

The *Bypassing the Blues* trial: Collaborative care for post-CABG depression and implications for future research

■ ABSTRACT

Depressive symptoms are reported by up to one-half of patients following coronary artery bypass graft (CABG) surgery, and are associated with numerous adverse outcomes, including poorer health-related quality of life, worse functional status, and delayed recovery. Strategies to detect and then manage depression in CABG patients and in cardiac populations are of great interest given the potential for depression treatment to reduce cardiovascular morbidity. Yet, many tested interventions have had little or no effect on mood symptoms in cardiac patients. “Collaborative care” is a safe and proven-effective strategy for treating depression in concert with patients’ primary care physicians; however, it had not been tested previously in patients with cardiac disease. This article presents the design and main outcome findings from the National Institutes of Health–funded *Bypassing the Blues* study, the first trial to examine the impact of a collaborative care strategy for treating depression among patients with cardiac disease, and our efforts to improve upon and expand the model for testing in other cardiac conditions.

Coronary artery bypass graft (CABG) surgery is one of the most common and costly medical procedures performed in the United States.¹ However, up to one-half of post-CABG patients report significant increases in mood symptoms following surgery,² and these individuals are more likely to report poorer health-related quality of life (HRQoL) and worse functional status,³ and to experience higher risk of rehospitalizations⁴ and death⁵ despite a satisfactory surgical result.

Strategies to detect and then manage depression in CABG patients and in cardiac populations are of

great interest given the potential for depression treatment to reduce cardiovascular morbidity.

In recognition of the prevalence and excess burdens associated with this condition, a recent American Heart Association (AHA) Science Advisory has advocated regular screening and treatment of cardiac patients for depression.⁶ Yet, the Advisory has been controversial,^{7,8} as most depression treatment trials conducted in patients with cardiac disease have had less-than-anticipated impact on mood symptoms,^{7,9–14} cardiovascular morbidity,^{7,9,10,14} or mortality.^{7,9–11,13–15} Possible explanations include: (1) dependence solely on single antidepressant agents^{9,14} that, in general, are often ineffective,¹⁶ intolerated, or otherwise discontinued by patients¹⁷; (2) reliance on psychologic counseling in elderly, medically ill populations who may be either unwilling or unable to adhere to successive face-to-face encounters with a therapist^{10,13}; (3) inadequate consideration of patients’ preferences for type and location of treatment^{18,19}; (4) insufficient treatment adherence^{20,21}; (5) perceived stigma of depression²²; (6) brief duration of treatment and followup^{9,13,14}; and (7) higher-than-expected spontaneous remission rates for depression.^{10,14}

In an effort to overcome the limitations of earlier interventions, interest has turned toward “collaborative care” strategies for treating depression.^{7,23–25} Based on Wagner’s Chronic Care Model (**Figure 1**),²⁶ collaborative care involves active followup by a nonphysician “care manager” who adheres to an evidence-based treatment protocol. The care manager contacts patients with the frequency necessary to educate them about their illness and proactively monitors their responses to treatment, all in collaboration with patients’ primary care physicians (PCPs) and with specialty backup care when indicated.

Over the past 15 years, numerous trials have supported use of the flexible real-world collaborative care approach to improve outcomes for depression^{27,28}

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as well as a variety of other chronic medical conditions^{29–32} and at a lower total cost of care.^{33,34} This strategy is supported even outside the framework of a trial.^{35,36} Moreover, collaborative care was the clinical framework³⁷ for a Robert Wood Johnson Foundation program to realign clinical and financial incentives for providing sustainable high-quality depression treatment in primary care.^{38–41} It is also embraced by depression improvement initiatives supported by the MacArthur (<http://www.depression-primarycare.org/>)⁴² and Hartford (<http://impact-uw.org/>)⁴³ Foundations. In recognition, a National Heart Lung and Blood Institute–sponsored working group on the assessment and treatment of depression in patients with cardiovascular disease endorsed testing of collaborative care strategies for treating depression in combination with “usual cardiologic care” as a method to improve clinical outcomes.²³ Collaborative care has also emerged as an integral part of the “patient-centered medical home” model presently advocated by leading professional organizations to organize and reimburse PCPs for providing high-quality chronic illness care.⁴⁴

Despite this interest in collaborative care, to date, only the “Bypassing the Blues” (BtB) trial has reported the impact of this depression treatment strategy on the clinical outcomes of a population with cardiac disease.⁴⁵ In an effort to help disseminate collaborative care more broadly into routine practice as envisioned by the AHA Science Advisory, we present the key design elements and main outcome findings from BtB, along with our efforts to improve upon and expand the model for testing in other cardiac conditions.

