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Pilot Trial of Acceptance-Based Behavioral Weight Loss and Neurocognition Among American Indians

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Abstract

Acceptance-based behavioral therapies (ABTs) for obesity may be superior to standard behavioral therapies but have not been adequately tested with American Indians (AIs). Neurocognitive function is also unexamined in relation to behavioral weight loss among AIs despite findings that neurocognition predicts outcomes in general samples, may help explain some of the benefits of ABTs, and may be relevant to marginalized groups. The primary objective of this pilot was to examine the feasibility/acceptability of ABT in an AI sample. Exploratory analyses examined the relationship between neurocognition and weight loss. Forty-eight AI adults with overweight/obesity (ages 43.3 ± 10.3 years, 85% female; baseline body mass index = 36.8 ± 4.4 kg/m^2) enrolled in a 6-month open ABT weight loss trial. Feasibility indices, including

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The authors declare that there are no conflicts of interest.

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screening/enrollment, session attendance, retention rates for posttreatment assessments, and program acceptability were examined. Percent weight loss (%WL) was assessed as well as fluid and crystalized neurocognition (National Institutes of Health Toolbox Cognition Battery [NIHTB-CB]). We enrolled 79% of the eligible sample and retained 75% ($N = 36$) at posttreatment assessments. Program completers lost an average of 5.2 ± 4.9% of initial body weight ($d_z = 1.14$), whereas intent-to-treat analyses show a mean loss of 4.1 ± 4.7%. Participants reported high satisfaction, effectiveness, and cultural appropriateness. Exploratory analyses of neurocognitive domains suggested that crystalized cognition was higher among completers, and higher baseline cognitive flexibility predicted greater %WL ($\beta = .34$, $p = .05$). ABT resulted in clinically significant weight loss in an AI sample. A controlled trial of ABT in a larger, more diverse sample is warranted to determine whether (a) the findings are robust, generalizable, and/or superior to other treatments and (b) neurocognitive factors moderate outcomes.

Keywords

acceptance-based behavioral weight loss; Native American; weight loss; cognition; obesity

OBESITY, DEFINED AS HAVING A BODY MASS INDEX (BMI) ≥ 30 kg/m^2 (Centers for Disease Control and Prevention [CDC], 2017), is a costly national epidemic that is treatment resistant, increases risk for medical disease and death, and disproportionately impacts ethnic-/racial-minority populations, especially American Indians (AIs; CDC, 2003; Flegal, 2013). An estimated 54% of AI adults live with obesity compared to 34% of non-Hispanic Whites (Levi, Segal, St. Laurent, & Rayburn, 2014). AIs are also at greater risk for type 2 diabetes (Barnes, Adams, & Powell-Griner, 2010). Collectively, these cardiometabolic comorbidities contribute to lower life expectancy among AIs compared to other U.s. ethnic and racial groups (Arias, Xu, & Jim, 2014). The reasons why AIs are disproportionately affected by obesity are complex and involve an understanding of the social determinants of health, including social, economic, and behavioral factors (Anderson, Spicer, & Peercy, 2016). Acknowledgment of these factors can facilitate the development of meaningful interventions to reduce health inequalities, which span generations (Anderson et al., 2016).

To begin, contemporary rates of obesity and related comorbidities in AI populations may be traced back to colonization and historical trauma (Brave Heart, Chase, Elkins, & Altschul, 2011; Edwards & Patchell, 2009; Fleischhacker et al., 2012; Wiedman, 2012). The establishment of settler colonies involved assimilation practices that transformed the social and cultural structures of AI communities and initiated massive group traumatic assaults (e.g., forced relocation, disease pandemics, and cultural prohibitions) with lasting negative health consequences. Forced land removal prevented AIs from engaging in traditional hunting and harvesting in postcolonial times. This loss of sustainable access to traditional foods negatively affected the diet and collective well-being of many AI communities (Compher, 2006; Elliott-Groves, 2018; Kuhnlein & Receveur, 1996; Whyte, 2015). In an effort to address the nutritional challenges faced by AI populations, the U.S. government has implemented food supply programs to AIs living on reservations or in rural communities, including the Food Distribution Program on Indian Reservations (FDPIR; Basiotis, Lino, & Anand, 1999; Food and Nutrition Service, 2018). Implemented by the U.S.

Congress in 1973, the FDPIR provides increased access to foods for low-income or rural AI households (Food and Nutrition Service, 2018). The FDPIR has been criticized for lacking in fresh produce, a fundamental staple to most effective behavioral weight loss therapies (Shanks, Smith, Ahmed, & Hunts, 2016; Story, Neumark-Sztainer, Resnick, & Blum, 1998). Programs like FDPIR also fail to address the psychological or neurocognitive impacts of poor nutrition and historical trauma or ongoing adversity/discrimination on the health of indigenous groups. Thus, effective behavioral therapies for weight loss are still critically needed as many AI communities continue to experience health disparities in obesity and related comorbidities (Arias et al., 2014; Barnes et al., 2010; Indian Health Service, 2014).

Unfortunately, few behavioral therapies have been empirically tested with AI adults with obesity. Notable exceptions are (a) the Special Diabetes Program for Indians Diabetes Prevention (SDPI-DP) demonstration project, one of the largest tests of a behavioral weight loss intervention with cultural adaptations for AIs at risk for diabetes (i.e., 16-session curriculum; $N = 2,553$; Jiang et al., 2013); and (b) the Look AHEAD trial (Wadden et al., 2009), which enrolled 130 AI adults (5.1% of the total $N = 2,570$) into an intensive behavioral/lifestyle intervention arm. Both SDPI-DP and Look AHEAD employed standard behavioral therapies (SBTs) for weight loss. Most SBTs focus on nutritional education, prescriptions for calorie deficits and physical activity, self-monitoring, behavioral strategies, social support, and cognitive restructuring. SBTs generally result in 8–10% weight loss at 12 months for non-Hispanic White participants. AI and other ethnic-/racial-minority group participants tend to lose less weight: AI participant weight loss at 12 months was 2.8% for SDPI-DP and 5.5% for Look AHEAD. Such findings suggest that alternative treatments to SBTs are still needed to enhance weight loss among AIs.

