

# Randomized Controlled Trial of a Collaborative Care Intervention for Mood Disorders by a National Commercial Health Plan

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**Objective:** Few individuals with mood disorders have access to evidence-based collaborative chronic care models (CCMs) because most patients are seen in small-group practices (<20 providers) with limited capacity to deliver CCMs. In this single-blind randomized controlled trial, we determined whether a CCM delivered nationally in a U.S. health plan improved 12-month outcomes among enrollees with mood disorders compared with usual care.

**Methods:** Aetna insurance enrollees (N=238), mostly females (66.1%) with a mean age of 41.1 years, who were recently hospitalized for unipolar major depression or bipolar disorder provided informed consent, completed baseline assessments, and were randomly assigned to usual care or CCM. The CCM included 10 sessions of the Life Goals self-management program and brief contacts by phone by a care manager to determine symptom status. Primary outcomes were changes over 12 months in depression symptoms

(nine-item Patient Health Questionnaire [PHQ-9]) and mental health–related quality of life (Short Form–12).

**Results:** Adjusted mean PHQ-9 scores were lower by 2.34 points (95% confidence level [CL]=−4.18 to −0.50,  $p=0.01$ ), indicating improved symptoms, and adjusted mean SF-12 mental health scores were higher by 3.21 points (CL=−.97 to 7.38,  $p=0.10$ ), indicating better quality of life, among participants receiving CCM versus usual care.

**Conclusions:** Individuals receiving CCM compared with usual care had improved clinical outcomes, although substantial attrition may limit the impact of health plan–level delivery of CCMs. Further research on the use of health plan–level interventions, such as CCMs, as alternatives to practice-based models is warranted.

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One in five individuals in the United States has a mood disorder (unipolar major depression or bipolar disorder) (1, 2), resulting in increased risk of long-term general medical conditions (3) and premature mortality (4), including suicide (5). Up to 70% of treatment costs for mood disorders are incurred outside the mental health sector, notably in primary care (6). In privately insured populations, mood disorders represent the most expensive conditions, with bipolar disorder incurring the most health care costs (7). Effective treatments for mood disorders include psychosocial interventions in addition to medications, yet only 40% of individuals with mood disorders receive adequate treatment (2).

Collaborative chronic care models (CCMs), which provide ongoing psychosocial support in conjunction with treatment coordination, have demonstrated improved outcomes for persons with mood disorders at little or no net health care cost (8–10). Recent meta-analyses found that implementation of at least three core components of the CCM (e.g., self-management, care management, and clinical information systems or case finding) resulted in improved

## HIGHLIGHTS

- Mood disorders affect one in five individuals yet less than half receive adequate treatment because of the limited capacity of many practices in providing effective collaborative care models (CCMs).
- This RCT determined whether a health plan–level CCM improved mental health outcomes for individuals with mood disorders.
- Individuals hospitalized for unipolar major depression or bipolar disorder and enrolled in a large national health plan were randomly assigned to receive either the collaborative care model (self-management sessions and care management) by telephone or usual care.
- Compared with usual care, those receiving the CCM had lower overall depression symptoms and potentially improved mental health quality of life in 12 months.

mental and physical outcomes for persons with mental disorders, with little to no net health care costs (8, 11). Often implemented by care managers, CCMs also support health care delivery systems that are subject to bundled payments under health care reform (12–14) and medical home mandates (15, 16). However, CCMs for mood disorders have primarily been implemented in large, integrated health care systems that have the capacity to hire on-site care managers and can scale up the necessary tools, including clinical information systems (16–18). In contrast, over 90% of U.S. commercial health plan enrollees receive care from small practices (<20 primary care physicians) (16, 19), which do not have the capacity to hire care managers at each site to provide CCM core components.

Rather than implement CCMs at the individual-practice level, another option is to implement the programs remotely at the health plan level, which may allow for the further implementation and sustainability of CCMs in solo or small group practices. A key advantage of health plan–level implementation is an economy of scale, made possible through the deployment of virtual care managers and use of common information technologies (20). However, prior studies of implementation of CCMs at the population level have been limited to unipolar depression treatment (21, 22) in large practices (23, 24).

