

Official title: Snacks, Smiles and Taste Preferences

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Document: Statistical Analysis Plan

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*A statistical design and power plan document was not required as part of the clinical trials submission at the date of submission of original funding application. The statistical plan was not sufficiently detailed in IRB Protocol. This document details the power and statistical analyses plan used to analyze the primary outcomes and selected secondary outcomes as specified on clinicaltrials.gov. This plan is also included in the manuscript reporting these results that is under peer review; the document date reflects the date of submission of this manuscript.

Power

Power was estimated based on experimental data from Methven (2012) demonstrating that liking of a “no salt added” soup significantly increased among adults who received 8 days of repeated exposure to either small samples or a bowl of the “no salt added” soup, but did not increase among adults who received 8 days of repeated exposure to higher-salt soup. Using G*Power we determined that the observed average effect size could be detected with a sample of 21 dyads, assuming a type I error rate of 0.05 and 80% power ($\beta = 0.20$). To account for an anticipated 20–25% attrition rate based on prior experience, we specified a minimum of 26 dyads per group.

Statistical Analysis Plan

Descriptive statistics were computed, and continuous variables were tested for normality using the Shapiro-Wilk test. Depending on the outcome, Fisher exact probability tests or one-way analyses of variance (ANOVAs) were used to compare the baseline characteristics of control and intervention groups, as well as demographic characteristics of completers vs. non-completers. Continuous data are presented as mean $\pm$ standard deviation (SD), range, and median [interquartile range (IQR)]; categorical data, as percentages (n/N).

Mixed-effects models were used to evaluate the effect of group (control vs. intervention), conditioned on baseline values and phase of study, on the primary outcomes: added sugar intake (tsp/d) and SSB intake (kcal/d). Analyses of primary dietary outcomes followed the intent-to-treat (ITT) approach: all participants were analyzed in their assigned treatment group regardless of adherence or study

completion. Mixed-effects models used restricted maximum likelihood estimation to account for missing dietary data, assuming missing at random; all other models used complete cases. Each model included group (0=control, 1=treatment), time (baseline, midtrial, end of trial, 1-month follow-up), group $\times$ time interaction, and COVID phase of trial (Phase 1, randomized prior to the COVID-19 pandemic lockdown, Phase 2, randomized following return to human research after the COVID-19 pandemic lockdown). All t-tests for individual coefficient estimates used Satterthwaite's approximation for computing degrees of freedom. All models were fitted using the R package in R version 4.4.0, from which estimated marginal (least-squares) means and 95% confidence intervals (CI) were obtained. For dietary outcomes, we adjusted for multiple comparisons using the Sidak correction for 4 tests per model (45). Dietary outcomes are presented as differences in adjusted group means $\pm$ standard error of the means (SEM) at each time point with 95% confidence intervals (CI).

For primary outcomes of laboratory-based measures of children's liking and intake of selected intervention foods as well as for child taste preferences measures, analyses were limited to complete cases, and for taste preference tasks, to children who demonstrated task comprehension. Generalized linear mixed models with a binomial distribution and logit link function were fitted using maximum likelihood estimation (Laplace approximation) to evaluate children's liking of intervention snacks and two gelatins that differed in sucrose concentration. Models included fixed effects for group, time, and their interaction; fixed-effects estimates and standard errors as well as odds ratios are reported for this analysis. Repeated-measures analyses of variance (ANOVA), with Tukey's honestly significant difference post hoc tests, were used to examine the

effect of treatment, time, and its interaction on *ad libitum* intake of low-sugar snacks and most preferred concentration of sucrose or salt (Statistica version 14.0; TIBCO, Tulsa, OK). COVID phase was included as a covariate, when appropriate. A square-root transformation was applied to taste preference data prior to analysis, although raw values are plotted in the figures.

For anthropometric secondary outcomes, linear regression models, conditioned on baseline and study phase, were used to predict child BMI_z/caregiver BMI at the end of trial with treatment group as the predictor, and baseline child BMI_z or caregiver BMI, and COVID phase as covariates; regression coefficients (β) and 95% CIs are reported for this analysis.