Concise and Focused Presentation

We are starting a new study where we test an exercise program for people with mild cognitive impairment (MCI) and mobility problems. The study will be 12 month longs. Participants will be seen at their home or at Baylor College of Medicine.

There are 15 visits in this study. In these visits, you will be asked to walk and do other exercises that may help your balance and mental ability.

There are no serious risks if you participate in this study. There is a small fall risk but it is not greater than the risk when doing your daily activities. A researcher will be with you performing the exercises to avoid any potential falls.

There is small risk of loss confidentiality. However, the study personnel will make every effort to minimize these risks.

You may choose to participate or not participate in this study. You may also withdraw from the study at any point without any penalty. Your regular care will not be affected.

Please read the detailed description below.

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

With the rapid aging of the population, there is an increasing number of older adults who living with mild cognitive impairment (MCI). Older adults with MCI often suffer from limited mobility problems, which can lead to falls or increased risk of falling.

Exercise has been shown to preserve mental and physical agility and slowdowns mental decline, which can increase the quality of life. Unfortunately, normal clinic-based exercise programs often are difficult for patients who have mobility problems or live far away from the clinic. For this reason, many patients cannot go to all their exercise appointments and are not able to receive the full benefits of the program.

Our exercise program may be easy to perform for those who are diagnosed with MCI and have mobility problems. We also designed the exercise to be interactive to increase engagement during the program. We are looking to develop a system to offer it at the patients' homes in future studies.

Purpose

We propose to develop an exercise program for adults with mild cognitive impairment or mild dementia that is specifically designed to improve balance and mental ability during distracting conditions. We are hoping in the future, this exercise program may be offered remotely for the patients¿ homes.

Subject ID: _____ Subject Initials: _____

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine.

There will be 15 total study visits. One baseline, 12 exercise sessions and 3 Follow-up visits. The visits may happen at your home or at Baylor College of Medicine.

The research procedures are described below:

Medical History: We will have access to your chart and record socio-demographics (e.g. age, gender, BMI, education, marital status, etc), medical history (health status including medical conditions, history of falls, history of hospitalization, priory surgery, duration of diagnosed as MCI, mental health test, other medical condition, you hearing and eyesight, etc), medication use, etc.

Social Factors: We will evaluate the following factors: marital status, years of education, type of work, tobacco history (pack years, current smoker, current use of chewing tobacco, previous smoker, no history), drug history (current, previous history, no history), and alcohol history.

Questionnaires: We will ask the subject to answer a series of health related questionnaires such as quality of life (Promise Global), demographics, anxiety (Beck Anxiety Scale), Pain-Mobility, fear of falling (FES-I), frailty (Fried Frailty), MOCA for cognitive status, and depression (CES-D), Trail-making task A and B, Neurotic questionnaire N-5. We will also ask them to fill out an acceptability questionnaire at the follow up visit.

Peripheral Neuropathy: We will use Vibration Perception Threshold (VPT) testing, evaluated at the distal great toe, heel and 5th metatarsal.

Gait and Balance Test ¿You will wear 5 sensors (for example, accelerometer) named LEGSys (one on lower back, 2 on each upper thigh and 2 on each shin) attached with elastic straps to test balance in different standing positions and record your walking pattern. Research staff will ensure that the elastic straps are not too tight in order to avoid poor circulation during the visit. You may also be asked to walk while counting backwards (dual task), and to walk in a fast but safe manner (fast walk).

Physical Activity Monitoring-You will be given a wearable device (PAMSys) that will be measuring several parameters including number of steps taken, duration of sitting, standing, walking and lying, time taken and number of transitions from sit to stand, and walking speed for 48 hours. At the end of the specific visit, you will be given a pendant with the device to wear. This device will not come in direct contact with your skin. Investigators will provide a pre-paid envelope where you may place the device and send it back to the investigating team.

Intervention: The investigators will provide a game-based exercise program for 6 weeks (twice per week). Exercise sessions will last approximately 30 minutes. You will be asked to play a video game during your sessions while wearing sensors that will be attached with Velcro straps around your ankle, shins and back while standing. Your task will be to move a small dot into the center of numbered and

lettered circles on the computer screen by moving your ankle. You will also be asked to play a game where you ¿cross and obstacle¿ on a computer screen by lifting your knees.

Timed-up-and-go (TUG): You be asked to stand up from a chair, walk 10 feet, walk back to the chair, and sit down as fast and safely as possible.

Upper Extremity Test ¿ We are going to measure your arm's motion. For this purpose, one sensors will be attached to your wrist using elastic Velcro straps. We will ask you to flex and extend your arm for 20 seconds in a fast but safely manner. We may ask you to repeat this task while counting backwards.

Phone calls: Research Coordinators may also call you for study related questions.

Digital Photographs ¿ Digital photographs/video/audio of you may be taken during the study to monitor progress or deterioration due to the intervention.

At Baseline, you will perform the following procedures as described above - Medical History, Social Factors, Questionnaires, Peripheral Neuropathy, Gait and Balance Tests, Physical Activity Monitoring, Intervention, Timed-Up-and-Go, Upper Extremity Test and Digital Photographs. The Baseline visit may take up to two hours.

Visit 1 ¿ 12: You will perform ¿Intervention¿ as described above. These visits may take up to 30 minutes.

