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Depression Treatment by Non-Mental-Health Providers: Incremental Evidence for the Effectiveness of Listening Visits

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Abstract

Maternal depression is a prevalent public health problem, particularly for low-income mothers of young children. Intervention development efforts, which often focus on surmounting instrumental barriers to care, have not successfully engaged and retained women in treatment. Task-sharing approaches like Listening Visits (LV) could overcome key instrumental and psychological barriers by leveraging the access of trusted, community caregivers to deliver treatment. A recent randomized controlled trial (RCT) demonstrated the efficacy of LV delivered by non-mental-health providers as compared to usual care. The present report presents results from a follow-up phase of that RCT during which participants who had completed LV were followed for an additional 8 weeks and completed measures of depression and quality of life. In addition, participants who were initially randomized to the wait-list control group received LV and were assessed. Treatment gains previously observed in participants completing LV were enhanced during the 8-week follow-up period. Participants receiving LV during the follow-up period experienced significant improvement in depressive symptoms. Results demonstrate the sustainability of LV delivered by non-mental-health providers, and provide preliminary evidence for the replicability of this approach in a sample of predominately low-income pregnant women and mothers of young children.

Keywords

Listening visits; Depression; Low income; Pregnant women; Mothers of young children; Sustainability; Non-mental-health providers

Introduction

The World Health Organization cites unipolar depressive disorder as the largest contributor to disease burden in middle- and high-income countries, surpassing heart disease, chronic obstructive pulmonary disease, HIV/AIDS, alcoholism, and diabetes (World Health Organization, 2008). In U.S. women, depression is the leading cause of non-obstetric hospitalization during childbearing years (Jiang et al., 2002), with low-income mothers of

young children affected to a disproportionate degree. While 12.9% of women in the U.S. national sample experienced major depressive episodes (MDE) within the last 12 months (Kessler, McGonagle, Swartz, Blazer & Nelson, 1993), the median prevalence rate of MDE among mothers on public assistance is 22%, nearly twice that rate (Lennon, Blome & English, 2001). This differential is confirmed in a separate study of 4332 new mothers representing a wide range of income levels (Segre, O'Hara, Arndt & Stuart, 2007), where the adjusted prevalence rates of MDE were nearly two and one half times higher at the lowest income level (20%) than at the highest income level (7.5%). The prevalence of clinically significant depression symptoms (as opposed to MDE) was also found to be alarmingly high (28.5–58.1%) among low-income mothers served by home-visiting programs (Ammerman, Putnam, Bosse, Teeters & Van Ginkel, 2010). The negative effects of maternal depression on the development of infants and children are well-documented (O'Hara & McCabe, 2013). Depression also has a direct impact on the economic well-being of economically poor mothers and their families. Depressed mothers on public assistance were 1.5 times (AOR = 1.52) more likely to lose food stamp support (Casey et al., 2004) and more than twice as likely (OR = 2.29) to become homeless (Curtis, Corman, Noonan & Reichman, 2014) than non-depressed mothers in similar social and financial circumstances.

Considered together, the evidence indicates that depression is prevalent among low-income mothers of young children who may not have the time, resources or desire to utilize treatments delivered by mental-health professionals. Task-sharing approaches can leverage the access of trusted, community caregivers (e.g., non-mental-health providers) to deliver an effective and acceptable first-line depression treatment to this at-risk and underserved group of women. Listening Visits (LV), a depression treatment developed for delivery by British home-visiting nurses, is an evidence-based, task-sharing approach that has been validated in a single U.S. multisite randomized controlled trial (RCT), which utilized a wait-list control group. To provide incremental evidence for this innovative approach to depression treatment, this present study examines data from the follow-up phase of this RCT to assess the sustainability of treatment effects among RCT participants who received LV immediately in Phase I, and examine whether the treatment effects realized in the immediate-LV group would replicate among in the delayed-LV group.

Treatment Use and Barriers

Despite the availability of effective depression treatments (Craighead, Johnson, Carey, & Dunlop, 2015), one national U.S. study indicates that only 27.7% of depressed men or women receive treatment (Kohn, Saxena, Levav & Saraceno, 2004). Although no published studies specific to treatment use among impoverished mothers were found, an Urban Institute report indicates that treatment utilization is markedly lower (40.3% vs. 60.1%) among mothers in lower as compared to higher income groups (McDaniel & Lowenstein, 2013). Two Michigan-based studies suggest that treatment use rates might be even lower across all income levels, only 13.8% of pregnant women with depression symptoms and 33% of pregnant women diagnosed with major depression disorder (MDD) reported that they had received or were currently receiving treatment (Flynn, O'Mahen, Massey & Marcus, 2006; Marcus, Flynn, Blow & Barry, 2003). Thus, the best available evidence on

treatment use suggests that considerably fewer than half of depressed low-income mothers receive treatment.

