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Comparative Effectiveness of Standard versus Patient-Centered Collaborative Care Interventions for Depression among African Americans in Primary Care Settings: The BRIDGE Study

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Objective. To compare the effectiveness of standard and patient-centered, culturally tailored collaborative care (CC) interventions for African American patients with major depressive disorder (MDD) over 12 months of follow-up.

Data Sources/Study Setting. Twenty-seven primary care clinicians and 132 African American patients with MDD in urban community-based practices in Maryland and Delaware. **Study Design.** Cluster randomized trial with patient-level, intent-to-treat analyses.

Data Collection/Extraction Methods. Patients completed screener and baseline, 6-, 12-, and 18-month interviews to assess depression severity, mental health functioning, health service utilization, and patient ratings of care.

Principal Findings. Patients in both interventions showed statistically significant improvements over 12 months. Compared with standard, patient-centered CC patients had similar reductions in depression symptom levels (-2.41 points; 95 percent confidence interval (CI), -7.7, 2.9), improvement in mental health functioning scores (+3.0 points; 95 percent CI, -2.2, 8.3), and odds of rating their clinician as participatory (OR, 1.48, 95 percent CI, 0.53, 4.17). Treatment rates increased among standard (OR = 1.8, 95 percent CI 1.0, 3.2), but not patient-centered (OR = 1.0, 95 percent CI 0.6, 1.8) CC patients. However, patient-centered CC patients rated their care manager as more helpful at identifying their concerns (OR, 3.00; 95 percent CI, 1.23, 7.30) and helping them adhere to treatment (OR, 2.60; 95 percent CI, 1.11, 6.08).

Conclusions. Patient-centered and standard CC approaches to depression care showed similar improvements in clinical outcomes for African Americans with depression; standard CC resulted in higher rates of treatment, and patient-centered CC resulted in better ratings of care.

Key Words. Depression, quality improvement, collaborative care, patientcenteredness, cultural tailoring, African Americans In the United States, most individuals with mental disorders are untreated or poorly treated, and this is particularly true for ethnic minorities (Wang et al. 2005; Cook, McGuire, and Miranda 2007). Despite the proven efficacy of pharmacotherapy and psychotherapy, African Americans with depressive disorders receive lower quality of care (Young et al. 2001; Alegria et al. 2008; Stockdale et al. 2008). When they do seek mental health care, African Americans are seen mostly in primary care settings (Cooper-Patrick et al. 1999), where disparities persist in diagnosis (Borowsky et al. 2000; Stockdale et al. 2008), pharmacotherapy, and psychotherapy referrals (Leo, Sherry, and Jones 1998; Sirey et al. 1999; Young et al. 2001; Stockdale et al. 2008). Disparities between African Americans and whites in the adequacy of treatment with antidepressant medications (Harman, Edlund, and Fortney 2004; Miranda and Cooper 2004) are not entirely explained by differences in education, income, and health insurance coverage (Padgett et al. 1994; Charbonneau et al. 2003; Alegria et al. 2008).

Physician knowledge (e.g., impact of race and other social determinants on health and health care), attitudes (e.g., respect for variations in cultural norms, awareness of their own biases), and skills (e.g., patient-centered communication, prescribing behaviors), and patient access barriers (e.g., cultural beliefs, attitudes, and preferences), social context (e.g., experiences of discrimination), and relationships with health professionals are intervention targets for improving outcomes and reducing disparities in depression care (Cooper, Hill, and Powe 2002; Cooper et al. 2006). Primary care physicians discuss depression and engage in rapport-building less frequently with African Americans than whites (Ghods et al. 2008); African Americans also rate their decision making with physicians as less participatory (Cooper-Patrick et al. 1999). Communication disparities may explain lower recognition and treatment rates for African American patients. Compared with whites, African Americans express stronger preferences for counseling (Dwight-Johnson and Lagomasino 2007) and spiritual approaches (Cooper et al. 2001), lower trust in physicians (Boulware et al. 2003), and more negative attitudes toward

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antidepressant medication (Cooper et al. 2003; Givens et al. 2007), the most common form of treatment of depression used by primary care physicians.

Standard collaborative care (CC) strategies (e.g., structured approaches to care based on chronic disease management principles and using depression care managers working in conjunction with a primary care physician and a mental health specialist to monitor mood and medications, coordinate care, and facilitate patient engagement) have demonstrated effectiveness for depression care (Gilbody et al. 2006). Two studies of standard CC interventions show similar improvements (Arean et al. 2005) or better responses (Davis et al. 2011) in treatment and clinical and functional outcomes for minorities versus whites. Another CC intervention that included attention to cultural issues in clinician and patient intervention materials was more effective among minorities than whites at improving depression status, but not at eliminating disparities in treatment or functional outcomes within 12 months (Miranda et al. 2003). In the same study, reductions in treatment and outcome disparities by race/ethnicity were observed after 5 years (Wells et al. 2004).

Patient-centeredness and cultural competence are approaches to improve health care quality that are promoted extensively (Institute of Medicine 2002). At the core of both approaches is the ability of health care providers to see patients as unique persons, build effective rapport, use the bio-psychosocial model to explore patient beliefs, values, and meaning of illness, and to find common ground regarding treatment plans. Similarly, both patient-centeredness and cultural competence emphasize the ability of the health care system to align services to meet patients' needs and preferences (Saha, Beach, and Cooper 2008).