Visit 13 (6 months) and Visit 14 (12 months): You will perform Questionnaires, Peripheral Neuropathy, Gait and Balance Test, Physical Activity monitoring, Timed-up-and-go, Upper Extremity Test and Digital Photographs. These visits may last up to 1 hour.

The researchers will take digital photographs of you and videotape you during the study. This is done using a normal camera. The images and videos may be presented in scientific presentations and scientific papers. Your photos and videos will not be used for commercial or marketing purpose. **We will NOT blur your face out in the photographs and/or videos. While we do all our efforts to mask your face in some cases (for example. journal policy) this may not be practical. We will only use videos and photographs of you for scientific presentations or scientific publications.

_____ I agree to have my photographs/videotape presented in scientific presentation or scientific publication

_____ I do NOT agree to have my photographs/videotape presented in scientific presentation or scientific publication

Please provide below Emergency contact information:

Subject ID: _____ Subject Initials: _____

Contact name: _____

Relationship:_____

Phone number:_____

We ask for the information of your emergency contact in case there is a fall or another medical emergency. The research team will also notify the medical team onsite as well as your emergency contact.

If you are eligible, the research personnel would like to contact you in the future for participation in other research studies. You are not required to participate in these studies and your medical care or involvement with the current research study will in no way be affected if you choose not to participate. You may ask us to stop contacting you at any time.

_____I agree to be contacted for future research studies

_____I do not agree to be contacted for future research studies

Data collected will be made public in different scientific journals and/or conferences. Your data will be presented along with other subjects from this project. Please notify the research staff if you would like these publications to be shared with you.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Your identifiable private information or identifiable biospecimens collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Full Social Security #
- Photographs, videotapes, and/or audiotapes of you
- Other: Patient contact information Admission/Discharge dates

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, and NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives.

Use or Disclosure Required by Law

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. 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.

The Certificate of Confidentiality will not be used to prevent disclosure of child abuse, neglect, or harm to self or others to state or local authorities.

Baylor College of Medicine is required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even

if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTES OF HEALTH (NIH) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Bijan Najafi, PhD
One Baylor Plaza,
MS:BCM390, Houston TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts
Your participation in this particular study and the protocols/procedures involve no more risks to you than you would come across in everyday life. The study device and technology is completely non-invasive, safe, non-toxic and non-ionizing. The potential risks to you are minimal. However, like any battery powered systems, there is a minimum risk of sensor malfunctioning. In addition, the study devices are not waterproof, and although they use a low powered battery (similar to a cell-phone battery), in order to avoid any risk of shock the monitor should NOT be submerged or saturated with fluids during operations, be worn while you shower or while you are cleaning. It does not emit any radiation to the human body, and does not offer any significant risk to the test you.
In addition, there might be risks that we can¿t predict at this time.

All balance and walking tasks will be performed during supervised conditions and a person will be always next to you during these tasks to minimize the risk of falling.

During the exercise program, it is unlikely that you will experience significant risks or discomfort. You will only be asked to stand on a stable platform and to lift your leg to balance on a single leg (like crossing an obstacle) and shifting your weight to different direction. To avoid fatigue, the tasks will be divided into several sessions with rest between. You may rest between each session. You may experience mild discomfort from the elastic bands used to secure the sensors on your legs. However, research staff will ensure the elastic bands are not too tight in order to avoid poor circulation. Like any physical exercise, you may also feel tired or joint pain after completing a balance training session. An attendant will stand near you throughout the experiment to prevent you from getting hurt.

If you are at high risk of falling, like any exercise or physical activity, there is some risks association with the exercise program and walking tests. Thus you should be careful when you are walking or shifting your weights during exercise and use a chair, which will be located in front of you during exercise when

it is needed. If you feel you may not be able to execute any of exercise tasks or tests please let the investigator know. We will stop any measurement or exercise program if you feel you are unable to do them safely.

The devices and exercise program have been used in several of our previous studies including patients with cancer and chemotherapy induced neuropathy and no adverse events were reported.

A vibration perception device will be used to monitor progress and diagnose severity of CIPN in lower extremities. The vibration range will be from 0-50 Volts. Participants may feel slight discomfort from the vibration. This device is compliant with medical electrical device safety according to IEC 601-1.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. All information we will collect about you will be stored in a secure location under double lock and coded in a way to maintain confidentiality. Only study personnel will have access to your records. Data collected during the study may be published and made publicly available.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: We cannot promise any benefit to you or to others from you joining this research. However, possible benefits include enhancing your balance and walking ability. In addition, what the researchers find out from this study may help other people with poor balance and MCI as well as to help scientist develop a remote exercise program. . However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you are unable to come to the research visits) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will be paid $50 after completing your baseline and every follow up visits. You will be compensated $10 for every completed exercise session.

You will be given a debit card called "ClinCard" at the first day of your visit. Each time you complete a visit, the coordinator will load the appropriate amount to your card. Please note that it may take up to 72 hours for the amount to be loaded in the card. The research coordinator will provide you with some instructions and useful information about your card. In order to issue this card, the research staff will be asking for your SSN.

You will parking will be covered if your visit is at BCM.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, BIJAN NAJAFI, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: BIJAN NAJAFI at 713-798-7536 AND IVAN MARIN AT 713-798-7538 during the day.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Subject ID: _____ Subject Initials: _____

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date

Subject ID: _____ Subject Initials: _____