STATISTICAL ANALYSIS PLAN
Version Number: 1.0

'Fourth Trimester': A Web-based Tool for Postpartum Care to Increase Information Accessibility and Address the Complex Needs of Underserved Women
(P-20167)

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1 INTRODUCTION

This document outlines the detailed statistical methods to be implemented during the analysis of the Phase I Joyuus study data, with the goal of providing the appropriate information to demonstrate the acceptability, usability, feasibility and commercialization potential of the Joyuus mobile web-based tool and informing the design of the Phase II effectiveness study.

2 STUDY OBJECTIVE

We are developing a prototype of a mobile tool to help moms in the postpartum period, or the 3 month period after having a baby. This program will provide tools, resources, and information to help you take care of yourself during this period.

We are conducting a research study to test a prototype version of the tool to see if users like it and think the information is trusted. We also want to know how it can be improved. We will also be learning from you if the tool provides helpful information about self-care, including managing stress, depression, and anxiety.

3 STUDY DESIGN

In order to evaluate the objectives outlined for Phase I of this study, we will conduct a mixed methods Pilot to understand whether:

a) The content is delivered at the appropriate level and depth for the audience;
b) The prototype and planned broader development of the tool provides engaging and helpful approaches to self-care, including managing stress/distress, depression and anxiety related to the postpartum period;
c) We met the developmental aims of the prototype on which to build a larger program (is it clinically accurate, is it user friendly, will they use it; what should be modified).

The Pilot will include pre- and post-tests and will solicit user feedback from 80-90 birthing people. Each participant will be provided access to the product for one month. During this time, they will be asked to complete a pre-test survey at initiation and answer 2 online surveys about their experiences using the tool. They will also complete a post-test after one month of having access to the tool. This will not be a fully functioning site, but a prototype to test the feasibility of the concept that will be fully developed with future funding.

We will alo conduct 75-90 minute individual or group discussions, by telephone or video conference, with a subset of 24-36 participants who have completed the pre-test, to further understand participants' perspectives on the consumer experience, the content and presentation of information, functionality, design and interactivity.

In order to be eligible to participate in this research study, potential participants must be:

- Inclusion Criteria
    - Age 18+;

    - Racial/ethnic minority (at least 75% of participants must be non-white, with at least 50% identifying as Black/African American);
    - Be a new or expectant birthing person – participants must be at least 28 weeks/6 months pregnant (3rd trimester), and up to 1 year post-birth (to allow for those who participated in the Needs Assessment to be eligible for continued participation) (*no more than 50% of participants will be currently pregnant, at least 50% will be postpartum*).
    - Have a smartphone with internet access and are willing to use this device to participate in all study activities.
    - Able to adhere to the terms of the study (available time commitment, have internet access; willing to comply with the specified focus groups and survey); and
    - Able to read, write and speak English (all research and product development activities will be conducted in English due to budgetary constraints).
- Exclusion Criteria
    - Unable to comply with the Inclusion Criteria
    - Did not have a live birth (for those who are post-birth)
    - Self-reported major medical/health issue which would impact participants' health or ability to participate.

4 STUDY OBJECTIVES

4.1 Primary Objective

The primary objective of these analyses is to evaluate the performance of the pilot instruments selected as measures of the five outcome domains (social support, resilience, depression, anxiety, and COVID-19 mental health impacts) in the target population. Pilot instruments chosen for each of the outcome domains are as follows:

- MOS Social Support Survey
- Connor-Davidson Resilience Scale
- Edinburgh Postnatal Depression Scale
- State-Trait Anxiety Inventory (Form Y-2 - Trait Questionnaire Only)
- COVID-19 and Mental Health Impacts

4.2 Secondary Objectives

There are two secondary objectives for these analyses: 1) to summarize the feedback provided on the content and approach of the Joyuus tool, and 2) to evaluate the impact of the product through change in the pilot outcome measures after 1-month of accessing the web tool.

While change in outcomes is not a foremost objective, it is an important element of the feasibility assessment to determine whether this product shows potential in preparation for Phase II at which point we will conduct a full-scale randomized trial to measure effectiveness.

5 ANALYSIS ENDPOINTS

5.1 Primary Endpoint

The primary endpoint of these analyses is the distribution of responses for the pilot instruments selected as outcome measures at baseline and after 1-month of using the web tool.

5.2 Secondary Endpoints

The secondary endpoints for these analyses include:

1. Descriptive summarization of demographic, descriptive, and pilot feedback pre- and post-test questions.
2. Change from baseline to 1-month in summary scores for the pilot instruments included as part of the primary outcome.

6 ANALYSIS SETS, OUTCOME MEASURES, & SAMPLE SIZE DETERMINATION

6.1 Analysis Sets

The Intent-to-treat (ITT) analysis set includes all subjects who consented to participate in the study and participated in the Baseline (Pre-Test) survey.

6.2 Outcome Measures

MOS Social Support Survey (19 items)
(https://cadc.ucsf.edu/sites/g/files/tkssra881/f/Description%20and%20Scoring%20Instructions%20MOS%20Social%20Support%20Survey.pdf)
Summary Score for Overall Social Support and 4 Subscales (Emotional/Informational Support; Tangible Support; Affectionate Support; Positive Social Interaction)

- Pre-Test Q81, Q90, Q91, Q92
- Post-Test Q81, Q90, Q91, Q92

Connor-Davidson Resilience Scale (10 items) (https://www.sralab.org/rehabilitation-measures/connor-davidson-resilience-scale-10-item)
Overall Summary Score

- Pre-Test Q62, Q93
- Post-Test Q62, Q93

Edinburgh Postnatal Depression Scale (10 items)
(https://www.fresno.ucsf.edu/pediatrics/downloads/edinburghscale.pdf)
Overall Summary Score

- Pre-Test Q64, Q65, Q66, Q67, Q68, Q69, Q70, Q71, Q72, Q73
- Post-Test Q64, Q65, Q66, Q67, Q68, Q69, Q70, Q71, Q72, Q73

State-Trait Anxiety Inventory (Form Y-2 - Trait Questionnaire Only) (20 items)
(http://oml.eular.org/sysModules/obxOml/docs/ID_150/State-Trait-Anxiety-Inventory.pdf)

- Pre-Test Q75
- Post-Test Q75

COVID-19 and Mental Health Impacts (12 items)
(https://www.phenxtoolkit.org/protocols/view/960101)

- Pre-Test Q79
- Post-Test Q79

6.3 Sample Size Determination

For the purpose of this Phase I proof-of-concept study, a sample size of 85 participants has been deemed adequate. Actual numbers recruited differed slightly and will be reported.

7.0 Current Status

Analysis, manuscripts and programming are currently ongoing. Additional information is pending to protect proprietary information.