Several instrumental and psychological barriers prevent impoverished mothers from accessing treatment from a mental-health profession. The instrumental barriers include prohibitive cost, lack of transportation and affordable child-care, and difficulty with meeting the expectation of regularly attending treatment sessions given the sometimes unpredictable work schedule associated with minimum wage jobs (Keefe, Brownstein-Evans & Rouland-Polmanteer, 2016; Levy & O'Hara, 2010). Psychological barriers include lack of awareness of being depressed, minimizing severity of symptoms and taking a "wait and see" approach, and normalizing symptoms as natural consequences of stressful life circumstances (Abrams, Dornig & Curran, 2009; Anderson et al., 2006). Yet, even when depression is recognized by women to be severe enough to require help, depressed impoverished mothers in one qualitative study openly rejected the option to use formal care (Abrams et al., 2009). Their perceptions of mental-health professionals included highly medicalized images of uncaring individuals, wearing white coats and carrying clipboards, who emphasized prescribing medication as a substitute for taking the time to listen. In contrast, they described their ideal provider as a "trustworthy woman who takes the time to sit and talk in an open, non-critical way, who listens, and who expressed care and concern...who is a warm 'regular person'..." (Abrams et al., 2009, p. 543). This additional psychological barrier, negative views of medication and desire to have someone listen, also emerged as a prominent theme in a second qualitative study assessing the views of low-income, Latina and African American mothers about post-partum depression and treatment (Keefe et al., 2016).

Culturally Attuned, Evidenced-Based Treatments

Most prior efforts to more effectively serve low-income mothers apply "top down" approaches to culturally attune existing evidenced-based treatments to boost their engagement and retention (Barrera, Castro, Strycker & Toobert, 2013), while leaving the underlying treatment framework untouched (see Levy & O'Hara, 2010 for a review of treatments developed for low-income women). For example, extensive outreach and logistical support were added to Cognitive Behavioral Therapy (CBT) to minimize access barriers among depressed, low-income mothers in Washington, D.C. (Miranda et al., 2003). Yet, even with the provision of transportation and day care, mothers were still reluctant to accept this form of care. To convince women to attend even one CBT session, the study psychologists had to make an average of ten phone calls. Based on these engagement difficulties, the researchers speculated that the treatment should be provided by someone familiar to the women who could leverage an established relationship. This suggestion to utilize familiar non-mental-health providers suggests that cultural attunements to address instrumental barriers may be inadequate. Instead of cultural attunement, cultural adaptation of the way depression treatment is delivered, in ways that are compatible with the client's values, may be required. In the context of a mental-health system that relies primarily on care delivered by mental-health professionals, treatment delivered by non-mental-health providers is the kind of change that aligns with the definition of cultural adaptation (Barrera et al., 2013).

Efficacy of Non-Mental-Health Providers

The effectiveness of non-mental-health treatment providers has long been established. The first published systematic review of 19 studies reported the following results: Outcomes for patients with a wide variety of diagnoses were either better when treatment was delivered by paraprofessionals or did not significantly differ as a function of provider expertise (Durlak, 1979). The first meta-analytic review similarly found that individuals who received help from paraprofessionals were more likely to achieve resolution of their problem than those receiving treatment from a mental-health specialist (Hattie, Sharpley & Rogers, 1984). Since those early reviews, evidence supporting the efficacy of non-mental-health treatment providers has continued to accrue (Atkins & Christensen, 2001; Montgomery, Kunik, Wilson, Stanley & Weiss, 2010). Moving beyond non-mental-health providers, a recent meta-analysis of 23 studies reported positive outcomes for depression treatment delivered by peers, i.e., lay individual who had experienced similar problems with no assistance from a health or mental-health profession (Bryan & Arkowitz, 2015). Finally, two studies specific to depressed mothers provide support for the effectiveness of non-mental-health providers with this population. In the first study, a culturally and linguistically tailored intervention led by trained community health workers was found to be effective in reducing depression symptoms in pregnant and early postpartum Latina mothers (Kieffer et al., 2013). In the second study, Cooper, Murray, Wilson and Romaniuk (2003) found that women who were treated by non-mental-health specialists (British home visitors) showed a significantly greater reduction in depressive symptoms than women treated by mental-health specialists (psychologists). The authors suggested that experience in home visiting was a key element in the success of the non-mental-health specialists.

