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Statistical Analysis Plan

Official Title: Korle Bu Teaching Hospital - Global Innovations for Reproductive Health & Life Healthy Birth Weight Study: A Cross-Section

NTC03062228

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Statistical Analysis Plan

1. Designation of Personnel

All analyses described will be performed by the Project Lead and Co-Investigator, Mr. Allan Kember, under the supervision of the consulting statistician, Mr. Michael Butler. The analyses described will be performed using the R statistical software package (version 3.2.0., "Full of Ingredients").

2. Outcome measurements

Primary Outcomes:

- Birth weight
- Customized birth weight centile

Secondary outcomes:

- Gestational Age at Delivery
- Small for Gestational Age
- Low Birth Weight
- Sex of Newborn
- Preterm Delivery
- Mode of Delivery

3. Sample size calculation

A sample size of one-hundred sixty-two (N=162) participants is selected for the KBTH-GIRHL Healthy Birth Weight Study. N=162 is the minimum combined group size for the Ghana PrenaBelt Trial (NTC02379728): n=81 treatments plus n=81 sham-controls. The Ghana PrenaBelt Trial sample size was statistically justified (using power of 0.8 and type I error probability of 0.05 and accounting for 20% lost to follow up) based on a previous study in a Ghanaian population by members of our team (Dr. O'Brien, Dr. Coleman) and using the PS Power and Sample Size Program (Version 3.0).

In order to avoid variance bias in comparison of the non-educated (KBTH-GIRHL Healthy Birth Weight Study) group to the back-sleep educated group (Ghana PrenaBelt Trial), the group sizes should be the same; therefore, one-hundred sixty-two (N=162) participants will be included in this study to match the 162 (minimum) participants in the Ghana PrenaBelt Trial. Since this is a cross-sectional study to recruit a control group only, no participants in this study will be lost to follow up; therefore, 162 participants are required in this study.

4. Treatment randomization

Not applicable. This is a cross-sectional study; therefore, no randomization is performed.

5. Interim safety analysis

Not applicable.

6. Analyses at study termination

Descriptive statistics will be employed for collected demographic, obstetric, and sleep habits information from the Data Collection Questionnaire and outcome measures from the Delivery Outcome Form.

Interpretation of the results from this study will be conducted in conjunction with results from the Ghana PrenaBelt Trial as follows:

- Comparison of groups (back-sleep education, no back-sleep education):
    - For continuous variables, the assumption of normality will be assessed using Q-Q plots and the Anderson-Darling test.
        - If normal, paired t-test will be used for evaluating differences.
        - If non-normal, Wilcoxon signed rank test will be used for evaluating differences.
    - For dichotomous and categorical data, we will evaluate for differences using Chi-squared, Fisher's exact test, or McNemar's test for repeated measurements.
- Note that all analyses will be conducted via the intention-to-treat approach in order to provide unbiased comparisons among treatment groups.

Central quantitative data will be sorted and stored in Microsoft Excel files. Quantitative data analysis will be performed in the R statistical software. We will report the number of participants with missing data.

7. Deviation from outlined statistical plan

All analyses will be performed as outlined above. Any deviation from this plan will only be done so under the guidance of the consulting statistician, Mr. Butler, who will give written justification for the modification from the protocol. A description of the changes and justification for such will be available to regulatory and ethics authorities.

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