



Participant Name: _____ Date: _____

Title of Study: **Rehabilitation of Executive Functioning in Veterans with PTSD and Mild TBI**

Principal Investigator: **Tatjana Novakovic-Agopian, Ph.D.** VA Facility: **San Francisco VAMC**

Principal Investigator for Multisite Study: **Tatjana Novakovic-Agopian, Ph.D.**

EXPERIMENTAL SUBJECTS BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a medical research study. As an experimental subject, you have the following rights:

1. To be told what the study is trying to determine.
2. To be told what will happen to you and whether any of the procedures, drugs, or devices is different from what would be used in standard practice.
3. To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to you for research purposes.
4. To be told if you can expect any benefit from participating and, if so, what the benefit might be.
5. To be told the other choices you have and how they may be better or worse than being in the study.
6. To be allowed to ask any questions concerning the study, both before agreeing to be involved and during the course of the study.
7. To be told what sort of medical treatment is available if any complications arise.
8. To refuse to participate or to change your mind about participating after the study is started. This decision will not affect your right to receive the care you would receive if you were not in the study.
9. To receive a copy of the signed and dated consent form.
10. To be free of pressure when considering whether you wish to agree to be in the study.

If you have any other questions, please ask the researcher or research assistant.

Signature of Participant

Date

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INTRODUCTION

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below. Your signature will also show that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

This is a research study about how Post-Traumatic Stress Disorder (PTSD) and history of mild brain injury or concussion influence everyday functioning. This study is also about what types of training or rehabilitation may help for problems that could develop because of PTSD and concussion.

Why is this study being done?

The purpose of this study is to learn more about the short-term and long-term effects of training on the thinking, emotions, and daily lives of individuals with PTSD and history of mild brain injury, such as concussion. We are especially interested in how training may influence how people pay attention, keep information in memory, organize plans for achieving important goals, and manage stress. With this research, we hope to better understand and treat cognitive and emotional difficulties that can occur due to PTSD and mild brain injury.

Why am I being asked to take part in this study?

You are being asked to take part in this study because you are between the ages of 18-75, with at least a high school education and a current diagnosis of PTSD. You have also had a mild traumatic brain injury or concussion at least six months ago. In addition, you have reported some difficulties in cognitive, behavioral and/or emotional functioning.

How many people will take part in this study?

Up to 80 people will take part in this study.

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Who will be conducting the study and who is sponsoring it?

The study investigators: Drs Tatjana Novakovic-Agopian, Anthony Chen, John McQuaid, Thomas Neylan, Gary Abrams, and their research team will be conducting this study. This study is sponsored by the Department of Veterans Affairs Rehabilitation Research and Development (R&D).

DURATION OF THE RESEARCH

This research study is expected to take approximately three years.

Your individual participation in the study will take up to six months. Your first visit after signing the Consent will be for testing and is expected to last up to 3-4 hours with scheduled breaks, or breaks whenever you request them. Provided you continue to be eligible to participate, we may then call you and ask you to return for further study activities. These further activities involve training over a period of 5 or 10 weeks. We will also ask you to come in for 3 more testing sessions. These sessions will occur after 5 weeks; 10 weeks; and 6 months.

STUDY PROCEDURES

If you decide to take part in this study, this is what will happen:

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.
- Interview and questionnaires. You will be asked questions about your cognitive and emotional symptoms to help determine whether you qualify for this study.

During the main part of the study: If two screening interviews, 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.

Testing:

You will be asked to do different tasks to see how well you can pay attention, remember different types of information and solve problems. 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 paper and pencil

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questionnaires' about your everyday and emotional functioning. Some of these tests may be recorded by a digital video recorder for researchers to review after the testing sessions, if you give us a permission to do so. The video recordings will be stored in a locked cabinet in a locked VA office. The video recordings will not be removed from the VA and will not be transcribed. Only researchers will look at the video recordings.

You may be asked to return to participate in similar tests on another day. On your second, third, and fourth testing visits, we will ask you to do tests again to see if anything has changed. These tests will be done at the San Francisco VA

Training: After your first visit, you may be asked to continue participation by attending training programs.

You may participate in one or two training programs. One is in brain health education and the other is in attention and problem solving. Both are in small group format. Each program is 5 weeks long and includes the same number and length of weekly sessions with a group leader, three individual sessions, and about the same amount of home activities. Sessions take place at either San Francisco VA Medical Center or VA Northern California in Martinez.

If you participate in just one training program, group sessions will last 5 weeks, followed by testing. In addition to your initial testing before the first group session starts, you will undergo testing three more times. This additional testing will occur right after training; in another 5 weeks, and one final time, at about 6 months after you started study activities.

