Official Title: Promoting Emotional Well-Being in Distressed NICU (Neonatal Intensive Care Unit) Mothers: A Phase 2 Evaluation of a Nurse-Delivered Approach

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Project Title: Mothers Emotional Experiences in the NICU-2

Background: NICU mothers face numerous stressors, including fears about their infant's survival, alteration of parental role, the challenges of caring for a critically ill child, and social isolation. In fact, 63% of NICU mothers report significant emotional distress in the form of elevated depression symptoms early in their newborn's hospitalization, with 30% still reporting distress 2 months later. Although these rates reflect depression symptoms rather than a major depression disorder, the associated psychosocial impairment is known to be equivalent in the general population,6-9 and in postpartum women. An analysis of the types of depression symptoms reported early in the postpartum period revealed that approximately 33% of NICU mothers experience suicidal thoughts, compared to the 14% of perinatal women in the general population. Not surprisingly, NICU mothers also report significantly more anxiety symptoms than mothers of term infants,13,14 with up to 32% meeting the criteria for Acute Stress Disorder in the first 3 to 5 days admission.

An extensive body of research has established that maternal distress negatively affects the social and emotional development of term infants,15 a finding that has also been replicated in premature infants. Although mothers of premature infants engage in more maternal interactions than mothers of term infants, distressed mothers, regardless of infant birth status, engage in fewer maternal interactions than non-distressed mothers. These effects persist: even two years later, distressed mothers of premature infants remain less receptive to their toddler's cues and less engaged with their play. A recent state-of-the-art report suggests that the diminished parenting associated with emotional distress may interfere with a family's readiness for discharge, which is determined by not only the newborn's clinical condition but also by parental confidence and competence. In summary, many NICU mothers are emotionally distressed, particularly early in their newborn's hospitalization. In the short term, this distress may lead to increased infant length of stay and later lead to deleterious effects on the social and emotional development of the child.

Nurse Parent Support: The principles of family-centered care, widely adopted by NICUs, call for an expanded focus on the well-being of the entire family,yet the emotional well-being of at-risk NICU mothers is often not directly addressed. For example, while one educational intervention designed to enhance parental coping with premature infants has been shown to also reduce depression symptoms in NICU mothers, the focus of this intervention is on parenting the newborn not the emotional needs of the mother. At best, emotional care of NICU mothers is often limited to screening and referral of mothers with significant depression symptoms to a mental health professional. Several common barriers prevent most perinatal women from taking the next step and receiving treatment. Moreover, because many NICU mothers often prioritize visiting their newborn and taking care of other family members, they may not feel that they have time to seek treatment from a mental health professional. A critical need for emotionally distressed NICU mothers is accessible support from an on-site healthcare professional who understands the medical issues of the newborn, in short, a NICU nurse.

The provision of nurse support is central to the Nurse Parent Support Model. While many theoretical conceptualizations of social support focuses on help provided by individuals who are part of a person's family or friend support network, the Nurse Parent Support Model uniquely recognizes the role of nurses in providing four overlapping aspects of support to parents of hospitalized newborns: 1) supportive communication and information giving (information about the newborn's physical status) 2) emotional support (concerns and listening), 3) esteem (giving affirmation and feedback), and 4)

instrumental support (tangible assistance, especially in terms of care provided to newborn). The significant impact of supportive nursing care on maternal mental health outcomes was the focus of one study of 62 mothers of hospitalized preterm infants. In this sample, 40.3% of mothers had elevated depression symptoms scores. Results of the logistic regression analysis indicated that significant predictors of maternal depression included maternal stress (an increase of one point in stress level score increased risk of depression by 14%), and perception of nurse support (as scores on the perception of nursing support scale decreased by a point, the risk of depression increased by 6%). Moreover, supportive care, in the form of providing empathic listening from nurses, has also been identified as a key predictor of parental satisfaction in neonatal settings.28 The National Perinatal Association has recently issued recommendations recognizing the importance of support for parents of hospitalized newborns. NICU nurses have also recognized the need to embrace these recommendations and the fact that they are ideally positioned to implement systems of support for NICU mothers. Additionally, compared to mental-health professionals, NICU nurses are medically knowledgeable about hospitalized newborn's physical status and are thus better able to understand the mothers medical concerns related to her infant.

