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Depression Treatment for Impoverished Mothers by Point-of-Care Providers: A Randomized Controlled Trial

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Abstract

Objective—Depression in low-income, ethnic-minority women of childbearing age is prevalent and compromises infant and child development. Yet numerous barriers prevent treatment delivery. Listening Visits (LV), an empirically supported intervention developed for delivery by British home-visiting nurses, could address this unmet mental health need. This randomized controlled trial evaluated the effectiveness of LV delivered at a woman's usual point-of-care, including home-visits or an ob-gyn office.

Method—Listening Visits were delivered to depressed pregnant women or mothers of young children by their point-of-care provider (e.g., home visitor or physician's assistant), all of whom had low levels of prior counseling experience. Three quarters of the study's participants were low-income. Of those who reported ethnicity, all identified themselves as minorities. Participants from four study sites (N = 66) were randomized in a 2:1 ratio, to LV or a wait-list control group (WLC). Assessments, conducted at baseline and 8 weeks, evaluated depression, quality of life, and treatment satisfaction.

Results—Depressive severity, depressive symptoms, and quality of life significantly improved among LV recipients as compared to women receiving standard social/health services. Women valued LV as evidenced by their high attendance rates and treatment satisfaction ratings.

Conclusions—In a stepped model of depression care, LV can provide an accessible, acceptable, and effective first-line treatment option for at-risk women who otherwise are unlikely to receive treatment.

Keywords

Listening Visits; depression treatment; home-visitors; low-income ethnic-minority mothers; point-of-care

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One in five women report clinically significant depressive symptoms, an estimate that is consistent among general community samples of women of childbearing age (Kessler, McGonagle, Swartz, Blazer, & Nelson, 1993) as well as specific samples of postpartum women (Gavin et al., 2005). Among impoverished women, depression is two to three times more prevalent in both community and postpartum convenience samples (Hobfoll, Ritter, Lavin, Hulsizer, & Cameron, 1995; Mayberry, Horowitz, & Declercq, 2007). An extensive body of research has documented that even in its milder forms, depression diminishes a woman's capacity for sensitive parenting and places infants at risk for a broad range of developmental delays, e.g., behavioral problems and cognitive delays in the form of poor language and lower IQ (O'Hara & McCabe, 2013). Further, among impoverished women, depression is associated with loss of welfare support, household food insecurity, and less optimal child health (Casey et al., 2004).

Over half of depressed adults never receive treatment of any sort (Kohn, Saxena, Levav, & Saraceno, 2004). Moreover, impoverished individuals, who are already at risk for depression, are actually the least likely to receive treatment; and for the few who do receive care, it is likely inadequate (Wang et al., 2005). Similarly, among perinatal women identified as depressed the percentage who access care is very low. Specifically in one study, only 13.8% of the 689 women identified with elevated depressive symptoms reported receiving some form of treatment (Marcus, Flynn, Blow, & Barry, 2003). Among perinatal women, there are numerous well- documented barriers to treatment (Dennis & Chung-Lee, 2006) that for impoverished women are compounded by additional obstacles (e.g., difficulties in finding a provider, transportation, and day care). Researchers in one treatment trial in an urban setting attempted to remedy logistical challenges of delivering Cognitive Behavioral Therapy (CBT) to depressed low-income ethnic minority women by providing services such as day care and transportation. Despite removing these perceived barriers to treatment, few women attended treatment sessions (Miranda et al., 2003). In that trial, the study psychologists typically made an average of ten phone calls before a woman would attend just one treatment session, a strategy unlikely to be adopted outside of the context of a funded trial. Even though the results of that trial supported the efficacy of CBT for impoverished women of childbearing age, the considerable difficulty of engaging these women suggests that this form of care will not be readily utilized. The study research team speculated that, to surmount engagement barriers, treatment should be provided by someone familiar to the women, thus leveraging an established trusted relationship (Miranda et al., 2003).

Listening Visits (LV) provide depressed, postpartum women counseling by a trusted and familiar provider. A complete description of the core techniques of this two-part, non-directive counseling intervention is published (Segre, Stasik, O'Hara, & Arndt, 2010). Briefly, LV can be described as a reflective-listening exploration of a woman's problems and, once genuine understanding is achieved, collaborative problem solving. In the United Kingdom (UK) where LV were developed, counseling is delivered by home-visiting nurses or health visitors (Holden, Sagovsky, & Cox, 1989) who have completed three years of university-level, generalist-nursing education and one year of specialist training. Because of the considerable evidence-base gathered in the UK and Sweden (Cooper, Murray, Wilson, & Romaniuk, 2003; Holden et al., 1989; Morrell et al., 2009; Wickberg & Hwang, 1996), LV

are now recommended by Britain's *National Institute for Clinical Excellence* as an evidence-based treatment for mild to moderate postnatal depression (National Collaborating Center for Mental Health, 2007).

Borrowing from the medical point-of-care testing model, in which laboratory testing is performed at the patient's bedside to expedite diagnosis, speed treatment, and lower expenses (Price, 2001), LV could leverage both the accessibility and trust of US home visitors and clinic nurses to provide depression treatment to an otherwise difficult-to-reach-and-engage, at-risk group. In the UK, implementing this approach is more straightforward because LV are embedded in a healthcare system that provides universal surveillance to all postpartum women in the form of a postpartum home visit within 10 days of an infant's birth. In contrast, universal surveillance of postpartum women is not the US norm; however, numerous home-visiting programs serve families with young children, particularly economically disadvantaged families, with small to moderate effects on a broad range of child and maternal outcomes (Olds et al., 2004; Sweet & Applebaum, 2004).

Home-visiting programs have considerable potential to reach vulnerable mothers because they typically serve at-risk, low-income pregnant and postpartum women (Leis, Mendelson, Tandon, & Perry, 2009). Moreover, two recent US-based randomized controlled clinical trials support the efficacy of maternal depression treatment delivered in the home by licensed mental health specialists, such as psychiatric nurses (Beeber, Holditch-Davis, Belyea, Funk, & Canuso, 2004) or licensed, masters-prepared social workers (Ammerman et al., 2013). Incorporating the provision of mental health services into the repertoire of US home visitors—similar to the model of care in the UK—has significant potential to address the gap in provision of mental health services to high risk population of women who otherwise will not receive treatment.