If you participate in both training programs, each program is 5 weeks, so total length of both programs is 10 weeks. In addition to initial testing before the first group session starts, you will undergo testing three more times. This additional testing will occur right after you complete the first 5 week training program; right after you complete the second program in another 5 weeks, and one final time, at about 6 months after you started study activities.

You may discontinue participation at any time you want.

All study procedures are being done solely for the purposes of the research and are not considered standard treatment. Dr. Novakovic-Agopian will oversee all study procedures.

This study includes experimental therapy that has not yet been proven beneficial. This is a randomized study, which means you will be "randomized" into one of the study groups. Randomization means that researchers put you in a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.

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Time Requirements of Study Participation:

Your first visit will be for testing and is expected to last up to 3-4 hours with scheduled breaks or breaks whenever you request them. We may then call you and ask you to return for further study activities. These will include additional testing and participation in one or two small group training sessions.

Small group training sessions will take place twice a week for about two hours a session, for either 5 weeks or 10 weeks. There will also be 3 or 6 one-hour individual sessions with a group leader in between the small group sessions. About 4 hours of homework a week will be assigned during group sessions. Homework may include reading, watching a DVD or practicing cognitive tasks. Homework is done 30-60 minutes a day, five days a week. Total time spent in group sessions will be 20-40 hours, plus 20-40 hours of homework.

In addition to group sessions, individual sessions, and homework, we will ask you to come in for testing at 4 time points. Testing will take place before starting small group sessions, then at 5 weeks, 10 weeks, and 6 months. Each testing session lasts up to 4 hours. Testing sessions can be spread out over two appointments with scheduled breaks or breaks whenever you request them.

What will be asked of me in this study?

- Keep your study appointments. If it you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Complete assignments as instructed.
- Complete questionnaires as instructed. However, you are free to skip any questions that you would prefer not to answer.
- Ask questions as you think of them.
- Tell the investigator or research staff if you change your mind about staying in the study.
- Let the investigator know if you are feeling stressed out by research activities.
- While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this research, as well as that of the other studies
- During testing sessions, do not tell the researchers who are giving you the tests anything about the training you are doing as part of the research study. The researchers who administer the tests are supposed to be "blind" – that is, they are not supposed to know what type of training you are undergoing, so that they can not be influenced by that knowledge.

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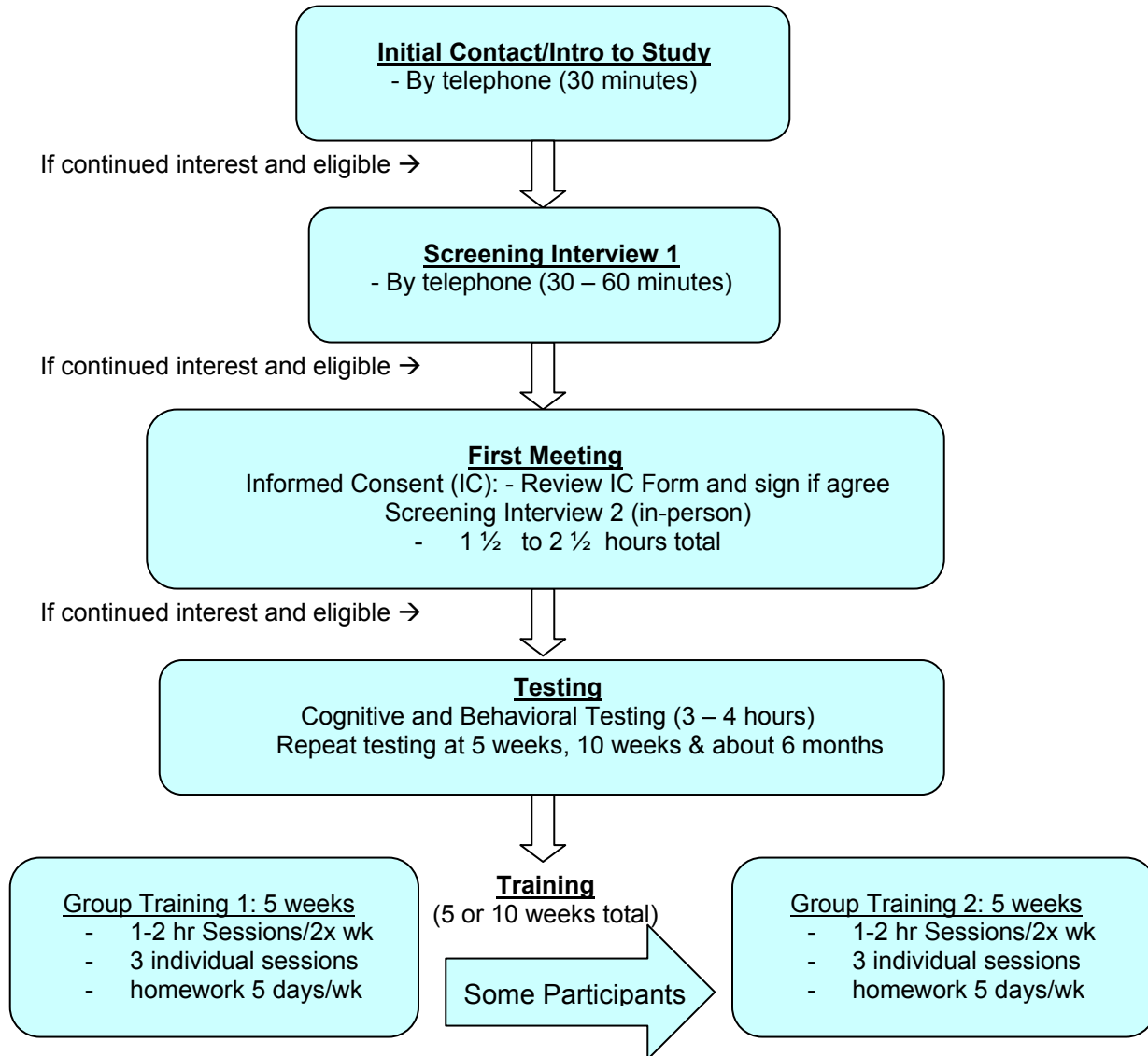
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Study Plan

