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Author manuscript *J Perinatol*. Author manuscript; available in PMC 2014 June 01.

#### Published in final edited form as:

J Perinatol. 2013 December; 33(12): 924–928. doi:10.1038/jp.2013.93.

# Emotional distress in mothers of preterm hospitalized infants: A feasibility trial of nurse-delivered treatment

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### Abstract

**Objective**—Mothers of preterm infants in a hospital neonatal intensive care unit (NICU) are at risk for clinically significant depression and anxiety but, for these women, their own treatment is likely a secondary priority. This study evaluated the feasibility, acceptability, and effectiveness of an evidence-based, nurse-delivered, on-site depression treatment: Listening Visits.

**Study Design**—Therapeutic Listening Visits were delivered on site to 23 distressed mothers of NICU infants. The intervention was conducted by a neonatal nurse practitioner; and the outcome examined in an open-trial, pre-post evaluation.

**Results**—A part-time nurse practitioner delivered six Listening Visits to each participant within a one-month timeframe. Listening Visits were associated with significantly improved mood and well-being in mothers. The majority of eligible women took advantage of Listening Visits and felt satisfied with their care.

**Conclusions**—This open trial provides "proof of concept", with results that warrant further evaluation in a multisite randomized controlled trial.

### Introduction

The hospitalization of a preterm infant puts mothers at great risk of distress from anxiety and depression symptoms that are often severe.<sup>1–3</sup> For example, one study found that in the first 3 to 5 days after an infant enters the NICU, up to 32% of their parents met the diagnostic criteria for an acute stress disorder.<sup>4</sup> Approximately one-third of those experienced suicidal thoughts<sup>4</sup>, a rate comparatively higher than the 14% of perinatal women reporting similar

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symptoms and equal to the 35% rate reported by adults with two or more medical conditions.<sup>56</sup> The most recent epidemiological study of distress in NICU mothers found that, at the time of infant discharge, 20% had elevated depressive symptoms and 42% reported moderate to severe levels of anxiety.<sup>7</sup>

Although interventions for NICU mothers have improved parental coping and reduced trauma impact,<sup>8</sup> none specifically target emotional distress. Women also tend to neglect their emotional well-being, so even when screening identifies depression or anxiety symptoms, women often view their own need for counseling as secondary to the needs of their hospitalized infants. Thus, NICU mothers likely do not prioritize counseling sessions with a mental health professional. A critical need for this population of women is on site access to treatment. Borrowing from the point-of-care testing model<sup>9</sup> (in which laboratory testing is performed at the patient's bedside to expedite diagnosis, speed treatment, and lower expenses), women's access to depression treatment could be enhanced if delivered by NICU nursing staff at the hospitalized infant's point of care. Indeed, NICU nurses are accessible and, importantly, provide support that can mitigate depressive symptoms in NICU mothers.<sup>10</sup> To date, however, no formal treatment leverages this strategic advantage.

Listening Visits (LV) were developed in the U.K. as a depression intervention delivered by nurses.<sup>11</sup> Substantial evidence from European clinical trials demonstrated that LV are effective<sup>11–14</sup>, prompting the British *National Institute for Clinical Excellence* to recommend them as an evidence-based treatment for mild to moderate postnatal depression.<sup>15</sup> Because LV can be delivered by nurses at the infant's point-of-care, they overcome many barriers that block treatment of NICU mothers.

Although preliminary evaluations of LV were positive in a U.S.-based, home-visiting setting<sup>16</sup>, LV in the NICU introduces several potentially critical changes: the treatment setting will be hospital-based; the provider will not be a home visitor; and the recipients will have significant symptoms of both depression and anxiety. These differences are not trivial, so we cannot assume that the intervention will be effective under the new circumstances. To evaluate the changes we followed the stage model, used to evaluate behavioral therapies.<sup>17</sup> In this model, stage 1 is dedicated to developing a manual and a therapist training protocol. Also during stage 1, a small feasibility trial is conducted to test for clinically significant improvement.<sup>17</sup> Here, we describe the first stage in the evaluation of LV in the NICU setting. This assessment evaluated both whether our implementation approach was feasible and whether it was deemed acceptable by NICU mothers. Using an open-trial, pre-post design we assessed our hypotheses that LV would be associated with the mother's clinical improved.

