Study Title: Manipulating Action Plans to Improve Physical Activity Behavior and Cognitive Health in Older Adults

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UNIVERSITY OF NORTH CAROLINA AT GREENSBORO

CONSENT FOR PARTICIPATION IN RESEARCH

Protocol Title: Planning Actions for Consistent Engagement

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Key Information

You are being asked to volunteer for research. *Below is some key information to keep in mind when thinking about why you may or may not want to be in the research. Additional details will follow.*

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether to take part. If you decide to be involved in this study, this form will be used to record your consent. You must be at least 18 years of age to participate.

Purpose of the Study

You have been asked to participate in a research study about forming weekly plans to promote a target health behavior and cognitive functioning. The purpose of this study is to determine which is the planning method that best promotes healthy behaviors and cognitive functioning in older adults.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because you are an adult age 60 years or older and are currently not meeting federal physical activity guidelines of 150 minutes per week of moderate to vigorous intensity physical activity but would like to become more active at some point in the next 6 months. Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits.

How many people will take part in this study and how long will it take?

About 160 people will take part in this study. Your total time commitment will be around 7.5 hours spread out over 9 months.

Here's what your participation will look like:

- **Training:** You'll attend three short training sessions (two 30-minute sessions and one 1-hour session), totaling about 2 hours.
- **Before the intervention:** You'll complete a short online survey (about 15 minutes), do mobile cognitive assessments twice a day for 7 days (about 6 minutes per day), and wear a Fitbit for 7 consecutive days.
- **During the 6-month intervention:** Each week, you'll spend about 4 minutes creating action plans and answering study questions. At the end of each month, you'll do cognitive assessments twice a day for 7 days (about 6 minutes per day). You will wear the Fitbit each day during the 6-month intervention.
- **After the intervention:** You'll continue to wear the Fitbit for 3 months after the intervention is over. At the end of the 3 months, you will complete another 7 days of cognitive assessments (about 6 minutes per day) and a short smartphone questionnaire (about 4 minutes).

What will you be asked to do?

If you agree to participate in this study, you will be asked to complete the following study procedures:

- Initially, you will take part in a 30-minute training session. The first session will walk you through downloading the Metricwire app onto your personal smartphone and using it to complete brief mobile cognitive assessments. These assessments will be administered twice daily for 7 consecutive days.
    - **Morning assessments** will be delivered approximately 30 minutes after your usual wake-up time, and you'll have up to 3 hours to complete them.
    - **Evening assessments** will be sent at 8:00 PM, and we ask that you complete them before going to bed.

  Each cognitive assessment takes no more than 3 minutes to complete, totaling about 6 minutes per day. You'll begin the first assessment the morning after your initial training session and continue for 7 days.
- After completing the cognitive assessments, we will evaluate how well you adhered to the cognitive assessment instructions, and you may be invited to the next part of the study.
- The next part of the study involves attending another 30-minute training session. The second training session will focus on setting up, wearing, and charging your Fitbit. Following this session, we'll ask you to wear the Fitbit monitor continuously for another 7-day period. We will mail you your Fitbit device prior to holding the second training session,
- After completing the baseline assessments, you will be assigned to one of three planning groups. Regardless of your planning group assignment, you will be asked to attend a 1-hour action planning training session. You will be asked to follow the planning instructions of the group you are assigned to.

- Following the action planning training session, on Sunday each subsequent week for 6 months, you will be instructed to create a plan for the upcoming week and to complete study measures. At the end of each month, for 7 consecutive days, you will complete mobile cognitive assessments. During the 6-month intervention, you will continue to wear the Fitbit monitor.
- After the 6-month intervention, you will stop creating weekly action plans but continue to wear the Fitbit monitor for 3-months.
- At the end of the 3-month follow up period, you will complete a smartphone-based questionnaire and 7 consecutive days of cognitive assessments.

What are the risks involved in this study?

The risks involved with participation in this study are low and may include:

In this study you will be asked to develop plans to engage in a target health behavior over the course of the 6-month intervention. There are risks associated with engaging in a new health behavior. For instance, changes in your eating habits could result in digestive issues. Similarly, adopting new sleeping patterns can results in temporary fatigue or grogginess during the day. Some individuals may be asked to plan to engage in physical activity as part of the planning intervention. Potential risks of physical activity participation include muscle fatigue, soreness, dizziness, and/or falls during or after physical activity. Abnormal changes in heart function, and, in very rare instances, heart attack (non-fatal or fatal) may also occur during physical exertion. However, the risk of this happening is reported as 1 in 10,000 deaths during maximal fitness tests and risks are dramatically lower for submaximal physical activities at a self-selected pace as will be implemented in this study. To reduce risks associated with changing one's behavior, we will encourage participants to consider the frequency, intensity, and/or duration of their engagement in the target health behavior, with the goal of ensuring that such changes are manageable, sustainable, and unlikely to results in injuries. We will also monitor participants injuries and changes in participant's medical history over the course of the study.

