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Physical Exercise for Augmenting Cognitive Health (PEACH)

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INFORMED CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Study Title: Promoting Cognitive Health among Adults Exposed to Early Life Adversity through Physical Activity

Study Sponsor: National Institutes of Health

Principal Investigator:

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Key information:

You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

The purpose of this study is to learn whether a 12-week home-based exercise intervention can improve thinking and mood among adults who have experienced certain events during childhood. Prior to starting the intervention, you will be asked to attend one in-person visit at the Psychology Department at the University of Pittsburgh and a second visit in your home, totaling 3 ½ hours combined. The first visit involves assessments of thinking and mood, and the second visit at your home is an exercise training session to familiarize you with the equipment you will be using. This equipment will be delivered to your home, after which you will complete three exercise sessions per week for 12 weeks. You will then be invited to come back to the lab for a

follow-up assessment visit lasting 2 hours, where you will complete assessments of thinking and mood. Possible risks of participation include exercise-related soreness or injury, or in very rare cases, a cardiac event. Study team members have extensive training in safety monitoring and will work closely with you to ensure that your exercise program is safe for you. If you participate in this study, no direct benefit will be obtained. However, you are contributing to medical science and helping to advance future understanding of how to implement home-based technology-assisted exercise protocols.

Why is this study being done?

Recent research shows that negative childhood experiences may influence health and well-being in adulthood. We are conducting this study to examine the feasibility of using a 12-week technology-assisted home-based exercise intervention among adults who report having one or more negative experience in childhood. We will also explore whether engaging in regular aerobic exercise at home improves aspects of thinking and mood. This study may provide new information that, in the future, leads to programs that improve health outcomes for adults with negative childhood experiences.

Who is being asked to participate in this study?

You are being asked to participate in this study because you are between 30 – 55 years of age and reported having at least one negative childhood experience. Up to 20 men and women are being asked to participate. This study is being conducted by the University of Pittsburgh.

What procedures will be performed for research purposes?

If you agree to participate in this study, you will first complete a set of questionnaires assessing your health history and certain childhood experiences. These questionnaires will be completed on your personal electronic device (phone or computer) via a secure online platform called REDCap and will be used to determine your eligibility for the study. If you meet eligibility criteria, you will be asked to complete 2 separate in-person visits, one at the University of Pittsburgh and one in your home. The first session will last approximately 2 hours, while the second session will last about 90 minutes, for a total of 3 ½ hours.

Initial In-Person Assessment Visit: At the first visit, you will be asked to provide information about your current level of physical activity, your thinking and mood. Some of these assessments will be completed using paper and pencil, while others will be completed on a computer or iPad. You do not need to have computer experience to complete these tests, all instructions will be explained to you. In these tasks, you will be responding to either letters, symbols, words, or faces presented on the display by pressing buttons as rapidly and accurately as you can on a standard keyboard/touch screen. For some of the stimuli, you may be asked to recall the items at a later time in the session. During this session, there will be break periods at regular intervals for you to rest your fingers and eyes. This assessment will be repeated after you complete the 12-week intervention.

At the end of this visit, you will be fitted with a (FDA approved) small physical activity monitoring device (Actigraph Link) to be worn around your wrist similar to a watch. This device will measure your energy expenditure, number of steps, physical activity duration and intensity, as well as your sleep duration and sleep efficiency. This is a safe device used to assess a person's activity

habits. You will be provided with detailed instructions on how to operate the device, (including the option to remove the device if it becomes a problem). We will ask you to wear the device for approximately 1 week to obtain activity information throughout daily life. While wearing this device, you will not be able to view any of the data. You will also not be able to keep the device as it will need to be used by other participants throughout this study.