Another way to find out what may happen to you during the study is to read the chart below. Start reading at the top and read down the list for possible steps in participation, following the lines and arrows.



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Whom will I be interacting with in this study?

You will be interacting with Dr. Novakovic-Agopian and her research team. The research team includes a study coordinator, co-investigators, evaluators, trainers, and research assistant.

Study location:

All study activities will take place at the same location. Your study location will be the San Francisco VA Medical Center.

POSSIBLE RISKS OR DISCOMFORTS

You may experience side effects like discomfort while in the study. Everyone taking part in the study will be watched carefully for any side effects. Side effects may be mild or very serious. You should talk to your study investigator about any side effects you experience while taking part in the study.

If you experience an increase of PTSD symptoms while participating in this study, talk to your study investigator. It is possible that you will experience increased distress during your participation in this study. We will be closely monitoring your level of distress during your participation. All our researchers are trained in recognizing the signs of emotional distress and will notify the study investigators if your level of distress appears to have increased. Should this occur, it is possible that the study investigators will refer you for an evaluation or treatment, and in some cases, may withdraw you from the study. Should this happen you will be told. The study investigators are licensed doctors who are experienced in the assessment and management of symptoms associated with PTSD and brain injury.

During the 6 months of your participation in this study we request that you continue taking same psychiatric medications, and not to start any new intensive behavioral therapy program (such as exposure therapy for PTSD). However, you and/or your health care provider may decide that it would be best for your health for you to change your medications and/or participate in additional clinical intervention during the same time period you would have been involved in study activities. If this happens, we may have to withdraw you from the study.

Risks and side effects related to the testing and training include those which are:

Likely:

You may find participation activities difficult, tiring, time consuming, and anxiety provoking, frustrating or boring. Some of the questions, tests and/or tasks may make you uncomfortable or

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upset. You are free to decline to answer any questions you do not wish to, or to stop your participation at anytime. To reduce fatigue, breaks are scheduled during testing and training sessions. If you need additional break, please let the investigator know and it will be provided.

Another potential risk is related to the fact that 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, we cannot guarantee that other subjects will not talk about your personal information outside the group.

Randomization Risks: Researchers will assign you to a study group by chance. The study group you are assigned to may receive less effective training than the other study group.

Less Likely

Unknown Risks: The experimental treatments may have risks or side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

All the procedures in this study are related to research and would not be part of usual medical care. Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

POTENTIAL BENEFITS

Previous research using the same training did show some improvement in cognitive skills in subjects with mild to moderate brain injury. We have expanded this research to include subjects with both PTSD and mild brain injury, which has not been done before. There may be benefits to you from your taking part in this research study, although benefit cannot be guaranteed. However, the information we get from this study might help us treat future patients, so an additional benefit would be your contribution to society.

ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH

You are free to choose not to participate in the 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.

You may discuss these options with your doctor.

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CONFIDENTIALITY

We will review your medical record information as part of determining your eligibility for this study. We will use your Social Security number to access your medical records.

VA policy requires that a note be placed in your medical record that identifies you as taking part in this research.