#### Methods

All study procedures were approved by the University's Institutional Review Board. An open-trial pre/post-test design was used to assess whether LV were associated with a significant decrease in depressive and anxiety symptoms.

#### Setting

The setting for this study was a Level III NICU of a Midwestern academic medical center with 70 private beds and approximately 850 admissions annually. As part of usual care, the NICU social work team provides social services to all NICU mothers, including depression screening one month after the infant's admission and, when needed, referral to treatment.

#### Recruitment/Screening/Enrollment

Within a week of infant admission, a recruitment brochure was distributed by staff nurses (also research team members) to mothers of NICU infants who were English speaking and 18 years of age and older. Interested mothers were enrolled into the screening phase and completed questionnaires assessing mood and demographics. Invitations to join the treatment trial were extended to women who met the following criteria: not already in counseling; Edinburgh Postnatal Depression Screening Scale score 12, without active suicidal ideation; and infant gestational age 32 weeks or extended hospitalization (to ensure the mother would be available for the one month needed to complete all six LV sessions). Enrollment was continuous from December 2010 to May 2012. Interested, eligible women gave informed consent.

#### Intervention: LV

**LV Description**—LV, extensively described elsewhere<sup>18</sup>, emphasizes two components: empathic listening, to fully understand a woman's situation, and collaborative problem solving, to generate specific solutions. The LV intervention consists of six, consecutive, 45 to 60 minute sessions, held in a private place in the hospital. Although the intervention is nondirective, the general structure of a single visit entails greeting, debriefing about the previous visit, updating on current issues, working an agenda through listening and problem solving, and, providing closure through summarizing the work of the visit. In the open trial implementation, the first two LV sessions generally focused on the birth experience; sessions three to five focused on the mother's needs, with the LV provider listening to the mother's concerns, thoughts, and feelings through active reflective listening and problem solving; and session six provided an opportunity to provide closure by reviewing progress, outlining strategies and skills to address future problems, and evaluating need for additional specialized mental health services.

**LV Training**—The provider was trained to deliver LV in the open trial. Training consisted of two four-hour workshops and one practice case of six LV sessions. Workshop 1 provided general information about perinatal depression (e.g., definitions, range of mood disorders, prevalence, negative effects, screening, and referral and treatment). In Workshop 2, the LV skills were taught (e.g., introducing LV, active reflective listening, and problem solving).

**LV Delivery**—Consistent with treatment-development trials<sup>17</sup>, LV were provided to all study participants by the second author, a doctorally prepared neonatal nurse practitioner. The LV provider met with participants for up to six 50-minute LV sessions, conducted in a private hospital location, every two to three days, as was convenient to participants' schedule.

Given that the social work team was ultimately responsible for the women's wellbeing, LV implementation was coordinated with the usual social work care, as described in "Setting." During the study, as required by both the NICU social work team and the University's IRB and with participant consent, if our screening detected significant depressive symptoms in a woman, then the social work team was informed. Also, with IRB approval and participant consent, the LV provider informed the social work team which women enrolled into the open trial.

#### **Study Assessments**

Participants completed three assessments: at enrollment before LV, four weeks after enrollment (after LV), and at follow-up, 8 weeks after enrollment.

#### **Participants**

During the study recruitment phase, from December 10, 2010 to May 4, 2012, 571 women were eligible (e.g., 18 years of age and English speaking) for the study. Of these 571 eligible women, 200 (35.0%) enrolled and completed the screening assessment. Of these 200, 32 (16%) met study entry criteria and 25/32 (78.1%) opted to have LV as part of an open-trial evaluation. However, two enrolled participants did not receive any LV because their infants were unexpectedly discharged before treatment was given. Table 1 shows the study participants' demographic characteristics, as well as the gestational ages of their infants.

