University of Southern California
USC Mrs. T. H. Chan Division of Occupational Science and Occupational Therapy
1540 Alcazar St., CHP-133, Los Angeles, CA 90089

INFORMED CONSENT

TITLE: A Smartphone Application to Improve Physical Activity in Underactive Older Adults

PRINCIPAL INVESTIGATOR: Stacey L. Schepens Niemiec, PhD, OTR/L

DEPARTMENT: Mrs. T. H. Chan Division of Occupational Science and Occupational Therapy

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

This study is about a smartphone application (app) that focuses on physical activity in older adults. We hope to learn what features of this smartphone app are useful in improving physical activity and reducing sedentary time of older individuals. You are invited as a possible participant because you are an older adult, own a smartphone, and are not meeting the nationally recommended amount of physical activity of 150 minutes of at least moderate intensity activity per week. About 100 participants will take part in the study.

WHAT IS INVOLVED IN THE STUDY?

If you decide to participate, this is what will happen:

Study activities:

- You will attend an assessment session at a convenient community location, or complete assessments by mail or email with instructions for electronic completion. The assessments will take about 1 to 1.5 hours to complete. The following procedures will be done:
  - Complete questionnaires about your background, health, and physical activity
  - Complete a brief walking task to test how well you move (during in-person assessment sessions only)
  - You will be shown, either in-person or via an instructional video or picture-based form, how to use an activity monitor that is worn on the thigh. You will wear this monitor for three (3) full days immediately following the testing session. We may ask you to enter some information into a log, like sleep and wake times. The monitor will tell us how much activity you do throughout the day.
- After the three-day home monitoring period, you will either return to a convenient community location to attend a group orientation session, or receive your orientation

online via videoconference with a staff member. This will last for about 2 hours. The following will be done:

- Learn about the smartphone application on physical activity
- Return the activity monitor and/or questionnaires you received at the testing session, if they were not returned by mail.
- You will be randomly assigned (like pulling a number from a hat) to one of 8 groups. Each group will receive a different set of features that are packaged with the smartphone app. You will be shown how to download a special physical activity app onto your smartphone and taught to use your assigned features. You will practice using the features as you would use them at home. Some features send messages throughout the day about standing up more often, the good things about growing older, or how much activity you have done each day. Other features might require you to complete an attention task once a week that involves focusing on a symbol and tapping the screen when you see a flash.
- You will be asked to carry your phone as much as possible throughout the day and use the app for four (4) months. Using the app may involve setting and entering goals related to your physical activity or sedentary time, checking picture and text-based messages that we send you, checking your progress related to your physical activity, completing an attention task once a week, and/or carrying the phone with you while you do physical activity.
- We will track your physical activity using the app if your phone *is* compatible with the in-app pedometer. If your phone is *not* compatible, we will loan you a very basic pedometer to wear that will track your steps. We will also check how often you use the app, such as how many times you open it on a daily basis. This information will be stored within the app and downloaded by the research team at the end of 4 months.
- We will telephone you once a month to see how things are going with the app and to help troubleshoot as needed. Additionally, you will have access to a troubleshooting hotline if you need more help with the app.

End of the study:

At the end of the 4-month period, you will either complete your assessments at a convenient community location, or by mail or email with instructions for electronic completion. You will be asked to do the following:

- Fill out questionnaires similar to what you completed at the beginning of the study. The session will last about 1 to 1.5 hours.
- Complete a walking task (at in-person assessment sessions only).
- You will be briefly interviewed about your experience in using the app. This interview, conducted at the in-person assessment session or via a phone call, may be audio/video recorded with your permission. You may decline to be audio/video recorded and still participate. In this case, the interviewer will only take notes during this segment.

- You will again be shown, either in-person or via an instructional video or picture-based guide, how to use a thigh-worn activity monitor to wear for three (3) days at home. You will be asked to enter information into a log, such as your sleep and wake times.
- Using a pre-stamped envelope, you will return the activity monitor and/or questionnaires to the research team when the three days are complete.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You might have some or all of the following discomforts or risks if you take part in this study:

1. Questionnaires/Interviews: Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions that make you uncomfortable.

2. Completing Physical Activity Testing (Walking task) during in-person sessions: There is a small risk that you may become unsteady or fall, as with any walking activity. You may also experience tiredness, fatigue, or mild muscle soreness which will likely resolve in less than one day. Chairs for you to sit on and rest will be available during the walking task.

3. Wearing Activity Monitor: Wearing an activity monitor on your thigh may irritate your skin. You may request a soft foam wrap that we will place on your body before fitting you with the monitor to help reduce any skin irritation.

