Impact of PTSD Comorbidity on One-Year Outcomes in a Depression Trial

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Low-income African American, Latino, and White women were screened and recruited for a depression treatment trial in social service and family planning settings. Those meeting full criteria for major depression (MDD;

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N = 267) were randomized to cognitive–behavior therapy (CBT), antidepressant medication, or community mental health referral. All randomly assigned participants were evaluated by baseline telephone and clinical interview, and followed by telephone for one year. Posttraumatic stress disorder (PTSD) comorbidity was assessed at baseline and one-year follow-up in a clinical interview. At baseline, 33% of the depressed women had current comorbid PTSD. These participants had more exposure to assaultive violence, had higher levels of depression and anxiety, and were more functionally impaired than women with depression alone. Depression in both groups improved over the course of one year, but the PTSD subgroup remained more impaired throughout the one-year follow-up period. Thus, evidence-based treatments (antidepressant medication or structured psychotherapy) decrease depression regardless of PTSD comorbidity, but women with PTSD were more distressed and impaired throughout. Including direct treatment of PTSD associated with interpersonal violence may be more effective in alleviating depression in those with both diagnoses.
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Major depressive disorder (MDD) is an important public health problem affecting nearly one-fifth of Americans (Kessler et al., 1994, Kessler, Berglund, et al., 2005). Women are nearly twice as likely as men are to develop depression and to have it at a given point in time (Kessler et al., 1994). Affective disorders are more common among those of lower socioeconomic status (SES; Kessler et al., 1994), and psychiatric disorders appear to be more persistent in this group (Breslau et al., 2005; United States Department of Health and Human Services (USDHHS), 2001). Major depressive disorder and other psychiatric disorders may also have a worse impact on low-income populations because of the lack of access to treatment for those without insurance, a problem more common among minority populations than among Whites (USDHHS, 2001). Identified barriers to care include the cost of mental health treatment and lack of insurance (Miranda & Green, 1999), the stigma of mental health problems, and a subsequent emphasis on self-reliance (Snowden, 1998; Sussman, Robins, & Earls, 1987; USDHHS, 1999), and a lack of culturally competent interventions (USDHHS, 2001). It is therefore critical to develop strategies to get low-cost mental health treatments to low-income and minority populations. Because specialty care is rarely available to those who lack insurance, primary care and social service settings are logical places to provide these treatments. Studies have shown that depression care can be delivered efficiently and cost-effectively in these settings (Katon et al., 2004; Katzelnick et al., 2000; Rost, Nutting, Smith, Werner, & Duan, 2001; Unutzer et al., 2002; Wells et al., 2000).

Trauma Exposure and Posttraumatic Stress Disorder

Until recently, the role played by trauma exposure has not been central in the study of MDD, yet epidemiologic studies suggest that over half, and up to three quarters, of individuals have experienced events that would likely meet Criterion A1 (the stressor

criterion) for posttraumatic stress disorder (PTSD; American Psychiatric Association [APA], 1994; Elliott, 1997; Kessler et al., 1995; Norris, 1992; Resnick et al., 1993). Interpersonal violence, in particular, takes a strong toll on mental health, resulting in a wide variety of emotional complaints, anxiety and depressive disorders, and interpersonal problems (Green, 1994; Weaver & Clum, 1995). Estimates of lifetime PTSD in the general population have ranged between 5 to 6% in men and 10 to 14% in women (Breslau, 2002; Breslau, Davis, Andreski, & Peterson, 1991; Kessler et al., 1995; Resnick et al., 1993). The differences in rates between men and women appear to be related to the higher rate of PTSD among women exposed to assaultive violence, such as rape and assault (Breslau, 2002). Among women exposed to domestic violence, rates of PTSD averaged 64% across studies, whereas rates of depression averaged 48% (Golding, 1999). Rape victims develop PTSD at exceedingly high rates as well (Breslau, 2002; Breslau et al., 1991, Kessler et al., 1995). Posttraumatic stress disorder also lasts longer in women than men (Breslau, 2002). Rates of current PTSD for women in the general population are about 5% (Resnick et al., 1993), although rates in primary care samples are much higher, at 9–18% (McQuaid, Pedrelli, McCahill, & Stein, 2001; Miranda, Azocar, Komaromy, & Golding, 1998; Miranda, Green, & Krupnick, 1997; Stein et al., 2000; Walker, Murphy, & Krupnick, 2003). Minority women (Greenfield et al., 1998; Tjaden & Thoennes, 2000) and those from low socioeconomic strata (Bachman & Saltzman, 1995; Sorenson, Upchurch, & Shen, 1996) are at significant risk for interpersonal violence (Miranda et al., 1997; 1998; Vogel & Marshall, 2001), and experience poorer psychological outcomes (Belle, 1990; Kessler et al., 1999; Miranda et al., 1997; Sullivan & Rumptz, 1994).

Comorbid Posttraumatic Stress Disorder and Major Depressive Disorder

Studies have shown that trauma exposure is a risk factor for MDD as well (Burnam et al., 1988; Cascardi, O'Leary, & Schlee, 1999; Chapman et al., 2004; McQuaid et al., 2001; Watson et al., 1997; West et al., 1990). Despite the link between trauma and depression, few studies have examined comorbid PTSD in depressed samples. A study that had a short screen for PTSD in depressed elderly patients indicated that 42% had comorbid PTSD; and in a two-site study of depression treatments, DeRubeis and colleagues (2005) found that 17% of their depressed patient sample had comorbid PTSD according to the Structured Clinical Interview for *DSM-IV* (SCID; First, Spitzer, Gibbon, & Williams, 1996).

