed a survey on perceived self-efficacy in self-managing chronic illness developed by Lorig et al. (49). Other treatment characteristics such as current medications were collected from medical records using a standardized chart review form.

Evaluation

This paper reports on the baseline characteristics of the study sample (demographics, behaviors, and baseline outcome scores), fidelity, feasibility/acceptance, and overall implementation. Descriptive statistics were used to assess baseline characteristics of the study population, describe the distribution of our main outcome (quality of life as measured by the SF-12 physical and mental health component scores), fidelity to the treatment model, and overall satisfaction with the self-management program. Our fidelity measures included number of self-management sessions offered by the care manager and attended by patients, number of calls made by the care manager and those completed by the patient, and the number of completed registry entries on each patient. We also evaluated the model's feasibility and acceptance (participant satisfaction). We also analyzed the BCM's implementation by reviewing care manager contacts, and estimated the total time the care manager spent on the BCM.

Results

Sample characteristics and retention (tolerability)

Between March and June 2006, 79 patients were confirmed to be eligible for the BCM study. Of the 79, 61 were randomly selected to be contacted for participation. Of the 61, three were lost to follow-up (4.9% dropout), leaving 58 patients who completed baseline and follow-up surveys.

Patient baseline characteristics are presented in Table 4. The mean age was 55.3 years (SD = 8.4; range: 30–73), and 29% (n = 17) were 60 years of age or older. Overall, 8.6% (n = 5) were female, and 8.6% (n = 5) non-white (African American). The demographics of our patients were similar to the demographic characteristics of all VA patients diagnosed with bipolar disorder based on the VA National Psychosis Registry (i.e., mean age = 52 years, 13% women, 9% African American) (34). In addition, 39.7% (n = 23) lived alone and 31.0% (n = 18) relied on a VA van or public transportation to get to appointments.

Most patients (76.8%, n = 44) were diagnosed with bipolar I disorder and 41% (n = 24) were prescribed atypical antipsychotic medications. The majority (80%, n = 47) were diagnosed with hypertension, 75% (n = 44), with hyperlipidemia, and 32% (n = 19) with diabetes; 88% (n = 52) were overweight (BMI > 25) and 19% (n = 11) were diagnosed with coronary artery disease. In addition, 90% (n = 52) were diagnosed with two or more CVD-related conditions. Almost a quarter (20.7%, n = 12) reported current alcohol use (binge drinking) or illicit drug use at the time of enrollment. Almost a quarter reported some trouble accessing medical care.

Mean overall physical and mental health-related quality of life (SF-12) scores at baseline were, respectively, 36.6 (SD = 7.6) and 33.1 (SD = 7.1). In contrast, mean SF-12 physical and mental health summary scores are 50 (SD = 10) for the U.S. general population.

Model fidelity

The mean number of completed self-management sessions (group or phone) was 3.7 out of 4 (SD = 0.7; range: 2–4). The mean number of group sessions completed in person was 1.8 (SD = 1.8; range: 1–4 sessions) and the mean number of phone-only sessions was 1.9 (SD = 1.6; range: 0–3 sessions). The primary reason reported for missing group sessions was lack of transportation. One patient did not attend remaining group sessions because he felt anxious in public settings. The mean number of post-group completed care management calls over the three-month period was 6.6 (SD = 2.8; range: 0–11 calls) and the mean number of attempted or completed calls was 10.6 (SD = 4.8; range: 3–18 calls). Most (95%) of these calls were recorded in the registry, and 85% of registry entries were completed by the care manager.

Satisfaction

We rated the overall satisfaction with the self-management program among the first 12 enrollees using an anonymous survey. Out of 12, nine returned the surveys. Of the nine, five (56%) rated the program (all four sessions) as 'excellent' and four (44%) rated it as 'very good.' The most common topics that they found helpful included coping with symptoms and making a plan for their medical provider. What respondents liked most included the opportunity to talk, the focus on bipolar disorder, and the workbook. Suggested improvements included providing more details regarding the specific medications for bipolar disorder (Table 5). At least two patients expressed to the care manager that they were using the self-management program as a 'new starting point' to help them maintain a new job after being out of work for several months due to bipolar disorder.