Exercise Training Session: After the 1-week period of wearing the activity monitor, we will schedule a second visit that will occur at your home. After you have completed the baseline assessments at the University of Pittsburgh and 1 week of activity monitoring, a bicycle and tablet will be delivered to your home by two staff members. The equipment will be set up for you and a supervised exercise session using the study tablet will be completed to establish safety, troubleshoot technology-related issues, and help you get familiarized with your prescribed exercise regimen. You will be supervised by an exercise physiologist. During this visit, you will learn to recognize how your body feels when you engage in moderate-intensity aerobic exercise on a stationary bicycle ergometer that is similar to the one that will be delivered to your home for the intervention. The exercise physiologist will show you how to safely use the stationary bike, as well as how to use the Neotiv application that you will log your at-home exercise sessions with. The exercise physiologist will also provide you with a commercially available heart rate monitor and show you how to properly use it. The heart rate monitor will be worn during all at-home exercise sessions. The exercise physiologist will also monitor your blood pressure during this session to ensure your safety during exercise. You will also return the activity monitoring device at this visit.

Intervention Description: After completion of this supervised exercise session at home, you will be asked to complete three moderate-intensity aerobic exercise sessions per week for 12 weeks, working up to 150 minutes of weekly moderate to vigorous intensity exercise by the end of the first month of the intervention.

Exercise Sessions: Prior to each exercise session, you will wear loose and comfortable clothing and walking shoes and put on the heartrate monitoring chest band provided to you by the study team. You will then turn on the study tablet, click on the Neotiv application, and answer any questions you are prompted to respond to prior to beginning the exercise session. These questions may include rating your mood and energy level. You will then begin the exercise session. After warming up with slow paced seated pedaling for 5-minutes, you will continue with the same exercise for another 45 minutes at a higher level of exertion. We will coach you to use a simple scale to rate how much you exert yourself with each exercise. The target will be for your exercise to be at the moderate exertion level. After completion of exercise on the bicycle, we will ask you to engage in 10-minutes of light stretching exercises per instructions provided by the study team. During the exercise session, you will view a sequence of pleasant, scenic pictures that will automatically appear on the tablet. After completion of the exercise session, you will hit the end button on the Neotiv application, after which you will be prompted to answer some additional questions on the tablet. Responding to these questions should take no more than 5-minutes. After responding to these questions, you will put the tablet into standby mode as instructed by the study team. A study team member will be reviewing data from each of your exercise sessions (exercise duration, bike resistance, your average heart rate) within 24-hours of your scheduled exercise to assess your safety and progress. If there is concern regarding safety based on review of exercise session data, a study member will contact

you over the phone. Each week during the weekly check-in, the trainer will gradually increase the intensity of your exercise (e.g., by requesting you increase pedaling speed or resistance or both) until you reach moderate to vigorous intensity. The trainer will use your heart rate data collected during your exercise sessions from the week to determine how much of an increase in intensity is needed. As you progress in the intervention, these increases in intensity may become smaller or may not be necessary if you have reached moderate to vigorous intensity. You will not have to increase the intensity until the trainer requests that you do so.

Weekly Check-in: Your prescribed exercise sessions will be reviewed with you with a study team member during weekly email, phone or via a video call using HIPAA-compliant zoom. The format of the check-in (email, phone, or zoom) will be determined by you and the trainer based on your progress and needs. If it is determined that you will check in via a phone or zoom call, these calls will be scheduled to last approximately 30-minutes but can take more or less time depending on your individual needs. The purpose of these check-ins is to answer any questions regarding exercise procedures, troubleshoot barriers to exercise adherence, evaluate exercise progress, and check-in regarding any changes you may experience in mood symptoms. Safety will be reviewed during these check-ins to address any concerns that may have arisen during the prior week. You will also be encouraged to contact study staff if concerns arise during or after your exercise sessions.

The staff person will also check in with you about the stationary bike and whether there are any repairs that will need to be made to the bike. In the event that a repair is needed, the staff person will schedule a time for someone from the study team to come to your home to make such repairs or to collect the bike to return to the manufacturer. If we have to return the bike to the manufacturer for repairs, we will provide you with another bike within 5 days and discuss with you how to make up any missed exercise sessions that occurred due to not having the bike in your home.

