Project Title: Testing Self-Control as a Behavior Change Mechanism to Increase Physical Activity

NCT04522141

Study Protocol and Statistical Analysis

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The overall goal of the study is to test the efficacy of a smartphone-based self-control intervention to increase physical activity among sedentary adults who are at risk for poor health. The specific aims of the study are threefold: The first aim is to test the efficacy of a self-control intervention to increase physical activity by comparing two experimental conditions (i.e., self-control treatment group vs. control group). It is expected that those who receive the self-control intervention, will show greater increases in physical activity compared to people in the control group, who do not receive the self-control intervention. Moreover, it is expected that effects in the self-control treatment group will last longer compared to any changes in the control group. The second aim is to compare changes in self-control between the self-control group and the control group. It is expected that people in the self-control group will show greater changes in self-control compared to people in the control group. The third aim is to examine self-control as a behavior change mechanism for physical activity. It is expected that those who show greater increases in self-control will also show greater increases in physical activity. Self-control is expected to mediate the relationship between condition and physical activity.

Methods

This study has been approved by the University's Institutional Review Board at Brandeis University (#20100R) and the protocol has been registered at ClinicalTrials.gov (#NCT04522141). Informed consent will be obtained from each participant. Ethical issues will be continuously considered. There is a data and safety monitoring plan and a safety officer is assigned to the study. Any adverse events will be recorded and reported.

Participants

A total of 70 sedentary middle-aged adults, who are at risk for poor health, will be enrolled. Participants will be recruited from across the US by posting flyers on public boards in libraries, churches, shopping centers/malls, or grocery stores. Moreover, we will post advertisements online on Social Media, on Craigslist, and on findparticipants.com. As

reimbursement, participants will receive a Fitbit Charge 4 step counter, which they can keep after the end of the study. In addition, as an added incentive, all participants will receive $25 for completing all aspects of the study.

Participants will be included if they indicate they want to become more physically active, are between 35 and 65 years, are fluent in English, fit enough to walk for at least 20 minutes at a time, and own a smartphone (Android or iPhone) with a data plan. Participants will be excluded if they have experienced a fall or heart problem/condition in the last 6 months, are currently participating in an exercise program to increase physical activity or currently using a Smartwatch (e.g., Fitbit, Garmin, Apple Watch etc.) to track their physical activity, already exercise at least 3 times per week and for more than 30 minutes at a time, and/or if a doctor has advised them to not walk due to health conditions.

Study Design and Procedure

The current study uses a two-armed randomized controlled trial design with assessments at pretest (baseline), at the end of weeks 1-7, posttest (week 8), and follow-up (week 12). Participants will be randomly assigned into two experimental conditions to ensure that the two conditions are fully randomized with respect to participants' baseline characteristics (allocation concealment). Thirty-five participants are randomized into each condition. Also, participants are blinded in terms of their experimental condition.

Recruitment flyers and advertisements specify: "Do you want to be more active, but find yourself making excuses to avoid exercise?" Flyers and advertisements also include a web link for interested participants. This web link will provide detailed information about the study and interested participants will be asked to fill out a screening questionnaire to check for all inclusion and exclusion criteria. If they are eligible for the study, they will be asked to provide their phone number and home postal address so we can send them the study materials. After that, participants will be randomly assigned into one of the two experimental conditions: The self-control treatment group or the control group. A research assistant will call all eligible

participants to receive their informed consent by phone, to help them installing the MindHike smartphone application on their own smartphone, and to answer any questions. Once informed consent is given, we will ship participants a Fitbit Charge 4 step counter, instruction materials, a face mask, and a stylus pen to their home postal address.

Both the self-control treatment group and the control group will use the MindHike smartphone application and will use a Fitbit. The control group will receive a more basic version of the MindHike app which only sends them daily reminders to sync their step data, charge their Fitbit and asks them for their daily mood. The self-control treatment group will receive the version of the MindHike app which delivers the self-control intervention. MindHike is a smartphone application which can prompt participants with messages using a chatbot system. The app is pre-packaged, which means that the app will deliver the same dialogues automatically to all participant in each condition. There is no bi-directional communication, but participants click on predesignated responses to advance the dialogue.