In the last decade, researchers have started comparing SBTs for weight loss to the newer wave of cognitive-behavioral approaches: acceptance-based behavioral treatments (ABTs; Forman & Butryn, 2015). Generally, ABTs differ from SBTs by focusing on commitment to values, tolerating uncomfortable emotional or physiological states to reach these values, and being aware of and defusing thoughts without actively trying to change them (Forman & Butryn, 2015). ABTs have demonstrated superior weight loss compared to SBTs in predominantly non-Hispanic White samples for both short- and long-term follow-ups. Specifically, results from randomized clinical trials show that ABTs produce greater weight loss at both 12-month posttreatment (ABT 13.3% vs. SBT 9.8%) and 24-month follow-up (ABT 7.5% vs. SBT 5.6%; Forman et al., 2013, 2016, 2019). At long-term follow-up (36 months), those in the ABT condition were about twice as likely to maintain 10% weight loss than those in SBT (Forman et al., 2019). While the exact mechanisms that underlie why ABTs outperform SBTs are yet unclear, one potential candidate is the relationship of ABTs with fluid neurocognition (e.g., Manasse et al., 2017).

Fluid neurcognition is conceptualized as a person's reasoning or problem-solving abilities and includes domains related to executive function (EF; e.g., inihibitory control, cognitive flexibility), which is in contrast to crystalized cognition that represents acquired knowledge available in long-term memory (e.g., language). EF is closely linked to self-regulatory abilities and lower EF adversely impacts participants' ability to adhere to behavioral therapies and their treatment targets (Butryn et al., 2019; Galioto et al., 2016; Hall,

Fong, Epp, & Elias, 2008; Manasse et al., 2017; McAuley et al., 2011). As such, poorer performance on EF indices like inhibitory control have been shown to predict poorer weight loss outcomes (Butryn et al., 2019; Galioto et al., 2016; Manasse et al., 2017). Critically, however, ABT techniques appear to attenuate the adverse impact of lower EF on weight loss while SBT strategies do not (Manasse et al., 2017). Specifically, lower inhibitory control predicted less weight loss while assignment to the ABT condition mitigated these adverse effects in a sample of 190 predominantly non-Hispanic White adults with overweight or obesity.

Though the exact mechanisms for this potential "buffering" are still unclear, these findings suggest that ABT may be beneficial especially for groups at risk for greater EF burden, such as AIs and other marginalized populations. AIs experience disproportionately higher rates of discrimination and early life adversity (Kenney & Singh, 2016), as well as obesity (Levi et al., 2014), all of which are associated with relative deficits in fluid neurocognitive indices (Hawkins et al., 2019; Ozier, Taylor, & Murphy, 2019; Yang, Shields, Guo, & Liu, 2018). Specifically, (a) experiencing subtle discrimination has been shown to undermine indices of EF (e.g., inhibition, set shifting, updating) among racial/ethnic minorities (Ozier et al., 2019), (b) a higher number of adverse events in childhood has been linked to poorer performance on measures of executive control and episodic memory (Hawkins et al., 2019), and (c) obesity itself has been linked to poorer EF performance (Yang et al., 2018). Thus, a behavioral weight loss therapy like ABT that may directly or indirectly offset the negative impacts of EF deficits, especially if they may be exacerbated or caused by health disparities, should be tested within AI populations.

Unfortunately, AIs are largely underrepresented not only in ABT weight loss trials but also in research that examines neurocognitive factors and weight loss. The current study addresses these omissions by providing the first open trial to pilot ABT for weight loss as a potential high-impact intervention for AIs and to include standardized neuropsychological testing of fluid and crystalized cognition. The primary aim of the current study was to examine the feasibility of delivering an empirically supported ABT program to an AI sample and the acceptability of ABT within this sample. The secondary, exploratory aim was to examine the role of neurocognitive function in adherence and weight loss outcomes. Our central hypotheses state that delivery of ABT would be feasible, acceptable, and result in successful weight loss (≥ 3–5%) in this pilot sample of AI participants. Importantly, no a priori cultural adaptations were made to the treatment protocol as the intent was to determine how the unmodified, standardized protocol would perform. Though exploratory in nature, we also hypothesized that lower scores on neurocognitive indices of EF would be associated with less weight loss among AIs given previous evidence from samples with limited AI representation.

Method

PARTICIPANTS

Participants were recruited from within or nearby AI-serving health facilities located in northeastern Oklahoma. Targeted mailings, e-mails, or phone calls advertised the Pilot of Weight Reduction in an Underserved Population (POWER-UP) program. From these

recruitment materials, interested individuals were directed to complete an online screener evaluating inclusion/exclusion criteria and ability to engage in physical activity using the Physical Activity Readiness Questionnaire (PARQ+; see description below; Warburton, Jamnik, Bredin, & Gledhill, 2014). Prior to participating, individuals were required to have a PARQ+ score that met the appropriate threshold or a written approval from their medical provider.

Inclusion criteria were (a) self-identified as AI, (b) BMI ≥ 27 kg/m^2 with BMI ≥ 45 needing provider approval, (c) ages 21–65 years at the time of treatment initiation, and (d) English fluency. Exclusion criteria were (a) history of neurological disorder or injury (e.g., dementia, stroke, seizures); (b) major medical condition (e.g., type 1 diabetes, cancer, liver problems) on the PARQ+; (c) history of bariatric surgery or plan to receive surgery in the next 12 months; (d) vision or hearing impairment; (e) current/past severe psychological symptoms (e.g., severe depression or anxiety, substance use, psychosis, mania, or disordered eating) as determined by using recommended clinical cutoffs on the following screeners: Patient Health Questionnaire–9 (PHQ-9; total ≥ 20 or ≥ 2 on item 9; Kroenke & Spitzer, 2002), Generalized Anxiety Disorder Scale (GAD-7; total ≥ 20; Spitzer, Kroenke, Williams, & Löwe, 2006), Alcohol Use Disorders Identification Test (AUDIT; total ≥ 8; Saunders, Aasland, Babor, De la Fuente, & Grant, 1993), Drug Use Disorders Identification Test (DUDIT; total ≥ six men, ≥ two women; Berman, Bergman, Palmstierna, & Schlyter, 2007), Hypomania Checklist (HCL-32; total score ≥ 14), Mini International Neuropsychiatric Interview Psychotic Disorder Module (Sheehan et al., 1998), or Eating Disorder Examination—Questionnaire (EDE-Q; item 16 or 17 ≥ 1; Luce & Crowther, 1999); (f) pregnant, plan to become pregnant in the next 12 months, or currently breastfeeding; (g) enrolled in another weight loss program at the time of treatment; (h) recent significant weight loss (>10% of body weight); and (i) taking medications that are likely to impact weight (e.g., mirtazapine, prednisone). Exclusion criteria were selected because these traits could either compromise the participant's safety while engaging in a weight loss program or inhibit the participant's ability to complete valid neuropsychological testing. The exclusion of persons with hypothyroidism was discontinued given very high base rates in recruitment sample. Given the strong inclusion/exclusion criteria and the modest size of the enrolled sample, it is important to note that this pilot sample is likely not representative of the general demographic distribution of enrolled citizens in this particular tribal nation. It is also important to note that participants did not have to identify as a member of any particular tribal affiliation to participate in this study.

