COGNITIVE INTERVENTION TO IMPROVE SIMPLE AND COMPLEX WALKING (CREM)

Principal Investigators:

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ALBERT EINSTEIN COLLEGE OF MEDICINE OF YESHIVA UNIVERSITY

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called **Cognitive intervention to improve simple and complex walking (CREM).** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights.

The researchers in charge of this project are called the "Principal Investigators." The PIs names are **Drs. Joe Verghese and Roee Holtzer**. You can reach Drs. Verghese or Holtzer at:
1225 Morris Park Ave.
Van Etten Building, #308
Bronx, NY 10461
Telephone #: 718-839-7344

For questions about the research study, or if you believe you have an injury, contact the Principal Investigators or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253 or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by
National Institutes of Health

Why is this study being done?

The goal of this research study is to evaluate whether a walking difficulties among senior citizens is a potentially preventable chronic condition rather than an irreversible consequence of aging and disease. The research aims to demonstrate how seniors can achieve improved mobility (the ability to move freely and easily) by receiving cognitive (learning and understanding) training. The results of this study will provide insight for future mobility treatment options and, if successful, will establish an accessible and low-risk method to enhance mobility among older adults who are not physically active.

This study compares two interventions, both include exposure to computers. One group will receive computerized cognitive training. The second group will receive interactive computer sessions which include health education.

This clinical research study will provide important information regarding the utility of computerized interventions to prevent ambulatory (walking) disabilities. The primary (first) prevention strategy is physical exercise. Physical exercise is not a part of this research study.

Why am I being asked to participate?

You are being asked to participate in this study because you are 70 years of age or older. You were recruited from a random sample of Bronx and Westchester residents.

What will happen if I participate in the study?

If you agree to participate in this study you will be randomly be assigned into either an eight-week individualized computerized cognitive training or computerized health education program.

Both interventions will be given in **3 sessions weekly for 8 weeks**. The training will be given either in **3 sessions in 1 day per week or 1 session per day for 3 days per week**. Total training time for both interventions is about **2.5 hours per week (50 minutes per session)**. In one group, the training will consist of computerized cognitive training games designed to improve attention and reaction time skills. In the second group, the training will consist of interactive computer based sessions that include health education classes.

If you agree to participate in this study, the study interviewer will ask you questions about your medical history, education, daily activities, occupation, and mood. You will receive tests that measure cognitive functions such as memory and attention. You will also receive neurological and mobility evaluations, which are exams of gait (the way you walk), balance, coordination, hearing, vision, sensation and the strength and tone of muscles.

We are interested in how brain responses vary during the gait and cognitive tasks. We will be measuring the amount of oxygen being delivered to your brain tissue by using a near infrared light (a spectrum of red light just above the wavelength of visible red light), called Functional Near Infrared Spectroscopy. This is a technique used to evaluate brain functions during activities, such as walking and talking, and is examined through light sources that are arranged on a noninvasive and lightweight headband which is secured around the forehead. You will receive gait, mobility, and cognitive assessments at baseline and post-intervention at 9 weeks, six months and twelve months after intervention to assess durability of effects. Baseline assessments will take place over 2 days and last about 90 minutes per day. The post-intervention assessments conducted at 9 weeks, six months, and twelve months will take place over 1 day each and last about 90 minutes per visit.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The ClinicalTrials.gov Identifier number is NCT02567227.

How many people will take part in the research study?
You will be one of about **420** people who will be participating in this study.

Will there be audio and/or video recording?
Your whole body including face may be video-taped while these evaluations are performed. The tapes will be used by the research team to score the evaluations and refine measurements already collected. You will not receive any monetary compensation for allowing yourself to be taped. The tapes will not be destroyed at the end of the study as they may be used as teaching tools to study personnel or other students who are not members of the research staff.

Information Banking (Future Use and Storage)
We will store information about you in a “bank”, which is a library of information from many studies. This information cannot be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose, or treat disease, including genetic research. Your information may be kept for a long time, perhaps longer than 50 years. If you agree to the future use, some of your de-identified health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government.

You can choose not to participate in the bank and still be part of the main study.

INITIAL ONE (1) OF THE FOLLOWING OPTIONS
_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. The information will be destroyed at the end of the study.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your information or for any tests, treatments, products or other things of value that may result from the research.

Will I be paid for being in this research study?
After successful completion of baseline assessments you will be assigned to one of the intervention groups. You will receive **$5 for each intervention session and each post-intervention assessment visit for a total of $135** for the study. If you choose to withdraw from the study before all sessions are completed, you will be paid only for the sessions you completed.

Will it cost me anything to participate in this study?
There will be no cost to you to participate in the study.

Are there any risks to me?
• You may be embarrassed if you have some difficulties with some of the cognitive and or motor tests that you will be asked to perform.
• Some people may experience mild temporary distress after taking cognitive tests. If any distress is experienced, you will have the opportunity to have your questions answered by the investigators.
• Sensitivity to light (same as being exposed to sunlight without a hat or sunglasses): The brightness of the near infrared light that will be used is very low, and is equivalent to spending the same amount of time under sunlight without a hat. Although there may be some as yet unknown effects from exposure to near infrared light, these risks are thought to be the same as those associated with exposure to sunlight.
• Skin irritation from medical grade adhesive (rare): The near infrared sensor pad will be attached to your forehead using medical grade adhesive, similar to skin tape. Rarely, a few individuals are known to have adverse reactions to this type of adhesive. If you have ever had significant irritation or an allergic reaction to a medical adhesive such as skin tape, please inform the investigator.
• Mild headache (rare): During previous experiments using a much heavier sensor pad, some individuals experienced mild headaches while engaging in tasks that involved watching flashing computer screens in a darkened room.

Confidentiality
We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All

information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

The only people who can see your research records are:

- the research team and staff who work with them
- clinicians and staff at Montefiore who review your records for your care
- the organization that funded the research: The National Institutes of Health
- groups that review research (the Einstein IRB, and the Office for Human Research Protections

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Certificate of Confidentiality
As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study was requested or subpoenaed by government agencies or the courts, we will use the Certificate to attempt to legally refuse to provide it. This is rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations that the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for a review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

Are there possible benefits to me?
You will not receive any direct benefit from taking part in this study. We hope you will participate because the study will generate important information about the treatment of mobility and provide information needed for rehabilitation of mobility disability. The information learned from this study may, in the future, help advance scientific knowledge about cognitive and mobility performance in aging.

What choices do I have other than participating in this study?
You can refuse to participate in the study.

Are there any consequences to me if I decide to stop participating in this study?
No. If you decide to take part, you are free to stop participating at any time without giving a reason. However, some of the information may have already been entered into the study and that will not be removed.

Can the study end my participation early?
We will not let you participate in the study any more if any unanticipated serious adverse events determined to be possibly, probably or definitely related to study procedures occur. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

***Note for residents of Co-op City only:* JASA is not involved in this research study and your participation will have no bearing on participation in JASA's services.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date
Printed name of the person conducting the consent process	Signature	Date