To establish that the open-trial participants were demographically similar to the general population of NICU mothers, we used IRB-approved de-identified data for all mothers who had infants on the NICU during the study recruitment. IRB data contained demographic characteristics, including maternal age, parity, race, ethnicity and infant gestational age. As indicated in Table 1, the demographics of the 23 open-trial participants generally reflected that of the population of NICU mothers on the same unit during the study timeframe. The only statistically significant difference was that LV participants' infants averaged a significantly lower gestational age at delivery (31.57 vs. 35.18 weeks); but gestational age of 32 weeks was one of the open trial inclusion criterion, so this difference was expected.

#### Measures

**Maternal and Infant Characteristics**—A 17-item questionnaire assessed maternal demographic and mental health characteristics as well as infant gestational age and health complications. The latter assessed whether the infants were likely to be hospitalized for at least one month, the minimum time that is required to complete a course of LV.

**Depressive Symptoms**—Depressive symptoms were measured using the Edinburgh Postnatal Depression Scale (EPDS), a 10-item self-report instrument developed to assess depressive symptoms in postpartum women.<sup>19</sup> In the early postpartum period, the optimal EPDS cutoff score was determined to be 12, with a sensitivity of 0.83 and a specificity of 0.77.<sup>20</sup> In the current study, the EPDS has an alpha reliability of 0.86 at the pre-LV assessment, with similar internal consistency at the post-LV ( $\alpha = 0.75$ ) and follow-up ( $\alpha = 0.91$ ) assessments.

**Anxiety Symptoms**—General anxiety was measured by the Beck Anxiety Inventory (BAI), which rates 21 affective and somatic symptoms on a 4-point severity scale.<sup>21</sup> In a sample of outpatient clients, the scale was internally consistent ( $\alpha = 0.92$ ) and had test-retest reliability (r = 0.75) over one week.<sup>21</sup> In our pre-LV assessment, the BAI had an alpha reliability of 0.94, and the post-LV ( $\alpha = 0.94$ ) and follow-up assessments ( $\alpha = 0.93$ ) were consistent.

**Quality of Life**—The 16-item self-report "General Activities" subscale of the *Quality of Life, Enjoyment and Satisfaction Questionnaire* (Q-LES-Q)<sup>22</sup> assessed quality of life/life satisfaction. Participants used a 5-point Likert-type scale to rate how they felt they were getting along at work, at home, and with other people, as well as how satisfied they were with their life in general. The Q-LES-Q has high internal consistency and strong external validity.<sup>22</sup> In the current sample, the scale had an alpha reliability of 0.91 at the pre-LV assessment, with similar internal consistency at the post-LV ( $\alpha = 0.88$ ) and follow-up ( $\alpha = 0.91$ ) assessments.

**Acceptability**—The proportion of eligible women who opted for LV captures the willingness to use the intervention. Additionally, among those who received LV, scores on the 8-item Client Satisfaction Questionnaire (CSQ)<sup>23</sup> reflected satisfaction with the treatment and the outcome. The CSQ has high internal consistency ( $\alpha = 0.93$ ) and correlates well with other estimates of satisfaction.<sup>23</sup> In this sample, the scale's coefficient alpha was 0.72.

#### Data Analyses

To examine overall rates of change from pre-LV to follow-up, the HLM 6 computer program and growth curve modeling (GCM) techniques were used with data from all three assessments.<sup>24</sup> Paired sample t-tests were also used to examine mean change from one assessment to the next (e.g., pre-LV to post-LV), and Cohen's *d* statistics were calculated to ascertain magnitude of change.<sup>25</sup> According to conventions, 0.20 to 0.49 effect sizes were defined as small, 0.50 to 0.79 as moderate, and 0.80 as large.<sup>25</sup>

To determine whether changes in depression scores were clinically meaningful, the Reliable Change Index, or RCI,<sup>26</sup> was computed and a cutoff score was set, as described by Matthey.<sup>27</sup> For the EPDS in the present study, a 4.85 point or greater change was required to be 95% confidant that the difference is clinically meaningful and does not reflect a measurement error. Using the cutoff score of 12 on the EPDS, the changes in EPDS scores from pre- to post-LV were classified as 1) "recovered" if the post-LV EPDS score was less than 12 and 4.85 points lower than the pre-LV score; 2) "improved without recovery" if the post-LV EPDS score was 12 but 4.85 points lower than the pre-LV score; 3) "no change" if the change in the EPDS score from pre- to post-LV was less than 4.85 points; or 4) "clinically deteriorated" if the post-LV EPDS score and 12.