The relationship between PTSD and major depression is beginning to be clarified, especially how exposure to trauma is related to the disorders jointly and separately. The National Comorbidity Survey (Kessler et al., 1995) found that, based on retrospective data, PTSD was usually the primary disorder (temporally) when examining the two together. Other studies have shown that MDD is a risk factor for the later development of PTSD (Koenen et al., 2002), or that PTSD is a risk factor for later depression (Breslau, David, Peterson, & Schultz, 1997). Several investigators looking more closely at this association have found that PTSD and MDD most likely represent a *joint vulnerability* with regard to trauma exposure, and are not therefore independent in trauma survivors (Breslau, Davis, Peterson, & Schwartz, 2000; O'Donnell, Creamer, & Pattison, 2004). In other words, those individuals who develop major depression in response to trauma are essentially confined to the subset that also develops PTSD. Trauma exposure without PTSD is not associated with higher depression rates, although O'Donnell et al. (2004) found some evidence for a "depression only" response in the acute phase (3 months) after trauma exposure. This set of associations suggests that those with depression alone, and those

with depression plus PTSD, may represent twodifferent populations. This possibility raises issues about how treatment is approached in these two groups.

Posttraumatic Stress Disorder in the Treatment of Depression

A few studies have examined the effect of PTSD in the treatment of depression, and the findings so far are mixed. Papakostas and colleagues (2003) did not find outcome differences between depressed patients with and without PTSD who were treated for 6 weeks with nortriptyline. Tucker and colleagues (2004) found that both depressed patients with PTSD and those with depression alone responded significantly to paroxetine after 10 weeks, with the PTSD patients slightly but significantly higher on self-report PTSD measures at the end, although these endpoint differences were not seen to be clinically meaningful. Neither of these studies reported on the demographic characteristics of their samples, except that the Tucker et al. sample was 65% women. Hollon and colleagues (2005) examined the impact of PTSD in the treatment of MDD by medication or cognitive psychotherapy, and found that patients with PTSD had a lower probability of response to depression treatment during the continuation phase. Their sample was predominantly White and middle class. Finally, Hegel et al. (2005) used a collaborative care model to study late-life depression in a primary care setting. Following patients for a year, they found no differences between patients with and without probable PTSD (based on a short screener) at the end of follow-up; however, those with comorbid PTSD showed a more *delayed* response to depression treatment. Their sample (also 65% women) was about one-quarter ethnic minority and about 80% had finished high school.

Present Study

The present study examined the impact of comorbid PTSD on depression treatment outcomes in a sample of low-income, mostly African American and Latino women recruited in county health and social service agencies in the Washington, DC metropolitan area (Maryland and Virginia). It was part of a larger study, the WE Care Study (Women Entering Care; Miranda et al., 2003), in which cognitive–behavior therapy (CBT) and antidepressant medication treatment (paroxetine) were compared to community mental health referral for low-income women. That study showed that both medication and CBT were superior to community referral in lowering depressive symptoms at the 6-month and one-year follow-up (Miranda et al., 2003, 2006; see below for additional information); the treatment was shown to be cost-effective as well (Revicki et al., 2005). The present study specifically examined the impact of PTSD on one-year depression outcomes, as well as how women with comorbid PTSD fared over this follow-up period. It was hypothesized that depressed women with comorbid PTSD would show significantly less improvement in their depression symptoms over the course of one-year follow-up than those without PTSD, and that this effect would occur primarily in CBT treatment. That is, it was hypothesized that there would be a significant interaction between comorbid PTSD and treatment condition. The interaction hypothesis was based on the fact that paroxetine is an FDA-approved treatment for PTSD as well as depression; thus, it would be expected to have similar effects in the two diagnostic groups (Tucker et al., 2004). Functional outcomes were expected to follow the same pattern because these outcomes have been shown to improve with treatment for depression (Coulehan et al., 1997; Kocsis et al, 2002; Miller et al., 1998; Simon, Revicki, Grothaus, & Von Korff, 1998; Simon et al., 1996; Wells et al., 2000), and treatment for PTSD (Drake et al., 2003; Ehlers et al., 2003; Falsetti et al., 2003; Power et al., 2002).

Method

Participants

Details about participant selection, exclusion criteria, and treatments in the WE Care Study have been reported elsewhere (Frank, Matza, Revicki, & Chung, 2005; Miranda et al., 2003; Miranda et al., 2006; Revicki et al., 2005). Briefly, 16,286 women who received county health and social services in the Washington, DC area suburban counties of Prince Georges and Montgomery, MD, and Arlington and Alexandria, VA were screened. Thus, the sample was recruited in settings where individuals were not seeking treatment for mental health problems. Clinic staff told women waiting for appointments in the various clinics that Georgetown researchers were screening for depression and that screening took 10 minutes; about 5% of women refused screening. Of those screened, 13,975 were eligible based on ethnicity (African American, Latina, or White) and country of origin (US for African Americans, Latin America for Latinas, and US for Whites). Approximately 11% (1583) of ethnically eligible women screened positive for MDD on the Primary Care Evaluation of Mental Disorders (PRIME-MD; Spitzer et al., 1994), of which 36% (566) were screened out based on previously established exclusion criteria such as already receiving treatment or breast-feeding. Five-hundred ninety women were subsequently excluded for not completing a structured diagnostic interview (Composite International Diagnostic Interview [CIDI]; World Health Organization [WHO], 1997) not meeting diagnostic criteria for MDD on the CIDI, not receiving a score of 14 or greater on a revised version of the Hamilton Depression Rating Scale [HDRS]; Williams, 1988), or for having serious comorbid disorders (schizophrenia, bipolar). Of the 427 who met criteria for MDD, 267 completed a baseline clinical interview and were randomly assigned to (a) antidepressant medications administered by a primary care nurse practitioner in consultation with a psychiatrist ($n = 88$), (b) CBT conducted by a psychologist ($n = 90$), or (c) referral to community mental health services ($n = 89$). Of these, 117 were African American, 134 were Latina, and 16 were White.