STUDY OVERVIEW

BtB was designed to examine the impact of a telephone-delivered collaborative care strategy for treating depression after CABG surgery on HRQoL, physical functioning, health services utilization, and health care costs, as well as on mood symptoms and other measures that could influence uptake of this treatment strategy. The trial was powered to test the primary hypothesis: whether an 8-month course of collaborative care provided by a nurse care manager via telephone could produce a clinically meaningful improvement in HRQoL at 8 months post-CABG, as measured by the SF-36 Mental Component Summary Scale (MCS), versus physicians’ “usual care” for depression. The 8-month period for testing our primary hypothesis allowed: (1) a therapeutic alliance to develop between patients, their PCPs, and our care managers; (2) patients initially unwilling

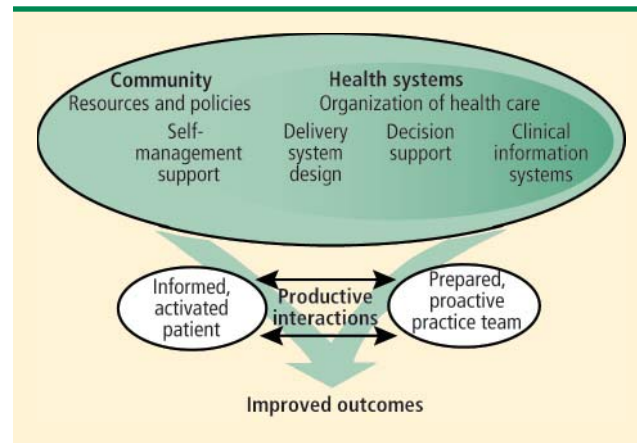


FIGURE 1. Overview of Wagner's Chronic Care Model.

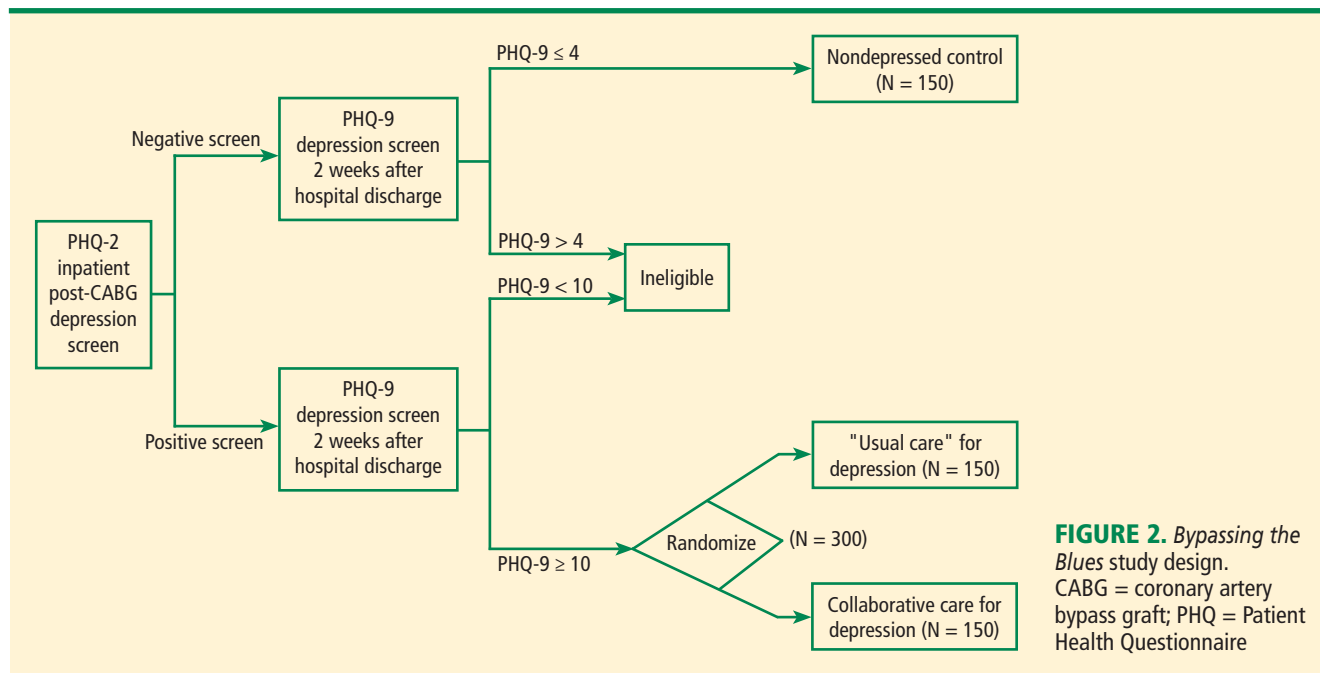
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or uninterested in trying any treatment modality time to change their minds, especially if their mood symptoms failed to remit; and (3) sufficient time for several therapeutic trials, if necessary, of antidepressant pharmacotherapy and counseling to take effect. Finally, BtB randomly sampled nondepressed post-CABG patients to better understand the impact of post-CABG depression and the benefits derived from its treatment (Figure 2).⁴⁶