#### Results

#### Feasibility

In the 17 months of study recruitment, twenty-three women received LV. In practice, never more than two received LV at the same time. Thus, LV delivery did not interfere with the other clinical duties of a part-time neonatal nurse practitioner in a Level-III NICU setting. All LV sessions were conducted in a private hospital setting selected by the woman. Scheduling the visits was easily accomplished as most women visited the NICU frequently. Completing six sessions within the one-month time frame also proved to be somewhat feasible. A little over half of the twenty-three women reported completing all six LV within the one-month time frame (n=13; 56.5%). Some infants were discharged earlier than others, such that three mothers completed five visits (13%); six completed four (26.1%); and one completed three. The average number of LV attended was 5.22 (SD=1.00).

#### Symptoms and Quality of Life

**Depression**—GCM results indicated that depressive symptoms declined significantly over time (from pre-LV to follow-up using all three waves of data), as measured by the EPDS, t(22) = -7.00, p < 0.001. Paired-sample t tests of mean differences between specific time points suggested large effect sizes for a decline in symptoms from pre- to post-LV and from pre-LV to follow-up (Table 2). With regard to individual study participants' depression recovery, analyses indicate that over half of the sample improved: 12 (52.2%) and were classified as "recovered." Two (8.7%) were classified as "improved without recovery." Approximately one third (n = 8; 34.8%) did not show reliable change in EPDS scores from pre- to post-LV (i.e., 4.85 points) and were classified as "no change"; and only one (4.3%) was classified as "clinically deteriorated" after LV. Depressive scores remained stable and low, from post-LV to follow-up, t(19) = -0.87, p = 0.39, suggesting no relapse.

**Anxiety**—GCM results indicated that, on average, anxiety symptoms declined significantly over time, as measured by the BAI, t(22) = -4.83, p < 0.005. Paired-sample t tests suggested large effects from pre- to post-LV, and from pre-LV to follow-up (Table 2). Levels of anxiety remained stable from post-LV to follow-up, t(19) = -1.01, p = 0.33.

**Quality of life**—GCM results suggested significant improvement in adjustment over time, as measured by the Q-LES-Q, t(22) = 4.87, p < 0.001. Levels of adjustment remained stable from post-LV to follow-up, t(19) = 1.32, p = *ns*. Paired-sample t tests suggested significant effects that were moderate in magnitude for improvement in adjustment from pre- to post-LV and from pre-LV to follow-up (Table 2). At the pre-LV assessment, the mean percentage score on the Q-LES-Q was 51%. At post-LV and follow-up, mean percentage scores were 64% and 70%, respectively, indicating improvement.

#### Acceptability

Of the 200 women who enrolled and completed the screening assessment, 55 (27.5%) had elevated EPDS scores. Not all of these women received LV, however, because 23 had infants discharged within a week of completing the screening assessment. Of the remaining 32 mothers, 25 (78.1%) enrolled. Immediately after enrollment, two infants of these enrolled

mothers were discharged, leaving 23 to receive the LV. The majority of women who received LV were highly satisfied with the intervention. The average score for the CSQ was 29.91 (SD = 2.15), comparable to levels of satisfaction reported by clients receiving depression treatment from a mental health professional.<sup>28</sup> Indeed, 91.3% of our participants rated the quality of help they received as "excellent."

#### Discussion

Clinically significant symptoms of depression and anxiety are prevalent in mothers of hospitalized, premature infants, highlighting the need for an intervention that can be delivered early on in the NICU.<sup>7</sup> LV, an empirically supported nurse-delivered intervention<sup>11–14</sup>, is a promising first-line, nurse-delivered approach for treating distress in mothers of hospitalized infants. This preliminary open trial evaluation convincingly demonstrated that it is feasible and acceptable to use this evidence based approach in the NICU setting and, based on pre-post intervention symptom scores, demonstrated that the mothers' felt improvement in both their mood and quality of life.