There were no significant demographic differences at baseline among the randomly assigned intervention groups. The average age of the sample was 29.32 ($SD = 7.93$) years, with 34% never married, and 20% widowed, separated, or divorced. Thirty-seven percent had less than a high school education and 82% were working or looking for work. Even so, 65% were uninsured and 15% were on medical assistance. Sixty percent were below the poverty level, and 34% were near poor (100–200% of poverty guidelines). Women randomly assigned to medications reported somewhat higher levels of depressive symptoms at baseline than did the other two groups ($p = .06$). On average, women reported an age of onset of depression of 23–24 years. About half the women were experiencing a mild-to-moderate episode, with 47% experiencing a severe episode. Fewer than 20% of the women had experienced a previous episode of depression.

Our earlier paper (Miranda et al., 2003) reported a PTSD comorbidity rate with no severity cut-off applied; and about 48% of the sample met criteria for PTSD. In the present report, we wanted to ensure that cases of comorbid PTSD were clinically meaningful. Because PTSD is an anxiety disorder, we expected that its severity would be reflected in a continuous measure of anxiety, the Hamilton Anxiety Rating Scale (HARS), also collected at baseline. Therefore, we added a cutoff of 13 on the HARS to our inclusion criteria for PTSD, similar to our cutoff on the HDRS for MDD for study entry, to reduce the possibility of false-positives. The addition of the cutoff reduced prevalence of comorbid PTSD to 33% across the entire sample. The three treatment groups had somewhat different rates of PTSD at baseline, with rates of 42%, 25%, and 33% for medication, psychotherapy, and referral only, respectively, $\chi^2(2; N = 266) = 6.14$, $p < .05$. We

discuss this difference further, below. The most common trauma associated with PTSD was rape. For 28% of the women with PTSD, rape was the initiating trauma. The next most common trauma associated with PTSD was physical assault or abuse as an adult (12%), which included domestic violence. Another 12% of women endorsed the "catch-all" item, "Have you ever been in any other situation that was extremely frightening or horrifying that has not been covered above?" This item picked up experiences in emigrating from country of origin, or other novel experiences not captured elsewhere. All other experiences accounted for less than 10% of the PTSD diagnosed.

Interventions

Given the multiple demands on these working-poor women, outreach and support for attending treatment sessions were provided, including transportation and reimbursement for childcare. Therapy and medication sessions were held at the county health clinics, WE Care offices, or, if necessary, in the participants' homes or other locations. The study also included multiple possibilities for outreach to overcome logistical problems and any concerns the women may have had about participation in the treatments or the research. Concerning outreach, women who screened positive for MDD were contacted by telephone a mean (*SD*) of 4.1 (4.4) times before completing the CIDI (WHO, 1997) by telephone. Clinicians (see below) then contacted the women an average (*SD*) of 7.8 (9.8) times to encourage them to attend an initial clinical interview. Women were allowed up to four educational meetings with their provider to learn about depression and its treatment prior to beginning treatment. In the medication condition, 85 women (96%) attended a mean (*SD*) of 1.89 (0.91) sessions before beginning treatment. In the CBT condition, 60 women (67%) attended 2.37 (1.76) education sessions before beginning psychotherapy (*ns*).

In addition to sensitivity to the economic and practical concerns of this low-income population, and to any concerns they may have had about treatment for mental health problems, we also endeavored to make the treatments as culturally sensitive as possible. Bilingual providers treated all Spanish-speaking women. All written materials, including psychotherapy manuals (which were distributed to the women in CBT) were translated into Spanish. We were only minimally successful in recruiting therapists of color. Of the six psychotherapists, one was African American, one was Asian American, and two of the three Spanish-speaking therapists were bicultural as well as bilingual. None of the nurse practitioners (NPs) was African American, but one was bicultural–bilingual. All psychotherapists and NPs had extensive experience with and commitment to treating low-income and minority patients (Miranda et al., 2003). Furthermore, recruitment strategies were flexible as needed. For example, Latinas often requested to include their family members in the education sessions, or appeared to require their participation in the decision to accept treatment, whereas African American women appeared to make treatment decisions on their own. The two groups also differed with regard to their comfort with group versus individual treatment once assigned to CBT (see below).

Medication. Nurse practitioners who had experience working with low-income populations served as clinicians in this condition; a board-certified psychiatrist (JYC) supervised them. The medication protocol offered 6 months of antidepressant treatment. Women were initially treated with paroxetine, prescribed according to a written dosing protocol informed by clinical guidelines. Adjustments in dosage were based on changes in HDRS scores and adequate time for medication effects. Paroxetine doses ranged from 10 to 50

mg daily, with a mean dose of 30 mg. If the participant did not tolerate paroxetine, or did not show a significant clinical response by 9 weeks (50% reduction in HDRS) despite dose adjustments, buproprion, an antidepressant with a different presumed mechanism of action as well as a different adverse effect profile, was administered.

Cognitive–behavioral therapy. Experienced psychotherapists (masters- or doctoral-level psychologists) trained in CBT administered the psychotherapy treatment. A licensed experienced clinical psychologist with CBT expertise, conducted weekly group supervision of therapists to ensure adherence to the treatment. The manual-guided treatment was an eight-session modification of a 12-session intervention developed for low-income English- and Spanish-speaking medical patients (Muñoz, Aguilar-Gaxiola, & Guzman, 1986; Muñoz & Miranda, 1986). 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. The manual was modified to be sensitive to the issues of young women, especially interpersonal trauma. Although we did not specifically elicit discussion of trauma during treatment, we consistently acknowledged these experiences, and pointed out that they were likely related to current thoughts and behaviors. We also presented the CBT skills as applicable to coping with trauma-related problems. Women who remained depressed (HDRS $>$ 7) following a course of CBT were offered eight additional sessions.

