Rehabilitation of Executive Function in Aging Veterans with History of TBI

NCT04111549

February 10, 2022

Department of Veterans Affairs	INFORMED CONSENT FORM UCSF University of California San Francisco

Subject Name:	Date:
Title of Study: Rehabilitation of Executive Function in Aging Veterans withTBI: Pilot Phase	
Principal Investigator: Erica Kornblith, PhD	**San Francisco VAMC**

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Research Project Director:	Erica Kornblith, PhD, Staff Neuropsychologist, SFVAHCS 4150 Clement Street, San Francisco CA 415-221-4810x24125

This is a research study about how history of brain injury affects brain functions like paying attention, keeping information in memory, organizing plans for achieving important goals, and managing stress, and if an in-person training adapted for and delivered via in-home video telehealth technology helps to improve these functions compared to previous in-person studies.

The study researcher, Erica Kornblith, PhD, or a member of the research team from the San Francisco VA Medical Center (SFVAMC), will explain this study to you.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by Erica Kornblith, PhD, at SFVAMC.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also answer any questions you have.

Purpose of the study: The purpose of this study is to learn about how the human brain pays attention, keeps information in memory, organizes plans for achieving important goals, and manages stress. We hope to learn more about how history of brain injury affects these functions, and if an in-person training adapted for and delivered via in-home video telehealth helps to improve these functions. This may allow us to better understand and treat cognitive problems due to brain injury.

You are being asked to participate because you are a Veteran age 65 years or older with a history of traumatic brain injury (TBI) and complaints of problems with attention, planning, and/or organizing. You also have endorsed comfort or familiarity with using technology to access the internet, and/or having a family member or caregiver willing to help you.

Study Procedures: If you choose to be in this study and are found to be eligible, you will participate in cognitive assessments via in-home video telehealth as well as a group training (10 in-home video telehealth group sessions and 3 in-home video telehealth individual sessions) focused on attention and executive function. This group is conducted via in-home video telehealth technology.

- Prior to training group and assessment participation, you will need to connect via in-home video telehealth for a screening visit to ensure you are eligible to participate.

You will be in this study for about 10 weeks, including assessments, 5 weeks of intervention, and any extra time for the investigators to prepare the group and collect feedback.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Risk of fatigue/distress
- Risk of loss of privacy
- Unknown risks

Possible Benefits: Although one of the goals of this research is to improve treatment of difficulties associated with traumatic brain injury and improve access to such treatment, the information we hope to gain is primarily for the future benefit of others. We cannot know in advance whether research participants will benefit from the study.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Getting treatment or care for your condition without being in a study,
- Taking part in another study, and/or
- Getting no treatment.

Please talk to your doctor about your choices before agreeing to participate in this study.

The following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are a Veteran age 65 years or older with a history of traumatic brain injury and complaints of problems with attention, planning, and/or organizing. You also have endorsed comfort/familiarity with using technology to access the internet, and/or having a family member or caregiver willing to help you do so.

Why is this study being done?
The purpose of this study is to learn about how history of brain injury affects brain functions like paying attention, keeping information in memory, organizing plans for achieving important goals, and managing stress, and what types of training help improve these functions, including training delivered via in-home video telehealth. We hope to determine if an in-person training adapted for and delivered via in-home video telehealth helps to improve these functions. This may allow us to better understand and treat cognitive problems due to brain injury.

This study is sponsored by the Department of Veterans Affairs Rehabilitation Research and Development.

How many people will take part in this study?
About 18 people total will take part in this study, with 2-3 people assigned to each group.

What will happen if I take part in this research study?
If you volunteer to take part in this study, and after you are determined to be eligible after the screening exams, you will be asked to participate in a small group cognitive training program delivered to you in your home via in-home video telehealth.

Before you begin the main part of the study: You will need to have the following "screening" exams, tests or procedures to find out if you can be in the main part of the study.

- Medical chart review: Your medical chart will be reviewed by the study doctors. The team will review general health information as well as information about your history of brain injury, mentalhealth conditions, and substance use.

