Treating Depression in Predominantly Low-Income Young Minority Women

A Randomized Controlled Trial

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Context Impoverished minority women experience a higher burden from depression than do white women because they are less likely to receive appropriate care. Little is known about the effectiveness of guideline-based care for depression with impoverished minority women, most of whom do not seek care.

Objective To determine the impact of an intervention to deliver guideline-based care for depression compared with referral to community care with low-income and minority women.

Design, Setting, and Participants A randomized controlled trial conducted in the Washington, DC, suburban area from March 1997 through May 2002 of 267 women with current major depression, who attended county-run Women, Infants, and Children food subsidy programs and Title X family planning clinics.

Outcomes Hamilton Depression Rating Scale measured monthly from baseline through 6 months; instrumental role functioning (Social Adjustment Scale) and social functioning (Short Form 36-Item Health Survey) measured at baseline and 3 and 6 months.

Interventions Participants were randomly assigned to an antidepressant medication intervention (trial of paroxetine switched to buproprion, if lack of response) (n=88), a psychotherapy intervention (8 weeks of manual-guided cognitive behavior therapy) (n=90), or referral to community mental health services (n=89).

Results Both the medication intervention ($P<.001$) and the psychotherapy intervention ($P=.006$) reduced depressive symptoms more than the community referral did. The medication intervention also resulted in improved instrumental role ($P=.006$) and social ($P=.001$) functioning. The psychotherapy intervention resulted in improved social functioning ($P=.02$). Women randomly assigned to receive medications were twice as likely (odds ratio, 2.04; 95% confidence interval, 0.98-4.27; $P=.057$) to achieve a Hamilton Depression Rating Scale score of 7 or less by month 6 as were those referred to community care.

Conclusions Guideline-concordant care for major depression is effective for these ethnically diverse and impoverished patients. More women engaged in a sufficient duration of treatment with medications compared with psychotherapy, and outcome gains were more extensive and robust for medications.

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Major depression, a disorder with early onset and often chronic course, imposes a high individual burden of pain, suffering, and disability.[1] Ethnic minority patients are less likely to obtain care for depression than white patients[2] and are less likely to receive appropriate treatment when they do seek care.[3,4] These disparities are partially due to minorities being less likely to be insured,[2] which results in poor access to care. In this study, we evaluated whether interventions that promote guideline-concordant treatments for depression among young, predominantly minority women would improve rates of appropriate care and clinical and functional outcomes.

Effective treatments for major depression include antidepressant medications and psychotherapies.[5,6] Most US psychiatrists favor the selective serotonin reuptake inhibitors for first-line treatment.[7] Two brief, structured psychotherapies, cognitive behavioral therapy (CBT)[8] and interpersonal psychotherapy,[9] have demonstrated effectiveness in treating psychiatric patients.[10-14] However, efficacy trials have been conducted on predominantly white patients in academic psychiatric settings. According to a review conducted as part of a surgeon general's report,[2] the studies forming the evi-

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dence base for the American Psychiatric Association[5] guidelines for depression care included 3860 participants; only 27 were identified as African American and none were of any Latino descent. These trials also included primarily upper socioeconomic status populations. For example, the National Institute of Mental Health Treatment of Depression Collaborative Research Program[11] sample included 40% college graduates. These science implementation studies have yielded a large gap in the knowledge base underlying treatment of low-income and minority women with depression, which could contribute to clinician uncertainty about the value of treating this group. This study addresses this gap in the literature by examining outcomes of care for low socioeconomic status and minority women.

Recent studies have examined care delivery systems for treating depression among primary care patients. Although these studies examined a more diverse population than smaller efficacy studies, the participants were predominantly insured and were current patients of a primary health care organization.[15-22] An early finding in this literature suggests that management interventions in primary care may be particularly beneficial for minority individuals,[23] but this study examined individuals who were already engaged in care. Young minority women, a group at high risk for depression,[2] are often uninsured[24] and many use county family planning and nutritional programs as a primary location of care. In addition, trauma and posttraumatic stress disorder (PTSD) are more prevalent in these subgroups of women with the lowest education and income.[25] New literature suggests that care management strategies are needed to engage low-income minority individuals in treatment.[26] Our intervention includes these enhancements. This study broadens the base of our current knowledge by testing whether guideline-based care for depression improves depressive symptoms and functioning in low-income minority women compared with women receiving community referrals for care.

METHODS

Women Entering Care was a randomized controlled trial of treatment for major depression in low-income women who received county health and welfare services in the Washington, DC, area suburban counties of Prince Georges and Montgomery, Md, and Arlington and Alexandria, Va. The study was reviewed and approved by the institutional review boards of Georgetown University, the University of California at Los Angeles, and the state of Maryland. All participants gave written informed consent for screening and separate consents for random assignment to care and for medical record abstraction.

Sample Participants

We screened 16 286 women: 11 151 in Prince Georges County and 3034 in Montgomery County, Md, and 2101 in Arlington and Alexandria, Va. Women were screened in Women, Infants, and Children food subsidy programs that target low-income pregnant and postpartum women and their children (≤5 years of age). Women were also screened in county-run Title X family planning clinics that are funded by national grants for comprehensive family planning services for young and low-income women. We screened 10 043 women attending Women, Infants, and Children program services, 5017 attending family planning services, 1144 bringing children to pediatric services for low-income families, and 82 living in subsidized housing projects or attending programs for county welfare recipients.

