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Title: Daily Activity Study of Health: Increasing Physical Activity in Aging (DASH)

Statistical Analysis Plan

NCT04315363

March 6 2021

Abstract

Sedentary behavior increases the risk for multiple chronic diseases, early mortality, and accelerated cognitive decline in older adults. Interventions to reduce sedentary behavior among older adults are needed to improve health outcomes and reduce the burden on healthcare systems. We designed a randomized controlled trial that uses a self-affirmation manipulation and gain-framed health messaging to effectively reduce sedentary behavior in older adults. This message-based intervention lasts 4 weeks, recruiting 80 healthy but sedentary older adults from the community, between the ages of 60 and 95 years. Participants are randomly assigned to one of two groups: 1) an intervention group, which receives self-affirmation followed by gain-framed health messages daily or 2) a control group, which receives daily loss-framed health messages only. Objective physical activity engagement is measured by accelerometers. Accelerometers are deployed a week before, during, and the last week of intervention to examine potential changes in sedentary time and physical activity engagement. This study will assess the effectiveness of a novel behavioral intervention at reducing sedentarism in older adults and examine the neurobehavioral mechanisms underlying any such changes.

Keywords: sedentary behavior, randomized controlled trial, self-affirmation, positive messaging, affective psychology, fMRI

Introduction

Sedentarism is an epidemic among older adults, given that they spend an average of over 8 hours being sedentary daily [1,2]. Moreover, physical inactivity has increased sharply during the COVID-19 pandemic [3]. The potential health risks of leading a sedentary lifestyle are well established. Time spent sedentary (as measured by metabolic equivalents of task (MET) ≤ 1.5 [4]), is positively associated with increased risk for all-cause mortality, cardiovascular disease, cancer, and type 2 diabetes [5,6] and negatively associated with cognitive status in later life [7,8]. Moreover, physical inactivity costs healthcare systems approximately 53.8 billion international dollars each year [9]. Consequently, developing effective strategies to motivate reductions in sedentary time in older adults will significantly improve their health and well-being, as well as reduce the costs associated with healthcare.

Although improving awareness and conveying knowledge about exercise is important, these educational manipulations might be ineffective if the health information is perceived to be threatening which can evoke defensiveness [10]. Investigating how to make health information persuasive for behavioral change in older adults is important but underexplored. Self-affirmation manipulations are potential strategies that have been found to be effective in decreasing defensiveness and increasing receptiveness to potentially threatening health messages in younger and middle-aged adults [11,12]. Underpinned by a psychological process whereby one reflects on their core values, self-affirmation can help promote greater self-integrity and improve adaptations to threatening circumstances [13], leading to less defensiveness and greater action initiation in response to potentially threatening health messages [14]. Although a self-affirmation manipulation has not been examined in older adults, the underlying neural mechanism provides evidence of its potential effectiveness in older adults. Greater activation in brain regions that are critical for self-referential processing (e.g., ventromedial prefrontal cortex [VMPFC]) and positive valuation (e.g., ventral striatum [VS]) were associated with greater changes in sedentary

behavior following a self-affirmation manipulated behavioral intervention for young and mid-aged adults [11,12]. These regions have previously been shown to be key nodes associated with self-affirmation [12,15–17]. Moreover, the medial prefrontal cortex is relatively spared during aging [18–20]. Thus, there is reason to posit that interventions that tap into self-referential processes would be effective in reducing time spent in sedentary in older adults.

There is growing evidence for a *positivity effect* in aging; this is an age-related shift favoring cognitive processing of positive over negative stimuli [21–23]. In older adults, positively-framed health messages (e.g., ‘Walking has important cardiovascular health benefits’) have previously been shown to be more effective at promoting walking compared to negatively-framed messages (e.g., ‘Not walking enough can lead to increased risk for cardiovascular disease’) [24]. In a follow-up analysis, those in the positive-framed group demonstrated greater memory for the intervention compared to the negative-framed control group[25]. Therefore, we predict that positive framing can add onto the effect of self-affirmation manipulation on behavior change; in other words, increasing the persuasiveness and bolstering the memory of health information both improve the intervention effect on behavior change. In this study, we combine daily positively framed health messages with a self-affirmation manipulation to take advantage of both of these techniques in an effort to enhance behavior change with regard to physical activity. Although positively-framed persuasive messages enhance physical activity in older adults, the underlying brain networks supporting this behavior are presently unknown. This study seeks to address this knowledge gap.