Implementation

Based on a review of completed call summaries from the file registry, we found a wide variation in

Table 4. Patient baseline characteristics of study sample (n = 58)

	Total (n = 58)	BCM (n = 27)	Usual care (n = 31)	*F* (df)	p-value
Demographics					
Age (range: 30–73), mean (SD)	55.3 (8.4)	54.5 (8.7)	56.0 (8.2)	0.46 (57)	0.50
	n (%)	n (%)	n (%)	χ^2 (df)	p-value
Age breakdown					
<50 years	9 (15.5)	4 (14.8)	5 (16.1)	0.27	0.60
50–59 years	32 (55.2)	16 (59.2)	16 (51.6)		
≥60 years	17 (29.3)	7 (26.0)	10 (32.3)		
Female	5 (8.6)	2 (7.4)	3 (9.7)	0.09 (1)	0.76
Non-white	5 (8.6)	2 (7.4)	4 (12.9)	1.52 (1)	0.29
Education: some college	15 (26.3)	7 (25.9)	8 (25.8)	0.00 (1)	0.99
Married/cohabitating	22 (37.5)	9 (33.3)	13 (41.9)	0.45 (1)	0.50
Lives alone	23 (39.7)	11 (40.7)	12 (38.7)	0.02 (1)	0.87
Takes van or bus to mental health appointments	18 (31.0)	6 (22.2)	12 (38.7)	1.83 (1)	0.18
Current substance use	12 (20.7)	7 (25.9)	5 (16.1)	0.84 (1)	0.36
Tobacco use	29 (50.0)	14 (51.9)	15 (48.4)	0.07 (1)	0.79
Trouble accessing medical care[a]	13 (22.4)	5 (18.5)	8 (25.8)	0.44 (1)	0.51
Bipolar disorder diagnosis					
Bipolar I	44 (76.8)	21 (80.8)	22 (73.3)	2.75 (2)	0.25
Bipolar II	4 (5.4)	0 (0.0)	3 (10.0)		
Bipolar NOS	10 (17.8)	5 (19.2)	5 (16.7)		
Current CVD-related diagnoses					
Hypertension	47 (79.7)	21 (77.8)	26 (83.9)	0.35 (1)	0.55
Hyperlipidemia	44 (74.6)	22 (81.5)	22 (71.0)	0.87 (1)	0.35
Diabetes	19 (32.2)	8 (29.6)	11 (35.5)	0.22 (1)	0.63
Obesity or BMI >25	52 (88.1)	23 (85.2)	29 (93.6)	1.08 (1)	0.30
Coronary artery disease	11 (19.0)	3 (11.1)	8 (25.8)	2.03 (1)	0.15
Any atypical antipsychotic use	24 (40.7)	10 (37.0)	14 (45.2)	0.39 (1)	0.53
Outcomes at baseline	Mean (SD)	Mean (SD)	Mean (SD)		
SF-12					
Physical health	36.6 (7.6)	37.2 (7.4)	36.2 (7.9)	0.24 (57)	0.63
Mental health	33.1 (7.1)	33.2 (6.6)	33.0 (7.5)	0.01 (57)	0.91
Global functioning (WHO-DAS)[b]	17.9 (9.9)	17.0 (10.1)	18.6 (9.7)	0.42 (57)	0.52
Bipolar symptoms[c]					
Well-being	14.6 (7.9)	14.8 (8.1)	14.5 (7.8)	0.03 (57)	0.86
Depressive	7.9 (6.1)	7.1 (6.3)	8.6 (5.9)	0.88 (57)	0.35
Manic	19.2 (12.6)	19.4 (17.5)	18.9 (13.5)	0.03 (57)	0.87

BCM = Bipolar Disorder Medical Care Model; NOS = not otherwise specified; CVD=cardiovascular disease; BMI = body mass index; SF-12 = 12-item Short Form Health Survey; WHO-DAS = World Health Organization Disability Assessment Scale.

[a]Based on a response of 'strongly disagree' or 'disagree' compared to 'uncertain', 'agree', or 'strongly agree' to the statement: 'I am able to get medical care whenever I need it.'