Women were screened for major depressive disorder (MDD) while they were at the service setting. Screenings were conducted from March 1997 through December 2001, with the treatment ending in May 2002. Refusal rates for screening were very low. FIGURE 1 depicts the screening and enrollment process for the study. To determine whether there were cultural differences in response to interventions, we recruited 3 distinct cultural groups: black women born in the United States, Latinas born in Latin America, and white women born in the United States. Of the 16 286 women screened for MDD, 13 975 were eligible based on self-reported ethnicity and country of origin. Approximately 11% of these women screened positive for MDD based on the Primary Care Evaluation of Mental Disorders,[27] and 36% met exclusion criteria, including bereavement, positive for current alcohol or drug problems, being pregnant or planning to become pregnant within the next 6 months, current breastfeeding, or current mental health care. Of those screened, 532 black, 71 white, and 408 Latina women met eligibility requirements for the study, representing 5.6%, 8.0%, and 7.6%, respectively, of the total screened within each ethnic group.

Engagement Into Care

Following the initial clinic screenings, we attempted to contact women who agreed to participate in the telephone diagnostic portion of the study. Participants were contacted by telephone a mean (SD) of 4.1 (4.4) times before completing the diagnostic interview by telephone. Despite repeated attempts, 345 participants (33.9%) were not reachable. Of those participants completing the screening, 427 (42%) completed a structured psychiatric diagnostic telephone interview (Composite International Diagnostic Interview[28]) and met criteria for the study. Of those participants not eligible, the majority did not meet criteria for major depression.

Clinicians contacted the women a mean (SD) of 7.8 (9.8) times to encourage them to attend an initial clinical interview; consent for random assignment was obtained at the beginning of the interview. Eleven women refused randomization. The clinicians were unaware of a participant's random assignment until the end of the interview, at which time the computer-generated random treatment assignment was re-

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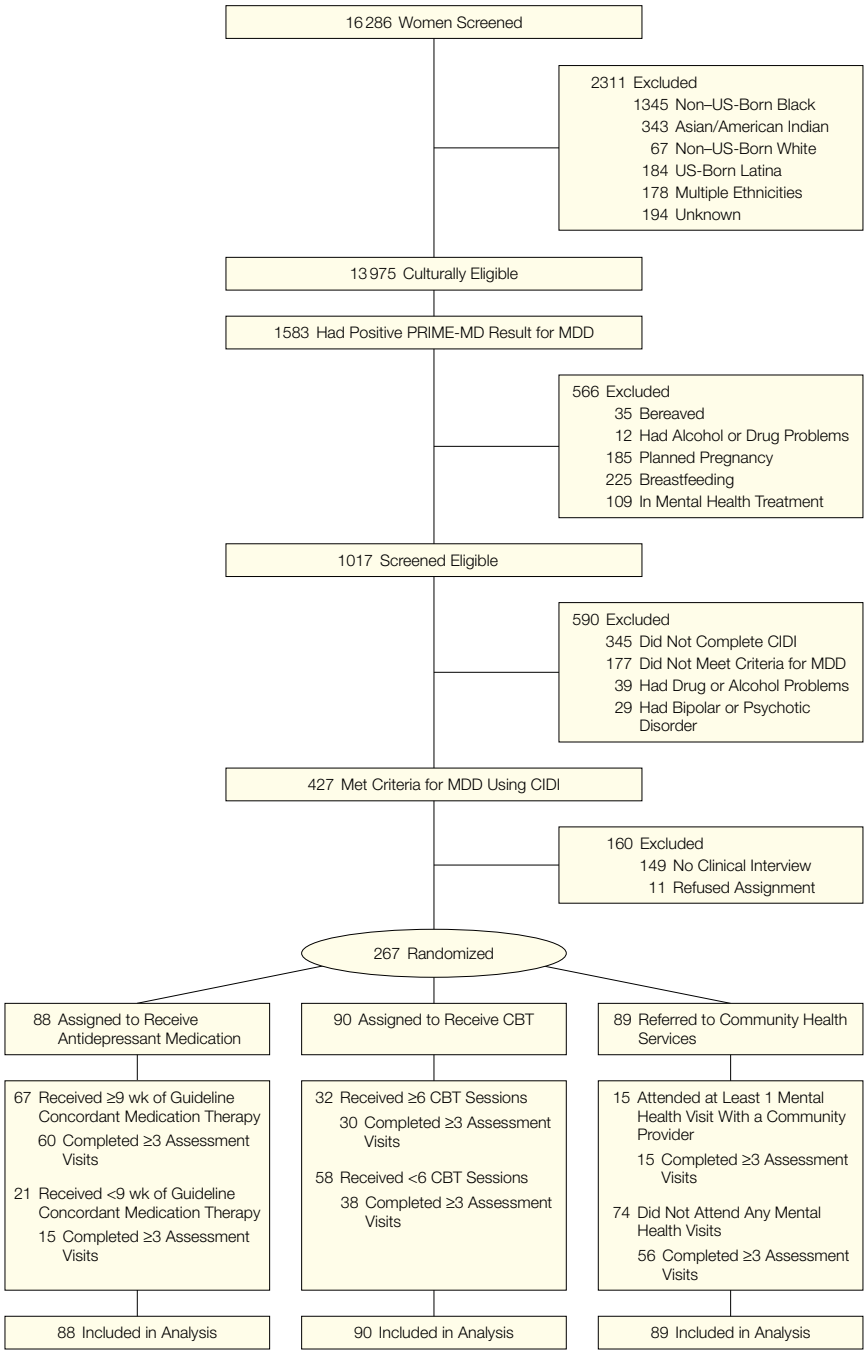
vealed by the interviewer telephoning a newly recorded message. A total of 267 Composite International Diagnostic Interview–eligible women (63%) completed the clinical interview, consented to treatment, and were randomized into the intervention trial. Women were randomized as follows: antidepressant medications administered by a primary care nurse practitioner in consultation with a psychiatrist (n=88), CBT conducted by a psychologist (n=90), or referral to community mental health services (n=89). Of those randomized, 117 were black women, 134 were Latina women, and 16 were white women. Among those women randomized, rates of obtaining care varied by randomized assignment. Response to follow-up interviews was generally high, with 80% completing 3 or more of 6 follow-up interviews.