Task-sharing Approach: Listening Visits in the United Kingdom

In the United Kingdom, instrumental and psychological barriers associated with treatment delivered by mental-health providers are addressed through the use of nurses to deliver an integrated model of depression care for postpartum women. As part of a program of universal surveillance, within the first 10 days postpartum all new mothers in the U.K. receive a home visit from a public health nurse, called a health visitor (Holden, 1996). During this visit, many health visitors assess mothers' emotional well-being (Cowley, Caan, Dowling & Weir, 2007). Among postpartum women identified as having mild to moderate levels of depressive symptoms, the health visitor can offer a first-line, home-based treatment: Listening Visits (LV), which was developed expressly for their use (Holden, Sagovsky & Cox, 1989). Three European RCTs have provided empirical support for LV as delivered by home-visiting nurses to postpartum women. Mothers who received LV reporting significantly lower levels of depressive symptoms compared to those who received usual health visitor care (Cooper et al., 2003; Holden et al., 1989; Wickberg & Hwang, 1996). Similarly, in a randomized cluster trial, nurses in 101 general medical practices in Trent, England were randomized either to provide usual health-visiting care or to provide one of two psychologically informed approaches to postpartum women with elevated depressive symptoms (Morrell et al., 2009). The results indicate that at 6 months postpartum, significantly fewer of the intervention cluster women (34%) reported elevated depression symptoms compared to those receiving usual care (46%). No significant differences in outcomes were found between the two intervention approaches. Recognizing

the usefulness of this approach, the National Institute for Health and Clinical Excellence recommended LV as an empirically validated, first-line treatment approach for mild to moderate depressive symptoms (British Psychological Society, 2007).

Importing Listening Visits to the U.S and Evaluations

Although universal surveillance of postpartum women is not part of the U.S. healthcare system, a proliferation of home-visiting programs provides health and social services to at-risk, low-income pregnant women and mothers of young children (Leis, Mendelson, Tandon & Perry, 2009). One such program, Healthy Start, is a federally funded nationwide, home-visiting program that serves families living in high-infant mortality areas, with the goal of reducing infant mortality and improving infant outcomes. In 2001, because of the association of maternal depression to poor infant birth and child development outcomes (Grote et al., 2010; O'Hara & McCabe, 2013), all Healthy Start projects were required to incorporate maternal depression screening into their program services (Segre, O'Hara, Brock & Taylor, 2012). To implement this new requirement, the director of the Des Moines Healthy Start Project requested consultation from our research team. Together, we developed, implemented, and evaluated a depression screening protocol for this site. Although depression screening rates were high early on (Segre et al., 2012), the home visitors reported that many of the Healthy Start program participants with elevated depression symptoms were not accessing treatment from a mental-health professional. Specifically, across the eight-year evaluation of the screening program, slightly less than half of mothers (47.2%) reported that they attended at least one treatment session.

To improve treatment use rates, the Des Moines Healthy Start Project director introduced several new culturally attuned treatment options, including a bilingual mental-health professional who went into the home. Although treatment rates gradually improved over time, ultimately these cultural attunements were not adequate. Embedding LV into established social and health services, like the Healthy Start program, seemed to provide an effective means to address key instrumental and psychological barriers preventing at-risk impoverished mothers from receiving treatment. The director of the Des Moines Healthy Start project agreed and in 2005, the British trainer of LV provided an LV workshop for the home-visiting staff of the Des Moines Healthy Start Project. Recognizing that the U.S. system of home visiting vastly differs from the U.K. healthcare context, this team of researchers conducted a multisite randomized controlled trial (RCT) that utilized a wait-list control group (WLC) to test the efficacy of LV (Segre, Brock & O'Hara, 2015) (see Fig. 1). The results of this trial demonstrated both statistical and clinically significant improvement in depressive symptoms among participants who had received LV immediately after randomization compared to WLC group participants who received usual care only. Effect size estimates across the three measures of depression were moderate in magnitude (effect size d s ranged from 0.56 to 0.72). Further, our qualitative assessments indicated that the women valued this approach (Orengo-Aguayo & Segre, 2016).

Study Purpose

Although promising, the evidence for the effectiveness of LV in U.S. low-income pregnant women and mothers of young children is limited to the results of this single randomized

RCT. Data collected during the follow-up phase of the RCT (depicted as Phase II in Fig. 1) provided an opportunity to further assess the effectiveness of LV. Among RCT participants who received LV immediately, these follow-up data allowed us to assess whether their initial improvement in mood was sustained beyond the active treatment period. We also had a means to assess whether the treatment effects realized by the immediate-LV group were “replicated” by RCT participants who received LV after an 8-week delay. We realize that in clinical trial research, the term “replication” typically refers to independence of investigators, settings, or samples. This *internal replication*, a novel analysis used by Sheeber et al. (2012), capitalizes on outcome assessments of WLC participants to provide a *preliminary* assessment of replication of effects, adding incremental evidence for the robustness of LV. Such an examination of replication also provides a means to assess the effectiveness of LV under real-world conditions. Specifically, various circumstances unique to the nature of this intervention may cause a delay in treatment (e.g., women may be reluctant to participate in LV before establishing an alliance with the home visitor, a full caseload may prevent home visitors from providing immediate treatment). If our RCT participants demonstrate significant improvement after receiving LV, despite an 8-week delay, this would provide evidence of the effectiveness of LV under such naturalistic conditions.

