STATISTICAL ANALYSIS PLAN

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR
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PROTOCOL TITLE
PREMIER: PREvention of Metabolic Illness through prEcision nutRition

FUNDING
Pilot and Feasibility Award program from the Nutrition Obesity Research Center at Harvard (NORCH)

VERSION DATE
04/22/2025

NCT ID number:
2019P002638

STATISTICAL ANALYSIS PLAN

Baseline characteristics will be reported as mean and standard deviation for continuous measures and number and percent for categorical variables. Characteristics will be reported stratified by genetic category (meal 1 and meal 2) and by meal selection (meal 2 only).

The primary exposures are genetic category (meal 1 and meal 2) and meal selection (meal 2). The co-primary outcomes are response profiles of insulin and glucose after meal 1 (0-180 minutes) and meal 2 (240-360 minutes). For each outcome, we will analyze the post-prandial response profile using linear mixed effects models adjusting for age, sex, BMI, three genetic principal components, and time, with a random effect for participant and a genetic category-by-time interaction to assess for between-group differences.

Secondary outcomes will include incremental area under the curve of insulin and glucose after each meal, meal selection, and lipid levels at 240 minutes after the first meal.