Interventions

Education Meetings. Participants assigned to receive either CBT or medications were given both time and opportunity for discussion of depression and treatment during education meetings with the clinician overseeing their care before beginning treatment. Up to 4 education meetings could be scheduled to help participants decide about initiating treatment.

Medication. Women assigned to the medication intervention were treated by primary care nurse practitioners supervised by a board-certified psychiatrist (J.Y.C.). The duration of the medication intervention was 6 months, in line with Agency for Healthcare Research and Quality guidelines for the acute and maintenance phases of depression treatment.[29] Women were initially treated with paroxetine, which was prescribed according to a written dosing protocol. Adjustments in dosage were based on changes in Hamilton Depression Rating Scale (HDRS)[30] scores and adequate time for medication effect. The range of paroxetine dose was 10 to 50 mg daily with a mean dose of 30 mg. Clinicians also assessed participants at face-to-face meetings by using the Clinical Global Impression Scale.[31] If a patient did not tolerate paroxetine because of adverse effects or, if by the ninth week, the patient did not show a significant clinical response despite dose adjustments, buproprion, an antidepressant with a different presumed mechanism of action as well as a different adverse effect profile, was ad-

Figure 1. Participant Flow in Women Entering Care Study



PRIME-MD indicates Primary Care Evaluation of Mental Disorders; CIDI, Composite International Diagnostic Interview; MDD, major depressive disorder; CBT, cognitive behavioral therapy. Community provider could be any mental health organization.

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ministered. Participants treated with medications were observed in person every 2 weeks until a stable dose was achieved, and then every 4 weeks thereafter. The nurses scheduled weekly telephone calls to assess adverse effects, adherence, and treatment effects.

Cognitive Behavioral Therapy. Women assigned to the psychotherapy intervention were treated by experienced psychotherapists supervised by a licensed clinical psychologist with CBT expertise. The psychotherapy intervention consisted of 8 weekly sessions, either in group or individually, depending on feasibility of women attending group. Sessions were conducted at the county clinics, Women Entering Care offices and, if necessary because of childcare or elder-care constraints, in a participant's home. Participants were each given a CBT manual that they kept after treatment was concluded. The manual-guided treatment was adapted from 12-session patient and therapist manuals developed for low-income English- and Spanish-speaking medical patients.[32,33] The manual was also shortened to 8 sessions by including more topics per session and modified to be more sensitive to the issues of young women and those with histories of interpersonal trauma. Therapists received training in understanding PTSD and trauma. The therapy protocol involved homework and daily monitoring, with a focus on cognitive management of mood, engaging in pleasant activities, and improving relationships with others. Improvement was assessed by using the HDRS and Beck Depression Inventory.[34] If after 8 weeks of treatment a participant's scores were still elevated, an additional 8-week treatment was offered.

Referral to Community Care. Women assigned to community referral as usual were educated about depression and mental health treatments available in the community. The clinician offered to make an appointment for the woman at the end of the clinical interview to facilitate the referral and to speak with the mental health care clinician. Approximately one quarter of the women declined referral. Referred participants were contacted to encourage them to attend the intake appointment for care.

Cultural Adaptation of Care. Bilingual providers treated all Spanish-speaking women. All written materials, including psychotherapy manuals, were available in Spanish. Of the 6 psychotherapists, 1 was black and 3 were Spanish speaking; none of the 4 nurse practitioners were black, and 2 were Spanish speaking. All psychotherapists and nurse practitioners had extensive experience with and commitment to treating low-income and minority patients.

Measures and Data Used

All measures were read to participants based on the high proportion of women who had not finished high school. Screening interviews assessed age, marital status, employment status, ethnicity, country of birth, and level of education. The mood disorders section of the Primary Care Evaluation of Mental Disorders[27] was used to identify women at high risk for MDD. Alcohol problems were ascertained using the 5-item TWEAK (Tolerance, Worry about drinking, Eye-opener drinks, Amnesia, Cut down on drinking) designed for obstetric-gynecology clinic patients.[35] Substance abuse problems were assessed by using items from the *Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (SCID).[36]

To determine whether women met criteria for MDD, the Composite International Diagnostic Interview[28] was administered by telephone, assessing 12-month major depressive episode, alcohol abuse or dependence, drug abuse or dependence, and lifetime mania and psychosis. To be eligible for the study, participants needed to have current major depression and a negative score for mania, psychosis, or past month alcohol or drug abuse or dependence.

During the initial in-person interview with clinicians, women completed a measure of trauma history (Stressful Life Event Screening Questionnaire).[37] Up to 3 events were evaluated for current PTSD by using the PTSD module of the SCID.[36] Women were reimbursed $15 for completing this interview.

During baseline and follow-up telephone interviews, participants completed a structured version of the HDRS[30] each month for 6 months. Functional outcomes, including instrumental role functioning (employee or homemaker role assessed by the Social Adjustment Scale[38] interview) and social functioning (measured by the Short Form 36-Item Health Survey)[39-41] were completed at baseline and months 3 and 6. Telephone interviewers were blinded to random assignment of the participants, and women were reimbursed $10 for completing each interview.

Data Analyses

Clinical outcomes were determined through a mixed-effects repeated-measures analysis comparing mean depression symptom and functioning scores across assigned treatment groups over successive time periods. For depressive symptom outcomes that were measured monthly, we fit models using outcomes from month 1 through 6 while controlling for the baseline values. For instrumental role and social functioning outcomes, we fit models using the baseline, month 3, and month 6 scores. In every model, we allowed for the within-participant correlations over time by using a random intercept or random intercept and slope covariance structure. We examined the effect of treatment over time, as well as the interaction of treatment and ethnicity.

