A Randomized Controlled Trial Examining the Neurocognitive Benefits of a Nationally Available Weight Management Program

Principal Investigator: Ariana M. Chao, Ph.D., CRNP University of Pennsylvania School of Nursing, Dept. of Biobehavioral Health Sciences University of Pennsylvania School of Medicine, Dept. of Psychiatry 418 Curie Blvd, Room 323 Philadelphia, PA 19104 215-746-7183 arichao@upenn.edu

Co- Investigators: Thomas A. Wadden, Ph.D. Ruben C. Gur, PhD

IRB Number: 834404

ClinicalTrials.gov Number NCT04202133

Study Site: Hospital of the University of Pennsylvania; Center for Weight and Eating Disorders University of Pennsylvania

Date: 01/17/2024

Statistical Analyses

Food Cues

Descriptive statistics summarized baseline and demographic characteristics. Baseline differences in BOLD response between stimuli classes (e.g., food vs. nonfood images and HCF vs. LCF) were examined using paired t-tests. Baseline differences between treatment groups' BOLD responses to image classes were examined using independent-sample t-tests. Statistical significance for baseline differences was $p < .05$ We tested changes in each ROI using general linear mixed models with repeated effects with the time variables (baseline vs. follow-up), group (BWL vs. WLC), and their interaction. Trial contrasts were assessed using the subtraction method (i.e., HCF minus neutral stimuli; LCF minus neutral stimuli). We also performed analyses with the individual stimulus type (i.e., HCF alone, LCF alone). Changes in self-report and behavioral variables were examined using general linear mixed models with repeated effects. We examined differences among groups in brain behavior relationships using correlations between BOLD activation changes in the ROIs and changes in self-report measures. For the primary analyses, p-values were adjusted for multiple testing of the ROIs using the Dubey/Armitage-Parmar Bonferroni method (Sankoh et al., 1997), as implemented in the Simple Interactive Statistical Analysis online calculator (https://www.quantitativeskills.com/sisa/calculations/bonfer.php?; Alpha = 0.05 & N = 08 & Corr = 0.40 & Df = 00). Based on this calculation, primary outcomes' significance level was $p = .01$. Statistical significance was defined as $p = .05$ for secondary exploratory outcomes.

Hippocampal Volume

Baseline and demographic characteristics were summarized by standard descriptive statistics. Neurocognition scores were converted to fully-demographically corrected T-scores. These scores have a mean of 50 and an SD of 10 and compare the score of the test-taker to those in the NIH Toolbox nationally representative normative sample, while adjusting for key demographic variables collected during the NIH Toolbox national norming study. Fully corrected T-scores represent an individual's level of cognitive functioning compared to age-, education-, sex-, and race/ethnicity-matched peers. Higher fully corrected T-scores indicate better performance. We tested change from baseline to follow-up in hippocampal volume and neurocognition using linear mixed models with maximum likelihood. We also explored whether, within the BWL group, baseline or change in hippocampal volume and neurocognition were correlated with percent weight loss. Statistical significance was defined as $p < 0.05$ for all outcomes.