This article reports outcomes following intervention from a randomized trial at the health plan level of a CCM delivered across mood disorders (depression and bipolar disorder). Our primary hypothesis was that patients in the United States who had recently been hospitalized for a mood disorder would have reduced 12-month depressive symptoms and improved mental health–related quality of life after receiving plan-level CCM versus usual care.

## METHODS

This single-blind, randomized controlled effectiveness trial included patients from Aetna health plan who were randomly assigned to receive either the CCM for mood disorders delivered at the health plan level or usual care. Aetna health plan is one of the largest health care insurers in the country, serving approximately 12 million covered lives, with 244,971 providers (19). Over 90% of Aetna health plan enrollees receive care from primary or mental health practices with fewer than 20 physicians (19).

### Participants

As described in detail elsewhere, eligible patients included Aetna health plan enrollees (beneficiaries or family members of beneficiaries) who were identified from Aetna claims data from across the lower 48 United States, who were ages 21 or older, and who had been hospitalized in the past 6 months for unipolar major depression or bipolar disorder (bipolar manic or depressed state) (25). We chose recent hospitalization as an inclusion criterion because inpatient care indicates greater clinical severity that could benefit from a CCM (26). The study received institutional review board (IRB) approval from

local IRBs, and all patient participants provided verbal informed consent. Prior to randomization, participants were approached, gave consent, and were enrolled by phone by the Aetna care manager, who used claims data from recent inpatient hospitalization history to identify potential participants. Recruitment began in July 2014 and ended in July 2015; follow-up assessments continued through July 2017.

The care manager contacted participants by phone to confirm eligibility and enroll participants. The care manager was trained by study staff in CCM procedures, assessments, and human subjects protection by using established CCM-based protocols (27). Participants were ineligible if they were no longer enrolled in Aetna health plan, were deceased, or were unable to provide informed consent because of an unstable condition, inpatient status, or inability to communicate in English.

### Randomization

The study analyst randomly assigned participants to CCM or usual care by using a computer-generated algorithm stratified by diagnosis at hospitalization discharge (unipolar disorder or bipolar disorder). The allocation sequence was concealed from recruiters until interventions were assigned. Those randomized to the usual care arm received standard care from their practice provider and none of the CCM components from the care manager.

### Intervention

Patients randomized to the CCM received contacts and psychosocial intervention from the Aetna care manager in addition to usual care from their provider. The care manager, with a master's degree in clinical social work, delivered the CCM intervention over a 6-month period, including the following core components: clinical information systems (Aetna clinical database to track and initially contact potentially eligible patients), self-management support (10 weekly sessions by phone), and ongoing care management (8, 10, 11). The self-management sessions were adapted from the evidence-based Life Goals program (27–31), a psychosocial intervention that focuses on symptom coping strategies to reduce stigma and promote wellness goals and that has been shown to improve outcomes for those with unipolar depression or bipolar disorder (28, 30, 32–34). Ongoing care management included up to six monthly brief contacts to determine status and symptoms. Fidelity to the CCM was supported through a 2-day training session for the care manager as well as regular calls with the care manager to review session content and how patient contacts were progressing (27).

Participants from both treatment arms who experienced imminent risk (e.g., suicidal or assaultive ideation) were cared for according to protocols used in prior CCM studies (25, 27). The care manager and research assistant were trained to handle emergencies involving participants with suicidal ideation and were instructed to contact their providers on an as-needed basis.

## Data Collection and Outcomes

Thirty-minute assessments of primary outcome measures and covariates were conducted at baseline and 6- and 12-month follow-ups. Baseline assessments were ascertained by the care manager at the time of enrollment and included demographic information, health status, and baseline measures for primary outcomes. Follow-up assessments consisted of follow-up measures of primary outcomes and were conducted by a study research assistant who was not employed by Aetna and who was blinded to the patients' randomization allocation. Clinical outcomes were measured at 12 months to assess durability of the 6-month CCM program.

Changes in depressive symptoms, the primary outcomes, were measured by the nine-item Patient Health Questionnaire (PHQ-9), a widely used assessment of depressive symptoms (35), and the mental health component score on the 12-item Short-Form (SF-12) Health-Related Quality of Life Survey (36). The PHQ-9 was chosen because depression symptoms are also a significant complaint among individuals with bipolar disorder.