In 2002, low-income and ethnic-minority women living in areas with high infant mortality rates were targeted by the *Health Resources and Services Administration* to receive standardized depression screening by the home-visiting program *Healthy Start* (Segre, O'Hara, & Fisher, 2012). Nevertheless, this directive did not produce the full intended benefit because over half of the women who screened positively for depression did not receive treatment. To address this problem, a subsequent open trial evaluated the efficacy of LV in the Des Moines Healthy Start program. Here, Healthy Start home visitors were trained to provide, when necessary, integrated depression treatment in the form of LV. This approach took advantage of the relationship between Healthy Start home visitors and their at-risk clients. Moreover, treatment demonstrated significant pre- to post-LV decreases in depression symptoms scores (Segre et al., 2010). Despite this early success, definitive conclusions regarding the effectiveness of LV in the US are limited by the open trial design, the small number of participants, and the limitation of the evaluation to a single site.

To address the methodological limitations of the open trial, we conducted a multisite, randomized controlled trial to assess the effectiveness of LV for impoverished mothers. In addition, we recognized that in the US not all women who fit the target demographic profile have home-visiting services but may instead be seen in OB offices, so this alternative setting was also included as a venue for conveniently accessed care. The primary aim of this study

was to assess the effectiveness of LV delivered at a woman's usual point-of-care, either in a home-visiting program or in an OB clinic, by home visitors or an OB clinical staff member. LV were offered to economically disadvantaged women of childbearing age, most of whom were also ethnic minorities. We hypothesized that compared to a wait-list control group (WLC), those who received LV would show a significant reduction in severity of depressive symptoms and a significant improvement in psychosocial adjustment at the 8-week assessment point. Finally, we also assessed women's satisfaction with this intervention.

Method

Design

This two-arm, four-site randomized controlled trial (RCT) assessed the effectiveness of LV as a depression treatment when delivered by point-of-care providers to low-income pregnant women or mothers of young children in home-visiting programs or in an OB clinic. Consistent with effectiveness designs and the goal of increasing external validity of the study results (Wells, 1999), we strove to include in the trial diverse participants, settings, and LV providers and to closely align our study procedures with those of usual social services or clinical care given at the four sites. Ensuring that this goal was met required some departure from traditional research methodology.

The major departure from standard RCT methodology was that we did not audiotape therapy sessions or assessment interviews. This decision stemmed from our concern that the study sample (low-income, ethnic-minority women, some of whom were undocumented immigrants) would likely be reluctant to participate in a study if their words were recorded. Indeed, audiotaping the sessions had the potential to undermine or disrupt the climate of trust essential for the intervention to be successful for this population of women. Usually, audiotaped treatment sessions is an expectation in clinical trials that facilitates the assessment of treatment integrity, so to ensure treatment fidelity, in three of the four sites LV providers obtained consultation from a mental health professional for every two LV sessions. This supervisory staff was typically a masters-prepared, clinical social worker. In all sites, phone consultation was available from the first author.

To ensure the integrity of the diagnostic assessments, interviewers were blinded, thus minimizing influence on diagnostic judgments. Additionally, as part of training, new interviewers were required to observe at least one diagnostic interview by an experienced, research team member and to provide their own ratings. After the interview they compared their ratings, and discrepant ratings were discussed. Next, trainees conducted an interview, in which they were observed by an experienced study interviewer who provided feedback on their performance. Participants also completed self-report depression-symptom assessments to corroborate the reliability of diagnostic assessment findings.

In another departure, our study-entry criterion was based on a mother's score on a depression-symptom screening scale. Such screens are typically used in clinical settings to assess a woman's mood and identify those in need of further services. This is in contrast to the usual depression treatment trial entry criterion, which typically requires a MDD diagnosis based on a diagnostic interview. Yet in clinical contexts identification of women

in need of services relies on screening scales because diagnostic interviews are not feasible. However, in line with traditional RCT methodology, clinical interviews were utilized to determine diagnostic status of enrolled participants with regard to MDD as well as depression severity level.

To maintain methodological rigor and protect internal validity, we retained additional key elements of efficacy designs, including the randomization of participants to treatment or wait-list control group (WLC), blinded outcome assessment, objective outcome measures, and use of intent-to-treat analyses (Carroll & Rounsaville, 2003). All procedures for this study were approved by the University of Iowa and Mercy Hospital and Medical Center Institutional Review Boards.

Settings/Sites

Recruitment/enrollment for this trial took place between November 2009 and September 2012. The study participants were recruited from four sites in in the Midwest United States. At each site, depression screening was already established through one-to-one consultation (Segre, O'Hara, Brock, & Taylor, 2012) or the Train-the-Trainer Maternal Depression Screening Program (Segre, Brock, O'Hara, Gorman, & Engeldinger, 2011). Thus, all sites utilized the Edinburgh Postnatal Depression Scale (EPDS: Cox, Holden, & Sagovsky, 1987) to determine clinically elevated depressive symptoms that warranted treatment; mothers deemed in need of treatment were those scoring 12 or above on the EPDS. Three of the sites provided home-visiting services to low-income women in a rural state. The fourth site was as an ob-gyn clinic in an urban hospital serving a predominately low-income minority population.

Procedures

LV training—Listening Visit providers at all sites completed a two-part LV curriculum provided by the first author. In the first 7-hour training workshop, attendees learned about maternal depression (i.e., the diagnosis of depression, prevalence, negative effects, screening and referral, and treatment). In the second 7-hour training workshop, attendees were taught how to implement key LV skills through didactic presentations, video exemplars, and role-play exercises. This second training workshop focused on key LV skills: introducing LV to women, and active reflective listening and problem solving. The second workshop also provided direction about the logistical aspects of implementing LV, including the number of visits (n=6), scheduling (once per week), and approximate duration of each session (from 30 to 50 minutes). There were minor site variations in LV implementation, such as the location of visits (i.e., in the hospital site, the visits occurred in the OB office, while in the three home-visiting sites, they typically occurred in the recipient's home).

