PREEMIE PROGRESS: A family management program for parents of preterm infants

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Study Protocol and Statistical Analysis Plan

Study Protocol

Study Description

The purpose of this study is to refine and pilot test a mobile health (mHealth), video-based family management program for parents of preterm infants hospitalized in the Neonatal Intensive Care Unit (NICU). By moving beyond the basic infant care tasks taught by parenting programs and instead comprehensively training parents to use evidence-based family management skills, we hypothesize that our intervention, called PREEMIE PROGRESS, will better equip parents to meet the chronic, complex healthcare needs of their preterm infant.

Detailed Description:

Increasing numbers of very preterm infants are surviving and have chronic, complex healthcare needs due to prematurity. These infants experience increased healthcare utilization, long durations of stay in the Neonatal Intensive Care Unit (NICU), and are at high risk of developing prematurity-related complications. As a result, their care is complex, and families need structured training to effectively understand, monitor, and manage their infant's care. PREEMIE PROGRESS is an innovative, video-based intervention that applies evidence-based family management theories to better equip parents to meet the chronic, complex healthcare needs of their preterm infant. This research aims to 1) refine a novel family management program, called PREEMIE PROGRESS, through iterative usability and acceptability testing and 2) test feasibility and acceptability of the refined intervention and study procedures in a pilot randomized controlled trial. This project will use implementation science tools and approaches to refine the intervention and study procedures to ensure that PREEMIE PROGRESS addresses key program elements that will be important for future adoption and implementation in NICU settings. We anticipate that the intervention will decrease parent anxiety and depression, increase infant weight gain and receipt of mother's milk, and reduce neonatal healthcare utilization. The long-term goal of this project is to develop, test, and translate into NICU practice an efficacious family management intervention for parents of preterm infants. Dr. Weber will significantly advance nursing science through this project by obtaining preliminary feasibility and acceptability data for a scalable and sustainable intervention to facilitate family management and improve parent-infant health outcomes.

Study Design

Study Type: Interventional (Clinical Trial)
Primary Purpose: Supportive Care
Intervention Model: Parallel Assignment
Actual Enrollment: 44 Participants
Number of Arms: 2
Masking: Triple (Participant, Care Provider, Outcomes Assessor)
Allocation: Randomized
Enrollment [Actual]: 64 mothers of very preterm infants

Arms and Interventions:

PREEMIE PROGRESS arm: PREEMIE PROGRESS is an innovative, video-based intervention that applies evidence-based family management theories to better equip parents to meet the chronic, complex healthcare needs of their preterm infant. PREEMIE PROGRESS is a video-based training program for parents of preterm infants hospitalized in the neonatal intensive care unit (NICU).

Attention Control arm: To maintain their attention, control parents will view "Welcome Videos" that explain hand hygiene, visitor IDs, parking, etc. on their mobile devices.

Randomization

Using STATA software, the Statistician will generate a random allocation sequence stratified by GA at birth (GA <28 weeks and >28 weeks) to balance representation of the youngest and sickest infants. We will use permuted block randomization for each stratum, with block sizes of 2, 4, and 6 and a 1:1 treatment allocation. The Statistician will upload the sequence into REDCap, have no contact with subjects, and will be independent of all assessment procedures. REDCap's secure randomization feature prevents the study team from viewing the treatment allocation sequence, ensuring allocation concealment. Research assistants will enroll and collect baseline data before randomization. The Principal Investigator (PI) / Clinical Research Coordinator (CRC) will randomize each family after baseline survey completion to minimize dropout effects on randomization.