PROCEDURES

This POWER-UP study was a separately funded, open-trial subsample of a larger, ongoing randomized clinical trial entitled "Cognitive and Self-Regulatory Mechanisms of Obesity Study" (COSMOS), which was simultaneously being conducted at Oklahoma State University (OSU) and used a nearly identical protocol. A full description of the methods for COSMOS is available (see ClinicalTrials.gov Identifier: NCT02786238; Hawkins et al., 2018). A clinical research coordinator (CRC) evaluated all individuals who completed the online screener to confirm that they met the inclusion/exclusion study criteria. If criteria were met, the CRC scheduled a 2-hour baseline assessment held at a local community

center or clinic and conducted by OSU assessors. At this session, participants enrolled in POWER-UP by providing written informed consent. All study procedures described in the informed consent document were approved by both the OSU and the Tribal Institutional Review Boards.

After their baseline assessment, participants were assigned to a treatment group and were given an electronic food scale, measuring cups, a calorie-counting reference book, and a binder for treatment handouts. These groups met weekly for 90 minutes over a 6-month period. Within 2 weeks of completing the final treatment session, participants were scheduled for a 2-hour posttreatment assessment where the baseline assessments were repeated. Participants received a $75 reimbursement for each of these assessment visits, totaling $150 if both visits were attended. An overview of the study procedures and assessments timeline is presented in Table 1.

Treatment—The 90-minute treatment sessions were held weekly. These sessions were held in local community or medical centers and were led by a local AI nurse trained in the study behavioral weight loss protocol and supervised by the study principal investigator, who is a clinical psychologist. Interventions were conducted over the course of 23 sessions, and included (a) nutritional education (e.g., recommended servings of various food groups); (b) prescriptions for a balanced-deficit diet (~ 1,200–1,500 kcal/day depending on weight) and for physical activity (i.e., gradual increase to 200 min/week of brisk walking or the equivalent by Week 23); (c) expectations for daily self-monitoring of calorie intake and activity; (d) stimulus control, behavior shaping, behavior analysis, and relapse prevention strategies; and (e) social support.

Acceptance-Based Behavioral Treatment for Weight Loss—The ABT program is adapted from the manualized protocol empirically tested and found to be effective for a predominately non-Hispanic White, urban sample in the “Mind Your Health” trials (Forman et al., 2013, 2016). It contains all of the features listed above, as well as unique ABT training designed to help individuals increase awareness of their perceptual, cognitive, and affective experiences, and the following exercises: (a) identifying weight-related goals from personal life values (e.g., health) and connecting these values to day-to-day eating; (b) increasing awareness of moment-by-moment behavior choices; and (c) tolerating aversive internal states that include eating-related states as well as affective states, such as stress, sadness, and anxiety (i.e., “urge surfing”). Brief descriptions of session content for this standardized protocol are available in Table 2. More details about these techniques can be found in the published treatment manual (Forman & Butryn, 2016).

MEASURES

Feasibility and Acceptability—To assess the feasibility/acceptability of the program, data were collected on screening, enrollment, session attendance, and retention rates for posttreatment assessments. First, we assessed the number of participants who (a) completed the online screening survey, (b) were eligible, and (c) enrolled in the program. Next, we tracked how many of the 23 treatment sessions participants attended. For retention in the treatment research program, we examined the number of participants who attended

our posttreatment assessment. These individuals showed willingness and availability to provide posttreatment research data, which was important for our findings to inform future, larger-scale treatment research programs. Program acceptability was examined by asking participants to rate POWER-UP on a 1 (*lowest*) to 5 (*highest*) rating scale on (a) how effective it was, (b) how helpful it was, (c) how satisfied they were, and (d) how culturally appropriate it was. Participants were also asked whether they would be interested in participating in future research opportunities.

Weight Loss—The primary outcome was percent weight loss (% WL) from baseline to posttreatment calculated using total weight (kg). We also measured changes in weight, percentage body fat (BF%), waist-to-hip ratio (WHR), waist circumference (WC; cm), and BMI (kg/m^2) from baseline to posttreatment. Measurements of body weight and BF% were assessed using a bioelectrical impedance device (Model TBF 310GS; Tanita Corporation: Arlington Heights, Illinois) and were measured to the nearest 0.1 kg. Participants were weighed wearing casual clothing and without shoes. Waist and hip circumferences were measured using a measuring tape placed per protocols from the World Health Organization (2011).

Cognitive Function—Participants completed a comprehensive, computerized neuropsychological battery, the NIHTB-CB, which measures attention, executive functioning, memory, processing speed, and language (Weintraub et al., 2013). The NIHTB-CB was administered at baseline and posttreatment. This battery was created by the NIH for participants ages 3–85 and was chosen because it is time-efficient (administration ~30 minutes), ensures generalizability of the trial results across existing NIHTB-CB studies, and allows for the examination of longitudinal measurement of change in cognitive indices in relation to the ABT interventions. The specific tests in the battery are Flanker Inhibitory Control and Attention, Dimensional Change Card Sort, List Sorting, Picture Sequence Memory, Pattern Comparison Processing, Picture Vocabulary, and Oral Reading Recognition. All tests in the battery have been validated and normed for use in the age ranges included in the POWER-UP trial (Weintraub et al., 2013).

SECONDARY MEASURES

Though not primary to the study objectives (feasibility/acceptability, weight loss, and neurocognitive assessment), secondary measures were included in the pilot and provide useful information. Each of these measures is categorized and described below.

Biomarkers—A trained research assistant acquired five seated blood pressure readings at 2-min intervals, per the guidelines from the American Heart Association (Pickering et al., 2005). A standard sphygmomanometer was used to measure blood pressure at baseline and posttreatment. Systolic (SBP) and diastolic (DBP) values were computed as the average of the last three readings. Fasting glucose was obtained using a self-monitoring blood glucose system (McKesson TRUE METRIX® Meter Kit) provided to participants for use in their home.