Covariate information ascertained from assessments included demographic characteristics (age, sex, race-ethnicity, education, employment status, and living alone) and health behaviors, including hazardous drinking (having six or more drinks on a single occasion within the past month, as defined by the Alcohol Use Disorders Identification Test) (37), illicit drug use, and smoking. Other covariates ascertained from Aetna claims data included enrollment status (beneficiary versus family member) and primary mental health diagnosis (bipolar disorder or major depression).

## Analyses

Primary clinical outcomes (change in PHQ-9 and SF-12 mental component summary [MCS] scores) were modeled by using mixed-effects models with random intercepts and baseline values of the outcome (at randomization), treatment arm indicator, time (6 and 12 months), and the interaction of treatment arm  $\times$  time as predictors. The interaction term was included to explore whether the outcomes changed between 6 and 12 months.

Missing data were handled by using a standardized process. First, possible missing patterns of the data were identified based on determining whether there was any relationship with missing data and outcomes or treatment arm. Multivariable logistic regression models were then run on dichotomous variables created to represent each missing pattern as a function of baseline patient characteristics, each outcome, and treatment arm. The final models of primary clinical outcomes (PHQ-9 and MCS) used multiple imputation methods to account for missing data. Variables employed in the imputation were empirically driven on the basis of the association between the variables to be imputed and auxiliary variables and included all model covariates, treatment indicators, and missing data pattern indicators. Twenty data sets were

imputed, and results were pooled according to Rubin's (38) rule of combining data sets.

## RESULTS

A total of 9,121 potentially eligible patients from the Aetna database were identified by clinical information systems as having a diagnosis of unipolar depression or bipolar disorder from an inpatient discharge in the past six months. Of those, 7,335 were deemed to be ineligible (<21 years old, not living within the 48 contiguous United States, or no longer covered by Aetna), leaving 1,786 potentially eligible patients. Of the 1,786 approached, 403 declined to participate, 999 could not be reached, and 104 were determined to be ineligible. Of the 238 enrolled, 115 were randomly assigned at baseline to receive the CCM and 123 to receive usual care. [A CONSORT diagram of the study is available in an online supplement.] Based on the actual sample size of 73 (165 patients dropped out of the study, a dropout rate of 69%), the resultant power to detect mean differences between treatment arms was 27% for the PHQ-9 (Cohen's  $d=.25$ ) and 19% for the SF-12 MCS (Cohen's  $d=.20$ ) scores.

At baseline, respondents were a mean  $\pm$  SD age of  $41.3 \pm 31.1$ ; were mostly female (66%), white (81%), and employed (58%); and had a mean score of  $12.7 \pm 6.6$  on the PHQ-9 and  $35.6 \pm 15.2$  on the SF-12 MCS (Table 1). Among those assigned to the CCM, the mean number of self-management sessions completed was  $8.4 \pm 2.7$ , and the mean number of care management contacts was  $4.7 \pm 2.6$ .

Dropout also difference across treatment arms in the 0- to 6-month follow up period, where dropout more likely for CCM participants (30%) than for usual care participants (19%). Later dropout (6–12 months) was similar among the treatment arms: usual care participants (21%) and CCM participants (22%). Indicators representing time of dropout (6 or 12 months) were included in the imputation process. By 12 months, lost coverage was the reason for dropout among more than 80% of participants who dropped out, which did not differ by study group.

Figure 1 presents the unadjusted mean scores for the PHQ-9 and SF-12 MCS at each assessment, demonstrating that the changes mainly occurred between baseline and 6 months. The final models did not include the interaction term, given that it was neither meaningfully nor statistically significant.

Based on the model fit with main effects of 12-month and treatment arm (CCM) indicators, adjusted mean  $\pm$  SE PHQ-9 scores among patients receiving the CCM were lower by  $-2.34 \pm 0.92$  points (95% confidence level [CL] =  $-4.18$  to  $-0.50$ ,  $p=0.004$ ), compared with those receiving usual care. Although not statistically significant, adjusted mean SF-12 MCS scores for patients who received the CCM were higher (indicating better quality of life) by  $3.21 \pm 2.09$  points (95% CL =  $-0.97$  to  $7.38$ ), compared with scores of those receiving usual care.