- Interview and questionnaires: You will be asked detailed questions about the brain injury you hadas well as about any current cognitive difficulties you may be experiencing. You will also be asked about current emotional symptoms such as symptoms of PTSD and/or depression you may be experiencing, current medications, and current alcohol use.

During the main part of the study: If the screening exams, tests or procedures show that you can continue to be in the study, and you choose to take part, then you will have the following tests and procedures done.

- **Cognitive tests:** At the assessment visits conducted via in-home video telehealth, you will be asked to do different tasks to see how well you can pay attention, remember different types of information, and solve problems. You may have paper forms mailed to your home that will be used during these visits. As a part of this testing, you may be shown pictures, words, and diagrams on paper or computer screen and asked to respond by pressing a key, writing, or making a spoken response. You may be asked to draw some of the items on paper or asked to remember things about them. You will also be asked to complete questionnaires about your every day and emotional functioning.

  You may be asked to participate in similar tests on another day. On your second and third testing visits conducted via in-home video telehealth, we will ask you to do tests again to see if anything has changed. The second testing visit takes place 5 weeks after the first, is identical to the first, and occurs before you complete any other study activities. You may also complete a third testing

session that takes place 5 weeks later, after you have completed the small group cognitive task training.

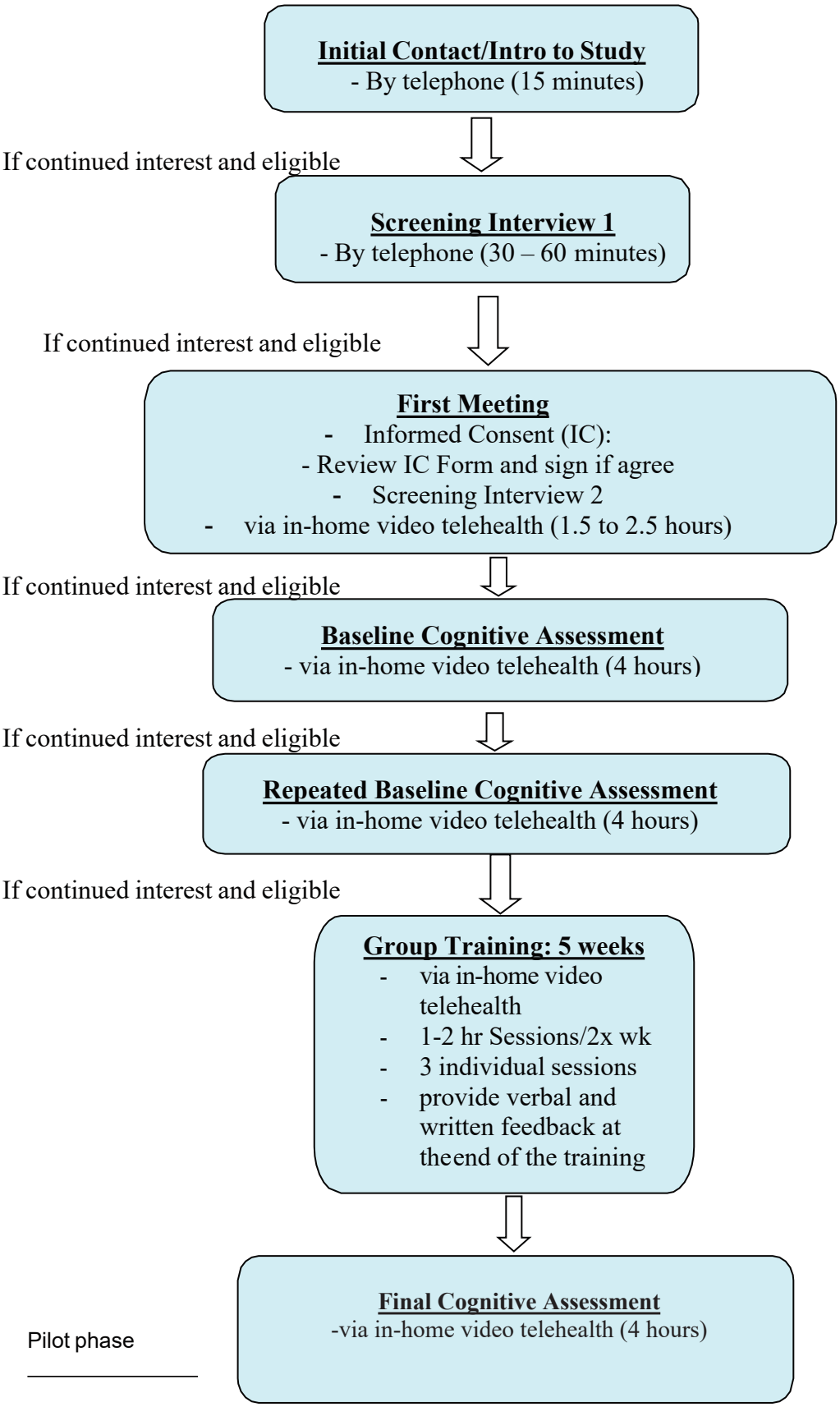
You may be asked to return the completed test forms to the study team by mail in a pre-addressed, stamped envelope that will also be mailed to you.