There are minimal psychological, social, or legal risks associated with completing the measures for this study. One foreseeable risk may be psychological in that, you may experience some guilt, discomfort, or embarrassment with your engagement in your target health behaviors.

There are potential risks of becoming frustrated when completing these assessments. However, you will receive written instructions on how to complete the tasks and be given opportunities to practice the tasks. Further, in the training session, we will verbally summarize study procedures in lay language and provide a brief video of an individual demonstrating completing the tasks.

One risk is the potential loss of your private information. We will take great care with your information by using a code, rather than your name, for all data collected and analyzed in this study. Your name will be matched with your number only on a master list. This master sheet will be stored on a university-approved, secure file storage system (e.g., Box) and will be accessible only to personnel directly involved with this study. All other means of subject identification (e.g., test protocols) will be by your number only.

This study asks you to use the Metricwire mobile application. Third party software is outside of UNCG's control. Your information could get out or be used by Metricwire for other purposes that are not related to the study. Your smartphone could be corrupted. Please carefully read and think about the Metricwire Terms of Service and Privacy Policies before agreeing to give them any of your information. If you do not want to share your data with Metricwire, that is completely acceptable, but you will not be able to enroll in this study.

Finally, the researchers will tell you about any important new information that is learned during this study, which might affect your condition or your willingness to continue participation in this study.

What are the possible benefits of this study?

The possible benefits of participation are potentially numerous. Creating detailed plans is an effective strategy for changing behavior. Therefore you are likely to increase engagement in your target health behavior. For those instructed to make plans about physical activity, the physical and psychological benefits that reliably result from regular physical activity participation far outweigh the minimal risks. Beyond the common physical and psychological benefits, there are additional benefits of becoming more physically active for participants including improvements in cognitive function.

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with the University of North Carolina Greensboro in any way. You may choose not to be in the study or to stop being in the study before it is over at any time. You may choose not to answer a question or question(s) for any reason. You will receive a copy of this form.

Will participating in the study cost you anything?

There is no direct cost to participate in this study. However, participants will be asked to download the Metricwire mobile application to their personal smartphone, which may result in minimal data usage charges depending on your mobile service provider.

Will there be any travel or other study-associated costs (for example, child care) and will researchers provide any money to cover those costs?

No. All appointments will be conducted virtually via Teams.

Will I be paid for taking part in this research?

You can earn up to $120 for your time and effort in this study. Each month, you will receive $15 if you complete mobile cognitive assessments on at least 6 out of 7 days, including both assessments each day.

Additionally, you will also be eligible to be entered into drawings if you achieve specific levels of compliance with study procedures. You will be entered into a drawing for every week that you provide at least 10 hours of valid wear time on the Fitbit device for at least 6 days per week and complete your weekly action planning prompt. If you reach this threshold, you will be entered into a drawing to win one of 6, $25 gift cards. These drawings will be held each week of the 6-month

intervention period. You will receive the payment in the form of an electronic gift card. Participants can choose between an Amazon gift card or another electronic gift card.

If you complete all aspects of the study, you will be able to keep your Fitbit device after the conclusion of the study.

How will my information be protected?

We will make every effort to protect the confidentiality of study records that identify you, but we cannot guarantee total confidentiality. Your information will be viewed by the research team and other people within the University of North Carolina Greensboro who help administer and oversee research. People outside of the University of North Carolina Greensboro may also need to see or receive your information for this study. Examples include government agencies (such as the National Institutes of Health), safety monitors, other sites in the study and organizations that sponsor or help conduct the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time**.**

If information from this study is published or presented at scientific meetings, your name and other identifiable information will not be used. Absolute confidentiality of data provided through the Internet cannot be guaranteed due to the limited protections of Internet access. Please be sure to close your browser when finished so no one will be able to see what you have been doing.

Could my information be used for future research without asking for my permission?

Yes. If all identifiers (name, date of birth, etc.) are removed, it is possible that the information collected for this study may be used for future research studies or distributed to another investigator for future research studies without your consent.

What will happen if you decide to withdraw from the study?

If you decide to leave the study, contact the researchers so they know. The researchers may ask you the reason but you are not required to provide it.

Whom to contact with questions about the study?

Prior to, during or after your participation you can contact the researcher, Dr. Jaclyn Maher at 336-256-1379 or send an email to jpmaher@uncg.edu for any questions or concerns or if you feel that you have been harmed or injured as a result of being in the research.

Whom to contact with questions concerning your rights as a research participant?

Prior to, during or after your participation you can contact the Office of Research Integrity at UNCG at ori@uncg.edu to:

- Discuss problems, concerns, and questions, including questions about your rights as a person in a research study
- Obtain information
- Offer input.

The Office of Research Integrity at the University of North Carolina at Greensboro is not affiliated with any specific research study. You can contact anonymously if you wish.

If you want to volunteer to be in this research, please indicate so below

You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. You agree to allow the researchers to use and share your information as described in this form. By selecting the option to participate below, you are not waiving any of your legal rights.

_____
Printed Name

Do you agree to participate in the research study described above?

___ I agree to participate

___ I do not agree to participate