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13 **Title: Daily Activity Study of Health: Increasing Physical Activity in Aging (DASH)**
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15 **Statistical Analysis Plan**
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47 **Abstract**

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

63
64 **Keywords:** sedentary behavior, randomized controlled trial, self-affirmation, positive
65 messaging, affective psychology, fMRI

66 **Introduction**

67 Sedentarism is an epidemic among older adults, given that they spend an average of over 8 hours
68 being sedentary daily [1,2]. Moreover, physical inactivity has increased sharply during the
69 COVID-19 pandemic [3]. The potential health risks of leading a sedentary lifestyle are well
70 established. Time spent sedentary (as measured by metabolic equivalents of task (MET) ≤ 1.5
71 [4]), is positively associated with increased risk for all-cause mortality, cardiovascular disease,
72 cancer, and type 2 diabetes [5,6] and negatively associated with cognitive status in later life
73 [7,8]. Moreover, physical inactivity costs healthcare systems approximately 53.8 billion
74 international dollars each year [9]. Consequently, developing effective strategies to motivate
75 reductions in sedentary time in older adults will significantly improve their health and well-
76 being, as well as reduce the costs associated with healthcare.

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

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

98 There is growing evidence for a *positivity effect* in aging; this is an age-related shift
99 favoring cognitive processing of positive over negative stimuli [21–23]. In older adults,
100 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.

113 **Study aims**

114 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].

125 **Methods**

127 **Study design**

128 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

139 to neutral messages which contain factual information (see Figure 3B for an example of gain-
140 versus loss-framed messages). All participants are informed about the randomization but blinded
141 to the group assignment. Participants are informed that the study aims to examine whether a 4-
142 week program promotes brain health and behavior. However, it is not possible to blind
143 experimenters, as they view the intervention related materials and give instructions during the
144 assessments. The randomization scheme is prepared by the Harvard Catalyst Biostatistical Group
145 using a stratified permuted block method with random blocks. All experimenters are blinded to
146 the block size. Sealed envelopes are provided to the investigator and stored at the designated site.
147 This trial is registered on clinicaltrials.gov with an identifier NCT04315363. This study received
148 ethical approval from Northeastern University Institutional Review Board (IRB).
149

150 **Participants**

151
152 We plan to recruit 80 sedentary older adults for this study between the ages of 60 and 95
153 years that engage in less than 150 minutes of moderate-to-vigorous-intensity aerobic exercise per
154 week and more than 8 hours of sitting time per day, as assessed with a self-report during an
155 initial phone screening. We plan to recruit a diverse population that is balanced across race, sex,
156 and socioeconomic status. The study is advertised via promotional flyers in and around the
157 Boston area and local senior citizen centers as well as online advertisements through websites
158 such as Craigslist and Facebook. Potential participants are screened by phone. The Telephone
159 Interview of Cognitive Status (TICS) is used initially to screen cognitive function. Sitting Time
160 questionnaire [27] and International Physical Activity Questionnaire [28] are used for screening
161 physical activity engagement and sedentary behavior. Potential participants are asked a series of
162 questions relating to the inclusion/exclusion criteria and past medical history.
163

164 **Intervention**

165 ***Study timeline***

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

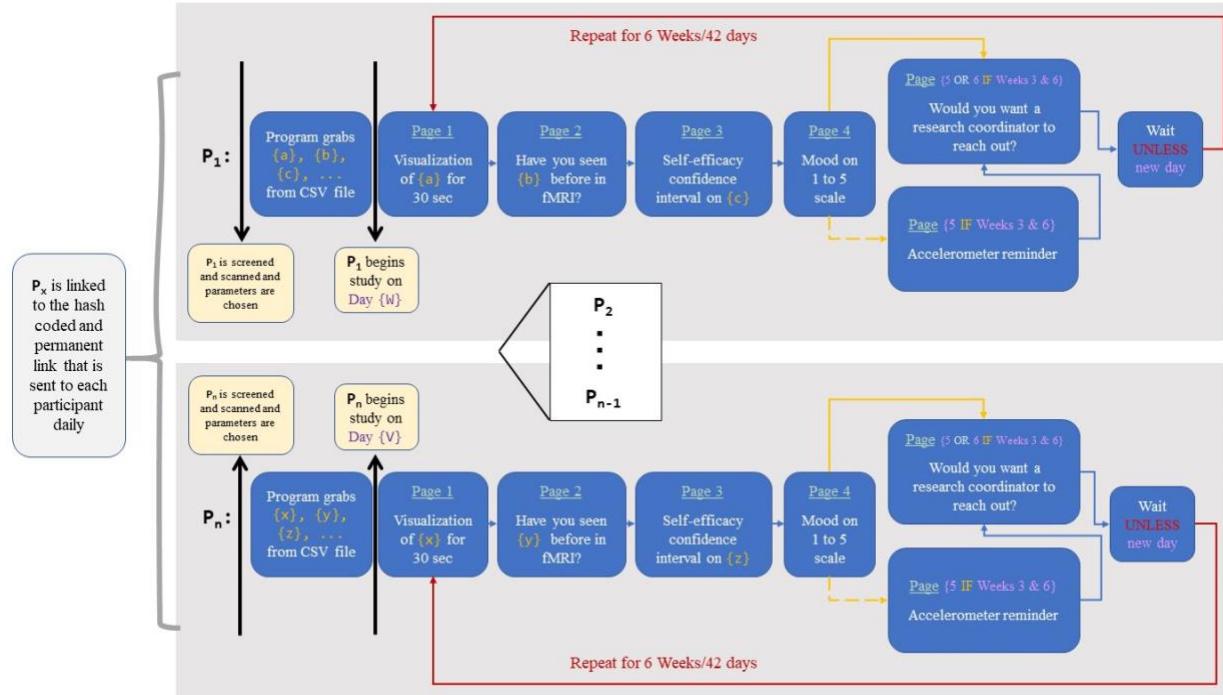
186 inventories, neuropsychological tests and physical assessments. Three accelerometer calls are
187 administered by two research assistants, for the purpose of giving instructions and answering
188 questions about accelerometers. The estimated overall participation time is 16 hours, which may
189 vary across individuals. To minimize attrition, each assessment session (i.e., T1, T2, T3, T4) is
190 self-paced and has been divided into smaller visits, each of which lasts no longer than 2 hours.
191 During each visit, participants take breaks every 20 minutes to minimize the risk of fatigue.
192