We also examined the interaction of treatment and PTSD on outcomes. In this study, the assigned clinician completed the PTSD measure during an initial clinical interview. All other measures were conducted by telephone by trained assessors. Despite comprehensive training on the standardized instrument (SCID), we found that nurse practitioners were significantly more likely to diagnose PTSD (61% of women interviewed) compared with psychologists (34%, $P<.001$), suggesting that nurses used less stringent criteria in

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judging presence of symptoms. Because of the importance of PTSD in this population, we performed analyses of medication vs community referral among participants diagnosed with PTSD by nurses and separate analyses for psychotherapy participants vs community referral among participants diagnosed by psychologists. There was no interaction of PTSD and treatment for either group, and PTSD was not included in other analyses.

To examine the robustness of our findings, we performed intent-to-treat unadjusted analysis of variance and permutation comparisons of 6-month outcomes. Because these 2 analytic approaches produce similar findings, we report only analysis of variance results. In addition, we replicated the major longitudinal analyses by using multiple imputed data sets. With the exception of income (n=10), no baseline data were missing. The extent of missing data at follow-up was similar across the 3 randomized groups. In total, 11 women (4%) missed all but the baseline interview, and 64 (24%) missed at least the last 2 interviews. Of all possible interviews, 29% were missing. To impute item-level missing data, we used an extended hot-deck multiple imputation technique that modifies the predictive mean-matching method.[42] We used an approximate Bayesian bootstrap method to impute unit-level missing data.[43] Imputations were produced separately for each intervention and the community referral groups. SAS statistical software version 8.2 was used for all analyses (SAS Institute, Cary, NC), and $P<.05$ was considered significant.

RESULTS

Participants

The participants in this study were primarily working poor Latina and black women. The mean (SD) age of participants was 29.3 (7.9) years (TABLE 1). Less than half were married or living with a partner, and 34.1% had never married. More than one third of the women (37.1%) had not graduated from high school or received a general equivalency diploma, and only 6.7% had completed college. The average woman in this study had 2 or more children, and 64.8% of women were medically uninsured.

The sample was predominantly poor. More than half (60%) of the women lived at or below the federal guidelines for poverty (during the years from 1997 to 2001). Furthermore, another 34.2% were near poor (between 100%-200% of poverty guidelines). In addition, the women in this study experienced extremely high rates of trauma exposure. More than one third had been raped and/or experienced child abuse, and 49.2% had experienced domestic violence. High rates of PTSD were also found.

Table 1. Characteristics of Intervention and Community Referral Participants*

Characteristics	Total (N = 267)	Medication (n = 88)	Cognitive Behavioral Therapy (n = 90)	Referral to Community Mental Health Services (n = 89)
Age, mean (SD), y	29.3 (7.9)	28.7 (6.6)	29.8 (7.9)	29.5 (9.1)
Marital status				
Married or living with partner	124 (46.4)	43 (48.9)	40 (44.4)	41 (46.1)
Widowed or separated/divorced	52 (19.5)	17 (19.3)	22 (24.4)	13 (14.6)
Never married	91 (34.1)	28 (31.8)	28 (31.1)	35 (39.3)
No. of children, mean (SD)	2.3 (1.4)	2.2 (1.2)	2.2 (1.5)	2.4 (1.6)
Education				
Less than high school	99 (37.1)	37 (42.0)	27 (30.0)	35 (39.3)
High school or GED	87 (32.6)	31 (35.2)	29 (32.2)	27 (30.3)
Some trade or college	63 (23.6)	15 (17.1)	26 (28.9)	22 (24.7)
College graduate	18 (6.7)	5 (5.7)	8 (8.9)	5 (5.6)
Ethnicity				
Black	117 (43.8)	34 (38.6)	41 (45.6)	42 (47.2)
White	16 (6.0)	6 (6.8)	6 (6.7)	4 (4.5)
Latina	134 (50.2)	48 (54.6)	43 (47.8)	43 (48.3)
Insurance				
Uninsured	173 (64.8)	55 (62.5)	58 (64.4)	60 (67.4)
Medical assistance	40 (15.0)	14 (15.9)	12 (13.3)	14 (15.7)
Private	54 (20.2)	19 (21.6)	20 (22.2)	15 (16.9)
Employment				
Working or looking for work	219 (82.0)	69 (78.4)	76 (84.4)	74 (83.2)
Not working or disabled	48 (18.0)	19 (21.6)	14 (15.6)	15 (16.9)
Poverty†				
Below federal poverty	149 (60.0)	48 (57.1)	48 (56.5)	53 (60.2)
Near poor (100%-200% poverty guidelines)	88 (34.2)	33 (39.3)	27 (31.8)	28 (31.8)
Not impoverished	20 (7.8)	3 (3.6)	10 (11.8)	7 (8.0)
Experience of trauma				
Life-threatening illness	51 (19.5)	23 (26.4)	12 (13.6)	16 (18.4)
Life-threatening accident	36 (13.6)	11 (12.5)	13 (14.6)	12 (13.6)
Robbed or mugged	48 (19.1)	16 (18.6)	16 (18.3)	18 (20.5)
Family/friend died violently	88 (33.2)	26 (29.5)	38 (42.7)	24 (27.3)
Raped	99 (37.2)	33 (37.5)	32 (35.6)	34 (38.6)
Child abuse	89 (33.5)	32 (36.4)	29 (32.2)	28 (31.8)
Domestic violence	129 (49.2)	45 (51.7)	49 (54.0)	37 (42.1)
Threatened with a weapon	56 (21.3)	16 (18.2)	20 (22.7)	20 (23.0)
Posttraumatic stress disorder‡§	127 (47.7)	53 (60.2)	31 (34.4)	43 (48.9)
Hamilton Depression Rating Scale, mean (SD)	16.9 (5.2)	18.0 (5.1)	16.3 (5.2)	16.5 (5.2)

Abbreviation: GED, general equivalency diploma.
*Data are No. (%) unless otherwise specified.
†Ten participants did not provide income information.
‡One participant did not receive the posttraumatic stress disorder measure.
§Differences in posttraumatic stress disorder among treatment groups appear to result from nurse vs psychologist diagnoses (P = .002).

