Early Cognitive Intervention in Delirium

NCT04740567

Informed Consent Document

Version Date: 04/04/2023

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Early Cognitive Intervention in Delirium (ECID)
Version Date:	March 28, 2023
PI:	Jin H. Han, MD, MSc

Name of participant:_____Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:
We are studying how brain training conducted in the hospital and for 12 weeks after hospital discharge improves brain function after an acute illness. An acute illness, such as an infection, can decrease brain function, especially in older adults. This loss of brain function can become permanent and many older adults lose their ability to live their normal lives before the illness. You are being asked to take part in this research study because you are (or were) a patient in our emergency room, and you are over 65 years old. This study is sponsored (paid for) through a grant from the National Institute on Aging, part of the National Institutes of Health (NIH). We will expect to enroll 350 patients.

What will happen to you if you are a part of this study:

Brain Training Program
One-third of those enrolled will be randomly assigned to receive the brain training program. If you are randomly assigned to the brain training group, we will have you do some brain exercises such as having you spell a word backwards or play games like "Name that Tune" twice a day during hospitalization. These in-hospital brain training sessions will last around 20 minutes each. After you are discharged from the hospital, we will meet with you at your place of residence once a week for 12 weeks. These sessions will last about one hour and will teach you strategies to help you overcome any brain deficits that you may have developed as a result of your illness. There may be homework assignments to further help your brain function. If you are placed in a skilled nursing facility for rehabilitation, we will go to your facility to do these sessions if possible. If the skilled nursing facility is restricting visitors, we will resume the brain training exercises once you go home. If you do not feel comfortable with us coming into your home, you can return to the medical center to have your cognitive rehabilitation sessions. Alternatively, we may attempt to do the intervention using videoconferencing (e.g., FaceTime, Skype, Zoom). We may audio record the brain training sessions in the hospital and your place of residence to help our team tailor the brain exercise program for your needs.

Emergency Room and Hospital
For all patients, we will ask you or a family member for basic information about you such as age, marital status, and education. We will also ask your family members about how you were thinking and functioning in everyday life before you got sick. We will also evaluate how well your brain is functioning while you are in the emergency room and the hospital. For example, I might

ask you to recite the days of week the backwards or ask you to answer some yes or no questions. We will do this once a day and should take about 5 to 10 minutes to complete. These tasks also exercise the brain and may benefit your brain function even if you are not selected to receive the brain training program. We will also collect 1 to 2 tablespoons of blood and a urine sample at enrollment. We will also collect additional blood and urine samples approximately 72 hours after enrollment. We may collect blood at 120 hours if you are still in the hospital, but this is optional. We will get the blood from your intravenous line whenever possible, but in a small number of cases, we may need to get the blood through a needle.

Four Month Follow-Up Visit

At 4 months, a neuropsychological examination will be conducted by a trained neuropsychologist. This neuropsychologist will ask you some questions to see how your brain is working. For example, he or she may ask you to name as many words as possible that start with the letter "D" or remember a list of words. This should take about 35 to 45 minutes to complete. We will also ask you questions about your health, your ability to do common daily activities, and how you are feeling. If you are unable to come to our research facilities because you are unable to travel, we may be able to come to your home.

As part of the 4-month visit, some of you will have the option to receive a brain MRI to look at your brain's structure and function. This will take approximately 45 minutes. For one part of the brain MRI, we will ask you to perform a memory task (5 to 10 minutes) to help evaluate your brain function. You can opt-out of the MRI portion of the study, especially if you are claustrophobic. We will not be able to give you medications to help you relax, because it may affect the MRI results.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

Because this is not a drug trial, the risks of participating in this study are minimal. Some patients may become tired or frustrated with the brain exercises or tests because some of the tasks are not easy to perform. We will draw blood from your IV line, but on occasion, we may have to draw blood using a needle which may cause mild discomfort, bleeding, and bruising. Rarely, blood draws can lead to infections at the site of the blood draw. For those who agree to receive an MRI at 4-months, some may feel distressed or claustrophobic.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: An acute illness leads to a loss of brain function for many older adults who are confused. Currently, there is no

treatment. This study may discover a new way to preserve brain function after an illness, and keep more older adults living full and independent lives.

Payments for your time spent taking part in this study or expenses:
You will receive $75 for any study activities performed in hospital and 12-weeks after the hospital. You will receive an additional $75 if you return to Vanderbilt to complete the 4-month follow-up visit; if we come to your house, you will be given $25. If you decide to complete the MRI portion of the study, you will be given an additional $100.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact

Dr. Jin Han at (615) 936-0253 or Karen Miller, RN at (615) 936-4790

If you cannot reach the research staff, please page the study doctor at 615-835-9745.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Your doctor may take you out of this study if he/she thinks it is not in your best interest. You will not be taken out without being given a reason why.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor or research staff.

Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. 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.

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Confidentiality:
All data will be stored in a secure, password-protected database only accessible by our study team. Your paper-based forms will only have your study ID number and initials; these forms will be stored in a locked cabinet located in an office only accessible by our research staff. Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Han and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study is supported by the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Results:
The results of the neuropsychological examination will not be provided to you or your regular doctor.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental

health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results. A single blood sample (about 2 tablespoons) will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

Blood samples – You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Han and his research team will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Giving samples for research is your free choice and you may be in the study even if you do not want your samples used or stored for gene research.

At any time, you may ask to have your sample destroyed. You should contact Dr. Jin Han at (615) 936-0253 or Karen Miller, RN at (615) 936-4790 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

❑ Yes ❑ No

My blood/tissue sample may be stored/shared for future gene research.

❑ Yes ❑ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

❑ Yes ❑ No

Signature:_____Date: _____

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Brain MRI Substudy

- ❑ Yes, I agree to participate in the brain MRI sub-study at 4-months.
- ❑ No, I would like to opt-out of the brain MRI sub-study.
- ❑ I'm not sure. I would like some time to think about it.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

Time: _____ _____
Printed Name and Title

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I,_____[name of decision-maker/surrogate], am the_____[state relationship to participant] of_____[state participant's name]. I have

read the informed consent document or it has been explained to me. I have had the opportunity to ask any questions and all of my questions have been answered. I have been informed that an investigational treatment may be administered to _____ [participant's name]. I believe receiving such treatment would be in the best interests of _____[participant's name] and is consistent with what he/she would have decided had he/she been able to do so.

Your decision to allow your family member/friend to participate in this research study is voluntary. You may choose not to allow his/her participation and he/she will receive alternative treatments without affecting his/her healthcare/services or other rights. You are also free to withdraw him/her from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to allow continued participation in this research study, you will be notified so that you can make an informed decision whether or not to continue your family member/friend's participation in this study.

Your family member/friend will periodically be re-evaluated for the capacity to give consent. If he/she is found to be capable, continued participation in this study would only occur with his/her consent.

_____ ___/___/___
Signature of Health Care Decision-Maker/Surrogate Date

_____ ___/___/___
Signature of Witness Date

_____ ___/___/___ _____
Name and Signature of person obtaining consent Date Time