Self-Regulation Indices—Participants completed a self-report questionnaire and two behavioral tasks assessing the ability to persist at and to refrain from certain behaviors. Participants completed the Brief Self-Control Scale (Tangney, Baumeister, & Boone, 2004); a 10-item self-report questionnaire assessing trait-level self-control and the ability to override an inner urge and refrain from acting on it. It is scored from 1 (*not at all like me*) to 5 (*very much like me*) and has demonstrated high internal consistency, test–retest reliability, and construct validity (Tangney et al., 2004). Two behavioral indices of self-regulation were also used. The first behavioral task was the Handgrip Strength Test (Muraven, Tice, & Baumeister, 1998) in which participants were timed while gripping a dynamometer. The second behavioral task was an unsolvable puzzle, in which participants were timed while attempting to solve a puzzle that has no solution (McFarlin, Baumeister, & Blascovich, 1984). Longer times (i.e., in seconds) on both tasks are associated with greater persistence.

Demographic, History, and Psychosocial Factors—Participants completed baseline self-report questionnaires on a computer that assessed the following factors: (a) demographics: age (years); gender; race-ethnicity (i.e., American Indian/Native American/Alaskan Native, White, African American, Asian/Pacific Islander, Hispanic/Latino); education level (i.e., middle school, high school, some college, associate's, bachelor's, graduate or professional); (b) Weight and Lifestyle Inventory (Wadden & Foster, 2006); and (c) psychosocial, including Adverse Childhood Experiences Survey (Felitti et al., 1998), Beck Depression Inventory–II (BDI-II; Beck, Steer, & Brown, 1996), Emotional Eating Questionnaire Revised (Koball, Meers, Storfer-Isser, Domoff, & Musher-Eizenman, 2012), Philadelphia Mindfulness Scale (PFS; Cardaciotto, Herbert, Forman, Moitra, & Farrow, 2008), and the Power of Food Scale (Lowe et al., 2009).

DATA REDUCTION/ANALYSIS AND MISSING DATA HANDLING

All data were checked for coding errors and outliers. Descriptive statistics were used to assess participant enrollment, eligibility, session attendance, and posttreatment assessment retention rates, as well as their ratings of program acceptability. To help characterize the sample, we categorically defined individuals who attended the posttreatment session as completers and those who did not attend the posttreatment assessment as noncompleters. Thus, the term "completer" in this study does not reflect treatment session attendance but whether a participant had complete, nonmissing posttreatment data. This decision was based on a preference to keep our examination of treatment effect estimates conservative and more likely representative of how ABT would perform in this population. We compared completer and noncompleter groups on all relevant variables using independent samples *t* tests or χ^2 tests. In order to directly address missing weight loss data, we employed two approaches: last observation carried forward (LOCF) and multiple imputation (MI). For LOCF weight loss analyses, we took the last observed weight of noncompleters and carried it forward as their posttreatment weight, thus assuming that they remained the same weight as the last session attended and allowing us to analyze all individuals in the study. Given that LOCF analyses may produce biased estimates compared to MI (Elobeid et al., 2009), we also reran our weight loss analyses using PROC MI in SAS with the Markov Chain Monte Carlo (MCMC) algorithm. The imputation model included all the raw variables used in the current study (i.e., no LOCF). Sixty separate data sets were imputed with the

number of burn-in imputation iterations set to 200. Bivariate correlations and multiple linear regression analyses were conducted to examine the relationship between baseline cognitive variables and weight loss. These primary analyses were conducted on all 60 imputed data sets using PROC MIANALYZE, and the statistics from the correlations and regressions were automatically pooled. Paired samples *t* tests were also used to compare participants' baseline scores to their posttreatment scores across all study variables utilizing PROC MIANALYZE to generate pooled mean difference and *t* test estimates.

Results

PARTICIPANTS

Enrolled participants were 48 AI adults with overweight/obesity who were predominantly middle-age, nondepressed, and female with some college or higher education (see Table 3). Participants' self-reported tribal affiliations represented five different federally recognized tribes, most of which are consistent with tribal representation in Oklahoma (e.g., Cherokee, Choctaw). Specific tribal information will remain anonymous to protect the tribal anonymity of participants (Norton & Manson, 1996), given the modest sample size and geographic location of the study. Average BMI at baseline was in the class II obesity range (BMI between 35.0 and 39.9). At the group level, participants' cognitive scores were within normal limits and in line with normative data from general samples. Individuals who completed the posttreatment assessment started with a significantly higher weight at baseline than the noncompleters group, and completers had significantly higher baseline scores on the cognitive tests of vocabulary and reading (i.e., crystalized cognition) than the noncompleters group (see Table 4). Participants' glucose scores were in the "prediabetes" range at baseline, whereas blood pressure was normotensive.

Feasibility and Acceptability—Evidence of feasibility includes program enrollment and retention rates and ratings of acceptability. Over 150 participants completed the screener for the study (see Figure 1). Of note, because this program was a pilot with limited enrollment space, recruitment efforts ceased after the number of participants who initiated the screener exceeded 175, so the number of completed screeners may be lower than was possible. Given stringent inclusion/exclusion criteria, 61 participants of the 150 with screener data were contacted as eligible to participate. Of these, 48 total participants enrolled, and 36 (75%) completed the posttreatment sessions. Importantly, the majority of participants (7 of 12, 58%) who discontinued the program cited work, family, or health conflicts as reasons for discontinuing, and not program dissatisfaction. Relatedly, program acceptability was explicitly assessed on a 5-point rating scale (1 = *lowest*, 5 = *highest*) for all participants who completed the posttreatment session. These participants exhibited high satisfaction with the program ($M = 4.7 \pm 0.6$, 97.2% reported a 4 or 5 on this scale) and high program helpfulness ($M = 4.6 \pm 0.7$, 91.6% reported a 4 or 5) ratings. Participants also noted high levels of program effectiveness ($M = 4.2 \pm 0.8$, 83.3% reported a 4 or 5) and cultural appropriateness ($M = 4.5 \pm 0.7$, 86.1% reported a 4 or 5). The majority of participants (88.9%) said they would be interested in hearing about future research opportunities. Overall, 60.4% of enrolled participants attended ≥12 or more of the total 23 sessions, whereas 72.9% attended

≥11 sessions. These rates suggest that the majority of participants attended at least ~50% of sessions with the average attendance at 13.0 ± 6.2 sessions.