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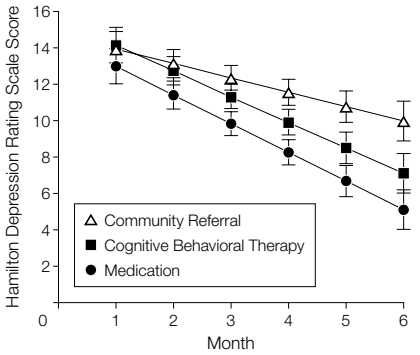
Figure 2. Adjusted Mean Hamilton Depression Rating Scale Scores



Results from regression model that used all the data at all time points available to predict each mean at each time point. Error bars indicate SE.

Recruitment and Participation in Care

Given the multiple demands on these working-poor women, outreach was an essential part of this study. Following the clinical interview, nurse practitioners spoke with women a mean (SD) of 8.8 (11.2) times to enable a first medication visit. The psychologists spoke with patients a mean (SD) of 10.2 (12.2) times before they attended a psychotherapy visit. Women who were reluctant to begin medications or psychotherapy could attend education sessions to teach them about depression treatment before agreeing to enter care. Eighty-five women (96%) attended a mean (SD) of 1.89 (0.91) educational sessions before beginning medications, and 60 women (67%) attended 2.37 (1.76) educational sessions before beginning psychotherapy. Of the women who were randomly assigned to medication treatment, 18 (20%) were switched to buproprion. Of the women assigned to psychotherapy, 15 (17%) received an additional 8 sessions of CBT. Transportation to care visits and child care funds were provided to enable women to participate in the 2 interventions. Child care was provided by either reimbursing women $10 per hour of treatment so that they could pay someone they knew for child care or when they were unable to identify a potential child care provider, child care was provided at the treatment site by study research assistants. Transportation was provided through taxi vouchers, a prepaid hired van, or reimbursement of subway or bus costs, depending on the availability of transportation at a particular site.

Participation in care was low for women in the community referral condition. After referral to a specific community provider, 74 (83%) of the women offered community referral failed to attend even 1 session. Only 8 women (9%) attended 4 or more sessions of community care. Of those randomly assigned to receive medications, 67 (75%) received 9 or more weeks of a guideline-concordant course of medications, and 40 (45%) received a guideline-concordant course for 24 or more weeks. Women were less likely to complete an adequate course of CBT. Of those randomly assigned to receive psychotherapy, 48 (53%) received 4 or more CBT sessions and 32 (36%) received 6 or more sessions. Likelihood of receiving an adequate course of treatment did not differ by ethnicity.

Longitudinal Outcomes

Results of repeated-measures analyses assessing change across time revealed a significant decrease in depressive symptoms for women in the medication ($P<.001$) and psychotherapy ($P=.006$) interventions compared with the community referral group when measured by the HDRS (FIGURE 2). There were no significant interactions in depression outcomes between the interventions and ethnicity. The women randomly assigned to receive medication and psychotherapy reported improved functioning compared with those referred to community care. Results on instrumental role functioning revealed a significant impact of the medication intervention ($P=.006$), but not the psychotherapy intervention ($P=.38$) when compared with the group referred to community care. Both medication ($P=.001$) and psychotherapy ($P=.02$) interventions were effective in improving social functioning vs community referral. The women randomly assigned to receive medications were twice as likely (odds ratio, 2.04; 95% confidence interval, 0.98-4.27; $P=.057$) to achieve an HDRS score of 7 or less by month 6 as were those referred to community care. By month 6, 44.4% of medication, 32.2% of psychotherapy, and 28.1% of community referral patients had achieved an HDRS score of 7 or less.

Comparisons were made between adjusted mean scores of those in the intervention groups and those in the community referral group at months 1, 3, and 6 (TABLE 2). Women in the medication intervention had lower depressive symptoms at months 3 and 6 and higher instrumental role and social functioning by month 6 than did those referred to community care. Women assigned to receive psychotherapy had lower depressive symptoms by month 6 and improved social functioning at month 6 compared with the referred participants. Women in the psychotherapy group did not differ from the referred controls on the instrumental role functioning measure. Women receiving medication reported lower depressive symptoms and better instrumental role functioning than did those receiving psychotherapy at month 6.

Examination of Robustness of Results

To examine the robustness of our longitudinal findings, we reexamined the major analyses using intent-to-treat analysis of variance test at 6 months, with no covariates. We replicated our finding that the medication intervention was superior to community referral in decreasing depressive symptoms ($P=.04$), improving instrumental role functioning ($P=.01$), and social functioning ($P=.01$). The psychotherapy intervention was not superior to community referral in decreasing depressive symptoms ($P=.32$) or improving role functioning ($P=.58$), but did result in improved social functioning ($P=.06$).