Interventions targeting patient-centered communication have shown improvements in patient adherence, satisfaction, and some mental health outcomes (Griffin et al. 2004). Those focused on cultural issues increase patients' knowledge, decrease access barriers, and improve providers' cultural competence (Beach et al. 2005; Fisher et al. 2007). Yet few standard care strategies for depression target the contribution of patients' cultural and social barriers to disparities in health care (Miranda et al. 2003; Loh et al. 2007). Most target provider knowledge of treatment guidelines and disease-oriented management of patients, rather than the quality of patient–clinician communication or cultural relevance of treatment approaches (Rost et al. 2001; Unutzer et al. 2002; Katon et al. 2004; Rubenstein et al. 2006). Interventions aimed at improving patient–clinician relationships and making health care systems more responsive to patients' needs may provide opportunities to improve outcomes in ethnic minority patients with depression beyond those achieved by standard CC interventions. The Blacks Receiving Interventions for Depression and Gaining Empowerment (BRIDGE) Study is a cluster randomized trial comparing a standard CC intervention for patients (disease management) and clinicians (review of guidelines and mental health consultation) to a patient-centered and culturally tailored CC intervention for patients (care management focused on access barriers, social context, and patient–provider relationships) and clinicians (participatory communication skills training and mental health consultation), hereafter referred to as the patient-centered intervention. We hypothesized that patients in the patient-centered group would have a greater reduction in their depression symptoms, higher rates of depression remission, and greater improvements in mental health functioning at 6, 12, and 18 months than patients in the standard group. We also compared patient ratings of care and receipt of guideline-concordant treatment for depression over time between the two groups and expected better patient ratings of care in the patient-centered group.

METHODS

Study Design and Setting

The BRIDGE Study included 27 primary care clinicians and 132 of their African American patients with major depressive disorder (MDD) from 10 community-based primary care clinics in Maryland and Delaware. These clinics were selected because they were community-based, interested in improving care for African American patients, served populations with a medium to large percentage of African Americans, and included patients with a range of socioeconomic backgrounds and types of insurance coverage. Seven of the sites were located in medically underserved neighborhoods; three of these were federally qualified community health centers. Just over half of the sites used electronic medical records. Only two offered onsite mental health services. The number of clinicians per site ranged from 3 to 12. Most clinicians were full time.

Clinician recruitment took place between June 2004 and March 2006. Eligible clinicians were general internists, family physicians, and nurse practitioners who saw patients at least 20 hours per week at one of the participating sites. Clinicians were invited to participate in the study through a letter cosigned by the principal investigator and medical directors of their respective organization. Of the 108 clinicians invited to participate, 63 refused to participate and 9 did not respond; 36 were randomized and 27 contributed patients to the study. The majority of refusals were from clinicians whose entire site did not participate; thus, at any participating site, clinician participation rates were high. Randomization was stratified by study site and conducted at the clinician level (to either standard or patient-centered CC) with patients sequentially selected from each randomized clinician (10 patients from each clinician). Eighty percent of the patient-centered clinicians and 71 percent of the standard clinicians contributed patients to the study.

Between October 2005 and August 2006, study staff screened 1,486 patients for eligibility. Patients were considered eligible if they were between 18 and 75 years of age and reported their race as African American; positive on a screener for MDD from the Composite International Diagnostic Interview (CIDI) (Geneva: World Health Organization 1997); met DSM-IV criteria for MDD (American Psychiatric Association 2000) in the past year; and had symptoms present for at least 1 week in the past month. Patients were ineligible if they had an acute life-threatening condition or cognitive impairment that prevented them from completing the screener; indicated they did not intend to receive care in the clinic on an ongoing basis; had no access to a telephone; were currently pregnant, breastfeeding, or less than 3 months postpartum; screened positive for current bereavement, lifetime mania, or current alcohol or drug abuse; did not speak English; were currently receiving specialty mental health care; or reported immigrating to the United States within the preceding 5 years. Of those who completed the initial screener, 231 were eligible for the second stage, 132 were available to confirm CIDI eligibility and complete a detailed baseline telephone interview, and 42 did not meet inclusion criteria. Further details of the trial and methods have been described elsewhere (Cooper et al. 2010) (ClinicalTrials.gov NCT00243425). The trial was approved by the Institutional Review Boards of Johns Hopkins and MedStar Health.