Weight Loss—Session attendance was highly correlated with %WL (r = .63, p < .001). Of the participants who completed the posttreatment assessment (n = 36), those with ≥50% treatment attendance (n = 27) lost 6.4 ± 5.0% compared to 1.9 ± 2.0% for those with <50% attendance (n = 9), $t(34)$ = 3.8, p = .001. For individuals with ≥80% attendance, %WL was 8.9 ± 4.3%. Completers had higher attendance (M = 15.1 ± 4.8 sessions) than noncompleters (M = 6.9 ± 5.6 sessions) and lost an average of 5.2 ± 4.9% (range from 3.5% gain to 17.2% loss; $t(35)$ = 6.3, p < .001, $d_{adjusted}$ = 1.14). For completers, 38.9% achieved 5% or greater weight loss, and 19.4% achieved 10% or greater weight loss. Intent-to-treat analyses with LOCF for all participants showed a mean loss of 4.1 ± 4.7%; $t(47)$ = 5.8, p < .001, $d_{adjusted}$ = 1.05. When examining change in weight, BF%, WHR, WC, and BMI using MI, all adiposity variables except BF% still significantly decreased with strong effect sizes for weight, WC, and BMI (d_z = 0.46–0.82; see Table 3). BF% and WHR exhibited smaller effect magnitudes (d_z = 0.24–0.29). All of the effect size estimates generated using MI were more modest than those reported for completer or LOCF analyses (see Table 3), but all suggest meaningful reductions in adiposity.

Cognitive Function—Bivariate correlations of the baseline neurocognitive indices with %WL showed that inhibitory control (r = .19), processing speed (r = .20), and cognitive flexibility (r = .45) had small-to-moderately sized positive effect sizes. In contrast, episodic (r = −.16) and working memory (r = −.20) as well as vocabulary (r = −.14) showed small negative effect sizes. Reading showed little to no effect (r = .03). The only correlation to reach statistical significance was for cognitive flexibility, so we followed up with a multiple linear regression analyses controlling for age, gender, education level, and baseline BMI to determine whether the effect was robust. Cognitive flexibility remained a significant predictor of %WL for completers (β = .47, SE = 0.08, p = .021). When regressions were run using MI in the total sample to reduce bias in parameter estimates, the pooled coefficient generated was β = .34, SE = 0.17, p = .056. Of the cognitive domains that changed from baseline to posttreatment, processing speed, $t(47)$ = 2.02, p < .001, and inhibitory control, $t(47)$ = 3.39, p < .001, increased over time (see Table 3).

Change in Secondary Factors—Significant reductions from baseline to posttreatment were found for (a) resting heart rate (2.42 bpm decrease), (b) depressive symptoms (BDI-II; 5.81-point decrease), (c) emotional eating (EES; 8.63-point decrease), (d) food susceptibility (PFS; 12.58-point decrease), and (e) self-control (11.45-point decrease) with a nonsignificant trend toward lower DBP (2.41 mmHg decrease; see Table 3).

Discussion

This trial was the first to attempt to deliver an empirically supported ABT weight loss program with neurocognitive testing to an AI sample with overweight/obesity within a tribal community. Results suggest that delivering this treatment in collaboration with a university research team and a supervised, local AI intervention leader was both feasible and acceptable. A full 75% of participants completed the 6-month, 1.5 hour/week treatment

as well as the baseline and posttreatment assessments, which were each 2 hours in length and included a neuropsychological test battery. Despite high participant burden, the large majority of participants reported a high level of program satisfaction. Nearly 90% of participants who completed the program indicated that they would be interested in hearing about future research participation opportunities. This positive response suggests a willingness to continue participation in treatment research, which is an essential element in building trust and effective collaboration between researchers and underserved tribal communities. Last, most participants also indicated that the program was not only culturally appropriate but also helpful and effective.

Participants' self-reports of program effectiveness are in line with the observed weight loss. Specifically, completers lost 5.2% of initial body weight, a clinically significant amount, over the 6-month treatment period. Using intent-to-treat analyses, the average weight loss fell to 4.1%, but this value is still within the 3–5% range for clinical significance (Jensen et al., 2014; Williamson, Bray, & Ryan, 2015). While these values may provide reasonable estimates of ABT effects in the larger AI population, they may underestimate outcomes for subgroups with high adherence to treatment sessions, as participants in our sample who attended at least 50 or 80% of sessions lost 6.4 and 8.9%, respectively. This pattern of significant reductions in weight, BMI, and central adiposity remained when utilizing multiple imputation for missing data. We also observed meaningful reductions in resting heart rate and DBP, suggesting cardiovascular benefits of the program. Reductions in depressive, emotional eating, and food susceptibility symptoms were also found, indicating positive psychological benefits. Overall, our findings are consistent with literature suggesting that behavioral weight loss therapies produce a clinically meaningful weight loss of 5–9% on average during the first 6 months of intervention as well as physiological and psychological advantages.

Importantly, our participants showed smaller weight losses than those reported for the ABT arm of the Mind Your Health randomized controlled trial (Forman et al., 2016). Mind Your Health participants exhibited 12.9% weight loss at 6 months. However, findings from the Mind Your Health trial may not generalize to tribal, rural, or other marginalized groups/settings, given that the racial composition of the sample was predominantly White, the setting was urban, and the treatment team was more experienced. Unfortunately, the lack of AI representation is not unique to the Mind Your Health trial (Forman & Butryn, 2016), as many large behavioral weight loss trials for adults do not recruit, enroll, and/or retain AI participants (Nierkens et al., 2013)—with the SDPI-DP and Look AHEAD trials as key exceptions (Jiang et al., 2013; Wadden et al., 2009). Our participants' weight loss is comparable with outcomes in these trials. SDPI-DP program participants exhibited an average weight loss of 4.4% initial body weight at 4–6 months, a value nearly equivalent with our intent-to-treat results. Look AHEAD showed that AI women lost 4.8% and AI men lost 6.9% of initial weight at 1-year follow-up (Wadden et al., 2009). Combined, 18.8% of Look AHEAD AI participants had lost ≥10% at 1 year. This finding is similar to the result that 19.4% of our completers lost ≥10% at 6-month posttreatment—however, we cannot directly compare our results because the 6-month weight loss values for Look AHEAD are not currently published.