Study aims

The primary aim of the DASH study is to test the efficacy of self-affirmation plus gain-framed messaging to reduce sedentary time, as well as secondary outcomes related to sedentary behavior change. The primary outcome, sedentary time (i.e., time spent in sitting and lying), is quantified by objectively measuring average sedentary time across a period of at least 7 days, measured during multiple weeks across the intervention. The secondary outcome is moderate-to-vigorous physical activity engagement (MVPA). This is a pilot study for a novel behavioral intervention with self-affirmation and positive messaging that will elucidate the individual differences and brain mechanisms underlying behavioral change. Therefore it represents a Stage I intervention within the context of the NIH Stage Model for Behavioral Intervention Development [26].

Methods

Study design

The DASH study is a stratified block randomized controlled trial. After reading and signing informed consent, recruited participants are randomized to either a self-affirmation plus gain-framed daily messaging group (intervention) or a loss-framed daily messaging only group (control) with a ratio of 1:1. Due to the constraints of in-person assessment during the COVID-19 pandemic, onsite participation in the MRI scans before and after the intervention is optional. Therefore, we stratify the randomization by MRI participation (yes/no) to ensure the same distribution of MRI and behavioral-only participants across the two groups. Loss-framed messages were chosen as a control group (over neutral messaging) as they provide the same contextual information as the gain-framed messages (only framed in a negative way), compared

to neutral messages which contain factual information (see Figure 3B for an example of gain-versus loss-framed messages). All participants are informed about the randomization but blinded to the group assignment. Participants are informed that the study aims to examine whether a 4-week program promotes brain health and behavior. However, it is not possible to blind experimenters, as they view the intervention related materials and give instructions during the assessments. The randomization scheme is prepared by the Harvard Catalyst Biostatistical Group using a stratified permuted block method with random blocks. All experimenters are blinded to the block size. Sealed envelopes are provided to the investigator and stored at the designated site. This trial is registered on clinicaltrials.gov with an identifier NCT04315363. This study received ethical approval from Northeastern University Institutional Review Board (IRB).

Participants

We plan to recruit 80 sedentary older adults for this study between the ages of 60 and 95 years that engage in less than 150 minutes of moderate-to-vigorous-intensity aerobic exercise per week and more than 8 hours of sitting time per day, as assessed with a self-report during an initial phone screening. We plan to recruit a diverse population that is balanced across race, sex, and socioeconomic status. The study is advertised via promotional flyers in and around the Boston area and local senior citizen centers as well as online advertisements through websites such as Craigslist and Facebook. Potential participants are screened by phone. The Telephone Interview of Cognitive Status (TICS) is used initially to screen cognitive function. Sitting Time questionnaire [27] and International Physical Activity Questionnaire [28] are used for screening physical activity engagement and sedentary behavior. Potential participants are asked a series of questions relating to the inclusion/exclusion criteria and past medical history.

Intervention

Study timeline

An illustration of the study timeline can be seen in Figure 1. Each participant undergoes a baseline session (T1) one week before the beginning of the intervention. Informed consent is obtained at baseline, during which participants specify whether they opt to participate in the MRI scans or not. Randomization takes place after obtaining informed consent (T1) and participants are assigned into either the intervention or control group. During the T1 visit, the participants also undergo baseline testing including neuropsychological tests and neurobehavioral inventories, which take about 3 hours in total. In order not to prime exercise for the baseline physical activity level, inventories that are related to exercise and self-perception are not administered during T1 visit. At baseline, participants wear an activPAL monitor on their thigh to assess postural aspects of sedentary behavior including time spent sitting and lying and a wrist-worn accelerometer on their non-dominant hand to assess physical activity (see physical activity monitoring). Both monitors are worn for a week. One week later (T2), physical assessments and the remaining neurobehavioral inventories related to exercise and self-perception will be administered, which takes about 1.5 hours. The intervention lasts 4 weeks, during which participants receive daily intervention messages via email or smartphone. Participants are fitted with the accelerometers again for a one-week mid-intervention period (week 3). The post-intervention visit (T3) is scheduled at the beginning of the last intervention week (week 4). After the last intervention week (T4), participants repeat the neurobehavioral

inventories, neuropsychological tests and physical assessments. Three accelerometer calls are administered by two research assistants, for the purpose of giving instructions and answering questions about accelerometers. The estimated overall participation time is 16 hours, which may vary across individuals. To minimize attrition, each assessment session (i.e., T1, T2, T3, T4) is self-paced and has been divided into smaller visits, each of which lasts no longer than 2 hours. During each visit, participants take breaks every 20 minutes to minimize the risk of fatigue.