Interventions

Table 1 provides the rationale and expected outcomes for each intervention component and a comparison of the two intervention approaches. Briefly, each clinician intervention was delivered by a primary care physician and consultation-liaison psychiatrist team. Clinicians in both interventions received 2 hours of academic detailing visits, for continuing medical education (CME) credit, on the clinical management of depression. In addition, all clinicians received a monthly newsletter with study updates and summaries of recent depression articles. Although the standard clinician intervention used a didactic, disease-oriented approach, the patient-centered clinician intervention used a case-based, interactive multi-media CD-ROM communication skills training program. The latter program contained the clinician's interview with a

Table 1: Comparison	n of Intervention Components, Rationale	e, and Exp	ected Ou	tcomes: The BRIDGE Study
Intervention Components	Rationale for Intervention Components	Standard	Patient- Centered	Expected Outcome/Improvement
Clinician interventions Standard academic detailing	PCPs infrequently use guideline-concordant strategies for depression care. PCP education is effective but only when combined with	Х		Improve recognition and management of depression; promote guideline-concordant care
Case-based, academic detailing	other approaches. PCPs engage in less PDM and rapport building with AAs. Patient-centered and cultural communication skills programs		X	Expected outcomes from standard intervention plus enhance PCP participatory communication skills; improve patient
Monthly newsletters	improve patient-reported outcomes. See rationale for standard and case-based academic detailing above.	X	X	experiences and MH outcomes Enhance knowledge of evidence base of treatments for depression in general
Consultative-liaison psychiatrist	Access to collaborative, expert support system enhances initiation and maintenance of treatment of depression in PC settings.	Х	X	(patient-centered) (patient-centered) Enhance initiation and maintenance of treatment. Assist PCP with management of complex patients; enhance MH outcomes
Patient interventions Depression case manager				
Initial needs assessment	Time and resources to comprehensively assess depressed patients' symptoms, barriers and influencing factors are limited in PC settings. Staff expertise to assess access barriers	X	X	Increase efficiency and effectiveness of patients' PC depression evaluation; improve initiation of treatment Expected outcomes from standard
	(e.g., cultural beliefs, attitudes, preferences), social context, and communication problems are lacking in PC.			intervention plus overcome cultural/social barriers to care; individualize treatment goals

continued

Standard vs. Patient-Centered Depression Care

Table 1. Continued

Patient- onents Standard Centered Expected Outcome/Improvement	ang PC X Improve patient knowledge of depressi If-efficacy self-efficacy, adherence to treatment, a self-efficacy ves depression and functional status outco	s, and poor X Expected outcomes from standard nals (lower intervention plus overcome barriers, i acceptance of treatment; and improve relationships with health professional.	rmation X Improve knowledge about depression i tments patients and family members rituality, X Expected outcomes from standard intervention plus improve attitudes; d misconceptions about treatment; supp of spirituality for positive coping
Rationale for Intervention Compo	Attrition from treatment is high amore patients with depression. Patient se and adherence to treatment improvedepression outcomes.	Access barriers, social context issues relationships with health profession trust, PDM) contribute to disparitic depression care.	Patients with depression desire infor about their illness and various treat AAs have concerns about use of spir addictiveness of medications, and experiences of care. Culturally targ messages address these barriers.
Intervention Components	Ongoing follow-up: Education/activation; Supportive counseling		Education materials

BRIDGE, Blacks Receiving Interventions for Depression and Gaining Empowerment; AA, African American; MH, mental health; PC, primary care; PCP, primary care clinician; PDM, participatory decision making.

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simulated patient at baseline, fully analyzed using the Roter Interaction Analysis System (RIAS), a widely used coding system for patient-provider communication (RIAS Works; Roter et al. 1997). Individualized feedback regarding communication was provided to each clinician, along with a companion workbook to introduce them to the software and guide them through case-based exercises targeting participatory skills. Ninety-five percent of clinicians assigned to the standard and 100 percent of those assigned to the patient-centered intervention completed their assigned programs.

The patient interventions occurred after the clinician interventions were completed and consisted of one-on-one telephone follow-ups carried out by depression case managers (DCMs) over a 12-month period. The standard interventionist was a Caucasian woman, and the patient-centered interventionist was an African American woman. Both were social workers with clinical experience who provided educational materials and extensive follow-up to assess patients' depression status and encourage adherence to recommended treatments. DCMs in both interventions conducted needs assessments at enrollment and asked standardized questions that monitored symptoms, functional status, and the patients' general health. Patients in both interventions were asked by their DCM to try at least two educational materials (books, print and visual media), mailed by the DCM. The follow-up schedule was standardized over both interventions with the frequency of follow-up calls dependent on the patients' depression level as measured by the Patient Health Questionnaire (PHQ-9) score (Spitzer, Kroenke, and Williams 1999).

In addition to the standard needs assessment questions, the patient-centered assessment explored access barriers, including the patient's attribution of his or her illness (e.g., biological vs. psychosocial vs. spiritual); their use of spirituality as an active coping strategy, and concerns about treatment (e.g., stigma, addictiveness of medication); social stressors known to disproportionately affect African Americans (e.g., exposure to discrimination, crime, financial hardship); and communication problems with health professionals (e.g., low health literacy, low participation in decision making). The patient-centered DCM also used an individualized approach to guide engagement and supportive counseling and provided contact information for culturally sensitive psychotherapists as appropriate. Finally, while the standard intervention group received generic depression educational materials, the patient-centered group received culturally targeted materials designed to address barriers to depression treatment. In response to focus groups with stakeholders, these materials incorporated images of African Americans and personalized viewpoints on safety and effectiveness of anti-depressant medication and counseling, spirituality, and suicide prevention from actual African American patients, clinicians, community members, and clergy (Cooper-Patrick et al. 1997; Primm et al. 2002).