Two findings support the feasibility of implementing LV in the NICU. First, prior to this trial, we were not sure whether the demand for this service would interfere with usual clinical duties. In practice, however, across the 17 months of study recruitment, the neonatal nurse practitioner never had more than two women receiving LV at the same time, suggesting it is possible to incorporate this type of care into the workload. Second, in determining whether it as feasible to deliver six visits prior to infant discharge, we found over half of the women were able to complete all six LV sessions.

The second purpose of this study was to evaluate whether depressed mothers of hospitalized infants would accept the LV treatment. Indeed, we found they did: 78% of eligible women elected to receive it. This treatment utilization rate far surpasses the disappointing 13.8% of depressed pregnant women who sought treatment from a mental health professional in a community setting.<sup>29</sup> Moreover, acceptability of LV was evident in the uniformly high ratings of treatment satisfaction. This relatively inexpensive, early treatment delivered at the infant's-point-of-care might not only alleviate symptoms, but might also improve satisfaction with hospital care, an outcome critically important to hospital administration.<sup>30</sup> Furthermore, although nursing staff views were not formally assessed during the study, NICU nurses often approached the LV provider about seeing NICU mothers who seemed distressed, suggesting the service was valued by nursing staff. Consistent with this observation, a separate survey showed that 96.2% of clinical nurses have positive views of a nurse-delivered counseling model.<sup>31</sup>

The ultimate goal of our study was to evaluate whether LV was associated with clinical and functional improvement. Previous studies by other groups suggested LV would be effective. For example, studies in the U.K. validated the approach<sup>11–14</sup>; and other groups affirmed that nurse support alleviates patient distress.<sup>10</sup> Our study extended this research by showing LV were associated with a statistically significant decrease in distress symptoms in NICU mothers. Moreover, the follow-up assessment showed the mothers' improved mood was maintained. The improvement was clinically meaningful, since cutoff analyses indicated

most women recovered or improved significantly (60.9%). A clinically significant reduction in EPDS score means a woman either endorsed fewer symptoms or rated them as less severe. The symptoms include anxiety, sleeplessness, feeling unhappy to the point of crying, symptoms that directly hinder everyday life. In addition participants also directly reported improvement in their quality of life.

While most women demonstrated clinically significant improvement in depressive symptoms, one third did not change and one woman's mood clinically deteriorated. It is notable, however, that no clinically adverse events were reported during the course of the study, even though suicidal symptoms are prevalent in this group of women.<sup>6</sup> So we posit that, as a first-line approach and in accordance with stepped models of mental health care<sup>32</sup>, LV on the NICU can potentially address mild to moderate symptoms early on, such that relatively few women will ultimately require additional services from a mental health specialist

Although these outcomes are promising, our conclusions are limited by two methodological weaknesses. First, we did not include a comparison group of depressed/anxious women who did not receive LV. Their mood would likely improve somewhat too, according to epidemiological research.<sup>33</sup> As such, it is impossible to claim definitively that the intervention elicited the improvements. Nonetheless, longitudinal studies of NICU mothers found that in the first two months approximately 30% of mothers report clinically significant distress.<sup>3334</sup> In contrast, during this early postpartum period, our study mothers' distress decreased.

The second major limitation is the narrow scope of the study, in terms of the small number of participants, their relative demographic homogeneity, the limitation to one NICU setting, and that LV sessions were delivered by a single doctoral-level nurse specialist. We recognize the methodological limitations of this preliminary trial and accordingly claim that the results of this open trial provide a "proof of concept" that indicates further evaluation, in the form of a larger randomized controlled trial is warranted.

According to the stage model for evaluating behavioral therapies,<sup>17</sup> next steps of this research should address two important questions. First, is the intervention effective? This question can be answered by a Stage 2 randomized controlled trial in multiple settings, with multiple LV providers (i.e., including bachelor's-prepared nurses).<sup>17</sup> Second, what are the barriers that might block providers from adopting LV, even if they are shown to be effective? Time/cost, willingness/comfort of nurses with providing mental health care, and dual-role relationship issues all might prove problematic. Finally, before broad dissemination of LV, critical parameters would need to be set: the limits of the intervention must be defined (e.g., who should be referred to specialist services immediately and who might safely benefit from LV), the optimal number of sessions determined, and protocols developed for referrals to specialists. These implementation issues would be the focus of Stage 3 research.<sup>17</sup>

In summary, although the evaluation results presented here are preliminary, they are bolstered by a substantial body of empirical evidence supporting the efficacy of LV in home

visiting settings both in the U.K.<sup>11–14</sup> and the U.S.<sup>16</sup> This considerable evidence base suggests that expanding neonatal nurses' role to provide supportive care in the form of LV to women with mild to moderate postpartum distress, although provocative, is an innovation warranting additional clinical evaluation.