Listening Visits (LV): A nurse-delivered mother-centered approach. The LV intervention was developed by a British psychiatrist/ nurse team to be provided by home-visiting nurses to depressed mothers of term infants. Based on Rogerian nondirective counseling methods, the central assumption of this approach is that talking about feelings to an empathic and nonjudgmental professional will help people to take a more positive view of themselves and their lives. Empathic listening, which is central to LV, is rarely thought of as a first-line intervention, instead it is viewed as a therapeutic skill to enhance delivery of specific treatments. Yet a recent meta-analytic review found that nondirective, empathic listening interventions achieved large effects sizes when compared to no treatment control, and also found a small differential in the effect size achieved by empathic listening compared with specialized interventions.33 Such findings bolster empirical support for the significant value of empathic listening as a stand-alone approach. In alignment, the results of the first UK-based RCT evaluation of LV were positive. Prompted by empirical support from four LV European trials,the British National Institute for Clinical Excellence recommended LV as an evidence-based treatment for mild/moderate levels of depression symptoms in postpartum women of term infants.

From 2007 to 2012, in a U.S.-based program of research, LV were validated for mothers of term infants in community-based settings. To address the critical need for emotional support in mothers of hospitalized newborns, this team also evaluated LV for the first time in the NICU.41 Here LV, were delivered in six, 30-50 minute sessions that were provided in a private hospital location hospital, every two to three days by a DNP nurse who had completed LV training. Results of this open trial were promising: 25.5% of 200 NICU mothers reported elevated depressive symptoms. Results demonstrated the feasibility of providing LV in the NICU, significant reductions in depression and anxiety symptoms, and that NICU mothers valued LV. 52,53. Nevertheless, without a control group, the observed improvement in maternal mood cannot be definitely attributed to LV. Furthermore, the NICU open trial employed a doctorally-prepared nurse practitioner for LV delivery, making eventual broad dissemination less likely because not all hospitals have such nurses and this level of nurse is expensive. Lastly, in order to justify the staff time required to implement LV, improvement in outcomes of central importance to nursing and hospital administration (e.g. perception of nurse support and infant length-of-stay) have not yet been demonstrated. To address these limitations of our prior work, we have proposed a pilot RCT,

evaluating LV delivered by bachelor's level NICU nurses as compared to the usual mental health care provided by the social work team. Our primary outcomes are depression symptoms (in line with the open trial) and two new outcomes: perception of nurse support and infant length-of-stay. A recent study has shown that the presence of maternal mental-health disorders is linked to decreased maternal readiness for infant discharge, which may in turn influence hospital staff perception of readiness. Secondary outcomes include worry, stress, anxiety symptoms, and parent satisfaction with hospital care.

During the RCT, we learned that it was difficult for the Listening Visits nurse to deliver all six session prior to infant discharge due to the hectic schedule of mothers. With the pandemic it is no longer possible for the nurses to meet with the mothers face to face due to the possible increased risk to all. With approval from NINR program officer, we are assessing the feasibility of telehealth LV in an open trial.

The admission of a newborn to the neonatal intensive care unit (NICU) is an extremely stressful postpartum outcome, as evidenced by data showing significant depressive symptoms in some 63% of new NICU mothers. As part of a Family-Centered Care philosophy, focus on the emotional well-being of the mother (and indeed the entire family) should be widely adopted by NICU nursing units. In current clinical practice, however, the emotional well-being of NICU mothers is often ignored. At best, NICU mothers are screened for depression and if indicated, referred to a mental health professional. We posit that the extremes of no treatment and full-on mental healthcare comprise an inadequate approach for treating mothers dealing with a normative reaction to a stressful event. In alignment with the Nurse Parent Support Model, we propose implementation of Listening Visits—a cost-effective nurse-delivered supportive approach, proven to relieve moderately severe depressive symptoms in mothers of newborns born at full term who were not hospitalized. In the NICU setting, Listening Visits were first implemented in a phase-1 feasibility trial conducted by PI Segre and her team. In that first trial, Listening Visits were delivered by a doctoral level nurse practitioner and showed promise as means to reduce distress in NICU mothers. A Listening Visit program for emotionally distressed NICU mothers is innovative because it is a cost-effective approach that uses resources that are largely in place, to serve a persistent unmet need in a vulnerable postpartum population. By having nurses provide support, the concept of emotional distress in NICU mothers is normalized. The promising results of the feasibility trial now must be challenged with a control group comparison to definitively attribute maternal improvements to Listening Visits.