What are the possible risks, side effects, and discomforts of this research study?

We believe that this research poses only minor risk. However, if at any time you feel uncomfortable with the exercise, mental tasks, or with any of the questions you are asked, you can stop participating in the study.

Risks of Cognitive Assessment: It is possible that during the completion of measures assessing your cognitive function, you may become bored, frustrated, or tired. In order to prevent these risks, you will be offered breaks during testing periods. You do not have to complete questions that you choose not to answer. You are encouraged to notify us of any discomfort or ask any questions you have at any time.

Risks of Questionnaires: Risks associated with completing questionnaires about mood, physical activity, health history, and childhood experiences are considered minimal. Some of the questions may ask sensitive information, including medication use and health history, and it is possible that this may make you uncomfortable. To minimize this risk, you can opt not to answer these questions. If you experience emotional distress while completing questionnaires, please notify the staff person working with you. They will alert the principal investigator, Dr. Kirk Erickson. You will also be provided with a list of mental health resources in the Pittsburgh area.

As with all studies that involve the collection of identifying information, there is a potential risk for breach of confidentiality. However, we minimize this risk by using a coded survey (i.e., your name or other identifiable information would not be directly linked to your responses), as well as keeping all consent forms, questionnaire data, and other identifying information confidential and maintained in locked files.

Risks of Blood Pressure Measurement: Blood Pressure measurement requires inflating a cuff around your upper arm and gradually releasing the air from the cuff. You may experience discomfort while the cuff is inflated. However, this procedure is very brief (less than 1 minute) and there are no safety concerns associated with taking a blood pressure measurement.

Risks of Activity Monitor: The wristband that secures the device to your wrist are tolerated well by most participants; however, you may experience mild chafing or skin irritation as a result of wearing the device. These risks can be minimized by cleaning the area of the skin as soon as possible and discontinuing use if skin chafing or irritation occurs.

Risks of Aerobic Exercise: There is a possibility that during or after participation in aerobic exercise, you may have an injury to a joint or muscle or have muscle soreness or fatigue. This risk is minimized by starting the exercise session at low level and increasing the level as you tolerate. Other infrequent risks include equipment malfunction, dehydration, and heat exhaustion. Falling is another infrequent risk involved in doing exercise, although this risk will be lessened by the close monitoring of exercise sessions by an experienced exercise physiologist. Physical activity may be related to serious cardiac events in less than 1 per 20,000 exercising adults, but this appears to be minimized when participation is directed by knowledgeable and experienced professionals and when progressed in a moderate and appropriate manner. Since assessment of vital signs and history of heart disease are included in the screening procedures, we anticipate that this risk is rare.

Risks of Privacy and Breach of Confidentiality: There is a possibility that your study research data could become generally known, however, all data will be identified by a code and would not contain identifying information (e.g., name, birthdate). All documents would be stored in a separate location from the data and the screening information in locked filing cabinets in a locked and secure room to which only lab personnel have access. Multiple levels of password protection (e.g., record, file, directory, server, and computer levels) are employed to ensure data security. All personnel involved in the study would be approved through the University's Institutional Review Board and would sign a statement agreeing to protect the security and confidentiality of identifiable information. All data pertaining to the individual would be stripped of all identifying information. Only authorized users are allowed to connect to the network, and the security of the network is actively monitored.

Risk of Email Communication: Although every reasonable effort will be taken, confidentiality during internet communication activities cannot be guaranteed and it is possible that information may be captured and used by others not associated with this study. However, email communications will be limited to scheduling of appointments (e.g., baseline or follow-up assessment visits, delivery of equipment) and brief check-ins involving your exercise program. Research personnel will never include sensitive personal information in their email communications to you.

How will my Confidentiality be Protected?

