Effects of a Gamified, Behavior Change Technique-Based Mobile App on Increasing Physical Activity and Reducing Anxiety in Adults With Autism Spectrum Disorder: Feasibility Randomized Controlled Trial

July 26, 2019

Technology-Guided Physical Activity for Reducing Anxiety in Adults with Autism Spectrum Diagnoses (ASD) (IRB approved: 1807483245)

You are invited to participate in a research study of the efficacy of a gamified mobile application intervention to increase physical activity and reduce anxiety in adults with ASD. You were identified as someone who may meet the eligibility criteria. We ask that you read this form and ask any questions you may have before agreeing to be participating in the study.
The study is being conducted by Dr. Georgia Frey and Daehyoung Lee, M.S. from Indiana University, School of Public Health, Department of Kinesiology.

STUDY PURPOSE:
The purpose of this study is to examine the effect of a gamified mobile game application on increasing physical activity and reducing anxiety in adults with ASD.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:
If you agree to participate, you will be one of 30 subjects who will be participating in this research.

PROCEDURES FOR THE STUDY:
If you agree to be in the study, you will do the following:
At the beginning of the study you will:

1. Answer demographic questions.
2. Provide height and weight information.
3. Complete the Autism Quotient 10 instrument.
4. Complete the International Physical Activity Questionnaire (IPAQ).
5. Complete the Beck Anxiety survey.
6. Learn how to install and respond to the Ecological Momentary Assessment (EMA) surveys.

After completing these initial tasks you will:

1. Be randomized to either the Puzzle Walk or Google Fit app group. Even if you are in the Google Fit group, you will be given the Puzzle Walk app at the end of the study.
2. Wear a motion sensor on the waist during waking hours for total 21 days: 7 days for pre-test, 7 days at 4-weeks, and 7 days at 8-weeks. You will be encouraged to wear a motion sensor at least 2 weekdays and 2 weekend days in each data collection period.
3. Install and utilize a physical activity mobile application during the data collection period.
4. If you have an Android phone, you will provide usage of the PuzzleWalk or Google Fit app through EMA app. EMA app will allow the researchers to collect location, physical activity, app usage pattern (when you use them, and for how long), where you are when using the app, and notification data. Any personal information or data (text message, contact information, private notification etc.) will not be collected. If you do not have an Android phone you will not have access to the EMA app.
5. If you have an Android phone, you will answer 6 questions about your physical activity and anxiety on a daily basis while wearing the motion sensor, using the EMA app. If you do not have an Android phone you will not have to answer the 6 questions.

6. At every data collection period (1-week, 4-week, and 8-week time points) complete the IPAQ and Beck surveys.

STUDY MEETINGS:

Participants who reside within a 100-mile radius of Bloomington, IN (= local participants, hereby)

Participants who reside outside a 100-mile radius of Bloomington, IN (= remote participants, hereby)

Meetings will occur at a location of your choice for local or via Facetime for remote participants. All documents can be completed in written or electronic form, according to your preference.

Meeting 1: time will be approximately 1 hr. (Study intake and Familiarization)

**Remote participants will receive consent materials, study materials and surveys before this call via email.*

Review and obtain informed consent.
Collect demographic information.
Measure/provide height and weight.
Explain motion sensor wear and go over the wear logs.
Distribute study materials
Complete IPAQ, Beck anxiety scale, and AQ10 autism screening.
Learn how to install and respond to the EMA surveys.

**Once remote participants complete this meeting, the motion sensor and study materials will be directly mailed to you.*

You can have as much time as you need to practice wearing the motion sensor until you feel comfortable.

Meeting 2: time will be approximately 30 min. (1-week beginning)

Explain motion sensor wear and go over the wear logs.
Complete IPAQ and Beck surveys.
Distribute study materials

Meeting 3: time will be approximately 15 min. (1-week end)

Collect all study equipment and materials from local participants.
Remind remote participants to recharge motion sensor.
Complete IPAQ and Beck surveys.

Meeting 4: time will be approximately 15 min. (4-week beginning)

Download the necessary mobile applications (PuzzleWalk or Google Fit/Pacer) and learn how to use the applications.
Distribute study materials for local participants.
Verify motion sensor has been charged for remote participants.
Explain motion sensor wear and go over the wear logs.

Complete IPAQ and Beck surveys.

Meeting 5: time will be approximately 15 min. (4-week end)

Collect all study equipment and materials from local participants.
Remind remote participants to recharge motion sensor
Complete IPAQ and Beck surveys.

Meeting 6: time will be approximately 15 min. (8-week beginning)

Distribute study materials for local participants.
Verify motion sensor has been charged for remote participants.
Explain motion sensor wear and go over the wear logs.
Complete IPAQ and Beck surveys.

Meeting 7: time will be approximately 15 min. (8-week end)

Collect all study equipment and materials.
Complete IPAQ and Beck surveys.
For remote participants, verify motion sensor is returned in the self-addressed, stamped envelope provided by the researchers.
Receive compensation.

Post-test Contact: time will be approximately 15 min (4-weeks post-test)

A follow-up phone call and or e-mail will be made to determine if you are still using the mobile applications.

RISKS OF TAKING PART IN THE STUDY:
Wearing the motion sensor may be mildly uncomfortable, but the device will not hurt you. We will attempt to minimize this discomfort by providing time for you to get used to wearing the device. You will dictate the time needed for this familiarization. During the informed consent process, if applicable, you will be informed of the precautions that will be taken to protect the confidentiality of the data and be informed of the parties who will or may have access, such as research team, the Indiana University Institutional Review Board, and Office for Human Research Protection. This will allow you to decide about the adequacy of the protections and the acceptability of the possible release of private information to the interested parties.

BENEFITS OF TAKING PART IN THE STUDY:
There are not direct benefits from participating in this study. You will be helping us develop interventions to increase physical activity and reduce anxiety in adults with ASD.

CONFIDENTIALITY:
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Your

identity will be held in confidence in reports in which the study may be published and in databases in which results may be stored. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies who may need to access your research records.

FUTURE USE OF INFORMATION:
Information collected for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

PAYMENT:
You will receive a gift card valued at $100 for taking part in this study. You must complete the 2-month protocol and return the motion sensor to receive compensation. No partial compensation will be provided for partial completion.

CONTACTS FOR QUESTIONS OR PROBLEMS:
For questions about the study or a research-related injury, contact the researchers Daehyoung Lee, MS at 812-272- 0649 or Dr. Georgia Frey at 812-855-1262. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (812) 856-4242 or (800) 696-2949 or you can e- mail Daehyoung at Lee2055@indiana.edu or Dr. Frey at gfrey@indiana.edu.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or [for Indianapolis] or (812) 856-4242 [for Bloomington] or (800) 696-2949.

VOLUNTARY NATURE OF STUDY:
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with your school, work, or program.

CONSENT:
In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Printed Name of Participant:_____

Date:_____
(must be dated by the subject)

Signature of Participant:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____

Date:_____