In the current analysis of follow-up phase outcomes, we had two specific hypotheses. First, we expected the treatment gains experienced by participants who received LV immediately during Phase I to be maintained during the 8 weeks following LV termination. Second, we expected significant improvement in mood among WLC participants during their active treatment phase, following an 8-week delay in initiating LV.

Method

RCT Overview: Phase I and Phase II

Although the RCT setting and procedures are described in detail elsewhere (Segre et al., 2015), information regarding the treatment sites, depression screening procedures, enrollment, randomization, and the LV intervention are also briefly described here to provide continuity for the current report. The four RCT sites included three home-visiting programs in Iowa and an Ob-Gyn office in Chicago. At each site, depression screening was integrated into the usual care provided by home visitors or the physician’s assistant (in the case of the Ob-Gyn office). In all RCT sites, eligible women with elevated depressive symptoms were offered a range of mental-health treatment options, including LV from the home visitor or physician’s assistant. Eligibility criteria included an elevated depression score, being able to speak English or Spanish, not currently receiving counseling services, and 14 years of age or older. Women who opted for LV were contacted by a research team member who described the study, and completed the informed consent process for the RCT, inclusive of both phases. For those <18 years of age, consent of a legal guardian to participate was also required. Enrolled participants completed a baseline assessment, and were then randomized to immediate or delayed LV. Participants were block randomized (in blocks of three), within site, using a randomization ratio of 2:1 (Immediate: Delay). A computer-generated randomization sequence was developed by an independent statistician, and allocation was

handled by the study coordinator. All LV sessions were provided by the home visitor or physician's assistant. In the RCT, there were 26 different LV providers across the four sites. All LV providers completed LV training provided by the third author. All procedures were approved by an Institutional Review Board.

Phase II Participants

Apart from the RCT eligibility criteria described above, enrollment into the RCT evaluation of LV was open to all women served by these programs at any point in time that they were eligible to receive services offered at their sites. Here, our enrollment procedures diverge from those typically used on studies of depression treatments for perinatal women. Specifically, our study participants were not limited to pregnant women at a certain time in pregnancy or women at a uniform time in the postpartum period. Rather our participants included all eligible pregnant women and mothers of young children typically served by the home-visiting program and the Ob-Gyn office located in a low-income area. Because these women were screened at multiple points in time during pregnancy and up to 24 months postpartum in the home-visiting programs, some may have entered the trial during pregnancy, while others enrolled later in the postpartum period when depression was identified. This enrollment strategy resulted in a group of pregnant women or mothers of young children who typically receive health or social services from these programs or clinics.

Of the 66 women who enrolled into the RCT during Phase I, a total of 54 completed the 16-week assessment at the completion of Phase II and were included in the present analysis (36 immediate LV and 18 delayed LV). The demographic composition of the Phase II participants is provided in Table 1. As indicated in this table, one third (33.3%) were employed and over half of the participants reported an annual income of \$20,000 or less. Among participants who reported their ethnicity, almost one third identified as Black (29.6%) and 5.6% indicated multiracial. Participants who identified their race as White were primarily those who also identified as Hispanic/ Latina ethnicity (42.6%). On average Phase II participants were 27 years old, a little over half were married or cohabitating (57.4%), and exactly half (50%) were pregnant at the time of randomization.

Table 1 also provides a comparison of the demographic characteristics of participants initially randomized to the RCT in Phase I as compared to those who ultimately completed the follow-up phase of the study (Phase II). There were no significant differences at baseline between participants who were lost to attrition and those who completed Phase II with regard to any of the outcome variables, $t(64)$ ranged from -1.73 to 0.96 , p s $> .05$. Relative to participants who remained in the study throughout the follow-up period, those who were lost to attrition were more likely to be single, $\chi^2(1) = 6.52$, $p = .011$, and identify as a race other than white, $\chi^2(3) = 8.04$, $p = .045$.

Phase II Procedures

As depicted in Fig. 1, participants who were randomized to the WLC group in Phase I, received LV during Phase II. Conversely, those who received LV immediately during Phase I, received usual services during Phase II.

Listening Visits

Six LV sessions were delivered within an 8-week time-frame, either in the home or at the Ob-gyn office, with each session lasting approximately 30–50 min. As a non-directive intervention, the direction of each session was based on the woman's needs. In general, each session included several elements: greeting the woman and finding a private place to talk, providing a brief review of the previous visit or 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: (a) empathic listening to gain a full understanding of a woman's situation without judgment, and (b) collaborative problem solving to identify problems and generate specific solutions. Early sessions typically focus on understanding a woman's situation, after which collaborative problem solving is gradually introduced. The final session usually focuses on summarizing, assessing the need for additional mental-health treatment, and closure. A case example of LV, describing LV delivered by a nurse to a low-income mother of an infant hospitalized in the neonatal intensive care unit, is published elsewhere (Chuffo Siewert, Cline & Segre, 2015).