LV providers—The LV providers were the point-of-care providers who delivered usual home-visiting or prenatal care services at the study sites. Across the four sites, the LV providers (n = 26) were all female with an average age of 35 years (SD = 8.67). Eighty-five percent (n = 22) identified as white/Caucasian, 8% (n = 2) as black/African American, 4% (n = 1) as Asian, 4% (n = 1) as multiracial, and 31% (n = 18) as Hispanic/Latino. Almost half (n = 11, 42.3%) were bilingual English/Spanish. The majority of LV providers had a

bachelor's degree (*n* = 23, 88.5%), with the remaining 11.5% (*n* = 3) reporting a master's degree. Educational backgrounds were as follows: psychology (*n* = 7, 27%), sociology (*n* = 4, 15%), social work (*n* = 7, 27%), nursing (*n* = 3, 12%), and other (*n* = 10, 39%). Note that some providers endorsed more than one educational background category. The majority of LV providers (25/26) were home-visitors, including 24 case managers and one nurse. The remaining Listening Visits provider was a master's level physician assistant who also provided usual prenatal care in an ob-gyn practice.

On average, the LV providers had been in their occupations for *M* = 58.04 months (*SD* = 60.29), and had been at their current position *M* = 38.46 months (*SD* = 39.90). With regard to mental health training and background, the majority of providers reported that mental health was a significant focus during their education (46.2% reported "a lot" of focus on mental health in their education, 42.3% "some" focus, and 11.5% "a little" focus), however counseling was not a central focus: 11.5% reported no focus on counseling in their education, 38.5% reported "a little" focus, 42.3% reported "some" focus, and 7.7% reported "a lot" of focus on counseling training.

Screening, enrollment, and randomization—At all four sites, as part of usual care, the clinical staff screened women for depression. Eligible women who were willing to be contacted about possibly participating in a clinical trial were referred to the research team. Women were eligible to be referred if they had an elevated depression screening score (EPDS score >12), were English or Spanish speaking, were not currently receiving counseling services although medication management was permitted; and were >14 years of age with consent of a legal guardian when required. From November 2009 through September 2012, across the four study sites, a total of 99 women were both eligible for referral and willing to be contacted by the research team. Reaching study enrollment goals required an extended period because the home-visiting programs were small and/or served many women who did not speak English or Spanish. Further many eligible women were not willing to have their contact information given to the research team. The consort statement in Figure 1 thus represents the 99 women who were willing to be referred to the study and whom the research team was able to contact.

The study interviewers contacted all referred women to confirm that they met the study entry criteria, which entailed re-administering the EPDS, verifying age and, if required, the availability of legal guardian consent, and verifying that they were not currently receiving counseling services. Additionally, to ensure that women did not meet DSM-IV-TR diagnostic criteria for any of the exclusionary diagnoses (i.e., current or past manic episode/s, current alcohol or substance abuse, or psychotic symptoms), the study interviewers also administered modules of the Structured Clinical Interview for DSM-IV (SCID-I/NP) at this screening assessment (First, Spitzer, Gibbon, & Williams, 2002).

Eligible women who were willing to participate in the clinical trial, were consented and enrolled, and then completed the baseline study assessment (see Study Assessments). The study interviewer then notified the study coordinator that the newly enrolled participant had completed the baseline assessment and was ready to be randomized. The study coordinator contacted the appropriate LV provider as well as the participant to reveal their

randomization allocation. Participants were block randomized (in blocks of three), within site, using a randomization ratio of 2:1 (LV:WLC). A computer-generated randomization sequence was developed by an independent statistician; and allocation was handled by the study coordinator.

Intervention—Typically, the LV protocol calls for six visits within eight weeks, with each session lasting approximately 30 to 50 minutes. Each session includes several elements: greeting the client and finding a private place to talk, providing a brief review of the previous visit, getting an update about the previous week, using key LV skills of reflective listening and problem solving, and summarizing to provide closure to the session. These skills emphasize the two key therapeutic components of LV: (1) empathic listening to gain a full understanding of a woman's situation, and (2) collaborative problem solving to generate specific solutions. In general, the early sessions focus on understanding the client's situation, after which collaborative problem solving is gradually introduced. The final session focuses on summarizing (to assess the need for additional mental health treatment) and closure. Depending on LV provider, the visits occurred either in the home or in an ob-gyn office. Women randomized to LV also received the usual home visiting or social services provided by their programs.

Wait-list control (WLC)—During the first eight weeks of the study, women randomized to WLC received the usual social or prenatal/postpartum healthcare services provided at the site, and were subsequently offered LV after the 8-week assessment. In the three sites that provided home visiting, these services included, but were not limited to (1) linking families to appropriate health and child development services; (2) educating clients about nutrition, newborn care, child development, and parenting, via a curriculum that includes parent involvement activities; (3) referring to community resources appropriate to family needs (e.g., ensuring adequate nutrition, ESL instruction, GED acquisition); and (4) providing a number of screening services (e.g., child development and maternal depression screening). At the hospital site, usual care consisted of prenatal and postpartum healthcare.

Study Assessments—Participants completed assessments at baseline and eight weeks after they enrolled. At the baseline assessment they completed a demographic questionnaire. At both time-points depression and adjustment were assessed (see Measures). Participants from the three study sites in Iowa were interviewed either in their home or over the phone, depending on their preference. Participants from the hospital site were interviewed either in the clinic office or by phone, depending on their preference. Study participants were compensated $25.00 for each interview, with a gift card from one of two chain retail stores.

All assessments were conducted by blinded interviewers who were members of the research team, including a PhD clinical psychologist, a bachelor's-prepared registered nurse, and three doctoral students, two in clinical and one in counseling psychology graduate programs. All doctoral students were bilingual (English/Spanish).

