

Exergame Study for Family Caregivers

NCT05032872

Informed Consent Form

Upload Date: 06/20/2023

Document Date: 09/02/2021



Brandeis University, Department of Psychology

IRB Protocol: #20104R

Title of Project: Exergame Study for Family Caregivers

Investigators: Dr. Margie E. Lachman & Xin Yao Lin, MA

Informed Consent to Participate in a Research Study

We are inviting you to take part in a research study. This form will tell you about the study. The researcher will explain the study to you first. You may ask this person any questions that you have. When you are ready to make a decision, you may tell the researcher if you want to participate or not. You do not have to participate if you do not want to. If you decide to participate, the researcher will ask you to sign this statement. The researcher will also give you a copy to keep. This is a study to find the best ways to help caregivers increase their physical activity. We know that caregivers are busy and often do not have a lot of time to take care of their own health. We are testing different methods to see which ones work best to help caregivers become more active.

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

You are being asked to participate in this research study because you are:

- A caregiver for a family member (e.g., relative, spouse, friend) who is 65 years or older
- Own an Android smartphone with Google play store/internet access

What will I be asked to do?

You will be asked to do the following:

- 1) **Initial contact:** Before session 1, you will be asked to complete a survey on your phone or computer. It will include demographic questions (e.g., about your occupation and education level) and a pretest survey that asks about your exercise and wellness. After you complete the questionnaires you will receive your Fitbit.
- 2) **Session 1 Phone Call:** A research assistant will teach you how to use the fitness tracker during session 1. You will then be asked to wear the fitness tracker every day for two weeks. You will also start completing your weekly surveys at the end of week 1.
- 3) **Session 2 Phone Call:** After two weeks, there will be another phone call in which a research assistant will teach you how to install/use Go&Grow, which is a digital fitness app designed for caregivers.
- 4) **Weeks 3-8:** After session 2, you will wear the fitness tracker every day, and use/interact with Go&Grow for 6 weeks. Your usage of the fitness tracker and the app will be saved and transmitted to our research computer using your study ID number. You will be asked to use the app for 5-10 minutes daily. Each day, you are asked to try your best to reach the step goal you set for yourself in the app. Once a week, you will respond to a weekly survey. The questions should take approximately 10-20 minutes to complete.



- 5) **End of week 8:** You will complete a posttest which is the same as the one you completed before session 1.

How much of my time will it take?

- Initial contact pretest questionnaire will take about 30-45 minutes.
- Session one phone call will take about 15 minutes.
- Session two phone call will take about 30 minutes.
- In week one and two, wear the fitness tracker every day. It will record all the steps that you take.
- In weeks 3-8, use the fitness tracker and the app every day. It will record your steps. You can spend as much time as you want walking and other physical activity.
- Once a week, you will respond to a weekly survey. The questions should take approximately 10-20 minutes to complete.
- The end of the study questionnaire will take about 30-45 minutes to complete.

Will there be any risk or discomfort to me?

Any risks involved in this study are minimal and no greater than those encountered in everyday life. In some cases, you may experience mild discomfort such as sore muscles or joints following participation in an exercise session. This discomfort is not expected to last more than 24 hours and will gradually improve over time.

Will I benefit from being in this study?

You will not have any direct benefits from being in this study. Your participation will help us to gather information about caregivers' needs and the best ways to increase physical activity for family caregivers. This information will help us to understand and develop ways of supporting family caregivers by helping them to care for their own health by increasing physical activity.

Will I be paid for my participation?

You will be given a fitness tracker to use during the study. At the end of the study, you can keep the fitness tracker. In addition, you will receive a \$25 Amazon Gift card for completing all aspects of the study.

Will it cost me anything to participate?

It will not cost you anything to participate.

Who will see the information about me?

Your responses in this study will be confidential. Only the study researchers from Brandeis University, and the Human Subjects Research Protection Office at Brandeis University, which protects the rights of program participants, will have access to the information you provide. Your



name will never be used in any of our reports and presentations. Your name will not be stored with any of your data. Instead, we will use a code number to identify you and link all of your information. All information from the app and Fitbit are transmitted and stored in a secure way.

Anonymous versions of all your electronic data will be stored on secure computer servers. It will also be stored on password-protected computers of the research staff. The fitness tracker will record your activity data. Information about how you use the app will also be saved. These data will be stored on secure computers and computer servers.

No reports or publications will use information that can identify you.

What will happen with your information once this research study is complete?

Your information will be de-identified, that is no names or other identifying information will be associated with your data (information that can identify you will be destroyed) and kept indefinitely. (Note that, despite our best efforts to conceal your identity, there is always a small chance that someone could find out who you are. This is highly unlikely, but we must inform you that there is a small risk. We also would like the opportunity to share our study results and data with other researchers who are interested in our work. Please indicate if you agree, to put the de-identified data from the questionnaire and fitbit into a digital data repository (a place that helps researchers to share on-line with other researchers the information that they learn from their research). This allows other researchers access to the data for use in their own research with our permission and supervision. Your name and other identifying information will not be accessible in the data used for this research.

Follow-Up

After this study is over, we may want to reach out to you with follow-up and clarification questions. We may also want to reach out to you to let you know about opportunities to participate in future studies. May our staff contact you?

_____ YES, you may contact me for follow-up information or to alert me to new study opportunities

_____ NO, you may not contact me for follow-up information or to alert me to new study opportunities

Can I stop my participation in this study?

Your participation in this study is voluntary; and you are completely free to withdraw from the study at any time or to refuse to answer any questions, or to decline participation in any component of the study. If you stop participating before you complete the study, we will ask you to return the Fitbit and you will not receive the \$25 gift card.



Who can I contact if I have questions or problems?

If you have any questions, you can contact the Principal Investigators, Margie Lachman (781-736-3284), or the student researcher, Xin Yao Lin (646-258-3562).

Who can I contact about my rights as a participant?

If you have any questions about your rights as a participant, you may contact the Human Subjects Research Protection (Bernstein Marcus, Mail Stop: 116, 415 South Street, Brandeis University, Waltham, MA 02453; tel. 781-736-8133). You may call anonymously or email irb@brandeis.edu if you wish.

Alternatives

The alternative is for you not to participate in this study.

I have read the contents of this consent form, have been encouraged to ask questions, and have received satisfactory answers to my questions. I understand that my participation is voluntary and that I may withdraw my participation at any time without penalty. I voluntarily agree to participate in this study.

- ☐ I do ☐ I do not agree to take part in this study.
- ☐ I do ☐ I do not give you my permission to share my de-identified, anonymous data with other researchers in a data repository.

After the study is over, you may continue to use the app. However, please be aware that we will still have access to your app data for as long as you use the app. We would like to ask your permission to continue using your data from Go&Grow for our research.

- ☐ I do ☐ I do not give you my permission to use my data for further analyses after the study is over.