Document type: Statistical Analysis Plan

Study title: Development and Pilot Test of an mHealth Interactive Education and Social Support Intervention for Improving Postnatal Health – Phase 2

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STATISTICAL DESIGN AND POWER

The proposed research includes two separate research phases to achieve our research aims: 1) To develop optimal intervention functions and mHealth technology delivery platforms for education and peer support among postnatal women in rural India; and to pilot test the optimized intervention and assess 2) feasibility and acceptability, and 3) preliminary effectiveness on maternal and infant health outcomes. Due to the exploratory nature of these aims, the sample sizes for our two study phases have been designed for feasibility, not for adequate power for statistical testing. After completing the study activities proposed herein, we plan to robustly test the effectiveness of our mobile educational and social support intervention through a larger multi-site R01 study.

Phase 1 (Aim 1). As described within our research strategy, the developmental phase 1 will employ a prototype platform will assess women's preferences for intervention functions, processes and platforms in order to design the most appropriate intervention for full piloting. Data collection during this phase includes capture of back-end data for participation and content, and survey (all participants) and in-depth interview (subset of participants) to understand preferences.

- Backend data: intervention participation, intervention engagement, content of group discussions, content of text messaging.
- Survey: Preferences regarding group components, functions and modalities.
- In-depth interview: Preferences regarding group components, functions and modalities.

Quantitative data will be analyzed for means and proportions using STATA version 15. Text data from discussion/messaging and in-depth interviews will be analyzed for content and themes using Atlas.ti software.

Phase 2 (Aims 2 & 3). Our pilot test of the optimized intervention functions, processes and platforms will use a four-arm controlled factorial between-groups design:

MeSSSSage components to be tested in Phase 2.	Arm 1	Arm 2	Arm 3	Control
Real-time live voice call group meeting: Interactive educational program with scripted didactic component plus discussion/question. Lead and moderated by health professional. **(voice)**	X		X	
Text-based, asynchronous, on-demand social support: App-based small group text-based communication. Moderated by health professional. **(text)**		X	X	
Standard of care: 3 visits in the first 7 days postnatal (facility and home)	X	X	X	X

The following intervention characteristics will be assessed:

Feasibility. To evaluate feasibility of the intervention, we will monitor enrollment rates and moderator effort required (e.g. number of staff hours). An enrollment rate of 70% or higher will be considered feasible, as the established standard in intervention literature. Through moderator report we will confirm effort required for preparation, session delivery, and follow-up. We will also capture any technological challenges. This information will inform staffing needs and retention protocols for a subsequent full trial.

Acceptability. To measure acceptability, we will use a client satisfaction questionnaire which will capture self-reported engagement in intervention components and topics, satisfaction with intervention components, likelihood of participating again, likelihood of recommending program, and value on knowledge and social support gained from participation.

Preliminary effectiveness. To measure effectiveness, we will health-related knowledge (maternal and neonatal danger signs, best practices for infant care, and family planning), health-related behaviors (breastfeeding and complementary food introduction practices (breastfeeding initiation, length of exclusive breastfeeding, length of breastfeeding, timing of complementary food introduction), appropriate management of early childhood

illnesses), and health outcomes (Early childhood immunization, postnatal depression and anxiety, postnatal contraceptive adoption.)

Quantitative analyses: With a between-groups design, each participant will participate in only one arm of the trial, thus we will assess quantitative intervention outcomes by factor (voice and text) through fitting a series of the following linear regression model:

$$y_i = \beta_0 + \beta_1 Z_{1i} + \beta_2 Z_{2i} + \beta_3 Z_{1i} Z_{2i} + \varepsilon_i$$

Where y_i is the outcome for the ith participant, β_0 is the coefficient for the intercept (standard of care), β_1 represents the mean difference in factor 1 (voice), β_2 represents the mean difference in factor 2, (text) β_3 represents the interaction between factor 1 and factor 2 (voice + text), Z_{1i} is the indicator variable for factor 1, Z_{2i} is the indicator variable for factor 2, and ε_i is the residual for the ith participant. Due to the modest sample size, significance testing will be deemphasized and we have not included power analyses for this study.

Hypotheses for preliminary/exploratory analyses on effectiveness. Exploratory hypotheses will be evaluated as part of the study feasibility assessment process. Means and proportions will be plotted by group over time to enable descriptive evaluation of overall patterns of change across time in the outcomes for the intervention and control groups. For example, we expect that following intervention exposure, relative to control group participants, intervention participants will have improved health-related knowledge, health-related behavior, and health outcomes. We also anticipate that intervention participants receiving both voice and text components will have the highest report of the prior outcomes and reported social support, and we will explore differences in these outcomes and in levels of reported social support between the groups as described above.