193 ***Daily messaging***

194

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

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



223
224 **Figure 2.** Messaging system setup and logic. Each participant (represented by P_x , where x designates the
225 participant number) receives their unique link. In that link, they follow a series of pages each day that
226 contains their unique questions and parameters based upon the inputted comma-separated values (CSV)
227 file. The system does not initiate until the participant begins on their first day and then repeats for 42 days
228 (4 weeks) for the duration of the daily messaging intervention. The process occurs synonymously for all
229 other participants. Links that are not activated simply remain idle until a participant is assigned that link
230

231 Measurements and materials

233 Physical activity monitoring

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

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

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

262

263 **Data management**

264

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

274

275 *Analysis plan*

276

277 Power calculations were performed to statistically determine the target sample size of
278 N=80 for this pilot study. The power is calculated in R based on a two-sample T-test model with
279 our primary outcome, the percent of daily sedentary time assessed using an activPAL. We
280 expected a similar baseline sedentary sample to the study by Falk et al., where participants were
281 sedentary an average of $50.6\% \pm 14.0\%$ of their time [11]. Our proposed sample size of 80
282 participants (40 per group) will allow us to detect a minimum detectable difference of 10.0%
283 between the two groups (i.e., the group difference in averaged sedentary time/total valid awake
284 time) at week 4 post intervention with a common standard deviation of 14.0% with 80% power
285 and a two-sided alpha of 0.05, with 20% drop-out rate accounted. We expect that the ratio of
286 sedentary time/total valid awake time in the self-affirmation + positive framing group will be
287 10.0% less than the control negative framing group, based on our power analysis.

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

297 physical activity) over time (3 time points) are analyzed using linear mixed effect models to
298 account for the correlated data and likely heterogeneous variability. These models will include a
299 random intercept and slope to account for subject-specific changes as well as a group (2) x time
300 (3) interaction fixed effect. This allows for modelling of the effect of our intervention as a
301 function of both group and time as well as accounting for potential confounding covariates. All
302 model assumptions will be tested both visually and formally and associations between covariates
303 will be assessed to protect against multicollinearity. All valid data are included in the model
304 initially, followed by per protocol analyses, in which the cases with (1) less than 4 valid days of
305 ActiGraph or (2) less than 5 valid days of activPAL or (3) more than 2 days with non-
306 compliance of daily message intervention are excluded in the analysis. For the final dataset, the
307 multiple imputation by chained equations (MICE) will be used for imputing missing values with
308 10 imputations.

309

310 Discussion

311

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

321 There are several notable limitations to this study, yet we have taken a number of
322 measures to minimize their impact. First, this is a pilot study with only a moderate sample size.
323 Nevertheless, a power analysis of our primary outcome measure was performed to ensure that a
324 sample size of 80 is sufficient to detect a true effect with 80% power. Additionally,
325 interpretations of individual component contributions of our intervention are to be taken with
326 caution given we cannot disentangle the effect of gain-framed messaging from self-affirmation.
327 Regarding the inclinometer and accelerometer-based assessments, we are limited to the
328 collection of data for 3 periods of 1 week (i.e., not assessing accelerometry throughout the entire
329 6-week intervention). However, the use of two state-of-the-art devices allows us to accurately
330 capture both sedentary time and physical activity, to get a more comprehensive picture of
331 physical activity and sedentary behavior of participants. Furthermore, continued monitoring of
332 daily engagement with the intervention is performed and a researcher will make contact with
333 study participants to maximize compliance.

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

341

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