The protocol called for women to attend group sessions of CBT, unless their schedules made this prohibitive. However, the Latino women were much less open to attending group meetings, and the project adjusted to this strong preference by offering individual treatment to these women. Indeed 93% of African American women attended group, whereas 88% of Latinas attended individual CBT, a difference that reached significance, $\chi^2(2; N = 63) = 38.81$, $p < .001$. Only three White women had CBT.

Referral to community care. Women assigned to community referral 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 clinician. Approximately one quarter of the women declined referral. Referred participants were contacted by the referring clinician within a week or two of referral to encourage them to attend the community care program.

Measures

All outcome measures were verbally administered; some women with less education may have been unable to read the materials. Screening interviews assessed age, marital status, employment status, ethnicity, country of birth, and level of education, and included the *PRIME-MD* (Spitzer et al., 1994) to screen for major depression. The *CIDI* (WHO, 1997) was administered by telephone, assessing baseline MDD, alcohol abuse or dependence, drug abuse or dependence, and lifetime mania and psychosis. To be eligible for the study, participants needed to have current MDD and to be negative for mania, psychosis, or past-month alcohol or drug abuse or dependence.

Participants completed a structured version of the HDRS (Williams, 1988) by telephone at baseline, at each month for 6 months, and then at months 8, 10, and 12. Interviewers listened to and scored tapes of this measure; then a trained clinician listened to tapes of each interviewer and provided feedback until each telephone interviewer was

judged reliable. For 28 interviews scored by two interviewers, kappa was .63, indicating substantial agreement.

Measurement of posttraumatic stress disorder (PTSD) required a three-part process that was part of the baseline clinical interview. The Stressful Life Events Screening Questionnaire (SLESQ; Corcoran, Green, Goodman, & Krinsley, 2000; Goodman et al., 1998) was used to assess history of exposure to traumatic events. The 13 events surveyed are those covered in the *DSM-IV* (Goodman et al., 1998; Corcoran et al., 2000), and are queried in behavioral language. The 2-week test–retest correlation for number of events reported was .89, and individual item kappas ranged from .31 to 1.00, with a median kappa of .73. The relationship between the questionnaire and an interview 2 weeks later was .77 for total number of events. Item kappas for validity between the questionnaire and the interview ranged from .26 to .90, with a median kappa of .64. Following a short discussion to choose the most stressful event, the PTSD module of the Structured Clinical Interview for *DSM-IV*–Non-Patient Version (SCID; First, Spitzer, Gibbon, & Williams, 1996) was administered. In the present study, interviewers could go through the PTSD module up to 3 times for three different traumas, but they discontinued the module once the participant met criteria for current PTSD, or clearly did *not* meet criteria. The goal of this procedure was to identify comorbid PTSD if it was present. The SLESQ and the PTSD module were administered again at the final interview by a clinician, at which time intervening trauma exposures were assessed.

Impairment in instrumental role functioning was measured by the employee, student, or homemaker role subscale of the Social Adjustment Scale (Weissman & Paykel, 1974), and social functioning and physical functioning were measured by subscales of the Short Form 36-item Health Survey (Ware & Sherbourne, 1992). All three functional measures were completed at baseline, and at months 3, 6, and 12. Telephone interviewers were blinded to group assignment. Clinicians were also blinded to group assignment until the end of the qualifying clinical interview when a computer-generated random treatment assignment was revealed to the clinician via a newly recorded telephone message they retrieved. The women were reimbursed $10 for completing each interview, except the final interview, for which they received $25.

Data Analyses

The impact of random assignment to care on clinical and functional outcomes over 12 months was evaluated through a mixed-effects' random intercept and slope repeated measures analysis comparing mean depression symptom and functioning scores across assigned treatment groups over successive time periods, with ethnicity, PTSD status, and PTSD status interacted with treatment and time as covariates. The mixed-effects' approach models change over time at both the group and the individual level. A separate trend is estimated for each subject, based on all available subject-specific data augmented by information from all other participants in the sample. This allows for the fact that over time, different individuals may respond to treatment differently. The model also accounts for the fact that repeated measures within subjects are correlated, providing accurate estimates of the standard errors. Because the individual trends are a weighted average of individual-level data and the overall data, mixed-effects' models will provide unbiased parameter estimates even when there are missing values as long as the data available for each individual adequately represent that subject's deviation from the estimated group trend line over the time frame of the study (Gibbons et al., 1993).

Models were fit using data from baseline through month 12. Because times varied for actual dates of interviews, number of days since baseline was used as the time covariate.

Depressive symptom outcomes were measured at months 1, 2, 3, 4, 5, 6, 8, 10, and 12. Functional outcomes were measured at baseline and months 3, 6, and 12. Differences in the intercepts, linear slopes, and quadratic slopes were tested among the three randomly assigned groups. The linear slope measures continuous change in scores over time. The quadratic slope was included to determine whether the interventions caused steeper linear changes in outcome scores, followed by a leveling out over time (quadratic slope).

To examine whether the interventions were more or less effective for the distinct cultural groups (African American, Latina, White), an interaction of treatment and ethnicity was examined. There was inadequate power to detect minority versus White differences, but African American versus Latina differences could be examined. Because treatment-by-ethnicity interactions were not significant, all results are presented averaging over ethnic groups. No differences in outcomes were found between attending group versus individual psychotherapy; thus, all results are presented for CBT care combined. Model results are summarized by reporting the adjusted means at each time point.

Baseline data were complete with the exception of 10 individuals missing data on income, 5 missing instrumental role functioning, 1 missing PTSD, and 2 missing social functioning. The extent of missing data at follow-up was similar across the three randomized groups, with the percentage of missing interviews at any particular month ranging from 24 to 38%. Furthermore, all assessments were performed separately from the clinical treatment sessions, so we were able to obtain follow-up data on many women who dropped out of treatment. Among those who did not complete treatment, 71% completed three or more assessments; among those who did complete treatment, 92% completed three or more assessments.

