

Multi-level Supermarket Discounts of Fruits and Vegetables' Impact on Intake and Health
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Statistical Analysis Plan

Linear mixed effects modeling was performed to evaluate the group-by-time interaction of all outcomes from the intent-to-treat (ITT) sample, as a primary analysis, and the per-protocol sample, as a secondary analysis. The ITT sample was comprised of participants with at least one post-randomization measurement. The per-protocol sample was comprised of all participants who completed the study. Primary outcome measures were grams (g) of fruit, vegetable, non-caloric beverage intake, and body weight (expressed in kilograms (kg)). Secondary dietary outcomes were high-ED food intake (g), total fat intake (g), and daily energy intake (kcal). Secondary clinical outcomes were BMI (kg/m²), percent body fat, waist circumference (cm), metabolic risk factors (fasting glucose (mg/dL), cholesterol (mg/dL), and blood pressure (mmHg). The linear mixed model included the group-by-time interaction term, where time was the within-subjects factor and group was the between-subjects factor (fixed effects), and the participant as the random effect to obtain the within-person differences in response to the intervention. No covariates were added to the main model because there were no baseline differences in covariates between discount groups and the RCT study design reduces between-group differences (29). First, an omnibus test was performed to test the overall effect of the group-by-time on interaction on the outcome variables. Then, a planned comparison approach using difference-in-difference contrast (DiD) was done to evaluate the differential change in primary outcome variables. The main comparison of interest was the change between groups between the baseline and the first 16 weeks of the intervention (the mid-point of the intervention period), 32 weeks of the intervention (the end of the intervention period), and 16 weeks post-intervention (the end of the follow-up period). A sensitivity analysis was also performed on the ITT sample by adding key covariates to the model: sex, age at enrollment, season at enrollment, primary supermarket, COVID presence, and income level. The presence of COVID was assigned if the COVID-19 pandemic and lockdown period occurred during the intervention between 2/20/20 and 4/6/2021. The absence of COVID-19 was assigned if the COVID-19 pandemic period happened prior to or after the intervention. Income level was a dichotomous variable: above or below the median income in NYC. Estimated means and 95% confidence intervals are shown in tables and figures. Missing data was assumed to be missing at random (MAR). Two-tailed $P < .05$ was considered statistically significant. RStudio (RStudio version 2023.12.0 Build 369) was used to analyze all data.