Study title: The Healthy Moms Study: Comparison of a Post-Partum Weight Loss Intervention Delivered Via Facebook or In-Person Groups

NCT 03700736

Statistical Analysis Plan

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Statistical Analysis

We will use Research Electronic Data Capture (REDCap) to administer participant surveys and for participant tracking and data management. We will use SAS 9.4 (SAS Institute, Inc., Cary, NC) to analyze quantitative data. Reporting of the feasibility outcomes and exploratory outcome of weight change will be descriptive (e.g., percent retention at 6 and 12 months).

Primary Outcomes: Feasibility

Examination of feasibility outcomes will inform the design of the subsequent full-scale non-inferiority trial.

Recruitment. We will report recruitment using a CONSORT diagram. We will compare yield from different recruitment approaches, and will examine whether any eligibility criteria are excluding an inordinate proportion of otherwise eligible women. In particular, we will examine the number of otherwise-eligible women excluded from participation because one or the other delivery mode is not feasible or unwillingness to be randomized to either treatment condition. If recruitment rates are lower than expected, we will adjust recruitment timelines as we plan the subsequent non-inferiority trial.

Sustained participation. We will report sustained participation in both conditions. We will modify the delivery of both intervention conditions to address logistical and other barriers to sustained participation.

Contamination. We will report the extent of contamination and reasons women sought these extra sources of support. If a significant proportion of women report seeking weight loss support from other sources, we will adapt our intervention to better meet their needs to reduce the occurrence of contamination in the subsequent trial.

Retention. We will report retention in each condition. If retention is lower than expected, we will explore reasons for drop-out and make changes to the protocol to address these challenges. We will also report the proportion of participants who become pregnant within the study period.

Feasibility of assessment procedures. We will examine the extent and mechanisms of missing data, particularly measures of costs associated with delivering and receiving the intervention. For measures with an unacceptable amount of missingness, we will consider alternate measures in the subsequent non-inferiority trial. We will resolve any issues arising in the collection of data needed for the cost-effectiveness aim of the subsequent efficacy trial and develop procedures for assessing time spent on Facebook to participate in the intervention.

Weight loss (exploratory)

We will report percent weight loss at 6 months and 12 months in each treatment condition.