Eligibility Criteria

Inclusion Criteria:

- •English-speaking parents
- •Parents preterm infants born 25 0/7-31 6/7 weeks gestational age (GA)
- •Parents who had a singleton or twin birth
- •Parents 18 years of age or older

Exclusion Criteria:

- •Mothers too ill (serious maternal complications, medications that impact alertness/ orientation) to provide informed consent
- •Infants with imminent or probable death based on the healthcare team's judgement

Outcome Measures

Measure Title	**Maternal Self-Rating of Depression**
Measure Description	Patient-Reported Outcomes Measurement Information System (PROMIS) 8a Higher scores indicate higher levels of depression: T-score: standardized score mean of 50 and standard deviation (SD) of 10
Time Frame	Assessed at Baseline14 days post-baseline (T2), 28 days post-baseline (T3), and 30 days after infant discharge from the NICU (T4). Change from Baseline to 30 days after infant discharge from the NICU (T4) Reported.
Measure Title	**Maternal Self-Rating of Anxiety**
Measure Description	Patient-Reported Outcomes Measurement Information System (PROMIS) 8a Higher scores indicate higher levels of anxiety: T-score: standardized score mean of 50 and standard deviation (SD) of 10
Time Frame	Assessed at Baseline, 14 days post-baseline (T2), 28 days post-baseline (T3), and 30 days after infant discharge from the NICU (T4). Change from Baseline to 30 days after infant discharge from the NICU (T4) Reported.
Measure Title	**Receipt of Mother's Human Milk**
Measure Description	(exclusive, partial, none).
Time Frame	Assessed at Baseline, 14 days post-baseline (T2), 28 days post-baseline (T3). Reported here is 28 days post-baseline (T3).
Measure Title	**Z Score of Weight Gain at 36 Weeks Corrected Gestational Age**
Measure Description	Z-score method; Z score Δ weight (g), Birthweight (g) - infant weight (g) at 36 weeks corrected gestational age
Time Frame	Calculated for the date that infant is 36 weeks corrected gestational age
Measure Title	**NICU Length of Stay**
Measure Description	Days of NICU hospitalization (calculated from days between date of birth to date of discharge from NICU)
Time Frame	Date of NICU discharge will be assessed until study completion, with maximum of 1 year
Measure Title	**Infant Hospital Readmissions and Emergency Department Visits Within 30 Days of Infant Discharge.**
Measure Description	Coded as Yes/No and extracted from the infant's electronic health record. Mothers were also asked "Did your infant have any re-hospitalizations or emergency department visits within 30 days of discharge?", to ensure all rehospitalizations and ED visits were captured.
Time Frame	Readmissions/ER visits counted within 30 days of discharge will be assessed date of NICU discharge will be assessed until study completion, with maximum of 1 year

Statistical analysis plan

Data Management.

All study data and tracking will be entered into an research electronic data system, REDCap (www.REDCap.org), a secure research electronic data management system with validated data entry, audit trails for tracking data manipulation and export procedures. It is HIPAA complaint satisfying all local, state, and federal regulation for the capture and storage of private health information for research purposes.

Power

We aimed to enroll at least 60 mothers (30 mothers per arm), with planned over recruitment to account for up to 20% loss to follow-up (i.e., 72 infants) during the pilot trial. Because we did not have reliable estimates for the confidence intervals, standard errors, or mean differences for our outcomes a priori, our sample size was based on Whitehead's recommendations to have at least 20 persons per treatment arm in a pilot trial when expecting a small standardized difference (δ=0.2) to achieve at least 80% in the main trial. Because our emphasis was on feasibility, this pilot trial was not powered to detect statistically significant changes in outcome and mediating variables between arms.

Analysis

REDCAP data will be exported to Stata 15 software, where we will analyze sources of missing data and calculate descriptive/summary statistics. We will graph trends for all variables over infant Day of Life (DOL) and CGA, comparing boxplots between arms and over time. We will compute means and 95% CIs for changes from baseline (T1 to T2-4) for each outcome by arm. At each follow-up (T2-4), we will compute mean differences and 95% CI between arms to evaluate trends in outcomes. Mothers with multiple births will have one infant randomly selected for analysis. We will not test for statistically significant differences between groups in outcome measures or estimate effect sizes in this pilot study, because the primary purpose is to determine feasibility of our procedures to inform the planning and design of a larger trial.