To examine the effect of treatment on PTSD status, a chi-square difference test was run comparing treatment groups on the percentage of individuals who still had PTSD at one-year follow-up. Further, we used a one-way ANOVA to explore differences across treatment in change in the number of PTSD symptoms endorsed from baseline to one-year follow-up.

Results

At baseline, depression severity (HDRS) for the sample as a whole was 16.90 ($\pm$ 5.18), and 91 women were diagnosed with PTSD. The PTSD/no PTSD groups did not differ on most demographics, including level of education, level of poverty, proportion who were working, insurance coverage, age, number of children, or marital status. They did differ on ethnicity, $\chi^2(2; N = 266) = 6.31$, $p < .05$, with those with PTSD (40% African American, 11% White, and 50% Latina), differing from those without PTSD (46%, 3%, and 50%, respectively), with the primary difference being the larger proportion of Whites in the PTSD sample.

Lifetime trauma exposure history can be seen in Table 1. Of the total sample, 90%, reported exposure to at least one traumatic event in their lifetime. The experiences that significantly ($p < .05$) differentiated those with and without PTSD were the experience of rape, of being beaten as a child, and of being otherwise assaulted (including domestic violence), with those with PTSD having the experiences more often.

Regarding clinical characteristics (Table 1), in addition to a higher number of PTSD symptoms on the SCID (11.98 vs. 3.90), the women with PTSD were significantly more impaired on all of the baseline measures of clinical symptoms and functioning, including greater anxiety and depression, and poorer physical functioning, social functioning, and role performance.

Table 1
Trauma Exposure and Clinical Characteristics of Women With and Without Posttraumatic Stress Disorder (PTSD)

	With PTSD (n = 175)	Without PTSD (n = 91)
Trauma exposure types (%)		
Life threatening illness*	25.8	16.2
Life threatening accident	17.6	11.5
Robbery or mugging	22.2	17.4
Violent death of friend/family	31.9	33.9
Rape***	52.7	29.1
Molested*	27.8	18.3
Beaten as a child**	41.8	29.1
Otherwise assaulted***	64.8	41.4
Threatened without weapon*	27.5	18.0
Witnessed death or assault*	26.4	16.8
Baseline Clinical Characteristics (M [SD])		
Depression***	19.21 (5.19)	15.69 (4.78)
Anxiety***	19.57 (5.40)	12.95 (6.06)
Physical functioning***	70.24 (22.72)	81.55 (20.99)
Social functioning***	51.79 (25.52)	60.70 (24.88)
Role performance***	3.71 (1.26)	3.35 (1.19)
PTSD symptoms***	11.98 (2.65)	3.90 (4.64)

*$p < .10$. **$p < .05$. ***$p < .01$.

Summary of General One-Year Outcomes

One-year outcome results for the entire sample, comparing treatment groups, are reported in detail elsewhere (Miranda et al., 2006). We briefly recap some of those findings here as a context for the current report. Despite our active outreach, many women did not complete treatment. Of those assigned to medication treatment, 76.1% received greater than or equal to 9 weeks of a therapeutic dose of antidepressant medications, and 47% received the full 6 months of medication. Twenty percent (n = 18) were switched to buproprion either because the participant did not tolerate paroxetine or did not respond to the original medication (50% reduction in HDRS by 9 weeks). Of those assigned to psychotherapy, 35.5% received six or more CBT sessions, which we considered to be an adequate course of treatment. Neither changing medication to buproprion nor completing a therapeutic dose of medication or psychotherapy was associated with ethnicity or with having comorbid PTSD. Among those completing a course of CBT, 15 completed group treatment and 17 completed individual treatment. As noted earlier, most of the African American women completed group and most of the Latinas completed individual treatment. Of the women assigned to community referral, 83% failed to attend even one session. Participants received minimal care during the posttreatment follow-up period.

One-year intent-to-treat outcomes showed that depressive symptoms declined for all groups over time. There was a significantly steeper initial decline for both medications and CBT, followed by a leveling out of scores, compared with the community referral group. The medication group showed a significantly steeper initial decline in depression symptoms than the CBT group. In terms of remission rates among treatment groups at month 12 (defined as HDRS score ≤ 7 and a 50% change from baseline to month 12), 51% of those assigned to antidepressants, 57% assigned to CBT, and 37% assigned to

community-referral were no longer clinically depressed. This difference in remission rates between those assigned to CBT with those referred to community care was significant ($p = .01$), while medication/community referral difference neared significance ($p = .08$; Miranda et al., 2006). Functioning scores followed a similar pattern but they were less striking (Miranda et al., 2006).

Changes Over Time for PTSD Versus Non-PTSD Groups

None of the PTSD by treatment or time interactions was significant for any of the outcomes, including depression symptoms, social functioning, physical functioning, and instrumental role performance (all ps $> .05$). Thus, treatment effects did not depend on PTSD status, and changes in symptoms and functioning over time were similar across individuals with and without PTSD. Given these findings, we examined the effect of PTSD on each of the outcomes across time collapsing across treatment groups. Results are presented in Figures 1–4. As can be seen in Figure 1, adjusted HDRS scores remained significantly worse over time for those with PTSD compared to those without, although the difference was only marginal by month 12 ($p = .10$). Figure 2 demonstrates a similar trend for improvements in social functioning, with those with PTSD showing significantly less improvement at 3 months, and tending to have less improvement at month 12 than those without PTSD ($p = .10$). Physical functioning remained significantly worse for those with PTSD than those without across the 12 months, as shown in Figure 3. Interestingly, Figure 4 demonstrates that differences in instrumental role performance by PTSD status were significant through 9 months. By month 12 differences were no longer significant.