IDENTIFICATION OF DEPRESSION

Applying the two-step Patient Health Questionnaire (PHQ) depression screening strategy recently endorsed by the AHA Science Advisory,⁶ BtB recruited medically stable post-CABG patients prior to hospital discharge from seven Pittsburgh-area hospitals between 2004 and 2007. To support our recruitment efforts, we developed press releases, wall posters, newsletter articles, and brochures to inform physicians, hospital staff, patients and their families about the impact of depression on cardiovascular disease and our study (available for download at: www.bypassingtheblues.pitt.edu).

Study nurse-recruiters obtained patients' signed informed consent to undergo screening with the two-item PHQ-2²² (“Over the past 2 weeks have you had: little interest or pleasure in doing things or “felt down, depressed, or hopeless?”).⁴⁷ We defined a positive PHQ-2 depression screen as patient endorsement of one or both of its items (90% sensitive and 69% specific for major depression among patients with cardiac disease when measured against the “gold-standard” Diagnostic Interview Schedule⁴⁸).



The psychologic and physical symptoms of depression often overlap with the post-CABG state (eg, fatigue, sleeplessness) and these elevations in depressive symptoms frequently remit spontaneously. Therefore, we administered the nine-item PHQ-9⁴⁹ over the telephone 2 weeks following hospital discharge to confirm the PHQ-2 screen. We required that patients score at least 10 to remain protocol-eligible, a threshold that signified at least a moderate level of depressive symptoms⁴⁹ and has been described as “virtually diagnostic” for depression among patients with cardiac disease (90% specific).⁴⁸

ASSESSMENT AND OUTCOME MEASURES

Upon confirmation of all protocol-eligibility criteria prior to randomization, we conducted a detailed baseline telephone assessment that included the SF-36⁵⁰ to determine mental (MCS) and physical (PCS) HRQoL, the 12-item Duke Activity Status Index (DASI)²⁶ to determine disease-specific physical functioning, and the 17-item Hamilton Rating Scale for Depression (HRS-D)²⁷ to track mood symptoms. Telephone assessors blinded as to randomization status readministered these measures at 2, 4, and 8 months’ followup and routinely inquired about any hospitalizations and mental health visits patients may have experienced since their last telephone assessment. Whenever they detected a potential “key event,” we requested a copy of relevant medical records from the hospital where the event occurred. These were then

forwarded to a physician adjudication committee that was blinded as to the patient’s depression and intervention status to classify the nature of the event (cardiovascular, psychiatric, or “other”).

COLLABORATIVE CARE INTERVENTION

Following randomization, a nurse care manager telephoned each intervention patient to: (1) review his or her psychiatric history, including use of any prescription medications, herbal supplements, or alcohol to self-medicate depressive symptoms; and (2) provide education about depression, its impact on cardiac disease, and basic advice for managing the condition (eg, exercise, sleep, social contact, alcohol avoidance); and (3) assess the patient’s treatment preferences for depression.