Usual Services—Throughout their study participation, women received the usual social or healthcare services provided by the site. In the three sites that provided home visiting, these services included, but were not limited to (a) linking families to appropriate health and child development services; (b) educating clients about nutrition, newborn care, child development, and parenting, via a curriculum that includes parent involvement activities; (c) referring to community resources appropriate to family needs (e.g., ensuring adequate nutrition, ESL instruction, GED acquisition); and (d) providing a number of screening services (e.g., child development and maternal depression screening). At Ob-Gyn office site, usual care consisted of standard prenatal and postpartum healthcare.

Assessments—In Phase II, participants were assessed at 8 and 16 weeks post randomization (see Fig. 1). Participants were interviewed either in their home, over the phone, or at the Ob-gyn office. Study participants were compensated \$25 for interviews, with a gift card from one of two chain retail stores. The assessments were conducted by blinded interviewers who were members of the research team, including a PhD clinical-community psychologist, a bachelor's-prepared registered nurse, and three doctoral students who were bilingual (English/Spanish).

Measures

Depression—Clinician-rated depression severity was assessed with the 17-item version of the *Hamilton Rating Scale for Depression* (HRSD; Hamilton, 1967) which is a reliable and valid measure of depression (O'Hara, Stuart, Gorman & Wenzel, 2000; Ross, Gilbert Evans, Sellers & Romach, 2003), and is sensitive to changes during treatment (O'Hara et al., 2000; Thompson, Harris, Lazarus & Richards, 1998). The HRSD demonstrated adequate internal consistency in the present study (Cronbach's α ranged from .71 to .74). Self-reported depression symptoms were assessed with the *Inventory of Depression and Anxiety Symptoms - General Depression* (IDAS-GD) scale, and the *Edinburgh Postnatal Depression Scale* (EPDS). The IDAS-GD (Watson et al., 2007) is a 20-item instrument assessing

dysphoria, suicidality, lassitude, insomnia, appetite loss and well-being (reverse-keyed). The EPDS is a 10-item scale assessing depressive symptoms in postpartum women (Cox, Holden & Sagovsky, 1987). The EPDS has been validated with adult and adolescent pregnant women and women with young children (J. Cox & Holden, 2003). Internal consistencies were adequate for the IDAS-GD (α s = .88 to .95) and EPDS (α s = .74 to .91). We also administered the Major Depression module of the Structured Clinical Interview for DSM Disorders Non-patient Edition (SCID-I/NP; First, Spitzer, Gibbon & Williams, 2002).

Adjustment—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). Women 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 *Work and Social Adjustment Scale* (WSAS) is a five-item scale assessing the extent to which sad mood is impairing functioning (Mundt, Marks, Shear & Griest, 2002). For each of five domains (i.e., work, home management, social leisure, private leisure, and interpersonal relationships), women rate the extent to which they feel impaired by sad mood. Internal consistencies were adequate for the Q-LES-Q (α s = .87 to .94) and the WSAS (α s = .86 to .95).

Data Analytic Procedures

Change During Phase II: Statistical Significance—There were two primary hypotheses regarding outcomes during Phase II of the trial: (a) treatment gains experienced by women in the immediate treatment group will be maintained during the 8 weeks following LV termination and (b) WLC participants will experience significant improvement in mood while receiving LV, following the 8-week delay in treatment initiation. There is limited precedence with regard to approaches for analyzing follow-up data gathered in RCTs that include WLC conditions, with one notable exception: Sheeber et al. (2012) have proposed examining mean change in outcomes during the follow-up phase within the WLC group as a means of internal replication. Because we also aimed to examine sustainability of treatment gains for participants who received LV immediately after randomization, we adopted a more comprehensive approach to data analysis. Specifically, we examined whether participants in the immediate-LV and participants in the delayed-LV (WLC) conditions experienced significant change during the 8-week follow-up phase via a 2×2 (Group [Immediate, Delay] $\times$ Time [8-week assessment, 16-week assessment]) repeated measures analysis of variance (ANOVA). It is well-established that an ANOVA is unequivocally preferred over separate *t*-tests (for distinct groups) given reduced risk of Type 1 error and greater power for the analysis (Tabachnick & Fidell, 2013). Further, although not a primary aim of the study, an ANOVA provides the additional advantage of examining whether mean change (i.e., “Time” effect) is comparable between the groups (i.e., “Group $\times$ Time” effect). Because there were no differences across treatment sites or providers regarding participant characteristics or outcome variables ($ps > .05$), provider and site were not included as covariates in the analyses.