**TABLE 1. Baseline characteristics among enrollees in a collaborative chronic care model (CCM) for mood disorders or in usual care<sup>a</sup>**

Characteristic	Overall (N=238)		CCM (N=115)		Usual care (N=123)	
	N	%	N	%	N	%
Primary enrollee (versus family member)	140	59	72	63	68	55
Practice size <20 providers	197	87	97	89	100	86
Female	156	66	77	67	79	64
White	193	81	99	86	94	76
Any college	168	71	75	65	93	76
Employed	139	58	70	61	69	56
Lives alone	53	22	30	26	12	19
Alcohol use (hazardous drinking) <sup>b</sup>	66	28	34	30	32	26
Other substance use	40	17	17	15	23	19
Current smoker	69	29	38	33	31	25
Primary diagnosis:						
Major depression	156	66	76	66	80	65
Bipolar disorder	82	35	39	34	43	35
Age (M±SD)	41.3±13.1		42.8±12.9		39.9±13.2	
PHQ-9 score (M±SD) <sup>c</sup>	12.7±6.6		13.0±7.1		12.4±6.1	
SF-12 score (M±SD) <sup>d</sup>						
MCS	35.6±15.2		36.9±15.3		34.4±15.2	
PCS	48.6±13.2		47.2±13.5		49.8±12.7	

<sup>a</sup> None of the comparisons between CCM and usual care groups were statistically significant.

<sup>b</sup> Hazardous drinking was based on the self-reported Alcohol Use Disorders Identification Test, which inquires about having six or more drinks on a single occasion within the past month. Responses were dichotomized as 0 (no) or 1 (yes).

<sup>c</sup> PHQ-9, nine-item Patient Health Questionnaire. Possible scores ranges from 0 to 27, with higher scores indicating worse depressive symptoms.

<sup>d</sup> SF-12, 12-item Short-Form Health-Related Quality of Life Survey. The mental component summary (MCS) and physical component summary (PCS) each use normed-based scoring derived from the general population, set to a mean±SD of 50±10 (range 0–100). Higher scores indicate greater quality of life.

Similar results were obtained from fitting the model to each outcome with an interaction term of time × treatment (see online supplement).

## DISCUSSION

We described 12-month results from the first study, to our knowledge, to implement the CCM within a nationwide commercial health plan for patients hospitalized for unipolar depression or bipolar disorder. We found that after randomization, patients receiving CCM had less reported depression symptoms and a trend toward more improvement in mental health quality of life compared with patients receiving usual care. Despite having private insurance, study participants reported substantial impairment in mental health quality of life (i.e., score on the SF-12 mental health lower by an average of 15 points compared with the general population) (36).

The observed effects of reduced mood disorder symptoms among patients randomly assigned to CCM compared with usual care are reflective of prior studies of CCM that focused on those with major depression or bipolar disorder (8). The study also adds to the growing body of literature on the effectiveness of collaborative care in improving mental

health outcomes across age groups (22) and mental health conditions (22, 39–42), reflecting the potential for a more cost-efficient approach to providing evidence-based care remotely to patients without access to on-site collaborative care.

CCMs to date have primarily been implemented solely for unipolar depression (21, 26, 43–46) or within large integrated health systems, which, unlike solo or small group primary care practices, have sufficient infrastructure to mount such integrated efforts. Implementing CCMs in health plans across mood disorders represents an important effort to overcome such geographic and administrative barriers (31). Most commercially insured individuals receive care from network model health plans and within small practices, which have limited capacity to provide organized CCMs or other disease management interventions (11, 16, 19). CCMs that address the range of mood disorders, including bipolar disorder, might be able to address suicide—notably through the reduction of depressive symptoms (47).

There were several limitations to this study that warrant consideration. Only a fraction of potentially eligible patients was enrolled. Participants may have been less inclined to engage in a program offered by an insurer rather than a care provider. Moreover, those who were recently hospitalized, especially patients from more rural settings, could be an especially difficult population to reach or engage (21). Post-randomization dropout was also substantial; the primary reason for participant dropout was disenrollment from Aetna coverage, given that enrollment in Aetna was a study inclusion criterion. Although we did not have information on reasons for Aetna coverage change, loss of coverage can be triggered by changes in employer/employment status or premium increases (48). Evidence suggests that about half of Americans switch health plans within 3 years (49).