Using a shared decision-making approach, patients then selected one or more of the following treatment options: (1) a workbook designed to impart self-management skills for managing depression⁵¹; (2) antidepressant pharmacotherapy, primarily a selective serotonin-reuptake inhibitor (SSRI) chosen according to patient preference, prior usage, and insurance coverage, but prescribed by the patient’s PCP⁴⁶; (3) referral to a local mental health specialist in keeping with the patient’s insurance coverage; and (4) “watchful waiting” if the patient’s mood symptoms were only mildly elevated and he or she had no prior history of depression.

Afterward, the nurse care manager telephoned the

CABG STUDY INTERVIEW - [Intervention CR]

File Edit Insert Records Window Help

INTERVENTION CASE REVIEW

CABG ID#

First Name

CONFIDENTIAL

Subject Select: **Contact History** Mental Health History Medications Treatment 1 Treatment 2 PHQ Scores PHQ Items 1-6 PHQ Items 7-9

GENDER AGE SOCIAL SUPPORT HISTORY SA RECRUIT DATE NEXT SCHEDULED APPT 1/1/2007

Female 54 Good N/A 6/20/2005

CONTACT DATE	PHQ	Med 1 Name	Med 1 Dose	Med 2 Name	Med 2 Dose	WORKBOOK CHAPTER	MHS REFERRAL	GOAL
3/23/2006	5	Wellbutrin	300 mg	N/A	N/A		No	refer to DH when depression or anxiety i
3/14/2006	2	Wellbutrin	300mg	N/A	N/A		No	READ DH chapters, listen to relaxation C
1/23/2006	7	Wellbutrin	300mg	N/A	N/A		No	read DH 14-17, walk, note s/s of increas
1/9/2006	8	Lexapro	20mg	N/A	N/A		Yes	READ: Chapter 18-think constructively, t
12/6/2005	6	Lexapro	20 mg	N/A	N/A		No	Will utilize DH CD
11/3/2005	4	Lexapro	20 mg	Benzodiazepines	N/A	1-15	No	READ CH 16, 17-constructive thoughts
10/12/2005	9	Lexapro	20mg	N/A	N/A		No	intervention session was interrupted by
10/4/2005	12	Lexapro	20 mg	N/A	N/A		No	attend CR, go to work, make appt w/ nonp
9/27/2005	10	Lexapro	20 mg	N/A	N/A	3, 4	No	get back to work, cont exercise, CH 5 DH
9/20/2005	12	Lexapro	10 mg	N/A	N/A		No	PT= read ch 1,2,3 and cont cardiac rehab
9/7/2005	9	Sleeping Meds	N/A	N/A	N/A	1-8	No	talk to MD re: Lexapro, read DH
8/31/2005	7	N/A	N/A	N/A	N/A	1	No	start CR on M, W, F. positive thoughts,
8/16/2005	9	Lexapro	10mg	N/A	N/A	1, 2, 3	No	PT goals
7/26/2005	18	N/A	N/A	N/A	N/A	1, 2, 3	No	Read chapters and go to surgeons office
7/12/2005	N/A	N/A	N/A	N/A	N/A		N/A	PT GOALS: Read DH 1, 2, 3. Some exercise

Close and Return to the Main Menu

FIGURE 3. Sample registry screenshot portraying an intervention patient's progress with our collaborative care program. Serial Patient Health Questionnaire (PHQ)-9 scores, pharmacotherapy usage, workbook lesson plans, and specialty referral (MHS) are all documented on this overview.

patient approximately every other week during the acute phase of treatment to practice skills imparted through workbook assignments, monitor pharmacotherapy, promote adherence with recommended care, and suggest adjustments in treatment as applicable. Depending upon the patient's motivation to complete workbook assignments and whether he or she accepted antidepressant pharmacotherapy, these followup contacts typically lasted 15 to 45 minutes and continued for 2 to 6 months. The patient subsequently transitioned to the "continuation phase" of treatment, during which the care manager contacted him or her less frequently until the end of our 8-month intervention.

