Official Title: **Decreasing Alzheimer's Disease and Related Dementias After Delirium- Exercise and Cognitive Training**

Brief Title/IRB Protocol Title: **Improving the Recovery and Outcome Every Day after the ICU (IMPROVE)**

NCT 03095417

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Improving Recovery and Outcome Every Day after the ICU (IMPROVE)

You are invited to participate in a research study of the benefits of body and brain training for older adults who had a hospital stay within the Intensive Care Unit (ICU). You were selected as a possible subject because you are an older adult living in the Indianapolis area who has been discharged from the ICU at a local hospital.

The project is being conducted by Babar Khan, MD of the Indiana University School of Medicine. It is funded by the National Institutes of Health.

STUDY PURPOSE

The purpose of this project is to determine the effects of certain kinds of body and brain training on thinking ability, physical fitness, mood, and daily living skills for older adults discharged from the ICU. The project will also examine how a person's background, things like age, gender, years of schooling, health history, and blood-based measures, affect training outcomes.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of about 344 people taking part in the project.

PROCEDURES FOR THE STUDY

If you agree to be in the project, you will do the following things:

A) You will complete 3 individual appointments with project personnel. The first appointment may take place in the hospital or in your home. The second appointment will happen about 3 months from now in your home. The third appointment will happen about 6 months from now in your home. These appointments include:

1. thinking and memory activities;
2. questionnaires about your mood, memory, health, medications, and daily activities;
3. measurements of height, weight, blood pressure, muscle strength, and stepping and walking;
4. a blood draw from a vein in your arm or hand totaling about 1.5 tablespoons. A separate appointment may need to be scheduled for the blood draw.

At the first appointment, we will also ask you to provide background information about yourself – things like age, race, ethnicity, and education.

These appointments take about 2½ hours to complete, and may be split into two sessions if needed.

B) You will be randomly assigned to one of four training groups who will receive guided training at home via a computer which we provide. The trainings may include exercise, stretching, or solving problems. "Random assignment" means that neither you nor the researcher gets a choice of what group you are placed in. Each group meets for 3 days per week for 12 weeks. Each session will last between 20 and 90 minutes depending on the group assignment. By joining this project, we hope that you will complete as many training sessions and individual appointments as possible.

You will participate in all training sessions in your own home by joining a video conference on the internet with the instructor and other project participants. Communication via video conference is like live, interactive television. The instructor and all group participants will be able to hear and see one another. Picture-in-picture view will display images of the instructor, yourself, and the other participants. The other group participants will be able to see you and hear your voice. There may be additional project personnel monitoring these video conferences as well.

Project personnel will install a computer in your home with internet service. A webcam will be included with the computer to allow you to participate in the video conference and complete your training sessions. You can decide

where you want the computer to be setup in your home. All you need is a solid chair (without wheels) and approximately a 6 foot by 6 foot space to move. The computer can only be used for the training sessions. You will be asked to sign a Computer and Equipment Use Agreement at time of installation. All equipment will be collected by project personnel when the training is complete. Project personnel will schedule additional appointments for the installation and removal of study equipment from your home.

RISKS OF TAKING PART IN THE STUDY

The risks of participating in this project include:

1. You may feel tired, stressed, or embarrassed during the training and assessment appointments. You can tell the researcher that do not care to answer a question or do a task or that you want to take a break.
2. You may have pain, bruising, or, very rarely, get an infection from the blood draw. To minimize these problems, blood will be drawn by a trained staff using sterile procedures.
3. You may have temporary stiffness and soreness from exercise. To minimize this, the instructor will direct you in the proper way to warm-up and stretch prior to each session. You will also be instructed not to do exercises that are painful to you and you can skip any exercise at any time.
4. You may fall as a result of the exercise. To minimize this, the exercises are consistent with standard recommendations for exercise among older adults.
5. You may have cardiovascular complications from exercise.
6. The training is conducted in small groups, so other people will know you are in this project. We store background and health information about you on our computers and there is a small risk that that information could be exposed accidently to people outside the study. To guard against this, project documents are labeled with code numbers, not first or last names, and project documents are stored in secure locations.

BENEFITS OF TAKING PART IN THE STUDY

Participation in this project will provide you a new experience, social contact, and feedback on blood pressure, height, weight, and eyesight.

ALTERNATIVES TO TAKING PART IN THE STUDY

You may choose not to participate. You will not miss out on any treatments or benefits by not joining this study or dropping out once it has started.

WILL I RECEIVE MY RESULTS?

We may learn things about you from the study activities which could be important to your health (e.g., blood pressure measurements, oxygen levels in the blood). If this happens, the study team will share this information with you during study visits or training sessions. The study will not cover the costs of any follow-up consultations or treatments to address these findings.

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 any published reports and databases.

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, the study sponsor, National Institutes on Aging, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH) who may need to access your medical and research records.

A description of this research project will be available on **ClinicalTrials.gov**, as required by U.S. Law. This website will not include information that can identify you; it will include a summary of the results and you can look at the website any time.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
2) if you consent to the disclosure, including for your medical treatment;
3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information or specimens collected from you 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 or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

GENETIC INFORMATION

This research follows the Genetic Information Nondiscrimination Act, a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and to discriminate against you based on your genetic information.

We may use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA.

COSTS

There is no cost to you or your insurance company for any procedures in this project.

PAYMENT

You will receive gift cards for participating in the study. You will earn $25 for completing the 3-month appointment, and $25 for completing the 6-month appointment. In total, you will receive gift cards totaling $50 for completing these study procedures.

COMPENSATION FOR INJURY

In the event of physical injury resulting from your participation in this research, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled. If you are participating in research which is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher Dr. Babar Khan at 317-205-7626. If you cannot reach the researcher during regular business hours (8:00 AM-5:00 PM), please call the IU Human Subjects Office at 317-278-3458 or 800-696-2949. After business hours, please call 317-274-5000 and ask that Dr. Khan or the Critical Care Resident on-call be paged.

In the event of an emergency, you may contact 317-274-5000 and ask that Dr. Khan or the Critical Care Resident on-call be paged.

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 800-696-2949.

VOLUNTARY NATURE OF STUDY

Taking part in this project is voluntary. You may choose not to take part or may leave the project at any time. Leaving the project will not result in any penalty to you or loss of benefits. If you decide not to participate in this project, it will not affect your current or future relations with Indiana University.

The project staff may stop your participation in the project if you become extremely anxious or disruptive to other participants. This will be done to protect your health as well as the training experience for the other participants.

The project is reviewed at regular intervals by a panel of outside scientists. They review project records for signs of troublesome side effects associated with participation such as study-caused injuries. If problems are detected, the investigator and the review board will work with the National Institute of Aging to determine if the project should be stopped.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research project.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this project.

Subject's Printed Name: _____

Subject's Signature:_____ **Date**:_____
(must be dated by the subject)

LAR's Printed Name, as applicable: _____

LAR's Signature, as applicable:_____ **Date**:_____
(must be dated by the LAR)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____