Other multisite weight loss trials and systematic reviews have also shown that participants from other minority groups (typically African Americans) lose significantly less weight compared to non-Hispanic Whites (Fitzgibbon et al., 2012; Kumanyika et al., 2002; Wing et al., 2004; Wing & Anglin, 1996). Thus, our findings are consistent with the notion that existing programs can generate clinically meaningful weight losses of ≥3–5% and corresponding cardiovascular health benefits among minority groups—however, these interventions could be further enhanced by including cultural or biopsychosocial adaptations to promote greater treatment engagement, session attendance, and weight loss among AI participants. Many tribal community-directed programs have received grants to set their own cardiometabolic health priorities, such as the SDPI-DP and Health Heart. Additional suggestions include tailoring healthy food messaging and informing comprehensive healthy retail interventions (e.g., THRIVE Study) for food purchasing and family meal planning decisions, which may serve as an upstream approach to improve access to healthy eating for communities and families rather than the individual (Wetherill et al., 2018). Other potential ideas for tailoring that arose directly from this study and its participants' feedback included (a) measures of outcomes or progress that are not just weight- or scale related, such as fitness or quality of life; (b) having a dietitian to teach how to modify native foods to be more nutritious; (c) an interest in learning about and comparing different types of foods and traditions, food sources, and food suppliers across various tribes; and (d) making a stronger connection between ABT and its utility in addressing historical trauma.

Other exploratory results of our pilot study that deserve discussion are the findings that fluid neurocognitive factors may play a role in weight loss success. First, we found that better cognitive flexibility (a fluid indicator of EF) predicted greater weight loss among our participants, a finding consistent with previous research in general samples (Butryn et al., 2019; Galioto et al., 2016; Manasse et al., 2017). Post hoc testing showed that participants with *relatively* lower cognitive flexibility (z score ≤−0.5) lost 3.8% of their initial weight, whereas participants with higher flexibility (z score ≥0.5) lost 8.3%. It is essential to note that those with relatively lower scores did not have cognitive impairment on average (i.e., T scores of 40–60 are within normal limits of cognitive functioning, and this group average was $M = 39.9 \pm 4.5$). With regard to crystalized cognition, vocabulary and reading scores were higher for completers compared to those who did not complete the program, suggesting a possible link between these scores and program adherence or engagement. Inhibitory control and processing speed were the only cognitive variables to show statistically significant increases from baseline to posttreatment though these changes could be related to practice effects and should not be overinterpreted.

Indeed, given the pilot nature of this study, the aforementioned relationship between neurocognitive factors and weight loss should not be over-interpreted and should not be ascribed as specific to AI samples—however, they do provide important hypothesis-generating information and are consistent with previous literature linking low EF to poorer weight loss. For instance, it is theoretically sound to assume that neurocognitive flexibility (i.e., the ability to switch between mental processes to generate adaptive behaviors; Dajani & Uddin, 2015) has a clear impact on a person's ability to consistently choose healthful, nutritious foods over highly processed, calorie-dense options, as well as to problem-solve ways to increase physical activity in environments that regularly encourage sedentary

behavior. Likewise, it is possible that lower crystalized cognition could be associated with a reduced enthusiasm to join a program that requested repeated cognitive testing or reduced engagement or attendance at sessions that included extensive health education components involving reading and writing. Last, one would expect that increases in inhibitory control might follow training in a weight loss intervention, as participants consistently practice inhibiting the consumption of certain types or quantities of foods and the desire to engage in sedentary behavior—however, practice effects are a likely alternative explanation. These speculations should be tested in larger trials powered to detect effects between neurocognitive function and weight loss in both AI and non-AI samples, as well to identify the risks for neurocognitive deficits that may be modifiable (e.g., discrimination, early life adversity).

While this study has a number of strengths, several limitations should be noted and addressed in future studies. First, as an open pilot, the trial lacked a control arm. Thus, while results suggest that ABT produces weight loss at posttreatment, it is unclear whether this rate or degree of weight loss would be superior to treatment as usual or to standard behavioral treatment. Next, the length of treatment (i.e., 6 months) was shorter than the typical 12-month intervention and also precludes investigation of weight loss maintenance. Next, our recruitment of men was low—thus, our results may be more applicable to female AIs from our recruitment region. There are currently 573 federally recognized AI tribes in the United States (Bureau of Indian Affairs, 2019). Given our modest AI sample, results should not be assumed to generalize to different tribes or even within all members of a single tribe. Relatedly, although the NIHTB-CB used national standardization, the initial validation sample of this computerized cognitive battery categorized participants' race/ethnicity into White, Black, or Hispanic/other/multiple categories, which means that the normative performance for AI participants is unclear. The lack of culturally nuanced and appropriate norms may be problematic given that demographic and sociocultural factors (e.g., education, socioeconomic status, language, acculturation) may impact neuropsychological test performance (Verney, Bennett, & Hamilton, 2016).

In summary, delivering a 6-month ABT weight loss intervention to a tribal sample was feasible. AI participants found the program to be acceptable and effective. Objective weight loss indicators suggest that the program generated clinically meaningful weight loss, and several neurocognitive factors were identified as variables that may be important to consider in successful weight loss. A randomized, controlled test of ABT in a well-powered, more diverse AI sample with a longer follow-up period is still needed to determine whether ABT is superior to standard treatments and whether neurocognitive factors are critical for successful weight loss or weight loss maintenance among AIs.