As an additional test of robustness, we used 5 imputed data sets to ensure that

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Table 2. Adjusted Mean Difference for As-Randomized Sample (Covariate Ethnicity)*

Measure	Medication (n = 88) Adjusted Mean (95% CI)	Cognitive Behavioral Therapy (n = 90) Adjusted Mean (95% CI)	Community Referral (n = 89) Adjusted Mean (95% CI)	Medication vs Community Referral *t*	Medication vs Community Referral *P* Value	Cognitive Behavioral Therapy vs Community Referral *t*	Cognitive Behavioral Therapy vs Community Referral *P* Value	Medication vs Cognitive Behavioral Therapy *t*	Medication vs Cognitive Behavioral Therapy *P* Value
Hamilton Depression Rating Scale Score									
Month 1	13.0 (11.1-14.9)	14.2 (12.3-16.1)	13.9 (12.0-15.9)	1.10	.27	0.26	.80	1.36	.17
Month 3	9.9 (8.6-11.2)	11.4 (10.1-12.7)	12.4 (11.1-13.7)	3.30	.001	1.36	.17	1.94	.05
Month 6	5.2 (3.0-7.3)	7.2 (5.0-9.3)	10.1 (8.0-12.3)	4.61	<.001	2.75	.006	1.86	.06
Instrumental Role Functioning									
Month 0	4.1 (3.6-4.5)	4.0 (3.5-4.4)	3.8 (3.4-4.2)	1.45	.15	0.97	.33	0.49	.62
Month 3	2.9 (2.6-3.1)	3.1 (2.8-3.3)	3.1 (2.8-3.3)	1.20	.23	0.14	.89	1.35	.18
Month 6	1.7 (1.2-2.2)	2.2 (1.7-2.7)	2.3 (1.9-2.8)	2.79	.006	0.55	.58	2.23	.03
Social Functioning									
Month 0	50.8 (42.0-59.6)	50.6 (41.9-59.3)	53.0 (44.2-61.8)	0.62	.54	0.66	.51	0.04	.97
Month 3	69.4 (64.2-74.5)	67.1 (62.1-72.2)	63.8 (58.6-69.0)	1.85	.07	1.12	.26	0.74	.46
Month 6	88.0 (78.7-97.3)	83.7 (74.4-93.0)	74.5 (65.2-83.9)	3.32	.001	2.27	.02	1.06	.29

Abbreviation: CI, confidence interval.
*Number of total participants vary across waves and outcomes: baseline, n = 262-266; month 1, n = 201; month 3, n = 186-212; month 6, n = 189-197.

our results were not due to missing data. The results for the medication intervention compared with community referral were replicated for decreasing depressive symptoms ($P=.04$) and improving instrumental role ($P=.009$) and social ($P=.03$) functioning. With the exception of improving social functioning ($P=.03$), there were no significant differences between the psychotherapy participants and the community referral group for the imputed data.

Analysis of Treatment Received

To examine the likely outcomes of current practice guideline treatment in this population, we compared those women in the medication group who received at least 9 weeks of guideline-concordant treatment (n=67) and those in the psychotherapy group who received at least 6 CBT visits (n=32) with those in the community referral group who did not receive any mental health treatment (n=74). Guideline medications ($P<.001$) and psychotherapy ($P=.003$) were significantly more effective than no treatment in decreasing depressive symptoms. There were no interactions between treatment and ethnicity. Medication ($P=.003$) was superior in improving instrumental role functioning compared with no treatment; psychotherapy was not ($P=.07$). The medication ($P<.001$) and the psychotherapy ($P=.003$) interventions resulted in improved social functioning compared with no treatment.

Comparisons were made between mean scores at months 1, 3, and 6 for women receiving guideline treatment compared with women receiving community referral with no treatment (TABLE 3). To determine the impact of guideline care above care received in the community, we also compared women receiving guideline medication or psychotherapy treatment with community referral individuals who entered community care (n=15). Guideline medications were more effective than community care at month 6 for reducing depressive symptoms ($P<.001$), increasing instrumental role functioning ($P=.01$) and social functioning ($P<.001$). Guideline psychotherapy was more effective than community care at 6 months for reducing depressive symptoms ($P=.01$) and social functioning ($P=.006$), but did not improve instrumental role functioning ($P=.78$).

COMMENT

These results demonstrate the effectiveness of the study interventions for depression when provided to low-income and minority women. The interventions included intensive outreach, child care and transportation to care when needed, and encouragement to comply with evidence-based medication or psychotherapy treatment. As a result of this care, women not only achieved lower levels of depressive symptoms, but they also achieved higher levels of instrumental role and social functioning.

The results for community referral show that few impoverished women engage in community care that is available to them. Although we could obtain appointments for care, very few women actually attended such care. Without the outreach, child care and transportation, and flexible scheduling of care offered, few impoverished women are likely to receive appropriate treatment for depression.

Engagement of women in care was demanding throughout this study. We were unable to obtain telephone diagnostic interviews for nearly one third of the women who screened positive for depression, despite persistent attempts. Of those who were interviewed, 26% who had screened positive did not meet criteria for major depression. Many reported that their mood was low at

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Table 3. Adjusted Mean Differences for Guideline-Concordant Medication and Cognitive Behavioral Therapy vs Untreated Community Referral Sample (Covariate Ethnicity)*

Measure	Medication (n = 88) Adjusted Mean (95% CI)	Cognitive Behavioral Therapy (n = 90) Adjusted Mean (95% CI)	Community Referral (n = 89) Adjusted Mean (95% CI)	Medication vs Community Referral *t*	Medication vs Community Referral *P* Value	Cognitive Behavioral Therapy vs Community Referral *t*	Cognitive Behavioral Therapy vs Community Referral *P* Value	Medication vs Cognitive Behavioral Therapy *t*	Medication vs Cognitive Behavioral Therapy *P* Value
Hamilton Depression Rating Scale Score									
Month 1	13.5 (11.2-15.7)	15.3 (12.7-17.9)	14.6 (12.3-16.9)	1.20	.23	0.57	.57	1.58	.11
Month 3	10.1 (8.6-11.6)	12.0 (10.1-13.9)	13.1 (11.5-14.6)	3.39	<.001	0.99	.32	1.82	.07
Month 6	5.1 (2.7-7.6)	7.1 (4.3-10.0)	10.7 (8.2-13.2)	4.75	<.001	2.60	.01	1.46	.15
Instrumental Role Functioning									
Month 0	3.9 (3.3-4.4)	4.1 (3.6-4.7)	3.6 (3.1-4.1)	1.31	.19	2.31	.02	1.24	.22
Month 3	2.8 (2.5-3.0)	3.2 (2.8-3.5)	2.9 (2.7-3.2)	1.11	.27	1.13	.26	2.04	.04
Month 6	1.7 (1.1-2.2)	2.2 (1.6-2.8)	2.3 (1.7-2.8)	2.50	.01	0.27	.78	1.82	.07
Social Functioning									
Month 0	47.3 (37.1-57.5)	48.3 (36.5-60.0)	53.0 (42.8-63.2)	1.49	.14	0.99	.32	.20	.84
Month 3	67.5 (61.9-73.0)	66.0 (59.1-73.0)	61.4 (55.6-67.1)	1.98	.05	1.24	.22	.38	.71
Month 6	87.7 (77.1-98.2)	83.8 (71.9-95.7)	69.7 (58.9-80.4)	4.19	<.001	2.80	.006	.76	.45