Daily messaging

The 4-week intervention consists of daily messages via email using the online software oTree, an open-source platform for implementing messaging survey, which allows for accessibility via desktop or smartphone [29]. Unique links are assigned each participant at enrollment.

Each day, all participants receive daily messages. Participants will be asked to rank 8 core values based on personal importance (i.e., politics, religion, family and friends, creativity, money, independence, humor, and spontaneity) during baseline assessment (T1). Participants in the intervention group receive daily prompts to reflect on their highest-ranked core value vividly (e.g., think of a time when you are inspired by your family) followed by a gain-framed message about being physically active (e.g., walking is good for your health). The control group will receive daily prompts to reflect on an everyday activity (e.g., think of a time when you charge your phone) as well as the same content of daily messages but in a loss-framed way (e.g., being sedentary is harmful to your health). These daily self-affirmation and health messages will consist of a combination of the same messages used in the fMRI tasks and novel messages. The Walk-BEST Workbook, a guideline to improve walking safely and effectively (<https://physiobiometrics.com/>), has been used as a reference source of health messages. At the same time, participants will be tested on their memory for health messages from the fMRI task. The participant will then rate their mood and confidence in implementing the health tips, the goal of which is to examine the changing of well-being and self-efficacy of physical activity throughout the intervention. During weeks 3 and 6, they also receive daily reminders to continue wearing their accelerometers. This daily message survey setup is displayed in Figure 2. The researcher's contact information is displayed on each survey page to enhance compliance. To monitor the participation adherence, participants' responses are tracked and those that do not complete the survey by a specified time of day are contacted the following day by research assistants to prevent technical failures. The time spent on the daily message intervention including the healthy messages and survey questions is recorded by the daily message system, no response to the survey questions or responses under 3 seconds to the self-affirmation probe are considered as non-compliance.