#### Acknowledgments

Funding for this research was provided by the Social Science Funding Program, Vice President for Research Office of the University of Iowa. During the period of the conduct of this research Lisa S. Segre PhD was supported by a NIMH K-23 Award grant MH075964. The authors acknowledge the assistance of NICU nursing staff (Jennifer Nieman MSN, NNP-BC & Jade Kalmes MSN, NNP-BC), social work staff (Ruth Truhlar MSW, Tara Clark MSW & the NICU social work team), Stephan Arndt PhD for statistical consultation, Diana Colgan PhD, the College of Nursing editor, and importantly, the mothers who participated in this research.

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#### Table 1

#### Participant Demographic and Infant Health Characteristics

	Listening Visits	NICU	
Variable	Study Participants $(n = 23)$	Mothers $(n = 840)$	Comparison <sup>a</sup>
Age (years; $M \pm SD$ )	28.13 (5.11)	27.86 (5.98)	t(22) = 0.25, p = 0.80
Parity $(M \pm SD)$	1.70 (1.03)	1.89 (1.25)	t(19) = 0.82, p = 0.42
Gestational age (weeks; $M \pm SD$ )	31.57 (5.30)	35.18 (4.37)	t(21) = -3.20, p = 0.004
Years in school $(M \pm SD)$	15.10 (2.88)	Not Available	
	n (%)	n (%)	Fisher's exact test
Race			
White	20 (87.0)	668 (79.5)	<i>p</i> = 0.56
Ethnicity			
Hispanic/Latino	0 (0.0)	48 (5.7)	<i>p</i> = 0.30
Married	12 (52.2)	Not Available	
Employed	15 (65.2)	Not Available	
Income			
< \$10,000	5 (22.7)	Not Available	

<sup>*a*</sup>One-sample t test.

Note: for all NICU mothers, de-identified demographic data were obtained from the hospital electronic database.

# Table 2

Outcomes: Depressive Symptoms, Anxiety Symptoms and Quality of Life

	Pre	Pre-LV	Post-L	-LV	Effect size d		:	Follow-up	đn	Effect size d		1
Measure	Mean	SD	Mean	SD	(Pre-LV to Post-LV)	t-test	đ	Mean	SD	(Pre-LV to Follow-up)	t-test	đ
Depressive Symptoms EPDS		14.26 4.68	9.00	3.28	-1.12	-6.78	22	7.65 5	5.86	-1.41	-6.86	19
Anxiety Symptoms BAI	16.57	16.57 11.14 9.13	9.13	9.42	-0.67	-5.71	22	6.70 8	8.14	-0.89	-4.55***	19
Quality of Life Q-LES-Q	42.77	9.49	50.18	8.81	0.78	3.54 ****	21	54.41 9	9.32	1.23	4.82***	16
Note.												
$_{p < 0.05}^{*}$ ;												
p < 0.01; p < 0.01;												
*** p < 0.005;												
**** p < 0.001.												
<i>Note:</i> Women who completed 6 or more LVs did not differ significantly from women who completed less than 6 LVs with regard to levels of depression, $t(18) = 1.73$ , $p = 0.10$ , anxiety, $t(18) = -0.12$ , $p = 0.91$ , and quality of life, $t(16) = -1.35$ , $p = 0.20$ , at post-treatment.	leted 6 or 1 (16)=-1.3	more $LV$ : 15, $p = 0.2$	s did not c 20, at post	liffer sig t-treatme	nificantly from ent.	women who c	comple	ted less th	an 6 L'	Vs with regard	to levels of d	epress