WEEKLY CASE REVIEW

Our nurse care managers presented all new intervention patients and followup on ongoing cases to the study psychiatrist, internist, and project coordinator

("clinical team") at weekly case review sessions. To efficiently focus these sessions, we programmed our electronic registry to display each care manager's patient load on a conference room wall via an LCD projector so the information was current and visible to all (Figure 3). Among the projected screens were: (1) the registry list of each nurse's intervention patients so as to focus group discussion on newly randomized patients and those with the highest levels of depressive symptoms; (2) an overview of a particular patient's progress, including serial PHQ-9 scores, pharmacotherapy usage, workbook lesson plans, and mental health specialty referral status; (3) additional clinical details to inform decision-making (eg, prior antidepressant experience); and (4) scores of individual PHQ-9 items to identify the precise domains where the patient was having difficulty (eg, sleep).

Following discussion, the clinical team typically

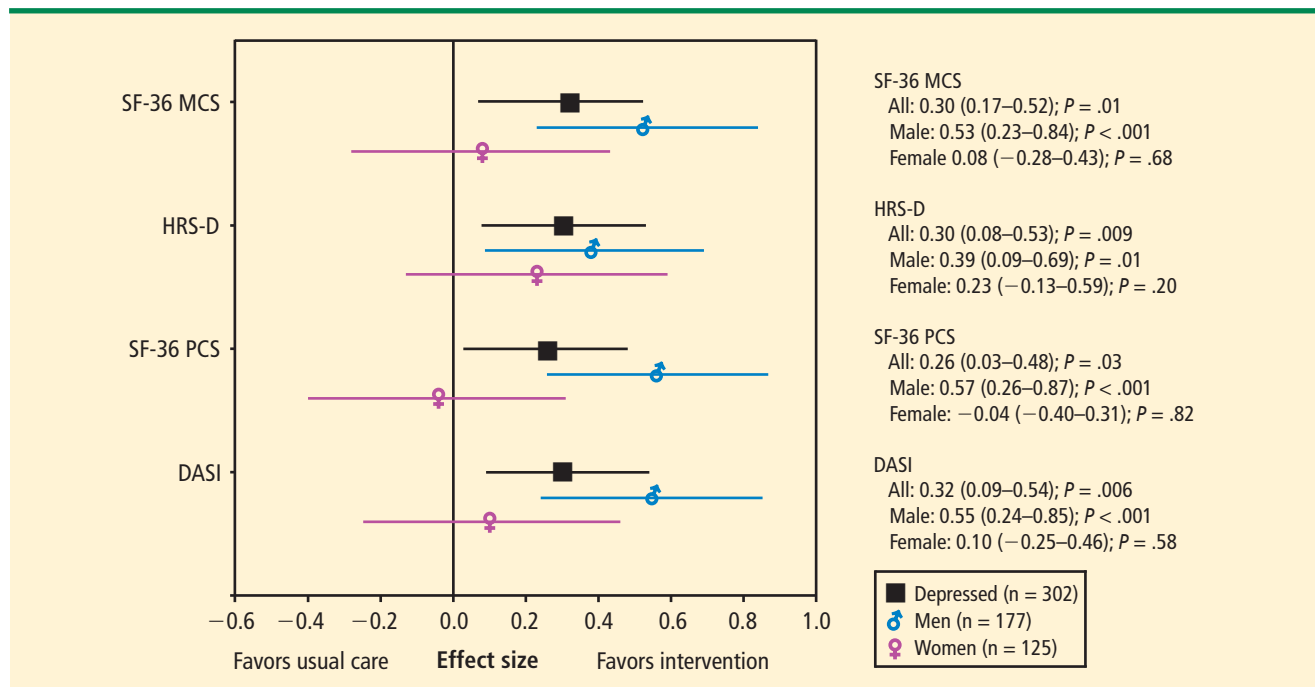


FIGURE 4. Main study outcomes.⁴⁵ DASI = Duke Activity Status Index; HRS-D: Hamilton Rating Scale for Depression (17-item); SF-36 MCS: Medical Outcomes Study 36-item Short Form Mental Component Summary; SF-36 PCS: Medical Outcomes Study 36-item Short Form Physical Component Summary

formulated one to three treatment recommendations that the nurse conveyed to the patient via telephone. As PCPs were responsible for prescribing all medications and dosage adjustments, we conveyed pharmacologic recommendations to them via telephone or fax. PCPs could accept or reject these recommendations at their discretion. If the patient demonstrated little response, had complex psychosocial issues (eg, impending divorce), or had an uncertain diagnosis (eg, bipolar disorder), we typically recommended referral to a mental health specialist. At quarterly intervals and at the end of the 8-month intervention, we mailed the PCP a summary of the patient's progress that included antidepressant dosages, PHQ-9 scores, and other pertinent information.⁴⁶

PROMOTING MEDICATION ADHERENCE

To promote adherence with our treatment recommendations, our nurse care managers offered to call in antidepressant prescriptions to patients' pharmacies under their PCP's verbal orders, and then forwarded an order sheet for the PCP to sign and return to document it.

