Official Title of the study: Project Impact: An Innovative Approach to Weight Loss Maintenance
NCT number: NCT02363010
Date of the document: August 1, 2020

**Design and Randomization**

This study was a three-arm, randomized controlled trial. The study was approved and monitored by the Drexel University institutional review board and preregistered at clinicaltrials.gov (Clinical Trials Identifier: NCT02363010). Participants provided informed consent during enrollment, which was conducted by the research coordinator and research assistants. The statistician conducted randomization using a random numbers table. Participants, counselors, and other study staff were blind to allocation, with no access to allocation data during Phase I. During Phase II, three different forms of behavioral treatment were tested and only outcomes assessors remained blinded to condition. An independent officer completed data and safety monitoring.

**Participants**

Participants were recruited from the community for this study from 2014 to 2016. Inclusion criteria were: BMI 27 – 45 kg/$m^2$ (measured in clinic), age 18-70 years, and completion of all steps in the enrollment process. Exclusion criteria were: medical or psychiatric conditions that could pose a risk during lifestyle modification or significantly limit the ability to begin a program of PA; history of bariatric surgery; current use of weight-affecting medication; weight loss of 5% or more in the past 6 months; current pregnancy, lactation, or plans to become pregnant during the study period; participation in or plan to participate in another weight loss program during the study period; having an immediate family member or household member participating in the study. Participants received compensation for assessment visits as follows: $25 for baseline, $25 for month 6, $25 for month 12, and $50 for month 18.

During project planning, estimates of the necessary sample size varied from 300 to 350, depending on attrition. At project launch, a final sample of 320 participants was selected, with

the assumption of up to 30% attrition, to provide 81% power to detect a medium effect size of weight loss or MVPA. Power analyses accounted for a three-level hierarchical structure, with repeated measures for each participant in a group within one of the three intervention arms, assuming a within-subject correlation of 0.5 and a within-group correlation of 0.05 (estimated from pilot data). A medium effect size was chosen because 1) an effect of that size may be needed to justify a departure from standard behavioral treatment (McGough & Faraone, 2009), 2) previous research comparing ABT to BT has observed a medium effect size for a primary outcome (Forman et al., 2016), and 3) medium or larger effect sizes have been observed for the comparison of weight loss in those engaging in high versus low MVPA (Tate, Jeffery, Sherwood, & Wing, 2007).

**Shared Intervention Components**

Phase I (Months 1 to 6) consisted of 16 closed-group sessions, held on a weekly (8 sessions) and then bi-weekly (8 sessions) basis, with approximately 12 participants in each group. During Phase I, all participants received BWL treatment designed to induce 10% weight loss, with materials adapted from Look AHEAD (2006) and the Diabetes Prevention Program (2002). Participants were instructed to keep daily records of dietary intake. Calorie intake was emphasized as the key determinant of weight loss. Stimulus control, problem solving, goal setting, and social support skills were taught. Participants were instructed to gradually self-monitor and increase free-living MVPA, with a goal of maintaining 250 minutes per week of MVPA by 6 months and beyond. Participants were instructed to conduct MVPA in bouts of 10 minutes or more. Participants self-reported weekly MVPA minutes and average calorie intake during each session's group check-in, and counselors also provided brief written feedback on self-monitoring records on which exercise and dietary intake were reported. Counselors had

doctoral-level psychology training. In Phase I and II, all group sessions began with private measurement of weight.

**Phase II Interventions (Months 7-18)**

Group sessions (14 total) continued in Phase II, beginning with 7 weekly sessions followed by 4 bi-weekly sessions. The final three sessions were held in Months 12, 15, and 18. Each participant also had a 15-minute phone call with a counselor between the quarterly sessions (three calls total) to promote continued engagement. Supplementary Table A details the intervention content in each arm.

***Behavioral Therapy (BT)***

The BT condition in Phase II continued to be based on Look AHEAD (2006) and Diabetes Prevention Program (2002) materials. Sessions were designed to apply traditional behavioral skills such as problem solving and goal setting to the challenges of long-term lifestyle modification. Approximately two-thirds of intervention content and session time was designed to be applied to eating behavior, with a secondary emphasis on PA.

***Behavioral Therapy with Physical Activity Emphasis (BT+PA)***

In the BT+PA condition, approximately two-thirds of session time and content was designed to focus on PA, with one-third of session time focused on eating behavior. The intervention was created by adapting material from the Look AHEAD (2006) and Diabetes Prevention Program (2002) protocols to be PA-focused, and by incorporating techniques from Michie's behavior change taxonomy (Michie et al., 2011). For example, when a session on "maintaining motivation" was conducted, exercises and discussion in session were focused primarily on enhancing motivation for PA. As another example, the application of goal setting skills was primarily focused on PA goals. Progress towards PA goals, particularly the barriers or

facilitators of such progress, was reviewed in each session in greater detail than occurred in the BT condition. PA, rather than eating behavior, was the primary target for problem solving skills. Group leaders frequently encouraged development of implementation intentions for PA.