- **Cognitive task training**: After your first visit, you will participate in cognitive training tasks. The training focuses on learning how to apply attention regulation and problem-solving strategies in your daily life and is delivered to you via in-home video telehealth. It is in small group format. The training program is 5 weeks long and includes 10 two-hour sessions with a group leader, three one-hour individual sessions, and home activities. You will be asked to provide verbal and written feedback at the end of the training

University of California San Francisco

Study Plan

Read the chart below for a visual representation of how the study works. Start reading at the top and read down the list, following the arrows.



Study location
The screening visit will take place in participants' homes via in-home video telehealth. In-home group activities will also take place in participants' homes via video telehealth. No study team members will come to participants' homes.

How long will I be in the study?
Your individual participation in the study will take up to 10 weeks. After signing the consent form, if you are eligible and interested in participating, we will ask you participate in further study activities. These activities involve training over a period of 5 weeks.

Can I stop being in the study?
Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping ordecide to stop. They will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?
You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Sideeffects may be mild or very serious. You should talk to your study doctor about any side effects that you experience while taking part in the study.

- Risks of fatigue/distress: You may find study activities difficult, tiring, time consuming, anxiety provoking, frustrating and/or boring. You are free to decline to answer any questions or to stop the assessments at any time. To reduce fatigue, breaks are scheduled during testing and training sessions. Additional breaks will be provided at your request. If you appear to be under undue strain, the session will be discontinued.

- Risks of loss of privacy: Participation in research may involve a loss of privacy. Because training takes place in a small group setting, other research subjects within the group may become aware of information about you that you would prefer they not share outside the group. Researchers will ask all subjects to keep private all information learned about other group members and to not talk about this information outside the group sessions. However, absolute confidentiality cannot be guaranteed. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, a court has subpoenaed research records. Other University of California personnel may also review or receive information about you. The study PI and research staff will retain the participant's research records indefinitely for research purposes. Your personal health information cannot be used for additional research without additional approval from either the participant or a review committee.

- Unknown risks: The experimental treatments may have risks or side effects that no one knows about yet. Members of the research team will inform participants about any new information that may impact their decision to remain in the study.

Are there benefits to taking part in the study?

Although one of the goals of this research is to improve treatment of difficulties associated with traumatic brain injury and improve access to such treatment, the information we hope to gain is primarily for the future benefit of others. We cannot know in advance whether research participants will benefit from the study. While doctors hope that cognitive training therapies will be beneficial, these trainings are still being studied.

We hope to learn more about how to treat attention and other cognitive problems from your taking part in this study. The information we get from this study may help us to treat future patients with brain injury better and increase access to treatment.

What other choices do I have if I do not take part in this study?

Your other choices may include not getting treatment, getting standard treatment for your condition without being in a study, or taking part in another study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?