Data Collection

Clinicians completed a self-administered survey prior to randomization, and patients completed a baseline telephone survey within 2 weeks of their enrollment visit. We compared clinicians' sociodemographic characteristics, preintervention training, attitudes and experiences, and study patients' sociodemographic, clinical, and attitudinal characteristics between the intervention groups at baseline. In general, we selected instruments that are brief, have been used successfully in primary care settings, and are reliable and valid in African Americans (Cooper et al. 2000, 2003; Givens et al. 2007). Telephone interviews to measure patients' depression status, use of health services and experiences of care, and reactions to the interventions at 6 and 12 months of follow-up are described in detail elsewhere (Cooper et al. 2010). During the time of this study, new evidence was generated regarding the need for longer follow-up to show improvements in functional outcomes and reduction in disparities in depression outcomes (Wells et al. 2004); thus, we amended our protocol and obtained IRB approval to re-contact study participants for an additional telephone interview at 18 months. Interviewers who collected data at 6 and 12 months were masked to clinician and patient intervention assignment. Outcome assessors at 18 months were not blinded to intervention assignment. The 12-month assessments remained the primary outcome.

Study Outcome Measures

Depression Outcomes. Primary outcomes were depression symptom reduction, as measured by the Center for Epidemiological Studies Depression Scale (CES-D) (Radloff 1977); depression remission, using the CIDI (Geneva: World Health Organization 1997); and mental health functional status improvement (Medical Outcomes Study [MOS-SF12] Mental Health Scale [MCS]; Ware, Kosinski, and Keller 1996) measured at 6 and 12 months.

Patient Reports of Depression Treatment. Receipt of depression treatment was measured at baseline and 12 months by patient reports of their receipt of either antidepressant medication or counseling in the preceding 6 months. We examined receipt of any treatment and receipt of guideline-concordant

treatment. Consistent with other studies, we defined receipt of guideline-concordant antidepressant medication treatment as a patient's report of taking a therapeutic dose of at least one antidepressant medication regularly for 30 days or more throughout the previous 6 months (Clever et al. 2006). The therapeutic dosage was based on the guideline recommendations reported in UpToDate (UpToDate) and receipt was based on patients' reports of consuming a therapeutic dose of antidepressants 24 of 30 days or 12 of 30 days for fluoxetine which may be prescribed for every-other-day use. Receipt of guideline-concordant counseling was defined as four or more visits with a mental health specialist in the past 6 months (Clever et al. 2006). We also constructed a binary variable indicating whether a patient had received any guideline-concordant pharmaco- or psychotherapy at baseline and 12 months. There is conflicting evidence on the rates of agreement of self-reporting compared to prescription fill data from a pharmacy database (Berk, Schur, and Mohr 1990; Katon et al. 1996; Saunders et al. 1998). We tried to reduce the likelihood of recall bias by encouraging patients to read from their medication containers during all telephone interviews.

Patient Ratings of Their Clinicians Participatory Decision-Making Skills. Patient ratings of their clinicians' participatory decision-making (PDM) style was measured at baseline (after the clinician interventions but before the patient interventions) and at 12- and 18-month interviews with the following question: "If there was a choice between treatments, how often would your provider ask you to help make that decision?" (Kaplan et al. 1995). Responses included a 5-point scale (1 = never, 2 = rarely, 3 = sometimes, 4 = often, and 5 = very often). We categorized the clinicians as participatory (ratings of 4 or 5) or not participatory (ratings of 1, 2, or 3).

Patient Ratings of the Depression Case Manager and Adherence to Case Management.

At 12 months, patients rated the helpfulness of their DCM with regard to identifying concerns, identifying barriers, providing support, and improving treatment adherence using a 4-point scale: not at all helpful, a little helpful, somewhat helpful, extremely helpful. Responses to these items were skewed toward the most positive response, thus dichotomized as extremely helpful versus all other responses. In addition, we assessed patient adherence to the case management intervention at the initial DCM contact, 6 months (mid-intervention) and 12 months (end-of-intervention), by the number who

received their scheduled intervention telephone session out of those eligible (based on the PHQ-9 depression level). We assessed the number of patients who completed a baseline assessment but could not be located to complete a 6-month assessment and the number who completed a 6-month assessment but could not be located to complete a 12-month assessment.

Statistical Analyses. The main independent variable for intent-to-treat (ITT) analyses was the indicator for the randomly assigned intervention group (standard vs. patient-centered). Our primary outcome variable was change in depression symptom severity, upon which we based the sample size evaluation to ensure statistical power. The data on outcome variables fall into two broad categories: continuous variables, such as depressive symptom score (CES-D) (Radloff 1977) and functional status scores (MOS SF-12) (Ware, Kosinski, and Keller 1996), and dichotomous variables, such as depression remission status and receipt of guideline-concordant treatment. Even though randomization was based on the primary care clinicians, the regression models for ITT analyses use patients as the unit of analysis, as patients received direct interventions from sources other than their primary care clinician.