Effects of Depression Treatments on Posttraumatic Stress Disorder

Of the women diagnosed with PTSD at baseline ($n = 91$), most ($n = 51$ of 64 reassessed, 80%) no longer had PTSD at 12 months. The percentages by treatment condition of those

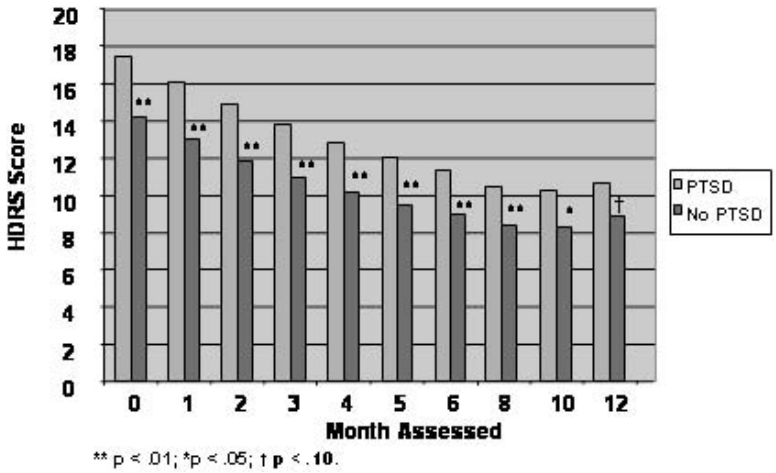

Figure 1. Adjusted Hamilton Depression Rating Scale (HDRS) scores by posttraumatic stress disorder status and time.

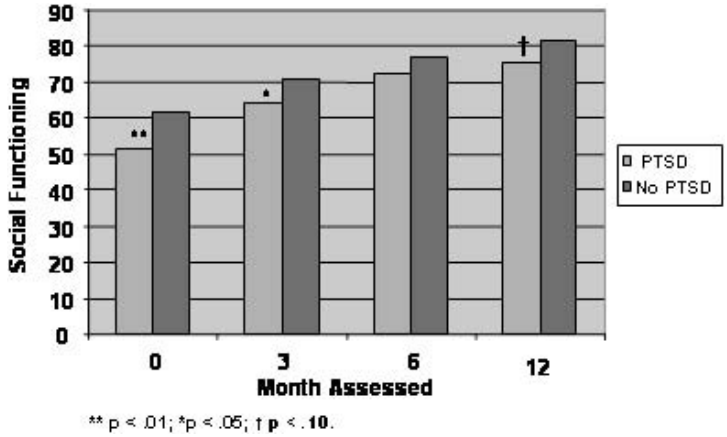

Figure 2. Adjusted social functioning by posttraumatic stress disorder status and time.

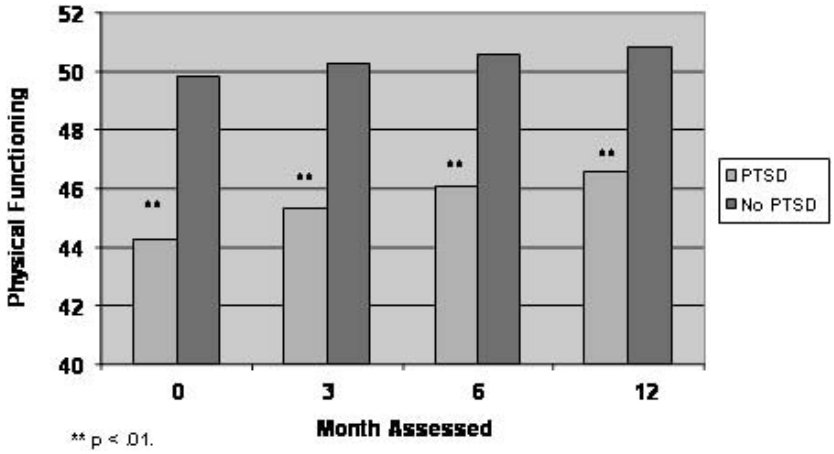

Figure 3. Adjusted physical functioning by posttraumatic stress disorder status and time.

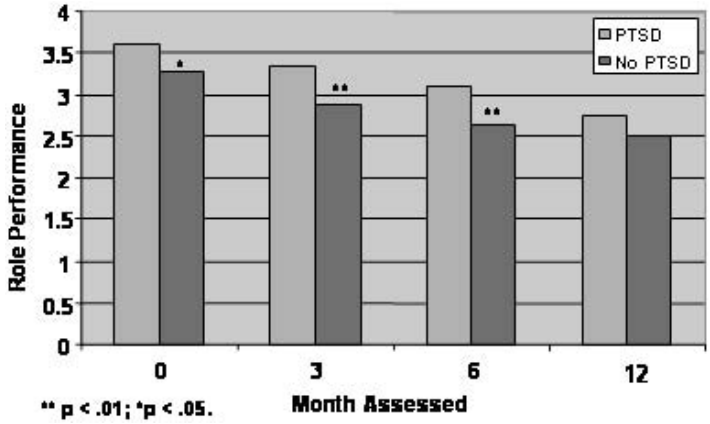

Figure 4. Adjusted role performance impairment by posttraumatic stress disorder status and time.

still meeting criteria for PTSD at month 12 were 12% of those in the medication condition, 31% of those in CBT, and 22% of those in the referral group. The rate of PTSD decreased significantly in each treatment group, and there were no differences across treatments.

Change in the number of PTSD *symptoms* endorsed from baseline to month 12 by treatment condition was also examined using a one-way ANOVA. The omnibus *F*-test was marginally significant ($F = 2.98$, $p = .06$, $n = 72$). Scheffe post hoc tests for multiple comparisons indicated that while all groups declined significantly in the number of symptoms endorsed, there was a marginally greater decline in symptoms ($p = .07$) among those in the medication condition ($M = 6.45$, $SD = 5.34$) compared to those in the CBT condition ($M = 2.82$, $SD = 5.41$). Interestingly, the community referral group showed a similar decline ($M = 5.96$, $SD = 4.49$) to the medication group; this effect did not differ significantly from either the medication or CBT groups.

