

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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Statistical Analysis Plan:

RCT: Preliminary Analyses. Chi-square- and t-tests will assess group differences in maternal demographics or infant health status. Missing data (e.g., early dropouts) are accepted by our random regression (mixed model analyses when covariates include variables related to missing data. For the survival analysis, dropouts will be considered as censored. All variables will be assessed for normality and homogeneity of variance (and transformed, as necessary). All randomized participants will be included in the analyses, an "intent-to-treat" approach. Per the Delphi criteria,⁵⁷ we will estimate baseline means and measures of variability for all major variables in the study, including confidence intervals, as appropriate.

Specific Aim #1: Compare the effects of Listening Visits with usual care (UC) on depression symptoms as assessed by the Inventory of Depression & Anxiety Symptoms-General Depression Scale (IDAS-GD).

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

Approach: Differences due to treatment condition will be tested for by repeated measures analyses (random regression/mixed model analysis) of depression symptoms (IDAS-GD). The primary test of interest is the time by group interaction on IDAS-GD scores. We will also assess potential within-group Listening Visits provider differences. We will review correlations between treatment exposure (the number and duration of contacts) in both groups to assess dose response relationship and adjust our analyses as necessary. Important biological variables, e.g. maternal age, will be assessed in this model.

Secondary, exploratory analyses will compare the effects of Listening Visits with usual care on additional indices on worry, stress, anxiety symptoms and satisfaction with NICU care. These secondary outcomes will be assessed using a simple t-test or Mann-Whitney test.

Specific Aim #2: Compare the effect of Listening Visits with usual care on perception of nurse support as assessed by the Nurse Parent Support Tool. NPST scores will be compared between the two groups using a simple t-test (or Mann-Whitney, as necessary). We will also attempt to compare Listening Visits providers. Secondary analyses will assess relationship of scores on NPST with depression symptoms within and between groups.

Specific Aim #3 Compare the effect of Listening Visits with usual care on infant length of stay. We will use a log-rank test in the event that any infant is still in the hospital at the end of the study. If no censoring occurs, as we expect, the equivalent Wilcoxon-Mann-Whitney test will be used. As necessary, baseline CRIB-II score will be added as a covariate.

LV Telehealth: We will first compare the demographics of the women recruited through UIHC, Ronald McDonald House UIHC, Unity Point Health --Saint Luke's Hospital, OVIA Health or NICU Families of Eastern Iowa--Women's Wellness Center UIHC or NICU Parent Support blog to determine whether there are significant differences in the two samples. We will then evaluate the feasibility of delivering Listening Visits virtually by assessing uptake of this treatment among eligible women, assessing

depression symptoms at baseline, 4 weeks, and 8 weeks, and assessing their views of receiving this intervention via telehealth.

Specific Aim #1: Compare the effects of Listening Visits with usual care on depression symptoms as assessed by the Inventory of Depression & Anxiety Symptoms-General Depression Scale (IDAS-GD).

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

Power: Assuming a large effect size ($d = 0.8$) at the endpoint (week 8), a moderate effect size at the midpoint ($d = 0.4$), with a moderate correlation in measures ($r = 0.7$), we have power of 0.82 for the interaction term of interest.

Secondary, exploratory analyses will compare the effects of Listening Visits with usual on additional indices on worry, stress, anxiety symptoms and satisfaction with NICU care. For secondary outcomes, we will only have sufficient power to detect large effects ($d \geq 0.8$).

Specific Aim #2: Compare the effect of Listening Visits with usual care on perception of nurse support as assessed by the Nurse Parent Support Tool. With 25 participants in each group, we have 80% power to detect a large effect size ($d \geq 0.8$).

Specific Aim #3 for RCT ONLY Compare the effect of Listening Visits with usual care on infant length of stay. Power for this test will only be reasonable (i.e., ≥ 0.8) for large effects.

Specific Aim #3 OVIA trial/Noon News/U of Iowa email, UIHC and Unity Point Health -Saint Luke's Hospital Cedar Rapids; Ronald McDonald House UIHC and NICU Families of Eastern Iowa, Women's Wellness Center UIHC, NICU Parent Support blog/FB page : we will not collect information about infant length of stay in this modification. Instead of infant length of stay (the primary outcome for specific aim 3 in the grant application), we will examine the effect of LV on patient satisfaction (another outcome of practical utility in hospitals).

LV telehealth: The goal is to assess the feasibility through an open trial, no power analysis is required.