Variables/Measures

Demographics—A questionnaire developed for this trial assessed demographic characteristics of participants including, age, ethnicity, race, marital status, education level, employment status, income, and past and current mental-health treatment.

Rule-out diagnoses—To identify women meeting study-exclusion diagnostic criteria, interviewers administered relevant modules of the Structured Clinical Interview for DSM-IV-TR, Non-patient Edition SCID-I/NP (First et al., 2002). This clinician-administered, semi-structured interview assesses for symptoms consistent with Axis I DSM-IV-TR diagnoses. The screening modules included current and past manic episodes, current alcohol and substance abuse, and the psychotic symptoms screen.

Depression—Three aspects of depression were assessed: severity, symptoms, and diagnostic status. Clinician-rated depression severity was based on a woman's responses to standard interview questions of the 17-item version of the Hamilton Rating Scale for Depression (HRSD; M. Hamilton, 1967). The 17-item version of the HRSD is sensitive to changes in depression level in women receiving treatment (O'Hara, Stuart, Gorman, & Wenzel, 2000; Thompson, Harris, Lazarus, & Richards, 1998) and is a reliable and valid indicator of depression severity in postpartum women (O'Hara et al., 2000; Ross, Gilbert Evans, Sellers, & Romach, 2003). In the current study, the HRSD had a (Cronbach's) alpha reliability of .71 and .73 at the enrollment and the 8-week assessment, respectively.

Two scales assessed women's self-report of depressive symptoms. For screening, women completed the Edinburgh Postnatal Depression Scale (EPDS), a 10-item self-report scale that assesses depressive symptoms in postpartum women (Cox et al., 1987). Women indicate which of four statements best describes their mood during the previous week. In the current study, the EPDS had an alpha reliability of .74 and .88 at the enrollment and the 8-week assessment, respectively.

The Inventory of Depression and Anxiety Symptoms General Depression scale (IDAS-GD) provided a second and more extensive assessment of depressive symptoms (Watson et al., 2007). Using Likert-rating scales, this 20-item depressive symptom scale assesses dysphoria, suicidality, lassitude, insomnia, appetite loss and well-being. Psychometrically, the scale correlates significantly with the Beck Depression Inventory–II (Watson et al., 2007). In the current study, the IDAS-GD scale had an alpha reliability of .88 and .93 at the enrollment and the 8-week assessment, respectively.

Depression diagnostic status was established using the Major Depression module of the SCID-I/NP), a clinician-administered, semi-structured interview for making Axis I DSM-IV-TR diagnoses (First et al., 2002).

Adjustment—Two aspects of participants' everyday functioning or adjustment were assessed. Quality of life was assessed using the 16-item, self-report "General Activities" subscale of the Quality of Life, Enjoyment and Satisfaction Questionnaire (Q-LES-Q; (Endicott, Nee, Harrison, & Blumenthal, 1993). For this assessment, women use a 5-point scale to rate how they feel they are getting along at work, at home, and with other people,

and how satisfied they are with life overall. The Q-LES-Q has both high internal consistency and strong external validity (Endicott et al., 1993). In the current study, the scale had an alpha reliability of .87 and .92 at the enrollment and the 8-week assessment, respectively.

The Work and Social Adjustment Scale (WSAS) is a 5-item, self-report scale assessing the extent to which sad mood is impairing day-to-day functioning (Mundt, Marks, Shear, & Griest, 2002). For each of five adjustment domains (i.e., work, home management, social leisure, private leisure, and interpersonal relationships), women use an 8-point Likert scale to rate the extent to which they feel impaired by sad mood. The WSAS has both high internal consistency and demonstrates sensitivity to treatment change (Mundt et al., 2002). In the current study, the scale had an alpha reliability of .86 and .91 at the enrollment and the 8-week assessment, respectively.

Treatment satisfaction—To assess participants' satisfaction with LV, we administered a modified version of the Client Satisfaction Questionnaire (CSQ: Larsen, Attkisson, Hargreaves, & Nguyen, 1979). Minor modifications were made to the wording (e.g., substituting "Listening Visits" for "treatment"). This 8-item instrument assesses perceived effectiveness and satisfaction with treatment. Using a 4-point Likert scale, women rated eight aspects of their treatment: the quality of the intervention; the degree to which the intervention met their expectations (2 items); amount of help provided, their satisfaction with the help received; their assessment of the effectiveness of the help; and willingness to receive it again or recommend it to a friend. The CSQ has a high degree of internal consistency (coefficient alpha = .93) and correlates well with other estimates of satisfaction (Larsen et al., 1979). In the current study, the CSQ had an alpha reliability of .84.

Analyses

All randomized participants, regardless of whether they received any LV sessions, were included in the analyses, according to their original group assignment.[i] A 2 × 2 (Group [WLC, LV] x Time [baseline, 8-week assessment]) repeated measures analysis of variance (ANOVA) was conducted for measures of depressive symptoms and social adjustment, to evaluate intervention outcomes. Cohen's *d* (Cohen, 1988, 1992) was computed for each effect, and effect sizes were defined as small (0.20–0.49), moderate (0.50–0.79), or large (>0.80). Effect sizes reflect the standardized difference in mean gain scores between the LV intervention group and the WLC group, and were computed using an online computation tool (Lipsey & Wilson, 2001) with mean gain scores, pre and post SDs, and pre-post *r* for each group. Power analyses conducted with G*Power 3.1.10 suggested that a total sample size of $N = 34$ was required to obtain the 80% power needed to detect a moderate effect size for the Time x Group interaction. There were no significant differences between the treatment and WLC groups at baseline for outcome measures of interest: HRSD, $t(64) = 0.85$, $p = .397$, $d = 0.22$; IDAS-GD, $t(64) = 1.76$, $p = .084$, $d = 0.45$; EPDS, $t(64) = 1.35$, p

[i]Note that completer analyses were also conducted, excluding $n = 2$ women who did not complete any LV, and the same pattern of results emerged; therefore, we only report the more conservative ITT results. We also conducted an intent-to-treat analysis using the last observation carried forward approach to impute missing values for the six participants who were lost to attrition. Group x Time interactions remained significant for the HRSD, $F(1,64) = 8.99$, $p = .004$, the IDAS-GD, $F(1,64) = 5.95$, $p = .017$, and the Q-LES-Q, $F(1,64) = 7.63$, $p = .007$. Further, with the larger sample size, the Group x Time interaction was significance for the EPDS, $F(1,64) = 5.05$, $p = .028$. The Group x Time interaction was non-significant for the WSAS, $F(1,64) = 0.65$, $p = .425$.