The primary mean models include the intervention group indicator, outcome assessment visit indicators, an interaction term for these indicators, and relevant baseline characteristics, described below. This parameterization allows estimation of adjusted mean differences in continuous outcomes and adjusted odds ratios for binary outcomes, between baseline and a given follow-up visit within each intervention group, and contrasts these estimates between intervention groups for changes over time from baseline to a given follow-up visit, all of which requires no assumption for a particular outcome pattern over time. The primary testing contrast was the baseline to 12-month change in outcomes between intervention groups; we then accommodated additional data obtained by extending the follow-up to 18 months. To account for longitudinal correlations between outcomes assessed over time within patients, mixed effects models (MIXED) using identity link linking the primary mean model with the expected outcome under normal distribution and unstructured covariance matrices were used to form the basis of likelihood based statistical inferences for CES-D and MOS outcomes. Similarly, generalized linear mixed effects modeling (GLMMIX) approach, employing the logit link with the primary mean models and unstructured covariance matrix, was used to compare longitudinal binary outcomes such as participatory decision making and reports of treatment. Depression remission measured by CIDI at 12 months was modeled using regular logistic regression, as all patients were CIDI positive at baseline per inclusion criteria. CIDI was not administered at 18-month follow-up. As a result, the mean model for the logistic regression included only the intervention group indicator, in addition to appropriate covariates.

Site was included as a covariate in all mean models to account for potential patient outcome clustering within clinical sites. We used descriptive statistics to describe and compare patient and clinician characteristics at baseline. Fisher's exact test and Wilcoxon rank-sum test were used to compare clinician characteristics between randomization groups due to the smaller number of clinicians. None of the clinician characteristics were found to be significantly different between intervention groups. However, because race concordance between clinicians and patients is an important predictor of patient-reported outcomes (Cooper et al. 2003a), it was included as a covariate. Clinician age and patient attitudes were also included as covariates in separate mean models to examine the robustness of main inferences.

The likelihood-based primary analyses were anchored on the missing at random (MAR) assumption that the probability of missing data occurrence depends only on the data that were observed, and not on information that was not observed. We further conducted sensitivity analyses through multiple imputations under plausible, non-MAR missing scenarios to verify the robustness of our inferences. All analyses were conducted using *SAS* version 9.2 (*SAS* Institute, Carey, NC, USA).

RESULTS

Study Sample Characteristics by Randomization Status

Table 2 presents clinician demographic characteristics, specialty, and CME hours by intervention assignment. Overall, clinician race distributions were marginally different between the intervention groups (p = .05). Although there were some differences between clinician intervention groups in years of experience at their current practice and hours devoted to various CME activities in the past 3 years, none of these differences were statistically significant.

Patients' sociodemographic characteristics, general and mental health status, and selected attitude scores by intervention assignment at baseline are presented in Table 3. The intervention groups did not differ significantly with regard to mean household income, education, employment, or health care insurance status. There were no differences with regard to the number of comorbid conditions, mean number of disability days, mean mental health

Characteristic	Total (N= 27)	Standard (N= 16)	Patient Centered (N = 11)	p-value
Age, years, mean (SD)	44.0 (9.7)	41.9 (9.3)	47.0 (9.8)	.19
Female	16 (59)	10 (63)	6 (55)	.71
Ethnicity	()	()	()	
African American	8 (30)	3 (19)	5(45)	
Asian	6(22)	6 (38)	0 (0)	
White	12(44)	6 (38)	6 (55)	
Other	1 (4)	1 (6)	0 (0)	.05
Experience at current practice, years (SD)	7.9 (7.3)	5.8 (5.6)	10.9 (8.7)	.15
Provider training				
MD	19 (70)	10 (63)	9(82)	
DO	3 (11)	2(13)	1 (9)	
Nurse practitioner	5 (19)	4 (25)	1 (9)	.59
Medical specialty				
Internal medicine	18 (67)	12 (75)	6(55)	
Family medicine	9 (33)	4(25)	5(45)	.41
Board certified [†]	18 (82)	9 (75)	9 (90)	.59
CME in the past 3 years, h	ours, mean (SD)			
Communication	7.1 (12.9)	4.6 (7.9)	10.8 (17.7)	.19
Depression	4.7 (7.2)	3.1(4.2)	7.1 (9.9)	.44
Diversity	7.0 (23.13)	1.7 (2.8)	14.6 (35.6)	.42

 Table 2:
 Primary Care Providers Demographic Characteristics by Randomization Status*

*Unless otherwise indicated, data are expressed as number of patients (%).

[†]Among physicians only.

DO, doctor of osteopathy; MD, medical doctor.

and physical health scores on the SF12, or mean CES-D score between intervention groups. Mean scores at baseline on most attitudinal domains did not differ between standard and patient-centered groups; however, patients in the standard group had higher mean scores on readiness for treatment (7.2 vs. 6.6, p = .02). A higher proportion of patients in the patient-centered group received care from an African American clinician (race-concordant relationship) (61.2 percent vs. 6.2 percent, p < .001).