Moreover, the care manager had limited contact with the patients' providers, limiting their ability to help manage pharmacotherapy for patients; however, in previous trials the Life Goals program was demonstrated to be effective as a stand-alone self-management program (30, 34). Although the research assistant made every effort to follow up with patients by using a brief survey, lack of available contact information once the individual disenrolled from the health plan and lack of subject compensation for survey participation may have contributed to follow-up attrition. We also used multiple imputations to account for the high rate of loss at 12 months; however, the method is limited by the number of available variables to impute and did not address the possibility that the remaining participants may be highly selected. In addition, whereas this study employed the core



components of the CCM found to be effective from previous meta-analyses (self-management, care management, and clinical information systems), we were unable to fully implement provider clinical decision support in regard to mood disorders medication management across the multiple practices. Finally, although the study incorporated well-established clinical outcomes measures, clinical outcomes were self-reported (8, 11).

## CONCLUSIONS

Overall findings from this study indicate that a health plan-level CCM was effective in reducing depressive symptoms and improving health-related quality of life for a cross-diagnosis group of individuals with mood disorders (depression and bipolar disorder). However, protocol dropout rates, primarily due to low initial acceptance of a health plan-level intervention and instability of health plan enrollment, mitigate the certainty of these conclusions as well as the willingness of commercial insurers to invest in such plan-level interventions. Nonetheless, delivery of CCMs at the health plan level may be the sole approach to extend these evidence-based interventions to patients with mood disorders who are managed in venues likely too small to implement CCMs on site.

Additional methods to enhance implementation at the health plan level warrant further investigation. Such methods include the use of virtual tools to allow care managers to engage with the patients' principal care providers, especially within small practices; additional mobile health or Web-based programs (39, 50) to enable providers and patients to extend care coordination and self-management; and other implementation strategies, such as practice-based facilitation or performance incentives (51). Ultimately, a health plan-based virtual CCM intervention is a potentially cost-efficient approach to delivering this evidence-based practice at the population level.

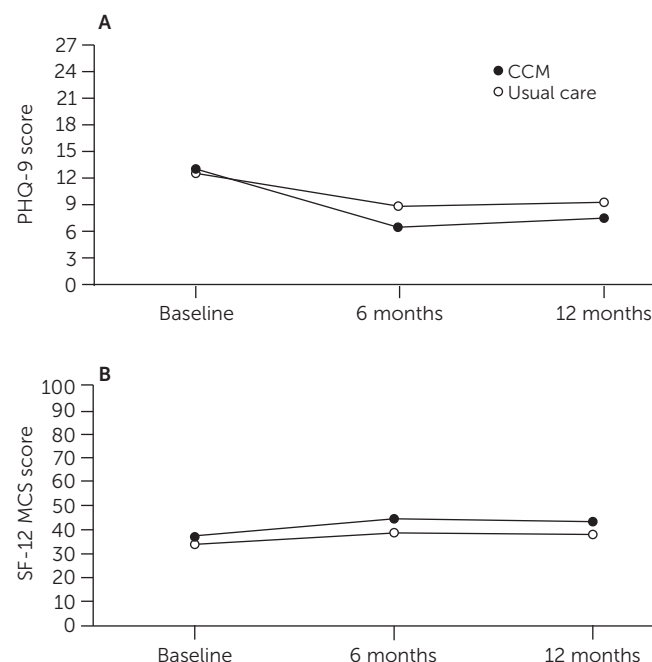
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**FIGURE 1. Mean unadjusted PHQ-9 (A) and SF-12 MCS (B) scores among 73 participants in a collaborative chronic care model (CCM) for mood disorders or usual care, by time of assessment<sup>a</sup>**



<sup>a</sup> PHQ-9, nine-item Patient Health Questionnaire; higher scores reflect worse depression symptoms. SF-12 MCS, mental component summary of the 12-item Short-Form Health-Related Quality of Life Survey; higher scores reflect better quality of life.

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