[b]0–48 points; higher score indicates worse functioning.

[c]Symptom scores based on the Internal States Scale. Total scores were generated for depressive (0–20 points), manic (0–50 points), and euthymic symptoms (0–30 points). For depressive and manic symptoms, lower is better. For euthymic symptoms (well-being), higher is better.

patient clinical issues that were addressed by the care manager. For example, one patient expressed concerns regarding medication side effects. After discussing these concerns with the care manager, the care manager relayed the patient's information to his mental health provider, who promptly scheduled a follow-up appointment. In another instance, the patient failed to show up for an appointment because of fatigue. The care manager prompted the health care provider to follow up with this patient to determine the cause of the fatigue. Additional issues covered in the calls included cutting down on alcohol use, grief regarding the loss of a loved one, encouraging exercise to relieve stress, encouraging the patient to obtain a fasting lipid panel, and physical symptoms (e.g., anemia). In all cases in which the care manager followed up with the patient's provider regarding urgent matters, the provider was able to see the patient or get back to him or her within a few days.

We also found that the care manager collected information from patients not available from the

Table 5. Results from the self-management program satisfaction survey (n = 9)

Things learned
Understand reactions to life
People let me talk
People gave me feedback
Make a plan before going to my general medical provider
Talk things out with MD
Try to evaluate side effects
About medications (2)
Sleep habits
Stress relief
Beware of episodes and triggers
Bipolar is a disease, not a character defect
Bipolar disorder is not necessarily a barrier to excellent achievement
I have value as an 'individual person'
Have manual to refer to – wallet cards on mania and depression triggers, medications (2)
Coping with mania and signs of manic, depressive symptom (2)
Positive ways to cope (2)
I'm not alone
I'm not 'crazy'
About the disease
Liked best
Got to talk about what I was interested in, and see that how it related to other group members (2)
Group discussion (2)
The focus on bipolar disorder
Just knowing I'm not alone
Care manager's understanding (2)
Like to see changed
Nothing
When meeting is opened ask everyone to say something; then those who have more to talk about can use up the remaining time
Missed the first session and would like to attend again at the future session
More information on medications
Suggested future topics
Dual diagnosis
Side effects of different meds
Posttraumatic stress disorder
Medications in more detail
Can't think of anything at this point
Other comments
Workbook is the best tool I've received from the VA since starting in 1991
Of my 'rapid cycling' bipolar psychosis—picked up a number of key points that can be put away to use that will help me stay out of the hospital
I'm always looking for signs of highs (manic) which happen to me, that I let them go too far. I begin to lose touch with the real world
Things that aren't real take me past the point that get me in trouble with loved ones, friends and relationships, affect my entire being

electronic medical record, including symptoms, moods, and disposition (e.g., current job or home). The care manager primarily relied on this information to monitor patient progress and track communication with providers rather than the electronic medical record, which was seen as 'information overload.' The VA electronic medical record was used primarily to record each session or phone call in order to count these encounters as visits.

Finally, we estimated the total time the care manager spent on the BCM. The care manager recorded the total amount of time spent on each patient over the three-month period, including group sessions, call attempts, calls, and charting (e.g., in the electronic medical record and registry) by recording this information on a continued basis for each patient encounter using the registry. We then totaled up the number of hours spent per patient and multiplied this number by four to reflect an annualized estimate. Overall, the care manager was estimated to spend an average 32 h on each patient per year, in which 20.5 h were spent on the phone care management, 4.9 h per patient on the self-management program, and 6.6 h documenting and charting.

Discussion

Our baseline results indicate that this randomized controlled trial of the BCM enrolled a vulnerable patient population. A disproportionate number of individuals live alone, rely on public transportation, report substance use, and report some problem accessing medical care. Baseline health-related quality of life scores were lower than national norms. It is noteworthy that many of these patients may not have been enrolled in more tightly controlled efficacy studies, which often directly exclude patients based on medical or substance use comorbidities, or indirectly exclude them through intensive treatment models (e.g., multiple visits and assessments requiring transportation to and from the clinic).

