PERSONALIZING SLEEP INTERVENTIONS TO PREVENT TYPE 2 DIABETES IN COMMUNITY DWELLING ADULTS WITH PREDIABETES: A PHASE 1 SINGLE-CENTER RANDOMIZED CLINICAL TRIAL OF THE EFFECTS OF IMPROVING SLEEP ON GLYCEMIC CONTROL IN PARTICIPANTS WITH PREDIABETES

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1.1 Statistical Hypotheses

Sleep intervention participants will have a lower percentage of time glucose is ≥ 140mg/dL compared to control intervention participants after 8-weeks of treatment.

1.2 Analysis Datasets

Primary analyses were performed within an intent-to-treat (ITT) sample, including all participants that were randomized to either the Sleep Intervention or Control Intervention.

1.3 Description of Statistical Methods

1.3.1 General Approach

The goal of this single site, parallel arm randomized clinical trial was to assess the impact of improved sleep on glycemic control (percent time glucose is ≥ 140) when compared to habitual sleep. Using descriptive analyses, the investigators described each variable using measures of central tendency (means, medians) and variability (standard deviations) for continuous variables; counts and percentages for categorical variables. Data were evaluated for anomalies (e.g., nonrandom missing data, erroneous outliers, multicollinearity, possible confounding) that may invalidate planned analyses.

1.3.2 Analysis of the Primary Efficacy Endpoint(s)

A multivariable Linear regression model was used to assess the effect of the sleep intervention with the subject specific change in the percent time glucose is ≥ 140 (Time above target) from baseline as the continuous outcome variable and intervention arm (0=Control Intervention [CI], 1=Sleep Intervention [SI]) as a dichotomous predictor. Effect sizes were presented as beta coefficients and associated 95% confidence intervals, equal to the expected difference between the SI and CI. Important covariates that will be controlled for in these analyses include demographic characteristics including age (continuous), sex (female/male), and race (Asian, Black, White, Other). Statistical significance was determined with a p-value < 0.05 using a two-tailed test for significance. Normality was assessed using a skewness cutoff of ±2, following established guidelines.