Abbreviation: CI, confidence interval.
*Number of total participants vary across waves and outcomes: baseline, n = 170-172; month 1, n = 134; month 3, n = 127-143; month 6, n = 128-200.

screening because of life circumstances but their mood had subsequently improved. Once diagnosed, our clinicians spent considerable time gaining the trust of the women, often through telephone contact, before they were comfortable receiving care.

We found no ethnic differences in response to care. Although our sample of white women was extremely small, these results argue against concerns that evidence-based treatment may not be effective for black and Latina women. Evidence-based interventions appear effective for poor and minority women if they are given support to overcome barriers to care. The interventions were moderately tailored for each ethnic population, providing care in Spanish when appropriate, and using professionals sensitive to low-income and minority populations. With these sensitivities, evidence-based treatment for depression appears effective for diverse populations.

Results of this study suggest that medication interventions may be more effective for low-income and minority women than are psychotherapy interventions. More women engaged in a sufficient duration of guideline treatment with medications compared with psychotherapy, and outcomes of care were more extensive and robust for medications. The nurse practitioners may be more accustomed to providing patient outreach than are psychotherapists. This finding could also reflect the lower time demands on patients of taking medications vs attending psychotherapy. Also, the results of psychotherapy may be slower to unfold.

Several limitations of this study should be considered. First, all measures were self-report, although the study measures have been used extensively in previous depression studies. Second, our measure of PTSD appears to be influenced by type of clinician completing the diagnosis. Nonetheless, presence of PTSD did not appear to lessen the impact of depression care. Third, nearly half of the women who screened positive for depression did not follow-up with diagnostic interviews, and others claimed to no longer be depressed when interviewed later. Thus, the extent to which this sample represents low-income young women in general is not known. Fourth, all women in the study received monthly telephone interviews to assess study outcomes. According to their self-reports, the women experienced these calls as helpful. The impact of multiple contacts for obtaining study measures could attenuate the results of the interventions compared with community referral. Finally, the impact of evidence-based treatment without the enhancements necessary to bring women to treatment cannot be determined in this study.

We conclude that our interventions, including medications and psychotherapy consistent with depression-treatment guidelines, are superior to community referral for low socioeconomic status young women. The health policy implications of this study are important. Engaging impoverished minority women in care is demanding, but outcomes are clearly beneficial. Engaging women through trusted providers could prove easier. Our results demonstrate that treating depression in this population has clear advantages, both in terms of reducing personal suffering and improving the ability of these young women to function.