Patient Outcome Assessment Rates at Follow-up

Overall, 89 percent (N = 117) of the sample completed the 6-month interview, 85 percent (N = 113) completed the 12-month interview, and 55 percent (N = 73) completed the 18-month interview. Follow-up rates for standard and patient-centered groups were as follows: 88 percent versus 90 percent

Characteristic	Total (N = 132)	Standard (N= 65)	Patient Centered (N = 67)	p-value
Age, mean year (SD)	46.5 (11.1)	47.0 (9.8)	45.9 (12.3)	.55
Female	105 (79.6)	50 (76.9)	55(82.1)	.46
Education				.50
High school or less	77 (58.3)	36(55.4)	41 (61.2)	
Annual household income [†]				.88
Less than \$10,000	16 (12.7)	7 (11.3)	9(14.1)	
\$10,000-\$35,000	51 (40.5)	26(42.0)	25 (39.1)	
More than \$35,000	59 (46.8)	29(46.8)	30(46.9)	
Employed				
Full-time/part-time	77 (58.3)	37 (56.9)	40 (59.7)	.75
Any health care insurance payer	117 (88.6)	59 (90.8)	58 (86.6)	.45
Medicaid	21(18.0)	11 (18.6)	10 (17.2)	.84
Medicare	25(21.4)	13 (22.0)	12 (20.7)	.86
Private	82 (70.1)	39 (66.1)	43 (74.1)	.34
Comorbid medical conditions [‡]				
Hypertension	72(54.6)	38 (58.5)	34(50.8)	.37
Arthritis/rheumatism	56(42.4)	33 (50.8)	23(34.3)	.06
Diabetes	46 (34.9)	24(36.9)	22(32.8)	.62
Took disability day in last 2 weeks	74 (56.1)	40 (61.5)	34(50.8)	.21
PCS-12 score, mean (SD)	42.13 (13.23)	41.07 (13.40)	43.12 (13.09)	.38
MCS-12 score, mean (SD)	36.18 (12.62)	36.41 (12.19)	35.97 (13.10)	.84
CESD score, mean (SD)	29.84(14.09)	30.17 (13.78)	29.52(14.48)	.79
CIDI,% positive	132 (100)	65 (100)	67 (100)	.67
Taking AD meds, past 30 days	48 (36.4)	26(40.0)	22(32.8)	.39
Patient attitudes, mean (SD) [§]				
Readiness for treatment	6.9(1.4)	7.2(1.4)	6.6(1.4)	.02
Perceived effectiveness of AD meds	13.5(2.1)	13.9(2.2)	13.2(2.0)	.06
Race of PCP seeing patients				<.0001
Concordant	45 (34.1)	4(6.2)	41 (61.2)	
Discordant	87 (65.9)	61 (93.8)	26 (38.8)	

Table 3: Patient Demographics and Clinical Characteristics at Baseline byRandomization Group*

*Unless otherwise indicated, data are expressed as number of patients (%).

 $^{\dagger}N = 126.$

[‡]Top 3 of 14 conditions.

[§]Readiness for treatment is measured with two items and perceived effectiveness is measured with three items, each with 5-point Likert scales from 1 = strongly disagree to 5 = strongly agree. Higher values indicate more positive attitudes.

AD meds, anti-depressant medications; CES-D, Center for Epidemiologic Studies-Depression; CIDI, Composite International Diagnostic Interview; MCS, Mental Component Summary Score; PCS, Physical Component Summary Score.

at 6 months and 83 percent versus 88 percent at 12 months. There were no significant differences in characteristics between participants who completed the trials and those who were lost to follow-up.

Depression Severity and Depression Functional Status

Table 4 presents change in depression severity and mental functioning over time within and between intervention groups, with corresponding 95 percent confidence interval (CI), controlling for patient–clinician race concordance and clinical site. Models that also adjust for clinician age or baseline patient attitudes toward treatment resulted in similar findings and thus are not shown. Both groups experienced statistically highly significant reductions in mean depression severity score over time that are clinically meaningful. However, none of the adjusted between-group differences in CES-D over the follow-up period were statistically significant (at 6 months, 1.8 points, 95 percent CI -3.4, 6.9; at 12 months, -2.4 points, 95 percent CI -7.7, 2.9; and at 18 months, -2.9 points, 95 percent CI, -8.2, 2.4). The change in mental health functioning over time showed the same pattern of statistically significant improvements in both groups and no significant differences in functional improvement for the patient-centered versus standard group at 12 months (+3.0 points; 95 percent CI, -2.2, 8.3) and 18 months (+4.0 points; 95 percent

	Within Group			Between Groups		
	Standard		Patient-Centered		Patient-Centered versus Standard	
	$\Delta M ean$ Score [†]	95% CI	$\Delta M ean$ Score [†]	95% CI	∆Mean Score	95% CI
CES-D Score*						
6 month	-9.2	(-12.7, -5.8)	-7.5	(-11.3, -3.6)	1.8	(-3.4, 6.9)
12 month	-10.5	(-14.0, -7.1)	-12.9	(-16.9, -9.0)	-2.4	(-7.7, 2.9)
18 month	-9.1	(-12.8, -5.4)	-12.0	(-15.7, -8.2)	-2.9	(-8.2, 2.4)
MCS-12 Score*		(, , ,		(, , ,		, , ,
12 month	8.3	(4.7, 12.0)	11.4	(7.6, 15.1)	3.0	(-2.2, 8.3)
18 month	5.5	(1.5, 9.5)	9.5	(5.5, 13.5)	4.0	(-1.8, 9.7)
Remission of	Rate (%)	95% CI	Rate (%)	95% CI	OR^{\ddagger}	95% CI
depression	()		()			
CIDI negative at 12 months	41.8	(28.8, 55.9)	32.8	(20.7, 44.8)	0.97	(0.34, 2.80)

Table 4: Change in Depression Severity and Mental Health Functioningover Time, by Intervention Status

*Adjusted for clinician race concordance with patient and clinic location, in analysis using mixed effects models with all available data.