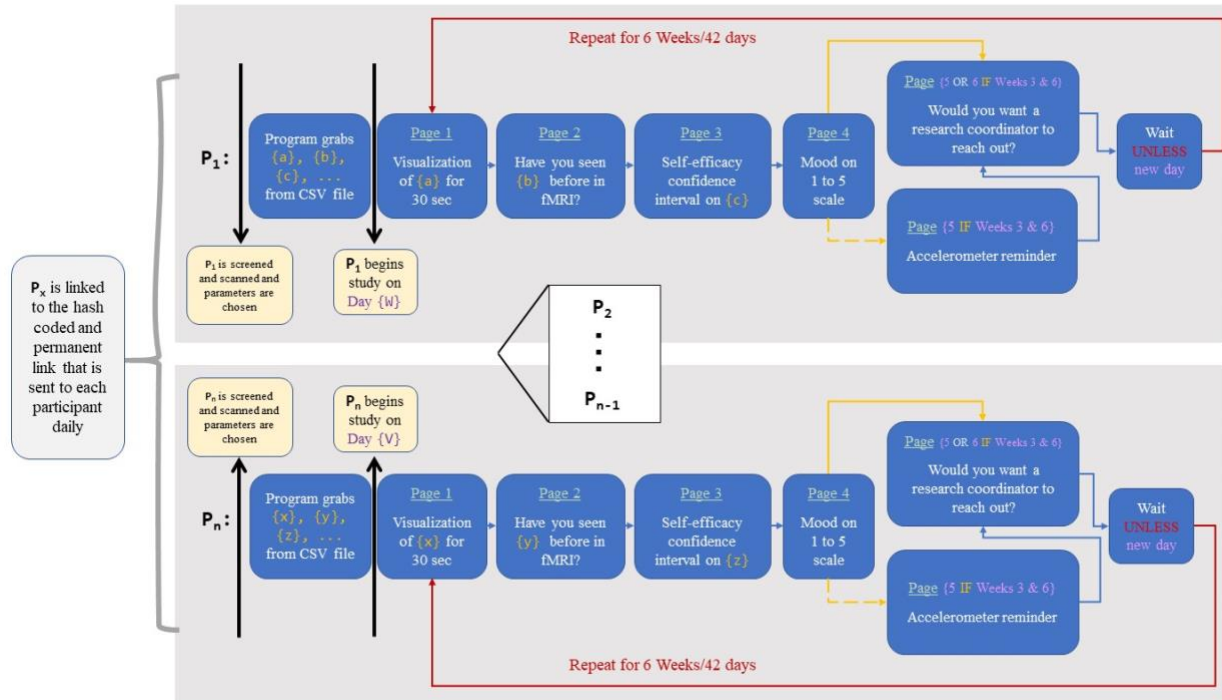


Figure 2. Messaging system setup and logic. Each participant (represented by P_x , where x designates the participant number) receives their unique link. In that link, they follow a series of pages each day that contains their unique questions and parameters based upon the inputted comma-separated values (CSV) file. The system does not initiate until the participant begins on their first day and then repeats for 42 days (4 weeks) for the duration of the daily messaging intervention. The process occurs synonymously for all other participants. Links that are not activated simply remain idle until a participant is assigned that link

Measurements and materials

Physical activity monitoring

Time spent sedentary as the primary outcome will be measured with an activPAL inclinometer (activPAL, PAL Technologies, Glasgow, UK). Sleep quality, duration, and physical activity engagement will be measured as secondary outcomes using an GT9X Link accelerometer (ActiGraph LLC, Pensacola, FL). Participants will be wearing two motion sensors at week 0 (between T1 and T2), week 3 (mid-intervention), week 6 (between T3 and T4) and week 14 (T5), 24 hours/day for seven continuous days (see Figure 1). To measure sedentary time, an activPAL monitor is attached on the mid-anterior surface of the right thigh. This device is used to measure postural aspects of sedentary behavior, including time spent lying and sitting, standing, and the number of sit-to-stand transitions. An accelerometer will be worn on the non-dominant wrist to improve compliance and allow for the assessment of sleep characteristics. Total time spent in physical activity, as well as time spent in light, moderate and vigorous intensities, are measured. Sitting and standing time as measured with an activPAL correlate highly with the direct observation (the gold standard) in classifying sitting and standing in older adults ($rs \geq .95$) [30]. ActiGraph accelerometers can reliably estimate daily physical activity based on a minimum of 4 valid days of wear (i.e., 70-80%) [31] and physical activity energy expenditure as assessed against a gold standard (i.e., doubly labeled water; $rs = [0.34-0.64]$) [32]. ActivPAL can reliably estimate sedentary time based on a minimum of 5 days of wear [33]. The

use of both devices affords accurate and sensitive measures of both sedentary behavior and physical activity. Participants are also asked to complete a sleep log and record times when they remove and replace the devices during each day (e.g., before and after taking shower). Sleep parameters will be captured through ActiGraph accelerometers.

To ensure compliance, there is a conference call prior to each of the three accelerometer weeks, during which the participants will be instructed how to wear the devices correctly. Tutorials for wearing devices are sent out prior to the meeting. During these weeks, participants also receive accelerometer reminders each day at the end of the health message intervention survey and they are instructed to respond to question of whether they are wearing the devices on that day (see Figure 2). A research assistant will reach out if they respond no or do not respond, to prevent any technical issue.

Data management

All research data are de-identified and only the research coordinator has access to identifiable information that is stored in a secure location. Data are stored electronically on password-protected servers behind university-protected firewalls. All pen and paper inventories and neuropsychological assessments are scored and uploaded to REDCap[70]. Computerized neurobehavioral inventories are collected directly in REDCap and computerized neuropsychological assessments are uploaded to REDCap. (3) The oTree library is used to distribute the daily intervention messages and collect survey data. This system runs on a Heroku server, a cloud-based system that sends and receives hash-encrypted links. Collected anonymized data are stored on the messaging site behind an administrative login on the Heroku server.