Change During Phase II: Clinical Significance—In addition to assessing whether there was significant mean change in depressive symptoms during Phase II of the trial, via

an ANOVA, we also computed reliable change indices (RCI) following procedures outlined by (Jacobson & Truax, 1991) and examined rates of diagnosable MDE at the beginning and end of Phase II. RCIs are often reported in clinical outcome research to determine how many *individuals* achieve reliable change over the course of an intervention while accounting for the reliability of the instrument used to assess change. The RCI has been adopted as a convention because it allows clinical researchers to determine the number of participants whose degree of change across therapy represents a clinically significant level (i.e., one that would be clearly recognized by clinicians; Jacobson & Truax, 1991).

Supplementary Analysis: Change Across Both Phases of the Trial—Finally, building on our aim of examining the effectiveness of LV despite an 8-week delay, we conducted a series of supplementary analyses to examine overall change in outcomes across *both* phases via a 2×2 (Group [Immediate, Delay] $\times$ Time [Randomization, 16-week assessment]) repeated measures ANOVA. This analysis provided a means of testing whether participants experienced significant improvement regardless of whether they received LV immediately after randomization, or following an 8-week delay in initiation of LV. We predicted that both groups (Immediate and Delay) would experience significant improvement across the 16 weeks, and that mean change in outcomes would be comparable between the two groups. Parallel to the principal analyses focused on the 8-week follow-up period, we also examined clinically significant change during the 16 weeks by calculating RCIs (based on several measures of depression) and rates of MDE.

Results

Change During Phase II: Statistical Significance

Results of the 2×2 (Group [Immediate, Delay] $\times$ Time [8-week assessment, 16-week assessment]) ANOVA support our hypotheses: (a) treatment gains experienced by participants in the active treatment group were not only maintained during the 8 weeks following LV termination, but women continued to improve and (b) WLC participants experienced significant improvement in mood while receiving LV. Specifically, the Time effects were significant for each of the three measures of depression such that mean scores decreased across the 8 weeks: HRSD, $F(1,52) = 9.99$, $p = .003$, $\eta_p^2 = .161$, IDAS-GD, $F(1,52) = 6.06$, $p = .017$, $\eta_p^2 = .104$, and EPDS, $F(1,52) = 4.15$, $p = .047$, $\eta_p^2 = .074$.¹ Time effects were marginally significant for adjustment measures including the WSAS, $F(1,52) = 2.86$, $p = .097$, $\eta_p^2 = .052$, and Q-LES-Q, $F(1,52) = 3.85$, $p = .055$, $\eta_p^2 = .069$, suggesting a trend toward improvement in adjustment during Phase II. Of note, the Group $\times$ Time [8-week, 16-week] interactions were *not* significant for any of the outcomes ($ps > .05$), suggesting a similar rate of improvement for both immediate and delayed groups during Phase II. A graphical depiction of the results for the HRSD is provided in Fig. 2. Mean levels of HRSD scores during the 8-week follow-up period (8 weeks and 16 weeks) are

¹Although the present investigation was focused on women who completed the follow-up phase of the study ($N = 54$), we also completed an intent-to-treat analysis with the full sample of women who were initially randomized ($N = 66$) using linear interpolation to impute missing data. Results generally replicated (except EPDS) such that significant mean change (i.e., significant “Time” effect) was detected *across the 8 weeks of Phase II*, regardless of condition (Immediate vs. Delay) as measured by HRSD, $F(1,64) = 10.85$, $p = .002$, $\eta_p^2 = .145$ and IDAS-GD, $F(1,64) = 5.23$, $p = .025$, $\eta_p^2 = .076$. The effect for EPDS was marginal in the ITT analysis, $F(1,64) = 3.51$, $p = .066$, $\eta_p^2 = .052$.

reported for each group, in addition to baseline levels (average HRSD scores at the time of randomization) for comparison. Other measures of depression (IDAS-GD, EPDS) demonstrated a similar pattern over time (see Figs 3 and 4).

Change During Phase II: Clinical Significance

Results of the RCI analyses, based on the HRSD, indicated that 11% of participants in the immediate-LV group continued to improve significantly during the follow-up period. An even larger proportion of participants experienced clinically significant change as measured by the IDAS (19%) and EPDS (25%). RCI statistics are reported in Figs 2–4. The percentages of women meeting MDE diagnostic criteria also decreased across study assessments: 36% (Randomization), 22% (8 weeks), and 11% (16 weeks). Only one participant in the immediate-LV group relapsed during Phase II (i.e., she did not meet diagnostic criteria for MDE at 8 weeks, but met criteria at 16 weeks).

We also examined reliable change during the active treatment phase for participants in the delayed-LV condition. Results of RCI analyses suggest that 22% of participants in the delayed-LV group experienced clinically significant change as indicated by HRSD change scores across Phase II of the trial during the weeks when they received LV. An even larger proportion of participants experienced clinically significant change as measured by the IDAS (28%) and EPDS (39%). RCI statistics are reported in Figs 2–4. The percentages of participants meeting MDE diagnostic criteria decreased across study assessments: 22% (Randomization), 17% (8 weeks), and 11% (16 weeks).