[†]Reference group is mean score at baseline.

[‡]Odds ratio of depression remission, as determined by being CIDI negative at 12 months, using logistic regression analysis adjusted for clinician race concordance with patient and clinic location.

CI, -1.8, 9.7). At 12 months, 33 percent of the patient-centered group and 42 percent of the standard group achieved remission from depression (as measured by the CIDI); this difference was not statistically significant (adjusted OR 0.97; 95 percent CI, 0.34, 2.80).

Patient Self-Report of Depression Treatment

Patient self-report of taking any anti-depressant medication remained low throughout the study regardless of intervention assignment, increasing from 40 to 47 percent (OR = 1.3, 95 percent CI 0.7, 2.3) between baseline and 12 months among patients in the standard intervention, and decreasing from 33 to 29 percent (OR = 0.8, 95 percent CI 0.5, 1.5) between baseline and follow-up among those in the patient-centered intervention. The odds of any medication treatment from baseline to 12 months were lower for patients in the patient-centered versus standard group (OR = 0.7, 95 percent CI 0.3, 1.5). Reports of receiving any counseling were also low, increasing from 17 to 24 percent (OR = 1.5, 95 percent CI 0.7, 3.2) among patients in the standard group and from 7 to 19 percent (OR = 3.0, 95 percent CI 1.1, 7.8) among patients in the patient-centered group between baseline and 12 months. Patients in the standard group increased their use of any treatment over time (from 43 to 58 percent between baseline and 12 months, OR = 1.8, 95 percent CI 1.0, 3.2), while those in the patient-centered group did not change their use of any treatment (36 percent at baseline and 36 percent at 12 months, OR = 1.0, 95 percent CI 0.6, 1.8). Receipt of guideline-concordant depression treatment increased from 25 percent at baseline to 40 percent at 12 months (in the standard group: from 29 to 51 percent, OR = 2.5, 95 percent CI 1.4, 4.6; in the patient-centered group: from 21 to 29 percent, OR = 1.5, 95 percent CI 0.8, 3.0). In the standard group, there was an increase in receipt of guidelineconcordant pharmacotherapy and psychotherapy (+14 percent, p = .049, and +10 percent, p = .07, respectively), while in the patient-centered group there was a smaller increase in receipt of guideline-concordant pharmacotherapy (+5 percent, p = .48), and a similar increase in receipt of psychotherapy (+9 percent, p = .05). Between-group comparisons from baseline to 12 months were not statistically significant for any type of depression treatment.

Patients' Ratings of Their Clinicians Participatory Decision-Making Skills

At enrollment, shortly after the clinician intervention, 73.4 percent of patients in the patient-centered versus 62.9 percent of patients in the standard group rated their clinician as participatory (p = .20, model based, adjusted OR, 1.4; 95 percent CI, 0.6, 3.4). There were no statistically significant differences in the odds of rating their clinician as participatory among patients in the patient-centered versus standard group from baseline to 12 months (OR, 0.7, 95 CI, 0.3, 1.9) and from baseline to 18 months (OR, 0.6, 95 percent CI 0.2, 1.8).

Patient Ratings of Care Managers and Adherence to Case Management

At 12 months, compared with patients in the standard group, patients in the patient-centered group had statistically significantly higher odds of rating their DCM as extremely helpful at identifying concerns (OR, 3.00; 95 percent CI, 1.23, 7.30) and improving adherence to treatment (OR, 2.60; 95 percent CI, 1.11, 6.08). Similar patterns were present, but not statistically significant, for other ratings of the DCMs (data not shown). Overall, patients in the patientcentered group participated in case management at higher rates than the standard group during the initial (81 percent vs. 75 percent), mid (69 percent vs. 55 percent), and end (70 percent vs. 54 percent) of intervention DCM contacts. Among those who completed the initial DCM contact, a greater proportion of patients in the patient-centered group continued to work with the DCM at mid-intervention (69 percent vs. 55 percent in the standard group). Similarly, among those who completed the mid-intervention contact, a greater proportion of patients in the patient-centered group remained in contact with the DCM at the end of the intervention period (70 percent versus 54 percent in the standard group).

DISCUSSION

To our knowledge, this is the first clinical trial to compare the effectiveness of patient-centered, culturally tailored CC for African American patients with depression to standard CC. Overall, patients in both patient-centered and standard interventions showed similar clinical improvements in depression severity and mental health functioning scores that were consistent at 12- and 18-month follow-up. Although the study design precludes disentangling effects of clinician and patient interventions, we discuss their potential effects separately below.

Most studies show no effects on depression outcomes for traditional educational interventions that target clinicians alone (Simon 2002; Sikorski et al. 2012). Interventions that target patient–physician communication show positive effects on patient experiences and modest effects on mental health outcomes (Griffin et al. 2004). In our study, the patient's rating of his or her clinician's PDM style is the outcome measure most specific to the clinician intervention. Consistent with previous research (Griffin et al. 2004; Loh et al. 2007), at the enrollment visit (which occurred after the clinician interventions), patients in the patient-centered CC group rated their clinicians' PDM style somewhat higher than those in standard CC. However, PDM did not improve over time in either group, and there were no differences between intervention groups over 12 months of follow-up.

