

Northeastern University and Brandeis University

College of Computer & Information Science and Bouvé College of Health Sciences

Title of Project: Roybal Center Pilot Project: Development of An Exergame for Caregivers of Family Members with Alzheimer’s Disease

Investigators: Dr. Andrea Parker, Dr. Carmen Sceppa, Dr. Margie E. Lachman

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.

Why is this research being done?

We are conducting a study to design and build a digital game. The digital game is for Alzheimer’s Disease / related dementia caregivers. This goal of the game is to increase caregivers’ physical activity and social connections.

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

We are asking you to participate because:

- you are a caregiver who spends a significant amount of time with a family member, partner, or friend with Alzheimer’s Disease or related dementia.
- you are 18 years or older.
- you are able to walk for at least 20 minutes at a time.
- you have regular access to an Android smartphone with Internet access.
- you are comfortable wearing a fitness tracker for the duration of the study.
- you have NOT had a cardiovascular event or a fall in the past 6 months.
- you are located in Massachusetts, New Hampshire, Rhode Island, Connecticut, or New York City.

What will I be asked to do?

You will be asked to do the following:

- 1) Session 1: You will first complete a survey with demographic questions (e.g., about your occupation and education level). Then, you will complete a survey that asks about your attitudes towards physical activity and other aspects of wellness. Next, a research assistant will teach you how to use the fitness tracker. You will then be asked to wear the fitness tracker every day for one week.
- 2) Session 2: After one week, you will come to a second session. A research assistant will teach you how to use a digital game. The digital game encourages physical activity and connections to other caregivers. You will then do a few tasks with the game. As you do these tasks, we will ask you questions about the game. You will also fill out a survey about the game.
- 3) Weeks 2-7: After session 2, you will wear the fitness tracker every day for six weeks. Your interactions with the fitness tracker and the game will be recorded. You will be asked to use the game for 15-30 minutes at least every other day. If more than three days have passed since your last usage, then you will receive a reminder to use the game, either through text messaging or the game. Once a week, you will respond to a couple of questions. These questions will be about your experience with the game. The questions should take approximately 2-3 minutes to complete. You will receive a \$5 Amazon Gift card each week upon completion of each weekly questionnaire. You can receive up to a \$30 of Amazon Gift card by the end of the study.
- 4) Session 3: Session 3 will take place after you use the game for six weeks. You will fill out a survey. The survey is on your attitudes towards physical activity and other aspects of wellness. We will then ask you about your experience with the game. We will also ask you about how the game could be improved.

How much of my time will it take?

- Session one will take about 60 minutes.
- Session two will take about 60-90 minutes.
- Session three will take about 60 minutes.
- In week one, using the fitness tracker will take about 15 minutes of your time.
- In weeks 2-7, using the fitness tracker and the game will take about 15-30 minutes every other day. You can spend more time using the fitness tracker and game if you like.

Will there be any risk or discomfort to me?

We do not foresee any risks associated with participating in this study.

Will I benefit by being in this study?

You will not have any direct benefits from being in this evaluation. Your participation will help us to gather information about the needs of caregivers of family members with Alzheimer's Disease or related dementia. This information will help us to understand and develop ways of supporting 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. The fitness tracker is worth over \$100. In addition, you will receive a \$5 Amazon Gift card each week upon completion of each weekly questionnaire. You can receive up to a \$30 of Amazon Gift card by the end of the study for completing all questionnaires.

Referral bonus. If you refer another person who is interested and eligible to participate in our study, AND that person successfully enrolls in our study, both you and the person you referred will receive an additional \$5 Amazon gift card reward. These gift cards will be provided to you upon completion of the study. You can receive up to a \$20 Amazon gift card reward for referring individuals that successfully enroll in the study. Enrolled participants can receive a maximum of a \$5 Amazon gift card for being referred. These referral bonuses will be available for enrolled study participants only, and until study enrollment has closed.

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 Northeastern University and Brandeis University, and the Human Subjects Research Protection Office at Northeastern 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 name or number to identify you.

Your paper records (e.g., surveys, consent forms) will be kept locked in filing cabinets.

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 and the game will record your activity data, such as step counts and GPS location. Information about how you use the game will also be recorded. These data will be stored on your phone and/or home computer and secure computer servers.

We would like to take photos and record audio and video during the interviews. These recordings may be used in our future reports and presentations. The attached form will provide more information about photographs and recordings.

No reports or publications will use information that can identify you, unless you provide your explicit permission.

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

Alternatives

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

Can I stop my participation in this evaluation?

Your participation in this evaluation is completely voluntary. You do not have to participate if you do not want to. Even if you begin to participate, you may stop at any time. If you do not participate you will not lose any rights, benefits, or services that you would otherwise have.

Who can I contact if I have questions or problems?

If you have any questions, you can contact the Principal Investigators, Andrea Parker (617-373-7228) or Margie Lachman (781-736-3284).

Who can I contact about my rights as a participant?

If you have any questions about your rights as a participant, you may contact Nan Regina at Human Subjects Research Protection (Mail Stop: 560-177, Northeastern University Boston, MA 02115; tel. 617-373-7570). You may call anonymously or email irb@neu.edu if you wish.

I agree to take part in this study.

Signature of person agreeing to take part

Date

Printed name of person above

Signature of person who explained the evaluation to the participant above and obtained consent

Date

Printed name of person above