***Acceptance-Based Behavioral Therapy with Physical Activity Emphasis (ABT+PA)***

The amount of emphasis on promoting PA was designed to be similar in BT+PA and ABT+PA. However, in ABT+PA, acceptance-based behavioral skills were taught, rather than traditional behavioral skills. This approach was adapted primarily from an acceptance-based weight loss protocol (Forman & Butryn, 2016). A key goal was to increase awareness of internal experiences that shape PA behaviors. The approach validated the sense that many aspects of PA are "uncomfortable," meaning that it can be difficult to tolerate the thoughts (e.g., "I would rather be doing something else"), emotions (e.g., boredom), urges (e.g., to avoid or end exercise), or physical sensations (e.g., sweating) that occur while one attempts to engage in PA or while making PA-related decisions. Participants learned how to respond to internal experiences with a stance of non-judgmental acceptance, which enables flexibility (i.e., the ability to engage in a wide range of behaviors, regardless of the accompanying internal experiences). Ultimately, acceptance was intended to promote long-term persistence in PA. Values clarity, which is integral to the use of acceptance skills, included the ability to consider the ways in which being physically active enables pursuit of what is most important in one's life (e.g., being physical fit can make travel or community service more feasible). Participants were encouraged to use their "long-term mind" to have a heightened awareness of their values at moments of PA-related decision making, rather than being driven by transient internal experiences.

**Measures**

Assessments were conducted at Months 0, 6, 12, and 18.

***Demographics.*** Race, ethnicity, sex, age, and education were self-reported at baseline.

***Moderate-to-Vigorous Physical Activity.*** Participants were instructed to wear ActiGraph (Pensacola, FL) GT3X tri-axial, solid state accelerometers for all waking hours for 7 consecutive days at each assessment point. ActiLife software was used with cutpoints defined by Troiano et al. (2008) to identify bouts of 10 minutes or more in which PA of moderate-to-vigorous intensity was detected. Data were considered valid and included in data analyses if the participant wore the accelerometer for at least 10 hours each day for 4 or more days.

***Weight and Height.*** Participants' weights were measured by research staff with a Tanita® model WB-3000 digital scale, with participants wearing light street clothing. Height was measured with a stadiometer. Measurements were taken two times and averaged.

***Half-Mile Walk Time.*** After a 30 second warm up period, participants were asked to walk 0.5 miles on a treadmill in the lab. Participants were shown how to adjust the speed of the treadmill and were instructed to walk as briskly as they could, adjusting the speed as they wished throughout the task. Participants were told that the task was a measure of physical fitness. Shorter times indicated a greater level of cardiorespiratory fitness (Mayorga-Vega, Bocanegra-Parrilla, Ornelas, & Viciana, 2016).

***Waist Circumference.*** Waist circumference was measured horizontally at the umbilicus. Measurements were taken two times and averaged if the measurements were discrepant by less than 2.0 cm (measurements were re-taken if the discrepancy was greater).

***Treatment Fidelity.*** All treatment sessions were audio-recorded, and 10% of recordings were rated for counselor fidelity to the treatment manual. The treatment manual was organized so that each session included a check-in, two or three topics of discussion or activities designed to build a particular behavior skill, and assignment of skill builders. Each of these sections of the

session was rated on a 1-10 scale for adherence, with adherence defined as the extent to which the material was delivered as specified in the manual, including pacing of each topic. BT sessions also were given a rating for the extent to which the counselor avoiding PA contamination (i.e., limited the focus on PA to that specified in the manual) and BT and BT+PA conditions were rated for avoiding ABT contamination.

**Data Analysis Plan: Results Through 18 Months**

Data were analyzed in R (Team, 2013) and SPSS Version 25 (IBM Corp., 2017). Data distributions and assumptions were examined before conducting any formal statistical test. Analyses were conducted on an intent-to-treat basis with multiple imputation via the mice package in R (van Buuren, 2011), such that all participants enrolled in the trial were included in analyses (BT: $n$ = 110, BT-PA: $n$ = 105, ABT-PA: $n$ = 105), with two exceptions noted for exploratory analyses. We performed the analyses for each of the imputed datasets separately, and combined the test statistics across datasets based on Rubin's rule as implemented in the miceadds package in R (Robitzsch, 2017). To account for the zero-inflated distribution of MVPA, compound Poisson linear regression models (cplm; Zhang, 2013) were used to test the treatment effect on MVPA at 12 and 18 months separately, controlling for MVPA measured at earlier time points. The effect of treatment on percent weight loss at 12 and 18 months were examined separately using general linear models controlling for weight measured at earlier time points. General linear models also were used to examine the treatment effect on half-mile walk time and waist circumference. Moderation analyses were used to examine whether the effect of treatment condition on MVPA or percent weight loss depended on sex, baseline BMI, baseline MVPA, weight loss in Phase I or change in MVPA during Phase I. Additional exploratory analyses using general linear models were performed to further understand the relationship between specific

levels of MVPA (regardless of condition) and weight loss outcomes among participants (n = 271) who provided data at 6 months; this subsample was chosen to reduce missing data to allow for greater precision in estimating dose-response for this analysis.