Your research information and data may be shared with investigators conducting other research at a future date, but your identity on these records would be indicated by an ID number, rather than by your name; the information linking these numbers with your name would be kept in a separate, secure location. Your identity would not be revealed in any description or publications of this research; only group characteristics would be published. All computerized records would be password protected.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from

willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information. Representatives from the National Institutes of Health may also review study data.

The University of Pittsburgh Office of Research Protection will monitor the study to ensure requirements are met. Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project. Your research information may be shared with investigators conducting other research, although we plan to share this information in a de-identified manner.

Will I be paid if I take part in this research study?

You will be compensated for some of your time associated with the assessments planned as part of this study. Payment will be $30 for your baseline assessments and $5 for the completion of activity monitoring prior to the start of the intervention. After the intervention is completed, you will receive $40 for the follow-up assessment and $10 for completion of a second round of activity monitoring. You will also receive a bonus of up to an extra $15 for completing the intervention with at least 80% completion of scheduled exercise sessions. You will not receive this bonus if your session completion rate is below 80%. You could be compensated up to $100 for completing the entire study.

Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

Who will know about my participation in this research study?

Any information about you obtained from or for this research study will be kept as confidential (private) as possible. As a participant, you will be assigned an identification number. This number, instead of your name, will be used in all data analysis and records. The database for which your identifiable information is located will be password protected and will have limited accessibility. Information not recorded electronically will be stored on file in a secured storage cabinet within a locked office also with limited accessibility. You will not be identified by name in any publication of the research results unless you sign a separate form giving your permission (release).

What are the potential benefits from taking part in this research study?

If you participate in this study, no direct benefit will be obtained. However, you are contributing to medical science and helping to advance future understanding of how to implement home-based technology-assisted exercise interventions.

Whom Should I Contact if I have Questions?

You may ask any questions about the research at any time. If you have questions about the research, you should contact Dr. Kirk Erickson, PhD at (412) 624-4533. If you are not satisfied with the response of the research team, have more questions, or want to talk with someone about your rights as a research participant, you should contact the University of Pittsburgh Human Subject Protection Advocate toll-free at 1-866-212-2668.

Is My Participation in this Study Voluntary?

Yes! Your participation in this research study is completely voluntary. You can choose to withdraw from the study at any time. If you decide not to participate or to withdraw from the study, there would be no consequences whatsoever on your current or future relationship with the University of Pittsburgh. If you choose to withdraw from this study, all data collected prior to the date of withdrawal would be continued to be used, unless you request that we destroy it. If you would like to withdraw from the study, contact the Principal Investigator, Dr. Kirk Erickson.

If I Agree to Take Part in this Research Study, can I be Removed from the Study Without My Consent?

You may be removed from the study if you are not able to complete the study procedures, or if the research staff determine that it is in your best interest to stop participating. For instance, if you experience an injury, illness or other condition at any time during the course of this study, your participation may be suspended (e.g., after temporary illness, such as a cold) or terminated by researchers to ensure safety and well-being. If removed from the study, any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you were withdrawn from participation may continue to be used and disclosed by the investigators for the purposes described.

Compensation for Injury:

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you would be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

Data Sharing:

De-identified data will be shared with collaborators at the University of the West Indies. We also plan to make the data from this study available to outside investigators under a data-sharing agreement. The data-sharing agreement provides for: (1) a commitment to using the data only for research purposes and not to identify any individual human participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. An oversight committee made up of the Principal and Co-Investigators will monitor, approve, and distribute the data. The oversight Committee will also monitor data analysis plans and development of manuscripts. Protecting the rights and confidentiality of your data will be our first priority. The National Institutes of Health may also review study data. All data will be de-identified before sharing; that means no data that we share will have anything that personally identifies you. In the future, once we have removed all identifiable information from your data, we may use the data for our future research studies, or we may distribute the data to other investigators for their research studies. We would do this without getting informed consent from you (or your legally authorized representative).

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions would be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

_____

Printed Name of Participant

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date