Researchers will use your information to conduct this study. Information gathered during this research study will only be used for this study. They will not be shared with other researchers.

Research results: There may be times when researchers using your information may learn new information. The researchers may or may not share these results with you, depending on several factors.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Institutional Review Board (otherwise known as the Human Subjects Subcommittee) at the SFVA and the University of California (UC)
- Representatives of the Sponsor (Department of Veterans Affairs Rehabilitation Research and Development)
- Representatives of UC
- UC San Francisco Online Database (REDCap)

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other health care providers may see your test results and become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

Your private information will be further de-identified by being stored as a numeric code in secured online study databases and paper forms stored in secured file cabinets on SFVAMC property. VA in-home video telehealth sessions are fully encrypted to protect the privacy of the provider and Veteran participants.

Are there any costs to me for taking part in this study?
No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed.

Will I be paid for taking part in this study?
In return for your time and effort, you will be paid up to $650 for taking part in this study. You will be paid for your time in the initial screening and training sessions, at the rate of $20/hour, and at the rate of $50 flat rate for your time in the 3 cognitive assessments (2 before the study and 1 after completion).

You will be paid by electronic fund transfer (EFT) within 6-8 weeks of completing participation. This may require setting up direct deposit with the VA Agent Cashier. In that case study staff will provide a form to complete.

Participant Reimbursement: Pilot Phase	
Visit	**Reimbursement**
Consent and Eligibility Screening ($20/hourfor 2 hours)	$40
Baseline Assessment 1 ($50 flat rate)	$50
Repeated Baseline Assessment 2 ($50 flat rate)	$50
IVT Training session 1 ($20/hour for 2 hours)	$40
IVT Training Session 2	$40
IVT Training Session 3	$40
IVT Training Session 4	$40
IVT Training Session 5	$40
IVT Training Session 6	$40
IVT Training Session 7	$40
IVT Training Session 8	$40
IVT Training Session 9	$40
IVT Training Session 10	$40
IVT Individual Session 1 ($20/hour for 1 hour)	$20
IVT Individual Session 2	$20
IVT Individual Session 3	$20
Post-intervention Assessment 3 ($50 flat rate)	$50
Total amount paid for Pilot Phase participation	**$650**

Treatment and Compensation for Injury
If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness due to being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available

at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable) or may be billed to you or your insurer just like any other medical costs, depending on several factors. The VA and study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

Who can answer my questions about the study?
You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the study's Principal Investigator, Dr. Erica Kornblith, at **415-221-4810 extension 24125**.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers, or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at **415-476-1814**.

CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, please sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent

University of California San Francisco

Video to Home Telehealth

Emergency Contact

Information

The in-home video telehealth intervention you have consented to participate in uses an encrypted technology so you may see, hear, and interact with the training leader(s) and other group members from your home computer, tablet, or smartphone.

To ensure your safety, please provide two individuals who we may contact in case of an emergency. The research team will only contact these individuals if you end the telehealth session abruptly and do not answer your phone, or if the Principal Investigator (PI) otherwise determines your safety to be atrisk.

Name:_____

Relationship to participant: _____

Phone numbers: Cell:_____Home:_____

Work, if applicable (indicate days/hours to call): _____

Name:_____

Relationship to participant: _____

Phone numbers: Cell:_____Home:_____

Work, if applicable (indicate days/hours to call): _____

The two people listed above are friends and/or relatives who may be contacted by the PI, Dr. Erica Kornblith, or her designee, in the event a suspected life-threatening emergency occurs during a telehealth session. I have informed each person that they may receive a call in the unlikely event that one is necessary and obtained permission to list their contact information above.

I understand and agree that Dr. Kornblith or her designee may call 911 and/or the individuals listed in order to protect me, should she determine it to be necessary. I agree to stay connected to in-home video telehealth or by telephone until assistance arrives.

Participant Signature:_____Date: _____

Private Computer Location:

Street Address: _____

_____

City:_____County:_____

State:_____Zip Code:_____Phone number: _____

Email Address: _____