= .182, d = 0.34; WSAS, $t(64) = 1.17$, p = .245, d = 0.30; Q-LES-Q, $t(64) = -1.61$, p = .112, d = 0.41.

Results

Participants Characteristics

As depicted in the participant flow chart in Figure 1, of the 99 women referred to the trial, 98 were reached for the screening assessment; 32 of these referred women did not meet the study eligibility criteria. Of the 66 women who enrolled, 41 and 25 were randomized to the treatment or the WLC group, respectively. Six of these 66 participants did not complete the 8-week assessment. The reasons for this missing data are depicted in Figure 1. Therefore, analyses were conducted with a final sample size of N = 60 (n = 39 in treatment and n = 21 in WLC). There were no significant differences at baseline between participants who were lost to attrition (n = 6), and those who completed the 8-week assessment with regard to the five outcome variables, ts(64) ranged from −.37 to 1.03, ps > .05.

The demographic and clinical characteristics of study participants at the baseline assessment are presented in Table 1. The treatment group was compared to the WLC group with regard to baseline descriptors. Statistical analyses (two-sample t tests for continuous demographic variables and logistic regression analyses for categorical demographic variables) suggest there were no significant group differences at baseline (ps > .05; see Table 1 for a summary of these results). Although Major Depressive Diagnosis (MDD) was not an inclusion criterion in the present study, 30% of the participants (n = 20) met MDD diagnostic criteria at study entry as assessed via the SCID (First et al., 2002); this included 24% of the WLC group and 34% of the LV group. The difference between groups was not significant, $\chi^2(1) = 0.76$, p = .384.

Mood and Adjustment Outcomes

Results of ANOVAs and effect size estimates are reported in Table 2. There were no differences across treatment sites or providers with regard to participant characteristics and levels of each outcome variable at baseline and the 8-week assessment (ps > .05). Consequently, provider and site were not included as covariates in the primary analyses. [ii] Group x Time interactions were significant for measures of depression severity and depressive symptoms (HRSD[iii] and IDAS-GD respectively). There was a significant Group x Time interaction for quality of life (Q-LES-Q). There was greater improvement in depression severity, depressive symptoms, and quality of life from the baseline to 8-week assessment for the LV group compared to the WLC group. Group x Time interactions were not significant for the EPDS (p = .06) or the WSAS; however, Time effects were significant for the EPDS, $F(1,58) = 49.47$, p < .001, and WSAS, $F(1,58) = 27.56$, p < .001, suggesting

[ii]Note that, when including site as a covariate, Group x Time interactions remain significant for the HRSD, $F(1,57) = 7.41$, p = .009, the IDAS-GD, $F(1,57) = 4.51$, p = .038, and the Q-LES-Q, $F(1,57) = 6.40$, p = .014.

[iii]Nine women were not administered all items on the HRSD due to interviewer error early in the treatment trial. Given the systematic error pattern, these data were missing not at random (MNAR). Missing data on the HRSD were imputed using multiple imputation procedures in SPSS 21 (m = 5 imputations). A 2×2 (Group x Time) ANCOVA was conducted with missing data status entered as a covariate. Results indicate that the Group x Time effect remains significant when accounting for the pattern of missing data, $F(1,57) = 7.32$, p = .009.

that scores improved from the baseline to 8-week assessment for both LV and WLC groups. Effect sizes for HRSD, IDAS-GD, EPDS, and Q-LES-Q were moderate in magnitude whereas the effect size for the WSAS was small (see Table 2).

Based on recommendations by Lambert, Hansen, and Bauer (2008), reliable change indices or RCI (Jacobson & Truax, 1991) were computed to examine the clinical significance of intervention outcomes. Approximately 36% of women in the LV group and 14% of women in the WLC group experienced clinically significant improvement from the baseline to the 8-week assessment as measured by the HRSD. None of the women in the treatment group deteriorated over time, whereas 5% of women in the WLC group experienced an increase in symptoms and surpassed the RCI threshold. A similar pattern emerged for other indicators of depression: approximately 69% of women in the LV group (compared to 29% of women in the WLC) experienced clinically significant improvement in IDAS-GD scores, and approximately, 64% of women in the LV group (vs. 43% of women in the WLC) experienced improvement in EPDS scores. With regard to adjustment, 56% of women in the LV group experienced significant improvement (vs. 14% in the WLC) in Q-LES-Q scores, and 49% of women in the LV group experienced improvement (vs. 38% in the WLC) in WSAS scores.

Dosage

Participants in the treatment group completed an average of almost five LV sessions (M = 4.78, SD = 1.77), ranging from zero to seven sessions. (Although the research protocol stipulated six sessions, one LV provider reported seven sessions for one research participant). The median and modal number of sessions was six. To assess whether the number of LV sessions women completed influenced within-subject change from the baseline assessment (before LV) to the 8-week outcome assessment, a repeated measures ANCOVA was conducted with the treatment group (n = 39) such that number of sessions was examined as a continuous variable interacting with Time (baseline, 8-week assessment). The Time x Number of LV Sessions interactions were not significant for the HRSD, $F(1,37) = 0.39$, $p = .538$; IDAS-GD, $F(1,37) = 2.53$, $p = .12$; EPDS, $F(1,37) = 2.95$, $p = .094$; WSAS, $F(1,37) = 1.01$, $p = .322$; and Q-LES-Q, $F(1,37) = 0.14$, $p = .706$.