The Phase 2 pilot RCT evaluated Listening Visits provided by bachelor's-level NICU nurses as compared with the care currently provided by the NICU social work team. In three specific aims we will assess the relative effectiveness of Listening Visits on depression symptoms, perception of nurse support, and infant's length-of-stay. In March the study was stopped due to the pandemic. The data and safety monitoring committee advised us to complete the analyses of the 45 out of 50 women in the RCT and to modify the RCT to evaluate Listening Visits delivered via telehealth as a feasibility extension. The use of the no cost extension period and funds to evaluate this expanded aim as a modification of the RCT was approved by the study's program officer at the National Institute of Nursing Research. Because recruitment at UIHC is slow, the modification (June 2021) proposed to recruit NICU mothers via the OVIA Health Parenting app.

Dr. Jane Hanley will review selected audio recordings of the study therapists to determine their fidelity to the treatment model. She is at the Swansea University in Wales and will access a secure university server to listen to these recordings.

Specific Arms:

Specific Aim #1: Compare the effects of LV with usual care (UC) on depressive symptoms as assessed by the Inventory of Depression & Anxiety Symptoms-General Depression Scale (IDAS-GD). Secondarily, the study will compare LV with UC on worry, stress, anxiety, and parent satisfaction with NICU care.

Hypothesis: LV recipients will have significantly lower IDAS-GD total scores than those randomized to UC at 4 & 8 weeks post enrollment.

Specific Aim #2: Compare the effect of LV with UC on perception of nurse support as assessed by the Nurse Parent Support Tool. Secondary analyses will assess relationship of nurse support and depression.

Specific Aim #3 Compare the effect of LV with UC on infant length-of-stay.

Expanded aim: Utilizing the same inclusion/exclusion criteria as the RCT and assessment schedule and instruments, modify the RCT protocol to evaluate the feasibility of delivering Listening Visits virtually, in an open trial design.

Expanded aim June 2021 Ovia Health modification: recruit for the open trial preliminary evaluation of virtual Listening Visits through the OVIA Health parenting app. In this modification inclusion criteria are as follows: mothers 18 years of age or older, not currently receiving counseling and EPDS score 12-19 inclusive and EPDS item 10 rating < 2 and infant currently hospitalized in the NICU.

Enrolled women will be invited complete screening phase questionnaires via a redcap survey (see Screening Questionnaires in the attachment section)

-Participant contact form (to gather information for compensation)

-Demographics and Mental Health Treatment Questionnaire

-The Edinburgh Postnatal Depression Scale (EPDS)

-Patient Health Questionnaire (PHQ-9)

Participants whose responses on screening phase questionnaires who meet the following inclusion criteria will be invited to enroll in the open trial evaluation of telehealth Listening Visits delivered by a NICU nurse.

EPDS score= 12 through 19, inclusive; with a rating of 1 or less on EPDS item #10

Women is not currently receiving counseling services

Study participation is complete among women whose responses on the screening phase questionnaires who do not meet the above criteria or among women who do not wish to enroll in the open trial.

The participants in the open trial will be women who have responded to the OVIA Health ad or email, the UI mass email or the flier in the UIHC NICU or Unity Point-Health-St. Luke's

Participants will be 18 years of age or older, whose babies are currently hospitalized on a Neonatal Intensive Care Unit meeting the following eligibility criteria:

Score of 12 through 19 (inclusive of 19) on the Edinburgh Postnatal Depression Scale and a rating < 2 on item 10 Not currently receiving counseling

Screening questions

-Newborn currently hospitalized in the NICU

-18 years of age or older

-Not currently receiving counseling

-Edinburgh Postnatal Depression Scale (repeated for assessment 2 and 3 in open trial)

Open Trial

Contact information (email, phone, and postal address) (Assessment 1 only)

Demographics &treatment use questionnaire (Assessment 1 only)

EPDS (Enrollment, assessment 2 and assessment 3)

Depression Symptoms in the Past Two Weeks: (Inventory of Depression and Anxiety Symptoms-General Depression Scale-IDAS-GD (assessment 1, 2, 3)

Neonatal Satisfaction Survey (assessment 2)

-Satisfaction with Care and Use of Mental-Health Service (assessment 2)

Screening/baseline survey: https://redcap.icts.uiowa.edu/redcap/surveys/?s=9EHCTMX8CY3P7JKH

4 week survey: https://redcap.icts.uiowa.edu/redcap/surveys/?s=6jnX8PH67X4vdGE9

8 week survey: https://redcap.icts.uiowa.edu/redcap/surveys/?s=9WkCPXnYZTnFNNnL

Listening Visits Nurse Log

July 2021 to present: OVIA Health Parenting App Recruitment (Note: The modification approved on 6-22-21 is focused on a new cohort of women: those who use the parenting app. In this cohort, the research is focused only on the mother. Hospital records will not be used to collect data either on the mother or the infant.)

