Supplementary Online Content


eAppendix. Statistical Analysis Plan
eReferences

This supplementary material has been provided by the authors to give readers additional information about their work.
1. **eAppendix. Statistical Analysis Plan**

The primary goals of this trial were to determine if, compared to the control treatment, behavioral and nutritional treatment would lead to (1) greater energy intake, (2) improvement in weight z-score over 6 months, from pre-treatment to post-treatment and (3) improvement over 18 months in height z-score from pre-treatment to follow-up assessment. Pseudomonas aeruginosa status at baseline (detected/not detected), sex, treatment modality (in-person or telehealth), and baseline value of the corresponding outcome variable were included as covariates in the analysis plan.

All analyses were performed on the full intention-to-treat sample (defined a priori as attending the first treatment session). Analyses of WAZ and HAZ change scores were carried out within the PROC GLM procedure (SAS Institute Inc.) using an analysis of covariance model with sex, Pseudomonas aeruginosa status at baseline, treatment modality, and baseline value of the corresponding outcome variable as covariates. Group main effects on these change scores in the presence of covariates were examined to determine the efficacy of the behavioral and nutrition treatment. Some data were missing for energy intake (N = 3 baseline; 13 post treatment; 14 follow-up), and thus the PROC MIXED procedure (SAS) with maximum likelihood estimation was used to analyze this outcome with time as a repeated measures factor, no group main effect at baseline for energy intake, and sex, baseline Pseudomonas aeruginosa status, and treatment modality as covariates in the statistical model. This model is similar to an analysis of covariance model with baseline energy intake included as an additional covariate, but the PROC MIXED model employs maximum likelihood estimation and consequently allows for data to be missing at random. The test of the time by group interaction within this PROC MIXED model indicated whether the behavioral and nutrition treatment was efficacious relative to our control treatment. Finally, we carried out two exploratory (i.e., post hoc) tests from the pre-treatment to the follow-up assessment at 18 months: (a) group differences in change in energy intake, and (b) group differences in change in WAZ. The same analysis approach was used to test both post hoc hypotheses concerning group differences in change as was used for the a priori hypotheses. Within an a priori power analysis, we expected group mean differences between behavioral and nutrition treatment and control of 640 calories, 0.34 z-score units, and 0.47 z-score units for energy intake from baseline to post-test, WAZ from baseline to post-test, and HAZ from baseline to follow-up respectively, corresponding to standardized mean differences of 1.2, 0.7, and 0.9. These respective group differences yielded power of 99%, 86%, and 98% for n=39 per group. We also examined minimum group differences between behavioral and nutrition treatment and control on these respective outcomes that yielded 80% power with n=39 per group and obtained 270 calories, 0.25 z-score units, and 0.27 z-score units.
2. **eReferences**