Supplementary Analysis: Change Across Both Phases of the Trial

The present report was focused on the 8-week follow-up period (Phase II); however, we also examined overall change across Phases I and II to determine whether participants improved regardless of timing of LV (i.e., immediate vs. delayed initiation). As expected, Time [randomization, 16-week assessment] effects were significant for each of the three measures of depression, HRSD, $F(1,52) = 48.94$, $p < .001$, $\eta_p^2 = .485$, IDAS-GD, $F(1,52) = 54.67$, $p < .001$, $\eta_p^2 = .513$, and EPDS, $F(1,52) = 43.72$, $p < .001$, $\eta_p^2 = .457$, and adjustment, WSAS, $F(1,52) = 29.68$, $p < .001$, $\eta_p^2 = .363$, and Q-LES-Q, $F(1,52) = 33.26$, $p < .001$, $\eta_p^2 = .390$. Group $\times$ Time interactions were not significant for any of the outcomes ($ps > .05$), suggesting that mean improvement from baseline to 16 weeks was similar regardless of timing of LV (immediate vs. delayed). Further, rates of MDE diagnoses at 16 weeks did not differ between the groups, $\chi^2(1) = 0.01$, $p = .972$. See Figs 2–4 for overall mean change in HRSD, IDAS-GD, and EPDS, respectively, in addition to RCI estimates across the 16 weeks. Notably, although mean change in scores was comparable across the two conditions, the immediate-LV group experienced higher rates of clinically significant change across the 16 weeks (50% HRSD, 64% IDAS-GD, 64% EPDS) relative to the delay group (33% HRSD, 61% IDAS-GD, 44% EPDS).

Discussion

The results of this follow-up investigation support the sustainability of treatment effects realized by LV. Specifically, the significant mood improvement realized in participants who

received LV immediately was not only sustained during the 8 weeks following completion of LV, but mood continued to improve significantly during the post-LV period. Because participants also received usual social or healthcare services during the follow-up phase, it is not possible to definitively attribute the continued improvement to LV alone. Nevertheless, having depressive symptoms addressed through the combination of LV and continuous usual care resulted in sustained improvement in participants' emotional well-being.

Results supporting the sustainability of LV effects are similar to those reported in two British LV trials. Specifically, in each LV trial that included a follow-up assessment (including the current trial), the average EPDS scores at the follow-up were lower than the average post-LV score and, moreover, these follow-up EPDS scores were similar across the three trials: 9.3 for the current analysis, 9.6 (Cooper et al., 2003), and 8.1 (Morell et al., 2009). This similarity of results across three different trials is notable given the diversity of LV providers, study contexts, and LV recipients, thus building the case for the robustness of LV delivered by non-mental-health providers. Building on a model introduced by Sheeber et al. (2012), we also demonstrated that study participants who were initially randomized to the WLC group experienced significant improvement while receiving LV (during Phase II) despite the 8-week delay in treatment initiation. These results add incremental evidence of the robustness of LV.

Results of the supplementary analyses provide additional evidence of the effectiveness of LV despite a waiting period. Specifically, results revealed that the two groups (immediate LV and delayed LV) did not differ with regard to mean change in depressive symptoms and adjustment *across the 16 weeks of the complete treatment trial* (Phases I and II), nor did they differ in rates of MDE diagnoses at 16 weeks.² Thus, regardless of whether women received LV immediately or were delayed for 8 weeks, they experienced significant improvement. In practice, it may not be possible to start LV immediately after detecting depression; thus, these results have implications for the implementation of LV in real-world settings. For example, during the trial, it was often difficult to enroll women when they were first approached. The home visitors indicated that women needed to get to know them before they were ready to engage in LV. Other scenarios that might cause delay of the start of LV include the provider having a full caseload and not having time to provide LV immediately or having to accomplish other home-visiting tasks associated with a firm deadline (e.g., finishing a parenting curriculum, record keeping). Nevertheless, estimated RCIs suggest that immediate treatment leads to greater *clinically significant* improvement (i.e., a larger proportion of participants in the immediate-LV group experienced reliable change across the 16 weeks than those in the delayed LV); thus, immediate treatment should be prioritized when possible.