In considering the potential impact of patient care management on outcomes, rates of adherence to scheduled contacts with DCMs were high, particularly for patients in the patient-centered program. Moreover, these patients rated their DCM as more helpful at addressing their concerns and helping them adhere to treatment than patients seeing the standard DCM. This is consistent with previous work showing that cultural targeting enhances access and patient experiences (Fisher et al. 2007). DCMs provided needs assessment, education, and activation designed to improve patients' treatment adherence; however, the majority of patients did not receive guideline-concordant treatment in either group. Although patients in the standard group showed a modest increase in their use of any treatment, the patient-centered intervention had minimal effects on traditional depression treatment rates. Achieving guideline-concordant care for depression among ethnic minority patients in primary care settings is a challenge noted in previous studies, suggesting that African Americans do not buy into traditional models of mental health treatment (Miranda and Cooper 2004; Arean et al. 2005). Patients may have relied upon their DCMs for supportive counseling and used them as a replacement for traditional mental health treatment. On the surface, this might be a cause for concern; however, it is possible that by addressing barriers and promoting self-efficacy, the DCMs, who were trained social workers supervised by mental health professionals, positively impacted patients' depression outcomes independent of pharmacotherapy or psychotherapy received from other health professionals. Indeed, patients in both intervention groups improved clinically, and there is strong evidence for the effectiveness of CC models that provide brief psychotherapy without requiring mental health referral (Gilbody et al. 2006).

This trial has limitations. Participating practices had high levels of interest in improving depression care for African Americans and thus may not be representative of all primary care practices. The cluster design presents unique challenges with regard to comparability of groups, allocation concealment, maintenance of ITT principles (e.g., the lack of any statistical method to handle differential patient recruitment across clusters), empty clusters (e.g., clinicians who do not contribute patients to the study), and participant contamination/switches (e.g., patients who switch between clinicians and therefore intervention groups, or switch to clinicians not participating in the trial) (Giraudeau and Ravaud 2009). The design also precludes disentangling clinician and patient interventions; this would require a resource-intensive factorial design and a larger patient sample. Statistically, there were three levels of possible clustering other than repeated measures within each patient over time that needed to be addressed: the clinical site level, the clinician level, and the DCM level. We adjusted for clinical site indicators and patient-clinician race concordance variables in the ITT analysis to control for potential site and clinician level clustering. Further adjustment for clinician age or years at the practice did not change the results. However, there was only one DCM per intervention group, so potential effects associated with DCM characteristics were indistinguishable from the intervention effects. In addition, failure to reach the patient recruitment target resulted in inadequate statistical power to detect small differences between groups in clinical outcomes. Specifically, the trial was designed to have adequate power to confirm a between-group difference of 3.6-point in reduction of CES-D score over 12 months with 250 patients enrolled (Cooper et al. 2010). With the sample size we have and parameter values derived from our observed data, the estimation precision for difference in mean CES-D score reduction from baseline to 12 months between groups would be ± 5.3 points.

Limitations of the interventions include lack of booster (or renewed) exposures for clinicians (due to concerns about interference of the clinician interventions with clinical care and productivity); reliance on telephone contacts for DCM interactions with patients and psychiatric-consultative support; and heterogeneous access to mental health specialists among patients with different health insurance coverage, living in different states. Data collection and follow-up limitations include the reliance on self-report of process and health outcomes, and relatively short follow-up time frames for assessment of functional outcomes for patients.

Notwithstanding these limitations, the BRIDGE Study serves as a prototype for incorporating patient-centeredness in programs to reduce racial health care disparities for depression. It addressed several limitations of previous studies, including following a larger sample size of African Americans, a group that has traditionally been under-represented in previous clinical trials to improve depression care; comparing culturally tailored to standard CC; and working with under-resourced community-based practices. Recruitment, retention, and implementation challenges were significant. Future research to enhance depression care of African Americans should include resources to strengthen partnerships between investigators, health care providers, and other community groups. This would promote the alignment of priorities and establishment of site-specific leadership teams; facilitate tailoring of recruitment and intervention approaches to unique needs of settings; and increase sustainability of effective programs. Future studies should also test DCM promotion of nontraditional models of depression management such as stress reduction, spiritual wellness, and self-help. These approaches reduce labeling effects, do not rely on pharmacotherapy, and may be more acceptable to African Americans. This work should also include longer timeframes for followup assessments and incorporate more patient-centered outcomes.

The results of this study should be interpreted in light of the full complement of evidence regarding effectiveness of CC for depression. Both intervention groups experienced approximately 20 percent improvement in depression symptomatology and mental health functioning, comparable to the effects of previously established standard CC interventions. Treatment rates were higher with the standard approach, while adherence to care management and patient-reported experiences were better with the patient-centered approach. However, our results do not justify advocating strongly for one approach over the other since there were minimal differences in clinical improvement between the two groups. Depending on the populations served and resources available for program implementation, either standard or patient-centered CC will likely lead to improved health outcomes and should be considered appropriate for treatment of African Americans with depression in primary care settings.

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