Discussion

The overall results of the study demonstrated the continued effectiveness over one year of short-term medication and psychotherapy interventions for low-income, mostly African American and Latino nontreatment-seeking women with major depression, with a fairly rapid reduction of depression symptoms and return to functioning, when they were offered care supported by educational outreach, childcare, and transportation (Miranda et al., 2006; Revicki et al., 2005). Even the minimal level of treatment reported in this study was associated with clinical improvement similar to more middle-class populations. Over the course of 12 months, 69% exposed to CBT, 53% continued on antidepressant medications, and 24% withdrawn from antidepressant medications were recovered at 12 months. On the other hand, women in the current trial were less likely to complete care than samples of more advantaged populations (DeRubeis et al., 2005); in our study, only 67% received 9 or more weeks of medication and 35% completed six or more sessions of CBT, compared to an 89% completion rate for medication and 85% for cognitive therapy in the DeRubeis et al. study. This difference could be a result of social class, or it may be related to the fact that our study was done in primary care, where women did not initially present seeking treatment for their depression.

The study showed that women with PTSD had more serious trauma exposure, and began treatment with higher levels of baseline clinical and functional impairment than their non-PTSD counterparts. In particular, interpersonal violence was higher in the PTSD group; those with PTSD reported more exposure to rape, child abuse, and later assault, which included domestic violence. Rape was the most common trauma associated with the diagnosis of PTSD. This finding goes along with other studies that have shown high rates of PTSD among those exposed to interpersonal violence (Breslau et al., 1991; Golding, 1999; Kessler et al., 1995), and with the fact that the higher rates of PTSD in women are apparently due almost exclusively to their response to assaultive violence (Breslau, 2002). The higher severity of symptoms in the PTSD group, however, was not limited to anxiety; depression and functional impairment were worse in this subgroup as well, highlighting the range of sequelae of trauma exposure (Gleason, 1993; Green, 1994; Stein & Kennedy, 2001; Weaver & Clum, 1995).

In the present study, we found higher rates of comorbid PTSD among those randomly assigned to medication compared to those in the CBT conditions. The conditions were confounded with type of provider: NPs provided the medication treatment and psychologists provided the CBT treatment. These same clinicians also did the initial diagnostic

assessments for PTSD. Referral only (nontreatment) participants were randomly assigned for initial evaluation to one of the two types of clinicians, and their rate of PTSD was intermediate between the two treatment groups. Part of the difference in rates of PTSD between the groups was due to patients with lower levels of anxiety receiving a PTSD diagnosis from the NPs. These individuals undoubtedly had milder PTSD, as determined by the structured interview. It is possible that primary care NPs are less used to evaluating and treating depressed patients, whereas psychologists who work in specialty mental health care, are more familiar with patients with more severe psychiatric symptoms. The cutoff of 13 on the HARS addressed this threshold effect to some extent. However, the NPs appear to have been assigned women who actually had more PTSD, as suggested by the fact that the NP-assigned patients had more recent interpersonal trauma exposure in the form of more recent molestation ($p <$ .03). In any case, we reported the results combining the three treatment groups, so this initial imbalance should not affect the findings.

The primary finding is that PTSD did not affect the outcomes for depression treatment. Women with PTSD were worse off at the beginning of the study and remained more impaired at the end of the study, but their rate of depression *change* was similar to women who did not meet criteria for PTSD. In the medication condition, this may have occurred because paroxetine is an approved treatment for PTSD as well as for depression. It has been shown to be effective for PTSD and its associated features in mixed samples of men and women, civilian and military populations (Davidson, 2003; Stein, Davidson, Seedat, & Beebe, 2003; Tucker et al., 2004). Indeed, studies that compared medication treatment of depression with and without PTSD did not find differences (Papakostas et al., 2003; Tucker et al., 2004).

However, we did not find the expected differences in those with and without comorbid PTSD in the CBT condition. Hollon et al. (2005) found that PTSD affected response to depression treatment during the continuation phase in their study, and Hegel et al. (2005) found that patients with comorbid PTSD symptoms showed a more *delayed* response to depression treatment. Participants in the current study were most like those of Hegel et al., whose study also was conducted in a primary care setting and included a larger percentage of minority patients. It seems most likely that the lack of difference between the medication and the CBT groups in our study was attributable to two factors. First, our CBT treatment endeavored to be trauma-sensitive. Indeed, in our first pilot group for this depression treatment study, five women had been raped, and they spontaneously discussed their PTSD symptoms in the group (e.g., how the smell of a hair product used by the rapist triggered intrusion symptoms), so we understood the need to incorporate trauma issues and references in the depression-targeted CBT. We consistently acknowledged these experiences, and linked them to depression symptoms, and we suggested that newly learned CBT skills would be useful for coping with trauma-related problems. Second, the PTSD in the present study may have been less severe than that in the Hollon study because our patients were recruited in primary rather than specialty care, and thus the PTSD of individuals in primary care may not have interfered as much with depression treatment.

However, while the depression improved with or without comorbid PTSD, the PTSD group was still worse off over the course of the year than the group with depression alone, showing significantly higher depression at 10 months (marginal at one year), worse physical functioning throughout the year, worse social function at 3 months and marginally worse at one year, and worse role functioning through 9 months. Because of multiple comparisons, we do not try to draw specific conclusions about the nature of the impairment, but there is a clear pattern that those with an initial diagnosis of PTSD and MDD were doing worse than those without PTSD across the period of the study. On the other hand, we did find that PTSD symptoms improved with the treatments, so that most of the women with

initial PTSD did not have it at the end of treatment (35% overall). The improvement in PTSD symptoms suggests that the depression treatment was helpful to some extent with PTSD symptoms, which is logical, because depression and PTSD symptoms overlap to some extent. On the other hand, it is possible that the women with PTSD, or those with more severe symptoms, were less likely to make it to follow-up, so that our findings may paint a more positive picture than was actually the case.