Analysis plan

Power calculations were performed to statistically determine the target sample size of $N=80$ for this pilot study. The power is calculated in R based on a two-sample T-test model with our primary outcome, the percent of daily sedentary time assessed using an activPAL. We expected a similar baseline sedentary sample to the study by Falk et al., where participants were sedentary an average of $50.6\% \pm 14.0\%$ of their time [11]. Our proposed sample size of 80 participants (40 per group) will allow us to detect a minimum detectable difference of 10.0% between the two groups (i.e., the group difference in averaged sedentary time/total valid awake time) at week 4 post intervention with a common standard deviation of 14.0% with 80% power and a two-sided alpha of 0.05, with 20% drop-out rate accounted. We expect that the ratio of sedentary time/total valid awake time in the self-affirmation + positive framing group will be 10.0% less than the control negative framing group, based on our power analysis.

After compiling all data across the 3 different data servers, data will be checked for completeness and correctness using frequency distributions (for missing data and out-of-range values). Group differences at baseline are examined for variables including demographic factors (i.e., age, sex, educational level, socioeconomic status, race/ethnicity), baseline sedentary time, self-report sitting time, in order to detect potential confounding factors. For the primary hypothesis that self-affirmation + gain-framed messages decrease sedentary time more so than loss-framed messages, and the secondary outcome of increased MVPA after the intervention, all outcome measures about sedentary behavior and MVPA are first quantified using available software. Changes in sedentary behavior (% daily sitting and lying time, minutes/per day in

physical activity) over time (3 time points) are analyzed using linear mixed effect models to account for the correlated data and likely heterogeneous variability. These models will include a random intercept and slope to account for subject-specific changes as well as a group (2) x time (3) interaction fixed effect. This allows for modelling of the effect of our intervention as a function of both group and time as well as accounting for potential confounding covariates. All model assumptions will be tested both visually and formally and associations between covariates will be assessed to protect against multicollinearity. All valid data are included in the model initially, followed by per protocol analyses, in which the cases with (1) less than 4 valid days of ActiGraph or (2) less than 5 valid days of activPAL or (3) more than 2 days with non-compliance of daily message intervention are excluded in the analysis. For the final dataset, the multiple imputation by chained equations (MICE) will be used for imputing missing values with 10 imputations.

Discussion

Efficacious behavioral interventions to decrease sedentary behaviors in older adults will have a critical impact on disease prevention, quality of life and public health. The COVID-19 pandemic has further heightened the urgency to reduce sedentary due to increased inactiveness among older adults [3]. We have designed a 6-week pilot randomized controlled trial to examine the efficacy of daily self-affirmation and gain-framed messaging in decreasing sedentary time. Through increasing receptivity to health messages via reinforcement of self-referential and positive valuation networks, we hypothesize there will be a significant reduction in sedentary time in the intervention group, compared to the control group (who receives loss-framed messages only).

There are several notable limitations to this study, yet we have taken a number of measures to minimize their impact. First, this is a pilot study with only a moderate sample size. Nevertheless, a power analysis of our primary outcome measure was performed to ensure that a sample size of 80 is sufficient to detect a true effect with 80% power. Additionally, interpretations of individual component contributions of our intervention are to be taken with caution given we cannot disentangle the effect of gain-framed messaging from self-affirmation. Regarding the inclinometer and accelerometer-based assessments, we are limited to the collection of data for 3 periods of 1 week (i.e., not assessing accelerometry throughout the entire 6-week intervention). However, the use of two state-of-the-art devices allows us to accurately capture both sedentary time and physical activity, to get a more comprehensive picture of physical activity and sedentary behavior of participants. Furthermore, continued monitoring of daily engagement with the intervention is performed and a researcher will make contact with study participants to maximize compliance.

In summary, this 4-week pilot randomized control trial examines the effect of a novel behavioral intervention on reducing sedentary time in older adults, by combining self-affirmation and gain-framed messages. The results will provide preliminary evidence for the efficacy of self-affirmation manipulation prior to health messaging to decrease sedentary behaviors in older adults and at the same time, provide mechanistic insight into the engenderment of behavioral change in older adults. Such insight can be used to optimize future behavioral intervention development.

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