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Statistical Analysis Plan

Official Title: Modifying Maternal Sleep Position in the Third Trimester of Pregnancy with Positional Therapy: A Randomized Pilot Trial

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Statistical Analysis Plan

1. Designation of Personnel

All analyses described will be performed by the Project Lead, 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:

- % of time spent in the supine and right-lateral positions with each intervention
- PrenaBelt User Feedback Questionnaires

Secondary outcomes:

- Apnea Hypopnea Index
- Peripheral blood oxygenation (SpO2)
- Maternal heart rate
- Sleep parameters (total sleep time, presence of snoring, RDI, sleep onset latency, sleep efficiency, sleep quality, number of arousals, number of position changes, mean AHI while supine, mean SpO2 while supine)

3. *Sample size calculation*

For a one-sided paired t-test with power (β) of 0.80, significance level (α) of 0.05, n=25 pairs enable a detectable effect (d) of -0.5, which is a medium effect size per the literature regarding Cohen; therefore, a sample size of twenty-five (n=25) pregnant volunteers is selected for this feasibility study.

Assuming an estimated loss of 20% of participants, the study would require a total of 30 patients, with 15 participants in each group.

4. Treatment randomization

A series of 30 unique alphanumeric codes were generated uniformly and checked for duplicates. Subsequently, 30 sleep test order arm labels were produced: 15 PrenaBelt on first night and sham-PrenaBelt on second night, and 15 Sham-PrenaBelt on first night and PrenaBelt on second night. These 30 labels were each iteratively sampled without replacement and assigned to a single alphanumeric label, ensuring that there were exactly 15 alphanumeric labels in the PrenaBelt on first night and sham-PrenaBelt on second night group, and 15 alphanumeric labels in the Sham-PrenaBelt on first night and PrenaBelt on second night group.

5. Interim safety analysis

None planned.

6. Analyses at study termination

Cross-over study design: each participant is her own control for comparison.

Descriptive statistics (mean, median, standard deviation, maximum, minimum, interquartile range) will be employed for collected demographic, sleep habits, and sleep variables information.

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, paired Wilcoxon signed rank test will be used for evaluating differences. For dichotomous data, we will evaluate for differences using chi-squared or Fisher's test. All testing will be done at 0.05 significance level. Cohen's kappa, Spearman's rho, and Bland-Altman will be used to assess agreement between participant's self-reported sleep behaviours and polysomnography-determined sleep behaviours.

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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