Cardiometabolic Effects of Pecans as a Snack

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The sample size calculation was based on FMD, the primary outcome. To detect a 1.2 percentage point (standard deviation 2.4; effect size 0.5) between-group difference in the change in FMD with 80% power (α=0.05), it was estimated that a sample size of 128 participants was needed (64 per group) (40-43).

All analyses were performed in SAS (version 9.4; SAS Institute Inc.). All data collected from randomly assigned participants were included in data analyses consistent with intent-to-treat principles. All residuals for regression models were checked for normality via normal probability (Q-Q) plots. When the residuals were non-normally distributed, log transformation was conducted, which improved the residual distribution to approximately normal. Linearity was investigated by plotting model residuals against the outcome of interest and for all variables the assumption of linearity was met. All models were adjusted for outcome baseline value, age (years), sex (male or female) and baseline BMI (kg/m2). For all described tests, effect modification by sex was examined by evaluating the group by sex interaction. If the group by sex interaction main effect was not significant it was excluded from the final model. The primary analyses for the vascular and cardiometabolic outcomes assessed between group (pecan or usual diet) differences in the change from baseline. The change from baseline was calculated by subtracting the endpoint value from the baseline value. Weight, lipids/lipoproteins, glucose and insulin were measured on two test days at each time point and values were averaged for analysis to improve measurement precision. Between-group differences in the change from baseline for all vascular and cardiometabolic outcomes were assessed using linear regression models.

For diet quality, linear mixed models were used to account for the repeated nature of the outcome. Group was included as a fixed effect and time point was included as a repeated effect. Intervention effects were determined by examining the group by visit interaction. When a significant group by time point interaction was detected, post hoc testing was conducted and the Tukey-Kramer method was used to adjust for multiple comparisons. Statistical significance was set at $p < 0.05$.