

Official Title: The Breakfast Study: A Small Steps, Low-literacy, Breakfast-focused Dietary Self-management Intervention for Adults With Poorly Controlled Type 2 Diabetes

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Statistical methods

Statistical methods for primary and secondary outcomes

A biostatistician will perform all outcome statistical analysis. An intention-to-treat analysis will be performed on all participants. A per-protocol analysis will also be used on participants who had high compliance with the very-low-carbohydrate breakfast intervention. We defined high compliance as breakfasts that have 20% or less of their calories from net carbohydrates.

Descriptive statistics will be computed for all outcome measures. Continuous variables will be reported using means and standard deviations based on the distribution. Categorical variables will be presented using frequencies and percentages.

Aim 1: Assess acceptability and feasibility. For this aim, we will explore how measures of acceptability and feasibility change from baseline to the end of the study using a two-tailed paired t-test for continuous measures and a test of proportions for dichotomous measures. The magnitude and direction of the effect will be reported. Graphical summaries and Q-Q plots will assess the appropriateness of the normality assumption for the t-tests. If normality is not indicated, we will take remedial measures such as transformations or non-parametric analyses.

Power Aim One

For the primary outcome measure of acceptability, we have denoted a mean rating of 4.0 on the 1-6 satisfaction scale our a priori benchmark for acceptability, above the mid-point of the scale, with a meaningful difference of 5.0, one point above. We based our estimate of variance on the satisfaction rating from our most recent two trials of adults using our 16-week program (SD=1.3 and SD=0.7). Our proposed trial has >90% power to detect this level of satisfaction, using the conservative values of 1.3 for the SD, using a two-tailed t-test at an alpha level of 5%.

For feasibility, we will record the mean number of completed sessions (out of 16 possible). We have denoted a 60% attendance of assigned sessions as our a priori benchmark for feasibility. Based on the completion rates from our most recent two trials of adults using our program (mean=73.9%, SD=28.9%; mean=79.3%, SD=32.4%) and using a SD of 30%, this trial has > 85% power to detect this level of completion (vs 60% completion) using a two-tailed t-test at an alpha level of 5%.

Thus, we have at least 85% power for both primary hypotheses of Aim One.

Aim 2: Assess changes in health and psychological outcomes. For continuous health and psychological measures, we will explore the change from baseline to the end of the study for each outcome, using a two-tailed paired t-test, with a significance level of 0.05 and 95% confidence intervals. For the dichotomous variable measuring achievement of glycemic control, we will report descriptive statistics in comparison to other interventions, such as the Diabetes Prevention Program [38].

Interim analyses

There are no planned interim analyses or stopping rules for this trial. All intervention-related serious adverse events will be reviewed by the Data and Safety Monitoring Board to determine if the study should be stopped.

Methods for additional analyses (e.g. subgroup analysis)

We will analyze whether baseline characteristics modify the benefits of the low-carbohydrate breakfast diet on HbA1c. We will explore differences in magnitude of HbA1c changes from baseline to four months later across three pre-defined subgroups: levels of obesity (BMI), levels of insulin resistance, women versus men. Linear mixed models will also be run with moderators of sex, BMI, levels on insulin resistance, and time, clustered on participant ID. These models will be used to estimate change in the outcome within subgroups and differences in change between subgroups over time. The focus of these exploratory analyses will be the magnitude and direction of change within and between subgroups.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

To assess the impact of missing data on our outcomes baseline characteristics of participants will be compared with and without missing data. Primary outcome analyses will use random-intercept-random-slope mixed effects models to approximate changes from the start to the end of the study four months later. If missingness is over 10%, we will employ sensitivity analyses such as multiple imputation, tipping point analyses, and last observation carried forward to ascertain the impact of missing data on the conclusions. Mixed effects models using maximum likelihood estimation allow appropriate assessment of repeated measures despite the effects of missing data.