Some patients agreed to a trial of antidepressant pharmacotherapy but then declined or quickly discontinued it because of cost, side effects, or concerns about dependence, safety, or stigma. In these

instances, particularly if the patient remained symptomatic, care managers attempted to overcome the patient's reluctance using various motivational interviewing approaches. Care managers also provided educational materials, including the workbook,⁵¹ to mitigate any concerns, and emphasized they would monitor the patient's clinical status closely and report back to the clinical team and the patient's PCP for ongoing guidance. The care manager also informed the PCP of the patient's reason(s) for nonadherence, raising the possibility that the clinician could help overcome the patient's resistance.

OUTCOMES

Self-reported measures

BtB enrolled 453 post-CABG patients (101% target goal) who lived across western Pennsylvania, eastern Ohio, and West Virginia and met all protocol eligibility criteria. At the 8-month followup, depressed intervention patients reported significant improvements in mental and physical HRQoL, functional status, and mood symptoms versus those randomized to usual care (**Figure 4**). Furthermore, intervention patients were more likely to achieve a 50% or greater decline from their baseline level of mood symptoms, as measured by the HRS-D, than patients randomized

to usual care (50% vs 30%), or an effect size (ES) improvement of 0.42 ($P < .001$)⁴⁵; and they reported lower levels of pain.⁵² As observed in other trials of depression treatment among patients with cardiac disease,^{53–55} the intervention tended to be more effective in men than in women (**Figure 4**).

■ PROCESSES OF CARE

Of the 150 patients randomized to our collaborative care intervention, 146 (97%) had one or more telephone care manager contacts and 83% had three or more contacts by the 4-month followup. At the 8-month conclusion of our intervention, the median number of care manager contacts per patient was 10 (range: 1–28). The proportion of intervention patients using antidepressants also increased from 15% at baseline to 44% by 8 months, and 4% reported a visit to a mental health specialist. In comparison, 31% ($P = .05$) and 6% (NS) of usual-care patients, respectively, were using an antidepressant or saw a mental health specialist during this period.⁴⁵

■ HEALTH SERVICES UTILIZATION

Depressed patients reported a similar 8-month incidence of all-cause (33% intervention vs 32% usual care) and cardiovascular-cause (15% vs 18%) rehospitalizations by randomization status. However, male intervention subjects tended to have a lower incidence of cardiovascular-cause rehospitalizations than men randomized to usual care (13% vs 23%; $P = .07$) and one that was similar to that of nondepressed BtB male post-CABG patients (13%). Notably, we did not observe a similar pattern among female patients enrolled in BtB. To better examine the “business case” for treating post-CABG depression, we are presently analyzing claims data from Medicare and from two large western Pennsylvania insurance providers and hope to report these analyses shortly.

■ DISCUSSION

BtB was the first trial to examine the impact of a real-world collaborative care strategy for treating depression in post-CABG patients or in any other cardiac population. The generalizability of our treatment strategy is enhanced by multiple design features including: (1) use of a brief, validated, two-stage PHQ depression screening procedure that was endorsed by the AHA and can be routinely implemented by nonresearch clinical personnel; (2) a centralized telephone-delivered intervention; (3) reliance on a variety of safe, effective, simple-to-dose and increasingly generic pharmacotherapy options, a commer-

cially available workbook, and community mental health specialists to deliver step-up care; (4) consideration of patients' prior treatment experiences, current care preferences, and insurance coverage when recommending care; (5) use of trained nurses as care coordinators across treatment delivery settings and providers across state lines; and (6) an informatics infrastructure designed to document and promote delivery of evidence-based depression treatment, care coordination, and efficient internal operations.