Suitability of Treatment

The majority of women in the treatment group (n = 33) completed the CSQ. Responses on the CSQ indicated that women in the treatment group had very positive views of LV (M = 30.27, SD = 2.83; possible range: 8–32). The majority (91%) of LV recipients rated the quality of the help they received as excellent and most (97%) indicated that LV provided the kind of help that they wanted. Ninety-seven percent reported that the LV intervention helped them to deal with their problems more effectively, with 79% reporting that LV helped them *a great deal*. The majority of women who participated in LV indicated they would go back to their LV provider for more help; 85% stated they would *definitely* return to their LV provider. Finally, they unanimously indicated that they would recommend this counseling to a friend in need.

Discussion

Empirical support for the effectiveness of LV has been broadly established in the UK (Cooper et al., 2003; Holden et al., 1989; Morrell et al., 2009), Sweden (Wickberg & Hwang, 1996), and most recently in Norway (Glavin, Smith, Sørum, & Ellefsen, 2010). In the US, evidence garnered in two open trials evaluations supports the effectiveness of LV in a home-visiting setting (Segre et al., 2010), as well as in the neonatal intensive care unit (Segre, Chuffo-Siewert, Brock, & O'Hara, 2013). The results of this first, US-based, randomized controlled evaluation of LV confirm these findings, demonstrating that LV delivered by point-of-care providers is an effective first-line depression treatment to add to usual social or health services. Specifically, compared to women who received only standard home visiting or prenatal/postpartum healthcare services, those who also received LV significantly improved in terms of levels of depressive severity, symptoms and quality of life. However, changes in depressive symptoms (as assessed by the EPDS), and day-to-day functioning (as assessed by WSAS) were not significantly different in the two groups. Of course the EPDS, although widely used, was not developed as an outcome measure for clinical trials, unlike the HRSD and the IDAS-GD. It has only about half as many items as the two more standard measures of depression severity and symptoms, suggesting the possibility that the EPDS could not capture the full range of depressive symptomology and was thus less sensitive to change. As for day-to-day functioning in work and home life, these are areas of traditional concern to point-of-care providers and it may be that adding LV offers no special advantage over their usual standard of care for these specific outcomes. Additionally, the WSAS scale has only five items, which may be too limited to capture the full range of change.

Three aspects of the significant results are particularly compelling. First, the standard services provided in our WLC group provided a stringent test for the effectiveness of LV. Specifically, in the three Iowa sites, which were all home-visiting programs, women in the WLC group received a broad range of intensive services, including parenting education, child development screening and education, as well as language interpretation and transportation for those who required such services. Indeed, one of these home-visiting programs was the Nurse Family Partnership Program, which is broadly recognized for making a positive impact on social and educational outcomes for mothers and their children at 6 years of age (Olds et al., 2004). At the hospital site, in line with standard prenatal/ postpartum care, women were in close contact with their obstetrician through regular visits. Thus, LV recipients in our study were embedded in strong systems of standard care. Not unexpectedly, depression levels decreased in both groups of women, suggesting the importance of these standard care services. Nevertheless, adding LV to these social/health services significantly boosted their impact. This finding suggests that supportive listening, in the form of LV, significantly improves mood and overall well-being, above and beyond services already provided.

A second, compelling aspect of the study’s results is that they were achieved by non- mental health specialists and required only a few sessions. Specifically, the LV providers were home visitors and a physician assistant, with half reporting that their educational preparation included “no” or “little” focus on counseling skills. Yet after only a brief training in the

delivery of LV, a statistically and clinically significant change in depression was realized in the LV group after an average of only five LV sessions. To place these results in context, we compared the effect size observed here with that for a similar evaluation of Interpersonal Psychotherapy (IPT vs. WLC) delivered over 12 sessions by highly trained mental health specialists to predominately White, middle-class, postpartum women (O'Hara et al., 2000). Although the moderate effect size (d = 0.72) obtained in our study was less than the large effect size achieved by mental health specialists in the IPT study (d = 1.33), our results were obtained by briefly trained non-specialists who delivered an average of only five LV sessions to predominantly ethnic-minority women of significantly lower economic means: a traditionally difficult-to-engage population. Moreover, although a formal cost analysis was not conducted, the cost of a few sessions of LV by a point-of-care provider is likely to be significantly lower than the cost of a more intensive treatment provided by a mental health specialist.

Finally, our study participants were satisfied with LV, which represents an important litmus test given the past difficulties with engaging impoverished minority mothers in depression treatment (Miranda et al., 2003). Two results support this claim. First, in this trial, women attended an average of five LV sessions and, notably, the modal and median number of LV sessions attended was six, suggesting a low dropout rate. In comparison, insurance claim data from 434,317 CIGNA Behavioral health patients, suggest that among 5,315,827 claims for psychotherapy sessions reimbursement, 98% of treatment recipients submitted a claim for only one session with the mental health professional (S. Hamilton, Moore, Crane, & Payne, 2011). Moreover, a meta-analysis assessing predictors of therapy dropout indicates significantly more risk for therapy dropout among low-income and ethnic-minority individuals (Wierzbicki & Pekarik, 1993), precisely the population under study here. Seen in this context, the fact that LV recipients attended five sessions on average is very encouraging. Second, the majority of women who received LV rated the quality of help they received as excellent on the CSQ. In fact, their overall reported satisfaction rating (M = 30.27, SD = 2.83) was higher than the average rating (M = 27.1, SD = 4.0) obtained in a larger sample of recipients who had received treatment from a mental health professional (Nguyen, Attkisson, & Stegner, 1983).

Limitations, Strengths and Future Directions

Some of the methodological limitations of this study are natural consequences of the challenges encountered when conducting RCTs in community settings. First, the LV sessions were not audiotaped, leaving some uncertainty about the integrity with which LV were implemented. Given that our LV providers were not mental health specialists, assessing and monitoring treatment integrity is an important priority. In the future, LV integrity might be monitored by a checklist, which LV providers and recipients could use to track each session. Similarly, the diagnostic assessments of depression severity were also not audiotaped, preventing the assessment of reliability for the diagnostic interviews. This limitation may not have compromised our results, however, because the assessment of depression yielded similar outcomes whether assessed by self-report or diagnostic interviews. Nevertheless, the reliability of these interviews cannot be directly verified.