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REFERENCES

1. Murray CJ, Lopez AD. Evidence-based health policy: lessons from the Global Burden of Disease Study. *Science.* 1996;274:740-743.
2. US Department of Health and Human Services. *Mental Health: Culture, Race, and Ethnicity: A Supplement to Mental Health: A Report of the Surgeon General.* Rockville, Md: US Dept of Health and Human Services, Public Health Service, Office of the Surgeon General; 2001.
3. Young AS, Klap R, Sherbourne CD, Wells KB. The quality of care for depressive and anxiety disorders in the United States. *Arch Gen Psychiatry.* 2001;58:55-61.
4. Wang PS, Berglund P, Kessler RC. Recent care of common mental disorders in the United States: prevalence and conformance with evidence-based recommendations. *J Gen Intern Med.* 2000;15:284-292.
5. American Psychiatric Association. *Practice Guideline for the Treatment of Patients With Major Depressive Disorder.* 2nd ed. Washington, DC: American Psychiatric Publishing; 2000.
6. Thase ME, Kupfer DJ. Recent developments in the pharmacotherapy of mood disorders. *J Consult Clin Psychol.* 1996;64:646-659.
7. Olfson M, Klerman GL. Trends in the prescription of antidepressants by office-based psychiatrists. *Am J Psychiatry.* 1993;150:571-577.
8. Beck C, Heacock P, Mercer SO, et al. Improving dressing behavior in cognitively impaired nursing home residents. *Nurs Res.* 1997;46:126-132.
9. Klerman GL, Weissman MM, Rounsaville BJ, Sherron ES. *Interpersonal Psychotherapy of Depression.* New York, NY: Basic Books; 1984.
10. DiMascio A, Weissman MM, Prusoff BA, et al. Differential symptom reduction by drugs and psychotherapy in acute depression. *Arch Gen Psychiatry.* 1979;36:1450-1456.
11. Elkin I, Shea MT, Watkins JT, et al, for National Institute of Mental Health Treatment of Depression Collaborative Research Program. General effectiveness of treatments. *Arch Gen Psychiatry.* 1989;46:971-982.
12. Hollon SD, DeRubeis RJ, Seligman MEP. Cognitive therapy and the prevention of depression. *Appl Prev Psychol.* 1992;1:89-95.
13. Persons JB, Thase ME, Crits-Cristoph P. The role of psychotherapy in the treatment of depression: review of two practice guidelines. *Arch Gen Psychiatry.* 1996;53:283-290.
14. Thase ME. Reeducative psychotherapies. In: Gabbard BO, ed. *Treatment of Psychiatric Disorders.* Washington, DC: American Psychiatric Press; 1995: 1169-1204.
15. Katon W, Von Korff M, Lin E, et al. A randomized trial of psychiatric consultation with distressed high utilizers. *Gen Hosp Psychiatry.* 1992;14:86-98.
16. Katon W, Von Korff M, Lin E, et al. Collaborative management to achieve treatment guidelines: impact on depression in primary care. *JAMA.* 1995;273: 1026-1031.
17. Katon W, Robinson P, Von Korff M, et al. A multifaceted intervention to improve treatment of depression in primary care. *Arch Gen Psychiatry.* 1996; 53:924-932.
18. Katon W, Von Korff M, Lin E, et al. Stepped collaborative care for primary care patients with persistent symptoms of depression: a randomized trial. *Arch Gen Psychiatry.* 1999;56:1109-1115.
19. Katon W, Rutter C, Ludman EJ, et al. A randomized trial of relapse prevention of depression in primary care. *Arch Gen Psychiatry.* 2001;58:241-247.
20. Rollman BL, Hanusa BH, Gilbert T, et al. The electronic medical record: a randomized trial of its impact on primary care physicians' initial management of major depression. *Arch Intern Med.* 2001;161:189-197.
21. Barrett JE, Williams JW, Oxman TE, et al. Treatment of dysthymia and minor depression in primary care: a randomized trial in patients aged 18 to 59 years. *J Fam Pract.* 2001;50:405-412.
22. Hunkeler EM, Meresman JF, Hargreaves WA, et al. Efficacy of nurse telehealth care and peer support in augmenting treatment of depression in primary care. *Arch Fam Med.* 2000;9:700-708.
23. Miranda J, Duan N, Sherbourne C, et al. Can quality improvement interventions improve care and outcomes for depressed minorities? results of a randomized controlled trial. *Health Serv Res.* 2003;38:613-630.
24. US Department of Health and Human Services. *Program Brief: Health Care for Minority Women.* Rockville, Md: US Dept of Health and Human Services, Public Health Services, Agency for Healthcare Research and Quality; 2002. AHRQ publication 02-P010.
25. Kessler RC, Sonnega A, Bromet E, Hughes M, Nelson CB. Posttraumatic stress disorder in the National Comorbidity Survey. *Arch Gen Psychiatry.* 1995;52: 1048-1060.
26. Miranda J, Azocar F, Organista KC, Dwyer E, Arean P. Treatment of depression among impoverished primary care patients from ethnic minority groups. *Psychiatr Serv.* 2003;54:219-225.
27. Spitzer RL, Williams JB, Kroenke K, et al. Utility of a new procedure for diagnosing mental disorders in primary care: the PRIME-MD 1000 study. *JAMA.* 1994;272:1749-1756.
28. World Health Organization. *Composite International Diagnostic Interview (CIDI) Core Version 2.1 Interviewer's Manual.* Geneva, Switzerland: World Health Organization; 1997.
29. *Clinical Practice Guideline Number 5: Depression in Primary Care, 2: Treatment of Major Depression.* Rockville, Md: Agency for Healthcare Research and Quality, US Dept of Health and Human Services; 1993. AHRQ publication 93-0551.
30. Williams JB. A structured interview guide for the Hamilton Depression Rating Scale. *Arch Gen Psychiatry.* 1988;45:742-747.
31. Guy W. *ECDEU Assessment Manual for Psychopharmacology.* Rockville, Md: Psychopharmacology Research Branch, National Institutes of Health; 1976: 217-222.
32. Munoz RF, Miranda J. *Group Therapy for Cognitive-Behavioral Treatment of Depression.* San Francisco, Calif: San Francisco General Hospital Depression Clinic; 1986.
33. Munoz RF, Aguilar-Gaxiola S, Guzman J. *Manual de Terapia de Grupo Para el Tratamiento Cognitivo-Conductal de Depression.* San Francisco, Calif: San Francisco General Hospital Depression Clinic; 1986.
34. Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. *Arch Gen Psychiatry.* 1961;4:561-571.
35. Russell M, Bigler L. Screening for alcohol-related problems in an outpatient obstetric-gynecologic clinic. *Am J Obstet Gynecol.* 1979;134:4-12.
36. First MB, Spitzer RL, Gibbon M, Williams JBW. *Structured Clinical Interview for DSM-IV-TR Axis I Disorders, Research Version, Non-patient Edition (SCID-I/NP).* New York, NY: Biometrics Research, New York State Psychiatric Institute; 2001.
37. Goodman LA, Corcoran C, Turner K, Yuan N, Green BL. Assessing traumatic event exposure: general issues and preliminary findings for the Stressful Life Events Screening Questionnaire. *J Trauma Stress.* 1998;11:521-542.
38. Weissman MM, Paykel ES. *The Depressed Woman: A Study of Social Relationships.* Chicago, Ill: University of Chicago Press; 1974.
39. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36), I: conceptual framework and item selection. *Med Care.* 1992;30:473-483.
40. Ware JE Jr, Snow KK, Kosinski M, Gandek B. *SF-36 Health Survey: Manual and Interpretation Guide.* Boston, Mass: The Health Institute, New England Medical Center; 1993.
41. McHorney CA, Ware JE, Rogers W, et al. The validity and relative precision of MOS short- and long-form health status scales and Dartmouth COOP charts. *Med Care.* 1992;30(suppl):MS253-MS265.
42. Little RJ. Missing data adjustments in large surveys. *J Business Econ Stat.* 1988;6:287-301.
43. Rubin DB. *Multiple Imputation for Nonresponse in Surveys.* New York, NY: J Wiley & Sons; 1987.

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