The research team respects your privacy. Your research data will be kept confidential after initial screening and enrollment into the study. Research data we collect on you, such as test scores and questionnaire responses, will be kept in locked cabinets in a locked room or in password-protected computer files kept on password-protected VA desktop and laptop computers. Our USB drives (which transfer information between computers) also have security features that prevent them from being used by anyone other than the researcher they are assigned to. All your personally identifying information will be removed from this data. Personally identifying information includes names and contact information. There will be a separate password protected computer file where we will have a key to match personal information with research data in the case we need to contact you.

This research study involves two sites: San Francisco VA Medical Center and VA Northern California Health Care System in Martinez. These sites are part of the same VA regional network (VISN 21). The research staff will be the same at both sites. Your personally identifying information will not be shared with anyone outside the research staff at these two sites.

We will keep your personal information confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. In general, we will not disclose any information about you without your written permission. We will disclose your information if it is necessary to protect your rights or welfare - for example, if you are injured and need emergency care. We will disclose your information if the researcher becomes aware that you may be a danger to yourself or to others. We will disclose your information if the researcher becomes aware that acts of child, elder, or dependent adult abuse or neglect may have occurred.

Taking part in this study will involve collecting private information about you. This information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

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We will not share your records or identify you unless we have to by VA regulation or law. There are times when we might have to show your records to other people. For example, someone from the VA Central IRB, our local Research and Development Committee, Office of Research Oversight, the Research Compliance Officer, and other study monitors may look at or copy portions of records that identify you.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants:

You will not be charged for any procedures that are part of this study. You will be responsible for transportation costs within 20 miles of the study site. Your study appointments will be scheduled to accommodate your work schedule, so you will not be expected to take time off from work to participate in this study.

Payment Offered for Participation:

You will be paid \$20/hour for the in-person meeting in which we review this Consent form with you and conduct a second screening. You will also be paid for time in testing sessions in this study: \$100 for completion of each of the testing sessions, or \$400 total for all 4 testing sessions. You will not be paid for travel time but will be reimbursed for any mileage over 20 miles each way for testing and training sessions. For example, if you travel 44 miles roundtrip to a study activity, you will be paid for 4 miles of travel. Travel will be reimbursed at the rate of \$.55/mile, not to exceed \$300 per visit.

If you do not participate in any further study activities after this meeting, you will be paid by mailed check within 6-8 weeks. If you continue to participate, you will be paid by mailed check within 6-8 weeks of participation in testing sessions. If you decide to withdraw from the study, you will be paid by mailed check in 6-8 weeks after any testing time you already completed before withdrawing.

The VA Financial Services Center (FSC), located in Austin, Texas, will send you a check. Due to limitations in the Financial Management System, payments made to subjects through Austin Financial Services Center generate Internal Revenue Service Form 1099 regardless of amount. Your Social Security number will be used for this purpose.

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MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

It is important that you tell your study investigators, Drs. Tatjana Novakovic-Agopian, Anthony Chen, John McQuaid, Thomas Neylan, or Gary Abrams if you feel that you have been injured because of taking part in this study. You can tell the investigator in person or call him or her at San Francisco VAMC 415-221-4810 ext. 4129 during normal work hours or at 415-752-1212 if you are calling after work hours or on the weekend.

Emergency and ongoing medical treatment will be provided as needed.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

SIGNIFICANT NEW FINDINGS

At any time during the study new findings may become available about other treatment options that might change your decision to stay in the study. If this happens, the study investigator will tell you about them and discuss whether you want to stay in the study or not. If you stay in the study, you may be asked to sign an updated consent.

PARTICIPATION IS VOLUNTARY

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you withdraw, the study investigators may continue to review any data already collected for the study but cannot collect further information, except from public records.

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RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION

In special cases the study investigator may terminate your participation in this study without your consent. This could occur if you do not participate in study procedures or if the investigator is concerned that your continued participation might result in you harming yourself or others. You may also be withdrawn from the study due to unforeseeable circumstances. For example, you may be withdrawn from the study if you get sick and cannot go to training sessions or attend make-up sessions. Should the investigator decide to terminate your participation, she will contact you to discuss the reasons for the termination. If you are terminated from the study without your consent, you may feel badly. If you request it, the study investigator will make a follow-up contact with you to discuss your concerns.

PERSONS TO CONTACT ABOUT THIS STUDY

You may contact Study Investigators Drs. Tatjana Novakovic-Agopian, Anthony Chen, John McQuaid, Thomas Neylan, Gary Abrams or their study coordinator Deborah Binder for any reason. You can talk to these individuals in person or call him or her at 415-221-4810 ext. 4129.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA

There are no plans to use data collected as part of this study in future studies.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms _____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

You voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record if applicable.

I agree to participate in this research study as has been explained in this document.

_____	_____	_____
Participant's Name	Participant's Signature	Date
_____	_____	_____
Name of person obtaining consent	Signature of person obtaining consent	Date

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