The RCT design is the gold standard approach to treatment evaluation. Nevertheless, "participant reactivity" (i.e., changes resulting from participating in a study) may account for the observed improvement (Nezu & Nezu, 2008), thus preventing drawing definitive conclusions regarding the effectiveness of LV. In this study, participants were aware of treatment assignment. For those in the LV group, their expectation to feel better as a result of receiving the treatment may have accounted for their report of improved mood. Conversely, those in the WLC may have expected that their mood would not improve. Additionally, the extra meetings with the LV provider may have also accounted for the observed differences. Further, in this trial, the concept of "participant reactivity" may also extend to the LV providers. Specifically, the LV providers were aware that their LV recipients were assessed extensively by the research team and this knowledge may have "enhanced" their implementation of LV. A comparative treatment design has been recommended as a means to control for nonspecific factors of expectation and increased attention (Nock, Janis, & Wedig, 2008). The influence of "LV provider reactivity" might be minimized in a broader implementation trial in which the assessment of LV recipients' mood would be obtained from client records and not directly assessed by the researcher.

Third, over the 36 months of recruitment, 99 women were willing to be referred to the study research team from four sites. Yet because we did not have access to women who had elevated EPDS scores but were not willing to be referred to the research team, we were unable to assess two key factors: 1) whether the study participants were demographically representative of women served at these sites, and 2) whether the 99 women who agreed to be contacted represents a small or large proportion of women with elevated depression scores. Thus, assessing acceptability, as defined by general utilization rates, is an important direction for future research. Relatedly, the present study was underpowered for detecting provider or site effects. Future studies should be powered to at least detect site effects, to account for the possibility that certain sites are more or less effective at implementing LV.

Another important direction for future research is to better determine the economic implications of implementing LV. A reasonable cost-effectiveness analysis should extend beyond simply calculating the hourly costs of LV providers' time to also include costs of training, consultation, making appointments with LV recipients, transportation, and missed sessions. These costs should then be compared directly with the costs of treatment provided by a mental health professional operating in a closely matched environment.

Finally, we did not obtain a dose-effect. This may have been due to several factors. First, 82% of participants completed between four and six sessions, so there was little variability. Second, women had the option of not continuing with LV; some may have been satisfied with their progress and participated in fewer than the prescribed number of LV sessions. Note that in the UK, where LV are recommended for mild to moderate postnatal depression, no explicit recommendation regarding the optimal number of LV sessions has been made (National Collaborating Center for Mental Health, 2007). Another area for future research would be to determine whether fewer than six LV sessions would yield the same effect as observed in the current study. Fewer sessions could increase the feasibility of implementing LV in social and health service settings, both in terms of cost as well as LV provider workload.

Offsetting these inherent limitations are several methodological strengths. This trial is the first RCT assessing the effectiveness of LV in the US. Our study sample size (N = 66) compares favorably to similar prior trials in the U.K. (N=50: Holden et al., 1989) and Sweden (N=41: Wickberg & Hwang, 1996) in which LV was compared to a usual care condition. Ours was a hybrid trial, testing efficacy and effectiveness of LV for low-income ethnic-minority women, as delivered by 26 providers, whose function typically had been to administer only health or social services. Among these providers, almost half were bilingual and could conduct LV in Spanish. Further, the providers were from four different sites, including three, home-visiting programs in a rural state and an urban hospital serving a low-income, Chicago neighborhood; however, levels of depression, adjustment, and treatment satisfaction did not vary as a function of provider or site at baseline or at the 8-week outcome assessment. Finally, the high participant retention rate achieved in this study is extraordinary in this sample of low-income ethnic-minority women: 90% completed the 8-week outcome assessment. We attribute this success in retention to the fact that women were already engaged, as they were receiving home-visiting services or prenatal/postpartum care at each of these sites and were thus not likely to be lost to follow-up. In short, embedding treatments like LV into social or health services seems to be an effective engagement strategy.

Conclusions

This study shows that depression treatment in the form of LV conveniently delivered at the patient's point-of-care by non-stigmatizing social or health-service providers is an effective first-line approach to depression treatment. While prior research has established efficacy of standardized depression treatments among impoverished minority group women, the difficulty that researchers had in engaging women in care led them to conclude that "engaging them through trusted providers could prove easier" (Miranda et al., 2003, p. 64). Indeed as a first-line approach in a system of stepped care, LV provide a particularly useful treatment tool for those trusted health and social service providers who serve low-income mothers. Finally, there is a strong link between mental health problems and maternal health. As has often been said, *there is no health without mental health*. This sentiment applies especially to mothers and children.

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Public Health Significance

1. This study shows that Listening Visits, delivered by home visitors or ob-gyn clinic nursing staff, are an effective first-line treatment for depression among low-income and ethnic minority mothers.
2. Acceptability of Listening Visits was demonstrated by the fact that 82% of women attended between 4 and 6 sessions as well as their high ratings of treatment satisfaction.