On the first study day, all participants will fill in a pretest questionnaire. The MindHike application will send a web link that forwards participants to this online questionnaire. All participants will be asked to wear their Fitbit every day during the entire study from when they wake up to when they go to bed. During the first study week, participants are only asked to wear the Fitbit to document the number of steps taken to establish an objective measurement of steps before the intervention. All participants will be contacted by the MindHike app twice each day for eight weeks. The first message is a push notification which reminds all participants to wear their Fitbit so they can get used to it. The timing of this Fitbit is set to 7 a.m. by default but participants can change the time if they get up earlier or later in the morning. The second daily push notification asks participants to open the MindHike app and to read through a short daily pre-packaged chat in the app. Again, the time for this second push notification can be customized by each participant. During the first week, this pre-packaged chat will only remind participants of both groups to sync their step

data with the Fitbit app and to charge their Fitbit. After this baseline week, the study will last for 7 more weeks, and participants will still receive a push notification reminder to wear their Fitbit at customized times in the morning. Across the study, participants will also fill in weekly assessments of self-control at the end of each week. After the seven weeks, participants will fill in a posttest assessment. The MindHike application will send them the web link to the online posttest. After the posttest, participants do not use the MindHike application anymore, but we will contact them via e-mail for a last online follow-up assessment four weeks later.

Control Group

After the first study week (baseline week), all participants will receive a push notification which reminds them to open the app at least once per day. If they open the app, participants will receive a pre-packaged chat. These daily pre-packaged chats will differ between the two treatment groups. Although both groups will use the MindHike application at the same frequency, the daily pre-packaged chat for the control group will only include a reminder to sync their step data, charge their Fitbit and ask them for their daily mood.

Self-Control Treatment Group

The daily pre-packaged chat for the self-control treatment group will include a short coaching session to deliver the components of the self-control intervention. For this study, the intervention was adapted to specifically target self-control in the domain of physical activity.

As part of the intervention, participants of the self-control treatment group set themselves a specific physical activity goal such as “Each evening after dinner, I will go for a 20-minute walk”. The self-control intervention will teach participants different strategies on how to achieve their personal goal. In general, participants learn how to change their behaviors in ways that potentiate their desirable impulses or weaken their undesirable ones. The intervention is based on the process model of self-control (Duckworth, Gendler, & Gross, 2016). This theoretical model will be used to describe the timeline of the development of

impulses to participants. The goal of the self-control intervention is to target each stage of this theoretical model (i.e., (1) how to proactively select situations, (2) how to proactively change certain situations, (3) how to shift attention in a given situation, (4) how to change appraisal of a given situation, and (5) how to change behaviors in a given situation). Interventional components include specific behavioral tasks (e.g., If-then plans; Gollwitzer, 1999), self-reflection tasks, and short film clips for psychoeducational purposes. Every week of the 7-week intervention, participants focus on one of the five stages of the self-control process model, while the first week is an introductory week on self-control and the last week serves to practice all learned strategies in everyday life. Each stage of the five stages of the self-control process model will be introduced with a short video clip.

Statistical Analyses

Sample size and power considerations. We conducted a power analysis for repeated measures and between-group effects based on the between-group effect size found in a previous physical activity intervention study (Robinson et al., 2019). The power analysis with an α error level of 0.05, a statistical power (1-β) of 0.80, a correlation of 0.50 between the pretest, posttest, and follow-up assessment, and a Cohen's $f = .30$ suggests a sample size of at least $N = 62$. As we learned from previous similar smartphone-based physical activity studies, about 10% of participants who sign up for the study discontinue their participation. As such, we will recruit a total of 70 middle-aged adults.

Data analyses. SPSS and R will be used to analyze differential effects between the two conditions. Multilevel models and the lme4 package in R will be used to examine group differences in change and maintenance of effects over time in objectively measured daily steps, self-reported physical activity, self-control as well as differential change over time in secondary outcomes such as Big Five personality traits, exercise self-efficacy, satisfaction with life, sense of control, and cognitive performance.

Another focus will be to examine self-control as a mechanism of behavior change. We will use multilevel models to examine whether individuals who change more in self-control also increase more in their physical activity. Moreover, we will use PROCESS in SPSS and multilevel mediation analyses in R to test whether self-control mediates the relationship between condition and physical activity.