FitLink: Improving Weight Loss Maintenance by Using Digital Data to Provide Support and Accountability

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Study Protocol and Statistical Analysis Plan

Setting and Population

This was a single-site, pilot randomized controlled clinical trial. Participants were recruited from the community from October 2017 to March 2018. Follow-up assessments were completed in May 2019. Inclusion criteria included age 18 to 70 years; BMI 25-45 kg/m^2; regular access to a smartphone and internet connection; ability to begin a program of physical activity; and completion of all enrollment procedures. Participants were excluded if they had a medical condition or psychiatric condition (e.g., active substance abuse, eating disorder) that could pose a risk or limit ability to comply with program recommendations. Participants were also excluded if they were pregnant or planning to become pregnant or move out of the area during the data collection period, were using a pacemaker, had a history of bariatric surgery, had recently begun or changed the dose of a medication that could cause a significant change in weight, or if they had a weight loss of $\geq$ 10% in the previous 3 months. The most common reasons for exclusion were out-of-range BMI (n = 34) and lack of availability at group meeting times (n = 30). All participants provided informed consent, and all study procedures were approved by the Institutional Review Board at Drexel University, where the study was conducted.

Phase I: Uniform, Initial Weight Loss Treatment

All participants received identical treatment during Phase I, the initial, face-to-face phase of treatment. Participants attended 12, weekly behavioral weight loss group sessions. The treatment protocol was adapted from Look AHEAD and the Diabetes Prevention Program (14, 15). Treatment included problem solving skills, strategies for stimulus control, goal setting, and social support skills. Participants were given prescriptions for reducing calorie intake and were

told to gradually increase their moderate-to-vigorous physical activity (MVPA) to 250 bouted minutes per week (i.e., a minimum of 10 minutes of exercise at a time).

All participants were provided with three self-monitoring tools: a Yunmai Smart Scale for measuring body weight, a Fitbit Flex for monitoring physical activity, and the Fitbit app for recording food intake and viewing data from all three devices. Participants were told to weight themselves weekly in weeks 1-10 and daily thereafter; to wear the physical activity sensor daily, paying particular attention to "active minutes" when reviewing device data; and to record food intake daily. During Phase I, device data were not available to counselors. Participants were instructed not to share device data with friends, family, or other participants at any point in the program.

Phase II: Remote Maintenance Treatment

At the conclusion of Phase I, participants were randomly assigned (matching for initial weight loss) to one of two treatments for Phase II (weeks 13-52): standard lifestyle modification (LM) or lifestyle modification plus device data sharing (LM+SHARE). Phase II treatment was delivered remotely. There were no further group meetings; participants received monthly, individual, 15-minute phone calls and weekly, one-way text messages. Participants in both conditions were instructed to continue using digital devices daily to self-monitor weight, physical activity, and food intake.

In LM+SHARE, counselors had access to a secure online portal that uploaded data from participants' self-monitoring devices. Counselors were instructed to attend to changes in weight, adherence to dietary intake and physical activity goals, and self-monitoring frequency when viewing data. In phone calls and text messages with participants, counselors used their data observations to cultivate a sense of supportive accountability, conveying to participants that they

were regularly monitoring adherence to program goals in order to sustain participant success. Counselors set goals with participants in monthly phone calls, subsequently viewed data relevant to the goals to determine if they were being met, and in the text messages and phone calls that followed provided praise to reinforce positive behaviors or expressed concern if adherence was poor. For example, a text message might say: "I'm so impressed that you started recording your food intake again! I saw you recorded for 5 days this week. Reflect on how you accomplished that, and how it was helpful, so that you can carry this success forward. Keep up this fantastic work!" As another example, in a phone call a counselor might say: "You set a goal last month of 5 bouts of exercise per week, and I see that you only averaged 2 per week. Tell me more about what happened." Counselors also used phone calls and text messages to review core behavioral skills or strategies and encourage their use.

In the LM condition, counselors did not have access to device data. Counselors used participant self-report in monthly phone calls (prompted by questions such as, "How successful have you been in meeting your physical activity goals since our last call?") to assess progress and adherence. As in LM+SHARE, LM counselors reviewed one or more core behavioral skills or strategies in each phone call. All participants in the LM condition received standardized, weekly text messages that highlighted a core behavioral skill or strategy; messages in this condition were not personalized.