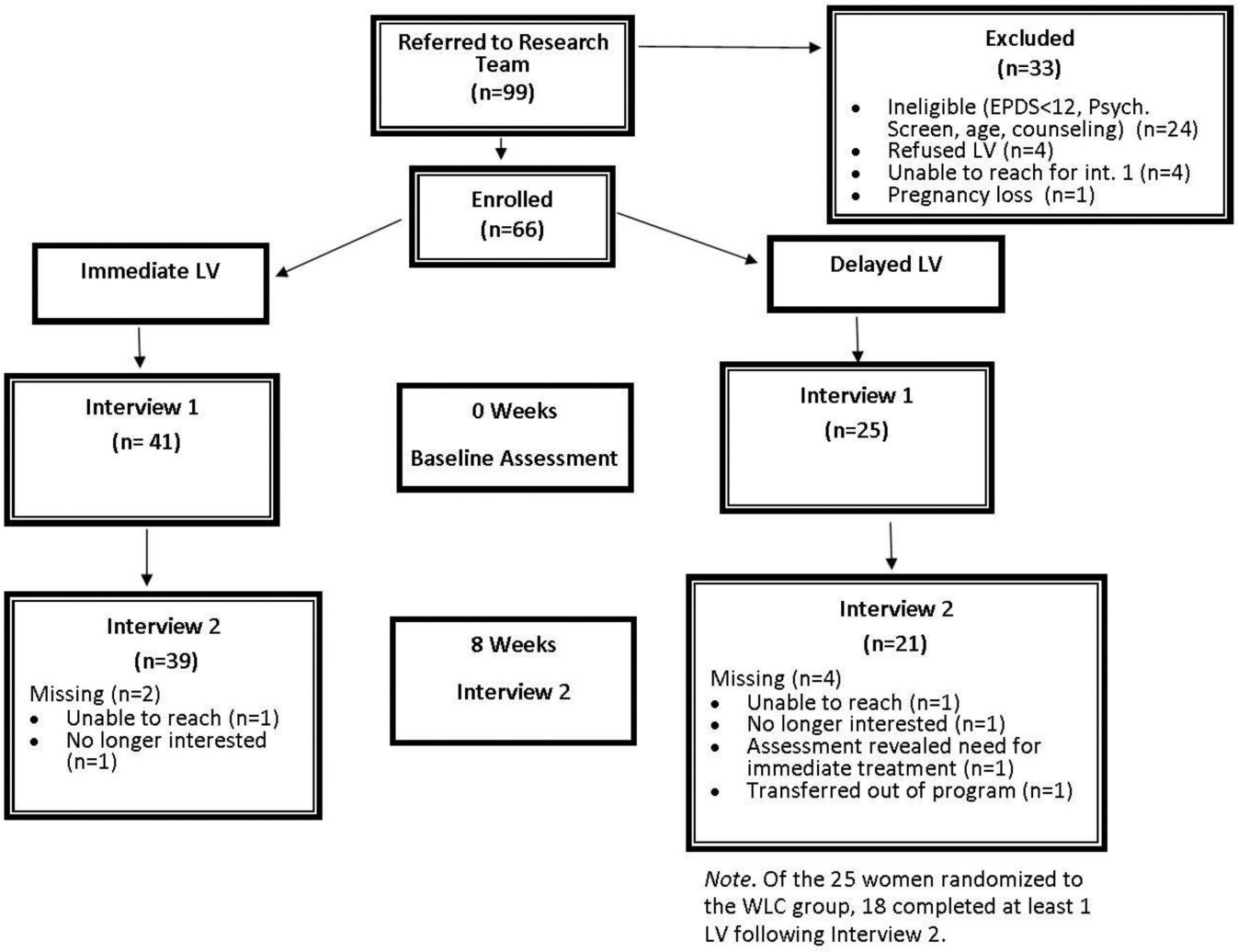

Figure 1.
Participant flow

Table 1

Participant Characteristics at Baseline

Characteristic	Wait-list control (*n* = 25)	Intervention (*n* = 41)	Group comparison
Age (*M* and *SD*)	24.56 (6.10)	27.37 (5.49)	$t(64) = 1.93$
Relationship status (married or cohabiting)	36.0%	58.5%	$\chi^2(1) = 3.16$
Race			$\chi^2(3) = 1.52$
White	36.0%	31.7%	
Black	28.0%	36.6%	
Multiracial	12.0%	4.9%	
Unknown/Declined	24.0%	26.8%	
Ethnicity (Hispanic/Latino)	36.0%	43.9%	$\chi^2(1) = 0.40$
Employed	28.0%	39.0%	$\chi^2(1) = 0.83$
Annual income			$\chi^2(5) = 8.26$
Less than $5,000	17.4%	14.5%	
$5,000 – $10,000	17.4%	28.6%	
$11,000 – $20,000	47.8%	20.0%	
$21,000 – $30,000	17.4%	20.0%	
$31,000 – $40,000	-	8.6%	
$41,000 – $50,000	-	8.6%	
Currently enrolled in school	24.0%	9.8%	$\chi^2(1) = 2.45$
MDD diagnosis (SCID) at baseline	24.0%	34.1%	$\chi^2(1) = 0.76$
Past counseling/medication for emotional problems	52.0%	58.5%	$\chi^2(1) = 0.27$
Medication use (for mood management) at baseline	12%	19.5%	$\chi^2(1) = 0.63$

Note. Group comparisons were not significant (*p*s > .05).

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Table 2

Summary of Outcome Measures at Baseline and 8-Week Assessment Using Analysis of Variance

	***M* (SD)**							
	Wait list control (*n* = 21)		**Intervention (*n* = 39)**					
Measure	**Baseline**	**8-week assessment**	**Baseline**	**8-week assessment**	**Group x Time *F*(1, 58)**	***p***	**η_p^2**	***Effect size d*[a] [95% CI]**
HRSD	16.57 (6.56)	14.29 (8.19)	18.39 (6.52)	11.03 (7.30)	7.46	.008	0.114	0.72 [0.2, 1.2]
IDAS-GD	57.33 (13.79)	47.86 (16.42)	63.13 (12.77)	44.67 (15.14)	4.43	.040	0.071	0.62 [0.1, 1.2]
EPDS	15.10 (4.44)	11.14 (6.04)	17.18 (3.97)	10.33 (6.03)	3.55	.064	0.058	0.56 [−0.03, 1.2]
WSAS	20.19 (11.17)	13.67 (10.98)	23.44 (9.03)	15.56 (10.95)	0.24	.625	0.004	0.13 [−0.4, 0.6]
Q-LES-Q	38.62 (10.77)	41.52 (10.48)	33.46 (8.38)	42.49 (11.57)	6.26	.015	0.097	0.60 [0.2, 1.03]

[a]Standardized difference in mean gain scores between LV intervention group and WLC group.