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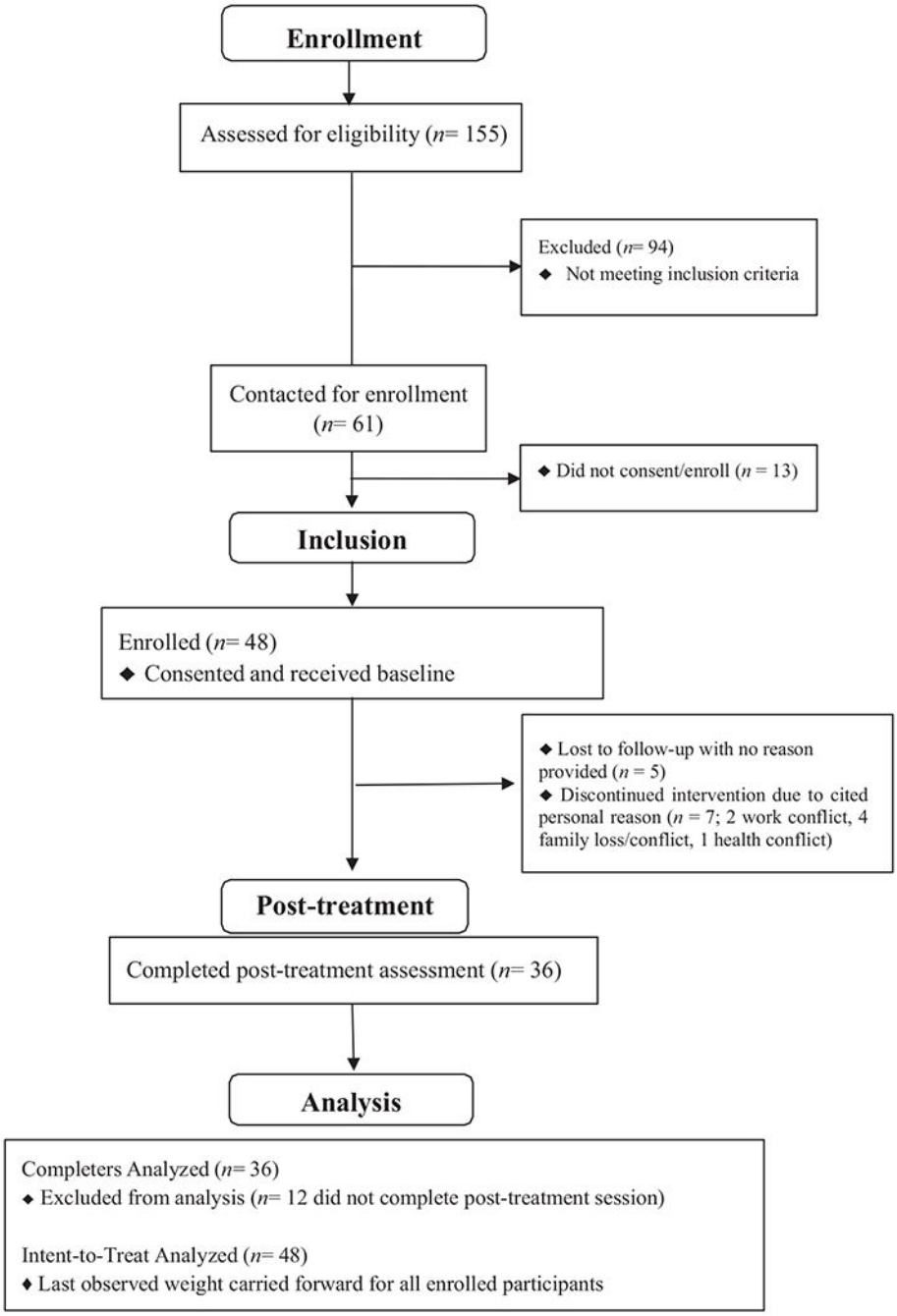

FIGURE 1.

POWER-UP open trial participant flow following the Consolidated Standards of Reporting Trials Guidelines (CONSORT).

Table 1

Timing of Assessments

Variable category	Baseline Time 0	Posttreatment Time 1
Demographics and history		
Age, gender, ACES, education	•	–
Psychosocial factors		
BDI-II, EES, PHMS, PFS	•	•
Biomarkers and obesity indicators		
Fasting glucose	•	–
Blood pressure		
SBP	•	•
DBP	•	•
Heart rate	•	•
Weight (kg)	•	•
Height (cm)	•	•
Fat mass (kg)	•	•
Body fat % (BF%)	•	•
Waist-to-hip ratio (cm)	•	•
Cognitive function		
NIH Toolbox Cognition Battery (NIHTB-CB)	•	•
Self-regulation		
Brief Self-Control Scale	•	•
Handgrip strength (seconds)	•	•
Unsolvable puzzle (seconds)	•	–

Note. ACES = Adverse Childhood Experience Survey; BDI-II = Beck Depression Inventory–II; EES = Emotional Eating Scale; PHMS = Philadelphia Mindfulness Survey; PFS = Power of Food Scale; SBP = systolic blood pressure; DBP = diastolic blood pressure.

Table 2

Intervention Schedule and Topics

Session	Topic
1	Welcome to program; setting initial calorie goals
2	Beginning to tip the calorie balance
3	Goal setting; weighing/measuring portions
4	Nutrition labels; meal planning; calorie accounting
5	Control what you can, accept what you can't
6	Home environment; willingness (Part I)
7	Move those muscles; willingness (Part II)
8	Restaurant eating; flexibility
9	Handling weekends/holidays; pattern smashing
10	Introduction to values; social support
11	Barriers to living a valued life
12	Introduction to defusion; portion sizes
13	Strategies to help defuse and increase willingness
14	Urge surfing; review healthy diet
15	Mindful decision making
16	Maintaining loss over the long term
17	Being active; physical activity-focused willingness
18	Committed action
19	Emotional eating
20	Lapse versus relapse; reversing small weight gains
21	Revisiting commitment
22	Maintaining motivation
23	Looking ahead; celebrating accomplishments

Note. These sessions are from the Mind Your Health program protocol draft (Forman et al., 2016); published manual also available (Forman & Butryn, 2016).

Table 3

Participant Characteristics at Baseline and Posttreatment ($N = 48$)[a]