Despite the fact that we enrolled a more vulnerable patient population, our retention, fidelity, and evaluation results suggest that the BCM was successfully implemented. Dropout rates were small ($< 5\%$) and fidelity to the BCM was on par with previous CCM-based models (80%) (33). In fact, in clinical trials, the rate of treatment adherence can range from 43–78% (50). We were able to improve model fidelity in our study by offering 'make-up' self-management sessions over the telephone to individuals who did not complete all sessions in person. While the telephone sessions did not include the group interactions that are crucial for helping patients discuss bipolar disorder management strategies, such contacts nonetheless provided comparable information, encouragement, and tips regarding symptom control, lifestyle changes, and provider engagement.

Most patients surveyed were satisfied with the self-management program, and it may have satisfied an unmet need for psychoeducation and promotion of healthy habits tailored to patients with bipolar disorder. A review of the care management contacts also revealed that the care manager served as an effective liaison between patients and providers, notifying the latter about more urgent patient concerns, which prompted the provider to schedule a visit or call with the patient. Hence, telephone contacts may have mitigated transportation barriers experienced by these patients, as many relied on public transportation or the VA van to get to appointments. The care manager primarily relied on the registry to track patient progress and collect information from telephone contacts, rather than the existing VA electronic medical record. Given that older patients often face transportation barriers, health service interventions should perhaps be customized to accommodate telephone or telepsychiatry contacts.

Our preliminary data on care manager time also suggest that the BCM can potentially benefit more patients than existing treatment models for serious mental illness. We estimated that the care manager spent on average 32 hours per patient per year, which is on par with estimates of care manager time previously reported in prior bipolar disorder interventions (33). This estimate results in a total yearly caseload of about 50–60 patients for a full-time nurse care manager, while alternative models such as Intensive Case Management often limit caseloads to 12 patients per case manager. This represents an appropriate caseload, as older patients with bipolar disorder are often too ill to be managed through routine outpatient care, yet are often functioning well enough not to need intensive case management. Moreover, future research will determine whether a BCM model solely based on telephone management is as effective and cost efficient as the current BCM, which includes in-person group sessions.

The strengths of this pilot study include the use of randomization to pilot test one of the first models designed to improve medical care quality in bipolar disorder, and the BCM's effectiveness-oriented design that facilitates its implementation in routine care practice. Still, there are limitations to this study that warrant consideration. First, the intervention was limited to a single VA site; however, this site served as the catchment area for the majority of veterans in care in the Western Pennsylvania region. The VA population is also an older and more indigent patient population, which can reflect other patient populations outside the VA (e.g., Medicaid clients). Second, the VA's extensive electronic medical record system, which includes medical and mental health care, may not reflect the resources seen in typical non-VA practices.

In light of the strengths and weaknesses of the BCM study, there are a number of future research directions regarding the further development and implementation of manual-based medical treatment models for older patients with bipolar disorder. Notably, additional studies should assess the long-term impact of the BCM on CVD-related risk factors such as high blood pressure and cholesterol, and determine if manual-based models can reduce the risk of CVD and related disorders. In addition, future research should focus on the implementation and dissemination of manual-based medical care models for bipolar disorder in community-based settings, especially those that are not well integrated compared to the VA setting. A number of older individuals with mental disorders live in rural areas, and emerging technologies such as telepsychiatry could play an important role in improving access to medical care for this group. Finally, an estimate of the intervention's cost and cost-effectiveness will be helpful in sustaining the models in routine care settings once the research project is completed.

Overall, the BCM is a promising and feasible treatment model for sites that cannot afford intensive treatment teams or co-locating providers from different specialties. Our preliminary data suggest that the BCM can be implemented in a routine care setting that serves a vulnerable, older, and more medically ill patient population. Ultimately, the BCM can potentially benefit older patients with bipolar disorder, who are increasingly suffering from medical illness, through a manual-based strategy that may ultimately improve outcomes and overall recovery.

Acknowledgements

This research was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service (IIR 02-283; Amy M. Kilbourne, PI). AMK is also supported by the Center for Health Equity Research and Promotion, VA Pittsburgh Healthcare System and by an Investigator-initiated grant from Eli Lilly & Co. The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

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