The seven counselors who provided treatment had degrees in psychology or a related field (1 = PhD, 4 = MA/MS, 2 = BA/BS). Counselors had previous training in behavioral weight loss and also completed a training workshop and weekly supervision for this study. All counselors provided both forms of treatment.

Measures

Assessments were completed at weeks 0 (baseline), 13 (i.e., baseline of Phase II treatment), week 26, and week 52 (end of treatment).

Demographics. Age, gender, education, race, and ethnicity were self-reported at baseline.

Height and weight. At each assessment, research staff weighed participants using a Tanita model WB-3000 digital scale. Participants were weighed in light street clothes without shoes. Height was measured at baseline using a stadiometer. Measurements were taken twice and averaged.

Physical Activity. Participants wore ActiGraph GT3X tri-axial, solid state accelerometers to measure MVPA at weeks 13 and 52. (To minimize "device burden," given that participants were asked upon enrollment to begin using three other self-monitoring devices, Actigraph measurements were not done at week 0.) Participants were told to wear the accelerometer for seven consecutive days during all waking hours, and data were considered valid when available for a minimum of four days for at least 10 hours per day. ActiLife software was used to calculate MVPA using established cut-points (16). Consistent with the intervention focus on bouted exercise, MVPA totals included only episodes of MVPA detected by the accelerometer to be $\geq$ 10 minutes.

Self-monitoring engagement. Device data were collected on a secure online portal, which allowed for calculation of the percent of days during which weight was recorded on the Yunmai Smart Scale; $\geq$ five foods were logged in the Fitbit app; and the Fitbit counted $\geq$ 500 steps.

Treatment engagement. Engagement with treatment phone calls was calculated as the number of calls the participant completed during Phase II, out of 8 possible calls. The number of text messages sent by the counselor also was calculated.

Treatment satisfaction. Treatment satisfaction was measured using the Treatment Acceptability Questionnaire (17), with some items modified to reflect specific treatment components of the current study. This measure has good internal consistency and concurrent validity.

Perceived accountability. The "Perceptions of Accountability" subscale of the Supportive Accountability Scale (18) was administered to measure the extent to which the participants feel accountable to others to achieve their weight control goals. Reliability and validity for this scale has been established (18).

Data Analysis

Retention was compared between the two conditions using Fisher's exact test. Permutation test was conducted to examine the difference between conditions in the number of phone calls and text messages (which could vary if a participant requested that contact be discontinued or temporarily suspended) and treatment acceptability ratings. Permutation test, a type of nonparametric test that uses sampling without replacement to test hypotheses, was chosen due to the violation of t-test assumptions in the data set (19). We conducted permutation based ANCOVA to compare self-monitoring engagement in Phase II between conditions controlling for Phase I self-monitoring engagement. This analytic method was implemented in the "permuco" package in R and has been shown to be robust to data with non-normal distribution (20). ANCOVA was used to test the difference in weight change between conditions, controlling for Phase I weight loss. Change in bouted MVPA during Phase II was compared between LM and LM+SHARE controlling for Fitbit-measured changes in Phase I MVPA using permutation based ANCOVA. One outlier for bouted MVPA at 13 weeks in the LM condition was removed from the analyses (MVPA was more than 3 SDs above others). Repeated measures ANCOVA

was used to compare perceived accountability controlling for Phase I change. Analyses examined whether the effect of condition on weight loss during Phase II was mediated by change in monthly adherence to self-monitoring during the first 6 months of Phase II, or change in perceived accountability from weeks 13 to 26. If weight and MVPA outcome data were missing, the most recent data from the participant's digital scale or Fitbit, respectively, were used for imputation; if those data were not available, baseline data were carried forward. Strong associations were found between weight measured in clinic and via home digital scale (r= .995, p < .001 at 52 weeks), and between Actigraph and Fitbit measurements of MVPA (r = .60, p < .001 at 52 weeks), validating this missing data approach. The study was designed as a pilot randomized trial, with a focus on having a large enough sample for estimates of feasibility, acceptability, and effect sizes to be reliable. Data were analyzed in SPSS version 25 and R version 4.0.0.