This overall pattern of findings suggests that the residual PTSD needs to be treated directly to reduce overall distress and impairment, and possibly also to reduce the likelihood of relapse of the depression over the long run. Although the depression was improved in the PTSD group, the residual symptoms of PTSD, anxiety, and functional impairment likely contributed to a poorer quality of life for this subset of women. Indeed, in separate analyses, comorbid anxiety was associated with poorer health-related quality of life outcomes in the African American women (Frank et al., 2005). Excellent CBT treatments for PTSD (Foa et al., 1999, Resick et al., 2002), as well as other types of PTSD treatments such as interpersonal therapy (Bleiberg & Markowitz, 2005; Krupnick, 2002), address PTSD directly, and these treatments, or elements of them, may need to be incorporated into a comprehensive treatment plan for those with comorbid PTSD and depression.

There were few ethnic differences in the study sample. The primary comparisons that could be made were between African American and Latino women, because White women made up only 6% of the total sample. Small but significant ethnic differences in PTSD comorbidity were found at baseline, with White women having slightly higher rates of comorbid PTSD (11%, compared to 3% without PTSD). In the general population, investigators have not found race differences in prevalence of PTSD (Kessler et al., 1999), although those of lower socioeconomic status have higher rates of this disorder (Kessler et al., 1999). One possibility is that the White women who attended clinics with predominantly minority populations were of lower socioeconomic status than minority individuals attending the same clinics. Again, however, the number of White women was too small to draw any firm conclusions about this subgroup.

We did not find differences in response to depression treatment between African American and Latina women. This was true for the overall study at 6 months (Miranda et al., 2003) and at one year (Miranda et al., 2006), and PTSD did not interact with ethnicity as it related to depression outcomes at one year. Generally, African American and Latino patients have been found to respond to depression interventions that are evidence-based similarly to White participants (Miranda et al., 2005). However, it is important to remember that in the present study, culturally sensitive education and encouragement were needed to get women who were depressed, but who were not seeking mental health treatment, into care. Even with help with transportation and babysitting, only 67% of treatment participants received 9 or more weeks of medication, and only 35% completed six or more sessions of CBT, our definitions of an adequate "dose" of these interventions. Thus, the women who came to the treatment improved, but it was difficult to engage this population in general. It is possible that the treatments offered in this study were not experienced as culturally sensitive or appropriate by the patients we recruited, despite our efforts to make them so. However, the women participants also led very demanding lives (multiple jobs, young children) that made it difficult to attend treatment sessions regularly, even with the flexibility of time and site, and with individual treatments being available. Tailoring treatment to settings that the women frequent, such as school or church settings, may add to their uptake in future studies and in dissemination in the community.

One major ethnic difference we found was that the African American women were evidently comfortable with, and accepted, group psychotherapy, while Latinas generally

rejected this format in favor of individual treatment. Although the literature on this topic is sparse, there is some support for this differential format preference (Dwight-Johnson, Lagomasino, Aisenberg, & Hay, 2004; Kohn et al., 2002), which undoubtedly relates to cultural values and attitudes (Muir, Schwartz, & Szapocznik, 2004). This difference clearly has implications for treatment planning, and perhaps should be considered an aspect of culturally sensitive care for each of these groups. To the extent that African American women are accepting of group treatments, this method of service delivery is potentially an efficient and cost-effective way to get more treatment to individuals in need. On the other hand, acceptance of this modality is only a starting place; as noted earlier, practical issues reduced women's ability to attend groups that met at regular times.

Several limitations to this study should be noted. First, all measures were self-report, although the study measures have been used extensively in previous depression studies. Second, we did not include a continuous measure of PTSD to track PTSD symptoms over the multiple times for which we had other measures. Third, nearly half of the women initially interviewed who screened positive for depression did not follow-up with a diagnostic interview, or they screened positive for depression, but failed to meet diagnostic criteria for MDD a few days later, so it is not possible to gauge how representative the sample was of depressed low-income young women more generally. Fourth, although the psychotherapists were closely supervised, we did not measure adherence to the manualized treatment, nor did we measure competence of the therapists. Finally, the supports offered to the women (education sessions, childcare, transportation) cannot be separated from the treatments offered, i.e., we do not know how much improvement is attributable to support and help versus the specifics of the treatment.

We conclude that providing evidence-based antidepressants or psychotherapy care for depressed low-income women decreases their suffering, regardless of whether or not they have comorbid PTSD. However, these treatments do not address residual symptoms of PTSD and the more severe distress associated with it, even among those who have been treated effectively for depression. The women in this sample had high levels of exposure to all types of trauma, and those with PTSD carried the burden of exposure to the most toxic experiences, those of interpersonal or assaultive violence. Not being able to treat this exposure and its associated PTSD likely leaves these women more vulnerable to future episodes of both depression and PTSD. How to deliver these treatments most practically and most effectively is an important area for future research. New research needs to examine systematically the preferences for different treatment formats among ethnic groups to enhance cultural sensitivity of care. It would also be useful to test empirically different methods of recruitment and retention, to learn what types of supports and incentives are most effective in contributing to engagement and continuation in care. Low-income women like those we studied have many challenges to overcome to begin and continue with treatment, and it is likely much more difficult for them than for others with more resources and perhaps more consistent schedules (e.g., many women in this study did shift work or had varied work schedules from week to week). Thus, formats like telephone therapy and flexible therapy appointments may make treatment more accessible. Finally, creation of effective treatments requires an understanding of the context in which care is delivered, from the federal policy level, in terms of program and funding possibilities, to the logistics and daily operations of the available health care access points.

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