	Baseline	Posttreatment	Mean	*t*	*p*	Effect size *d*
	***M* (*SE*) or *N* (%)**	***M* (*SE*) or *N* (%)**	**difference (*SE*)**			
Demographics and history						
Age	43.58 (1.50)	•	•	•	•	•
Gender (female)	41 (85.4)	•	•	•	•	•
ACES	2.22 (.36)	•	•	•	•	•
Education level						
High school	14 (29.2)	•	•	•	•	•
Some college	14 (29.2)	•	•	•	•	•
Associate's degree	8 (17.0)	•	•	•	•	•
Bachelor's degree or higher	11 (22.9)	•	•	•	•	•
Psychosocial factors						
BDI-II—Depressive symptoms	12.32 (1.61)	6.52 (1.23)	−5.81 (1.51)	3.85	.000 **	0.56
EES—Emotional eating	26.45 (3.91)	17.81 (2.54)	−8.63 (3.91)	2.21	.027 *	0.32
PHMS—Mindfulness	66.53 (1.57)	66.82 (1.48)	.29 (1.42)	0.21	.835	0.03
PFS—Food susceptibility	53.6 (3.51)	41.02 (2.50)	−12.58 (3.25)	3.88	.000 **	0.56
Biomarkers and obesity indicators						
Fasting glucose	104.07 (25.70)	•	•	•	•	•
Blood pressure						
SBP (mm Hg)	116.19 (1.87)	116.0 (2.28)	−0.19 (1.59)	0.12	.903	0.01
DBP (mm Hg)	77.44 (1.34)	75.02 (1.51)	−2.42 (1.27)	1.91	.057	0.28
Heart rate (beats/min)	73.99 (1.51)	68.61 (1.61)	−5.38 (1.57)	3.43	.001 **	0.49
Weight (kg)	101.96 (2.09)	94.24 (2.28)	−5.14 (.90)	5.70	.000 **	0.82
Body fat percentage (BF%)	44.36 (.92)	43.11 (.93)	−1.24 (.76)	1.63	.104	0.24
Waist-to-hip ratio	0.88 (.01)	0.86 (.01)	−.02 (.01)	2.33	.020 *	0.29
Waist circumference (cm)	107.65 (1.50)	93.76 (4.00)	−13.89 (4.36)	3.19	.002 **	0.46
BMI (kg/m^2)	36.83 (.63)	34.86 (.74)	−1.98 (.53)	3.73	.000 **	0.54
Cognitive factors (NIHTB-CB)						

	Baseline	Posttreatment	Mean	*t*	*p*	Effect size *d*
	***M* (*SE*) or *N* (%)**	***M* (*SE*) or *N* (%)**	**difference (*SE*)**			
Vocabulary	54.23 (1.33)	56.06 (1.65)	1.83 (1.22)	1.50	.134	0.23
Reading	52.10 (1.31)	53.87 (1.20)	1.78 (1.03)	1.72	.086	0.25
Processing speed	55.26 (1.91)	59.02 (2.11)	3.76 (1.86)	2.02	.045 *	0.29
Episodic memory	56.83 (1.49)	57.82 (1.73)	.99 (1.83)	0.54	.589	0.08
Working memory	53.13 (1.29)	52.45 (1.57)	−.68 (1.49)	0.45	.651	0.06
Cognitive flexibility	51.24 (1.59)	53.62 (1.67)	2.37 (1.85)	1.28	.200	0.18
Inhibitory control/attention	42.31 (1.03)	45.80 (1.11)	3.49 (1.03)	3.39	.001 **	0.49
Self-regulation factors						
Brief Self-Control Scale	36.37 (.80)	24.92 (1.04)	−11.45 (1.37)	8.34	.000 **	1.21
Handgrip strength (seconds)	19.61 (2.89)	20.80 (2.69)	1.18 (2.98)	0.40	.691	0.06
Unsolvable puzzle (seconds)	727.59 (366.76)	•	•	•	•	•

Note. *M* = mean; *SE* = standard error; ACES = Adverse Childhood Experience Survey; BDI-II = Beck Depression Inventory-II; EES = Emotional Eating Scale; PHMS = Philadelphia Mindfulness Survey; PFS = Power of Food Scale; SBP = systolic blood pressure; DBP = diastolic blood pressure; BMI = body mass index; NIHTB-CB = NIH Toolbox Cognition Battery.

[a]Presented values were generated using multiple imputation, which utilizes all observed values in the data set to produce multiply imputed estimates for all 48 participants at baseline and posttreatment.

*$p \leq .01$.

**$p \leq .05$.

Table 4

Baseline Differences in Completer Versus Noncompleter Groups

Baseline variable	Group		*p*
	Completer (max *N* = 36) *M* (*SD*)	Noncompleter (max *N* = 12) *M* (*SD*)	
Demographic and history			
Age	43.92 (9.74)	42.58 (12.52)	.704
Gender (female)	32 (88.9%)	9 (75.0%)	.340
ACES	2.29 (2.55)	1.83 (1.17)	.684
Higher education (> high school)	25 (71.43%)	8 (66.67%)	.233
Psychosocial factors			
BDI-II—Depressive symptoms	12.95 (9.39)	10.37 (9.98)	.553
EES—Emotional eating	27.05 (22.86)	20.05 (16.38)	.514
PHMS—Mindfulness	65.08 (8.09)	73.00 (11.92)	.057
PFS—Food susceptibility	52.92 (17.64)	50.60 (25.51)	.805
Biomarkers and obesity indices			
Fasting glucose	106.14 (27.01)	94.75 (16.94)	.262
Blood pressure			
SBP	115.41 (10.81)	116.75 (17.50)	.756
DBP	78.14 (8.27)	74.54 (11.27)	.243
Heart rate	74.52 (10.32)	72.54 (10.98)	.574
Weight (kg)	101.96 (13.68)	91.65 (14.69)	.031 **
Body fat percentage (BF%)	45.07 (6.53)	42.19 (5.74)	.181
Waist-to-hip ratio (cm)	.875 (.076)	.898 (.084)	.382
Waist circumference (cm)	107.49 (9.51)	108 (12.47)	.848
BMI (kg/m^2)	37.47 (4.45)	34.83 (3.73)	.073
Cognitive factors			
Vocabulary	57.19 (10.37)	55.75 (10.58)	.004 **
Reading	54.20 (8.54)	45.92 (8.21)	.005 **
Processing speed	56.23 (12.61)	52.42 (14.48)	.341
Episodic memory	57.19 (10.37)	55.75 (10.57)	.679
Working memory	54.00 (8.59)	50.42 (9.67)	.233

Baseline variable	Group		*p*
	Completer (max *N* = 36) *M* (*SD*)	**Noncompleter (max *N* = 12) *M* (*SD*)**	
Cognitive flexibility	51.14 (11.03)	51.75 (11.21)	.871
Inhibitory control/attention	42.86 (7.40)	40.67 (6.26)	.364
Self-regulation factors			
Brief Self-Control Scale	35.98 (4.59)	38.26 (3.38)	.264
Handgrip strength (seconds)	17.20 (13.08)	23.80 (30.50)	.302
Unsolvable puzzle (seconds)	736.27 (369.51)	703.91 (375.86)	.806

Note. M = mean; *SE* = standard error; ACES = Adverse Childhood Experience Survey; BDI-II = Beck Depression Inventory–II; EES = Emotional Eating Scale; PHMS = Philadelphia Mindfulness Survey; PFS = Power of Food Scale; SBP = systolic blood pressure; DBP = diastolic blood pressure; BMI = body mass index.

** $p < .05$.