Modification request November 2021: This modification proposes to continue recruitment with OVIA Health and to also recruit from UI mass email, and via a flier at the UIHC NICU or (Modification Feb 2022) the NICU in Unity Point Health St. Luke's Cedar Rapids and

Modification Request March 2022: Have fliers available in the Ronald McDonald House UIHC in appropriate places: front desk, provided to mothers of NICU newborns, in the public areas.

Modification Request April 2022: Place an ad on the website of NICU Families of Eastern Iowa (the ad has the same description as the mass email)

Modification Request May 2022: Mothers of hospitalized newborns seeking care through UICH Women's Wellness Center who are interested in learning more about the study will receive an email describing the study and containing the Redcap link to find out more about the study, and if interested enroll (see attachment "DESCRI~1.DOC).

Modification request May 2022: Users of the NICU Parent Support blog/FB page will see an ad on the blog/page: see attachment labeled "NICU Parent Support Blog ad". Those who are interested in learning more about the study will click a link that will take them to the Redcap survey

As with the Ovia Health Parenting app, in this cohort the research is focused only on the mother. Hospitals records will not be used to collect data either on the mother or the infant.

1. Immediately after enrolling into the open trial, participants will complete questions pertaining to her contact information (email, phone number and postal address) as well as the baseline assessment questionnaires. The REDCap survey will be programmed to send an email to a member of the research team when a new participant has enrolled. A member of the research team will give the woman's email and phone number to the Listening Visits nurse, who will contact the participant to arrange the first Listening Visits zoom session. A member of the research team will use the address to provide compensation for the completion of the baseline assessment.
2. Listening Visits will be provided by a NICU nurse research team member virtually. Women who enroll into the open trial will be invited to meet virtually with a NICU nurse up to 6 times, approximately twice per week, for about 45 to 60 minutes for the listening sessions. The zoom platform will be used to connect with women. This is the platform used by the Seashore Clinic at the University of Iowa to conduct psychotherapy sessions. It is a platform that women are likely familiar as are the nurses. When nurses connect with women via zoom, they will check with her if it is still a good time for her to talk and that she feels she has sufficient privacy. If no, then a different time will be arranged. The nurse will send the woman a zoom link for each session. With consultation from IT on how to set up the zoom session so that it is compliant and secure, the NICU Listening Visit nurses will send the link to the participant via email. Participants will meet for up to six sessions with the NICU nurse for the Listening Visits. This intervention is nondirective; thus, the specific focus of each session is directed by the needs of the participant. Each session provides a time for the woman to discuss her concerns with a nonjudgmental listening who utilizes reflective listening and problem solving to provide an empathic interchange. Early sessions are oriented toward listening while in later sessions the nurse and woman work collaboratively to identify specific problems and generate solutions. The last session involves a summary of the sessions.

LV Telehealth Time Period Over Which Procedures Will Occur

-From IRB approval through end of study funding

LV Telehealth Time Commitment --Research Assessments:

-All LV telehealth participants will be invited to complete 3 study assessments, at enrollment, and 4 and 8 weeks post enrollment. The questionnaires will require approximately between 5-20 minutes to complete. They will be sent via redcap.

-In the event that an infant dies, mothers will not be asked to do further assessments. They may continue with the Listening Visits, up to six sessions, if they wish.

Risks to subjects including

Risk 1. The hospitalization of an infant is a stressful experience and participation in research can be perceived as a burden by some mothers.

Risk 2. Answering questions about mood may be upsetting

Risk 3. Clinical safety screening phase participants. Women who complete the screening phase assessment may score high on the EPDS scale, or have suicidal ideation and they may not be eligible or want to participate in the intervention evaluation phase.

Risk 4. Clinical safety LV telehealth phase open trial. Among study participants, women may experience a clinically significant worsening of mood or symptoms, or suicidal feelings may newly emerge.

Risk 5. Loss of confidentiality of data