4. Performing physical activities from the smartphone app: The smartphone app encourages physical activity. There is risk in performing any kind of physical activity while unsupervised. The severity of the risk might depend on your individual ability and medical history; however you were asked to be in this study because you believed you are healthy enough to walk regularly. Please consult with a healthcare provider before changing your physical activity routine.

5. Use of the smartphone app: The app may not be accurate in detecting how much physical activity you are doing because every smartphone is different. You may also feel uncomfortable carrying a smartphone during physical activity. The general risks of using a smartphone in daily life apply, such as a risk of tripping if you are walking and using the smartphone at the same time.

6. Positive aging messages: There is a slight risk that viewing positive messages about aging may have a neutral or negative influence on your physical activity or your attitudes about growing older.

7. Loss of confidentiality: There is a small risk that people who are not connected with this study will learn your identity or your personal information.

WILL YOUR INFORMATION BE KEPT PRIVATE?

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The University of Southern California's Institutional Review Board (IRB) may review your records. The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

Access to your personal information will be restricted to members of the study team. We will use a unique code identifier instead of your name. The link between the code and your personal information will be kept in a single master key document on a secured network. All other information that we collect from you will also be labeled with a code and not your name. Hard copies of any records will be stored in the principal investigator's office; digital copies will be stored on a secure, password-protected network. Documents with your name on it, such as this consent form, will be stored separately from coded documents.

Because the interview sessions may be video/audio recorded with your permission, you also will have the right to review and edit any recordings. During audio/video recorded sessions, we will refer to you using a false name to protect your identity. If personally identifying information is recorded, the research team will delete this information from the recording. The people who work on the study will see the notes and typed discussions of recorded interviews. Audio/video files will be stored on a secure data server at the University of Southern California until the transcription and analysis processes are completed. Once complete, the audio/video files will be destroyed.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

You may not receive any direct benefit from taking part in this study. However, your participation in this study may help us learn how to improve smartphone apps that address the issue of physical activity in older adults. Eventually, this app could become available to the general public.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be not to take part in this study.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

You may receive up to a total of $185.00 for your participation in this study:

- $25 to complete a baseline testing session
- $25 to complete a 3-day home-monitoring period
- $20 to complete orientation
- $40 toward each month of data plan usage and for completing each monthly telephone check-in ($10/month and check-in)
- $50 to complete a follow-up testing session
- $25 to complete a second 3-day home-monitoring period

If you receive more than $600 per year for taking part in one or more research studies, including this study, you may be required to pay taxes on that money. You may receive an Internal Revenue Service (IRS) Form 1099 if you receive more than $600 in one year for taking part in one or more research studies.

WHAT ARE THE COSTS?

There are no costs for participating in the study. However, you may incur a cost if you are required to provide proof of medical clearance from your doctor to participate in the study.

WHAT HAPPENS IF YOU GET INJURED OR NEED EMERGENCY CARE?

If you think you have been hurt by taking part in this study, tell the primary investigator immediately. This can be either face-to-face or by using the smartphone app hotline provided to you at the orientation session. If you require treatment because you were injured from participating in this study, treatment will be provided. You or your health plan/insurance will be billed for this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

WILL YOU RECEIVE NEW INFORMATION ABOUT THIS STUDY?

During the study, we may learn new things about the risks or benefits of being in the study. If we do, we will share this information with you. You might change your mind about being in the study based on this information.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this study is voluntary. Your decision whether or not to take part will not affect your current or future care at this institution. You are not giving up any legal claims or rights. If you do decide to take part in this study, you are free to change your mind and stop being in the study at any time. If at any time during or after the study you wish to withdraw information collected on yourself, you may do so and this information will be destroyed.

CAN YOU BE REMOVED FROM THE STUDY?

You may be removed from this study without your consent for any of the following reasons: you show any unforeseen side effects, you do not follow the investigator's instructions, or at the discretion of the investigator. If this happens, the investigator will discuss other options with you.

Study ID: HS-16-00670 Valid From: 3/23/2020

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Stacey Schepens Niemiec, PhD OTR/L at (323) 442-2069 with any questions, concerns, or complaints about the research or your participation in this study, or if you feel you have been hurt by taking part in this study. If you have questions, concerns, or complaints about the research and are unable to contact the research team, contact the Institutional Review Board (IRB) Office at 323-442-0114 between the hours of 8:00 AM and 4:00 PM, Monday to Friday. (Fax: 323-224-8389 or email at irb@usc.edu).

If you have any questions about your rights as a research participant, or want to talk to someone independent of the research team, you may contact the Institutional Review Board Office at the numbers above or write to the Institutional Review Board at 1640 Marengo Street, Suite 700, Los Angeles CA. 90033-9269.

You will get a copy of this consent form.

AGREEMENT:

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed (and Time)

I have personally explained the research to the participant using non-technical language. I have answered all the participant's questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time)