Although promising, the results from the follow-up phase of the RCT have some limitations. First, in terms of sustainability, the 8-week follow-up period in the current trial is relatively short compared to 5-month (Cooper et al., 2003) and 8-month (Morell et al., 2009) follow-up-periods in two of the British clinical trial evaluations. Second, the replication of treatment

²Notably, as reported in Segre et al. (2015), women in the immediate condition experienced significantly greater improvement in depression *during Phase I* of the trial (while actively receiving LV) relative to women who were receiving usual care (delay condition).

effects among participants who waited for LV is not an independent replication of this trial. Third, the extent of engagement with usual services was not assessed. Fourth, the number of participants completing Phase II was small. Finally, without a control group for the WLC participants, we cannot definitively attribute improvement in the WLC group during Phase II to LV. Although the stability of untreated maternal depressive symptoms reported in other studies (Beeghly et al., 2002; Teissèdre & Charbrol, 2004) suggests that these symptoms would not diminish to a substantial degree on their own, definitive assessment would require an additional control group.

To address these methodological limitations, a direction for future research is the replication of this evaluation in an independent, larger study with a longer follow-up period. Further, inclusion of a “pure control group” of participants who only receive usual care during both phases of the trial would provide a more stringent test of the efficacy of LV regardless of timing of the intervention (i.e., immediate vs. delayed treatment). However, the ethical considerations of withholding what is now an empirically supported treatment would need to be carefully evaluated, particularly in studies enrolling vulnerable women. Consistent with the NIH mission to ensure the translation of research into clinical practice (Glasgow & Chambers, 2012), another promising direction for future research would be a randomized cluster trial evaluation of LV in multiple clinical settings, including an assessment of individual outcomes as well as rates of implementation and the factors related to implementation success.

In conclusion, the incremental support for the sustainability and replicability of LV provided in this analysis of data from the follow-up phase of an RCT supports a wider and more formal dissemination of LV. Although some women may prefer receiving help from a mental-health professional, others may not have access to such options (e.g., immigrants for whom there is no bilingual mental-health professional), and some women may not feel comfortable utilizing this form of help. Adding LV to a range of treatment options may ensure that more depressed, low-income women receive the support services that they need during pregnancy and the early years of their children’s lives.

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Highlights

- Significant treatment barriers often prevent depressed low-income mothers from receiving care.
- Listening Visits delivered by non-mental-health providers are an effective treatment for depression.
- Listening Visits are considered a culturally attuned, evidenced-based treatment for depression.

Fig. 1.
Listening visits RCT research design

Fig. 2.

Mean HRSD Scores at Randomization, 8 and 16 weeks for the delay and immediate treatment groups ($N = 54$). The percentages of women experiencing clinically significant improvement as measured by the Reliable Change Index (RCI) are also reported for each group during each phase. During Phase II, both groups improved over time, $F(1, 52) = 9.99$, $p = .003$, and improved at a similar rate, $F(1, 52) = 1.25$, $p = .268$. LV, Listening Visits

Fig. 3.

Mean IDAS-GD Scores at Randomization, 8 and 16 weeks for the delay and immediate treatment groups ($N = 54$). The percentages of women experiencing clinically significant improvement as measured by the Reliable Change Index (RCI) are also reported for each group during each phase. During Phase II, both groups improved over time, $F(1, 52) = 6.06$, $p = .017$, and improved at a similar rate, $F(1, 52) = 1.10$, $p = .300$. LV, Listening Visits

Fig. 4.

Mean EPDS Scores at Randomization, 8 and 16 weeks for the delay and immediate treatment groups ($N = 54$). The percentages of women experiencing clinically significant improvement as measured by the Reliable Change Index (RCI) are also reported for each group during each phase. During Phase II, both groups improved over time, $F(1, 52) = 4.15$, $p = .047$, and improved at a similar rate, $F(1, 52) = 0.14$, $p = .713$. LV, Listening Visits

Table 1

Participant characteristics

Characteristic	Randomized in Phase I (<i>n</i> = 66)	Completed Phase II (<i>n</i> = 54)
Age (<i>M</i> and <i>SD</i>)	26.30 (5.85)	26.80 (5.94)
Relationship status (married or cohabiting)	50%	57.4%
Pregnant (at randomization)	50%	50%
Race		
White	33.3%	40.7%
Black	33.3%	29.6%
Multiracial	7.6%	5.6%
Unknown/Declined	25.8%	24.1%
Ethnicity (Hispanic/Latino)	40.9%	42.6%
Employed	34.8%	33.3%
Annual income		
\$5000	15.5%	17.0%
\$5000–\$10,000	24.1%	19.1%
\$11,000–\$20,000	31.0%	27.7%
\$21,000–\$30,000	19.0%	23.4%
\$31,000–\$40,000	5.2%	6.4%
\$41,000–\$50,000	5.2%	6.4%
Currently enrolled in school	15.2%	18.5%
MDD diagnosis (SCID) at baseline	30.3%	31.5%

Relative to participants who remained in the study during Phase II (*n* = 54), women who were lost to attrition (*n* = 12) were more likely to be single, $\chi^2(1) = 6.52, p = .011$, and identify as a race other than white, $\chi^2(3) = 8.04, p = .045$; however, there were no significant differences on any other demographic characteristics.