The ES improvement in HRS-D we observed in the BtB trial was at the upper end of a meta-analysis of 37 collaborative care trials for depression involving 12,355 primary care patients (ES: 0.25; 0.18–0.32).²⁷ It compared favorably with the improvements reported by the ENRICH (Enhancing Recovery in Coronary Heart Disease Patients) randomized trial (ES: 0.22; 0.11–0.33),¹⁰ the SADHART (Sertraline Antidepressant Heart Attack Randomized Trial) (ES: 0.14; –0.06–0.35),⁹ and the citalopram arm of the CRE-ATE (Canadian Cardiac Randomized Evaluation of Antidepressant and Psychotherapy Efficacy) trial (ES: 0.29; 0.05–0.52).¹³ However, our ES improvement was smaller than those generated by the more labor-intensive and face-to-face interventions provided by Freedland et al's trial of cognitive behavioral therapy (CBT) for post-CABG depression (ES: 0.73; 0.29–1.20; $N = 123$),¹⁵ the COPEs (Coronary Psychosocial Evaluation Studies) trial of problem-solving therapy (ES: 0.59; 0.18–1.00) that was the first to report a significant reduction in major adverse cardiac events from treating depression,^{15,56} or a recent meta-analysis of psychologic treatments in patients with medical disorders (ES: 1.00; 0.57–1.44).⁵⁷

Although the BtB intervention focused on depressed post-CABG patients, it is also generalizable to patients with other cardiovascular conditions. Moreover, the model can be readily adapted into practices at a variety of integrated health care delivery systems.⁵⁸ Therefore, we believe collaborative care interventions such as ours will become more widespread as elements of the 2010 Affordable Care Act are phased in.

■ FUTURE DIRECTIONS

Despite positive outcomes on HRQoL and mood symptoms generated by BtB and other recent trials,^{15,56} it remains unclear whether effective depression treatment can reduce cardiovascular morbidity and mortality. Given the trend toward a reduced incidence of rehospitalization for cardiovascular causes among depressed male patients in BtB and findings

from COPEs⁵⁶ and other trials,⁷ we believe a comparative effectiveness trial of reasonable size ($N < 2,000$ study subjects) and cost will require an intervention capable of producing an ES reduction in mood symptoms of at least 0.50. Furthermore, because of declines in morbidity and mortality over the past decade following CABG surgery and myocardial infarction,¹ we also believe heart failure remains the only prevalent cardiovascular disorder for which to conduct this future comparative effectiveness trial.

Because an improvement of at least 0.50 ES in mood symptoms is higher than the ES improvements presently generated by collaborative care treatment approaches, it is critical to develop new interventions that blend the scalability and patient acceptability of telephone-delivered collaborative care with the greater efficacy of more intensive face-to-face counseling strategies. To address this need, we are investigating how best to incorporate Internet-delivered computerized cognitive behavioral therapy (CCBT) and other online strategies for treating depression into the BtB model. CCBT is a new and evolving technology that can improve patients' access to personalized, convenient, and effective treatment for depression.⁵⁹ Used primarily in the United Kingdom, Australia, and the Netherlands, CCBT has attracted growing interest by US investigators.⁶⁰ Importantly, some CCBT programs are able to produce the ES improvements in mood symptoms needed to potentially demonstrate a reduction of cardiovascular morbidity⁶¹ and do so reliably, at scale, and at low cost compared with more labor-intensive methods of care.^{62–64} Still, pilot testing of this innovative treatment approach is necessary to evaluate: (1) whether CCBT will be as effective among depressed patients with cardiovascular disease as among those recruited from primary care settings; (2) how best to integrate CCBT within a collaborative care program linked to cardiovascular patients' usual sources of cardiac and primary care; and (3) whether incorporating Internet-delivered CCBT into a "traditional" collaborative care program that provides active follow-up, pharmacotherapy monitoring, and mental health specialty referral as options provides either no additional benefit (ES ~ 0.30), benefit approaching that of CCBT alone (ES: ~ 0.60),⁶¹ or an additive or synergistic benefit approaching face-to-face CBT (ES: ≥ 0.80).^{15,65} Findings from these studies could also have profound implications for changing the way both cardiovascular and mental health conditions are treated⁶⁶ and direct further attention to the emerging field of e-mental health by other US investigators.⁶⁰

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