Optimizing Cognitive Remediation in VA Mental Health Rehabilitation Settings

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VA | U.S. Department of Veterans Affairs	**Agreement to Participate in Human Subject Research** IRB Protocol #: **H190131**
Study Title: Optimizing Cognitive Remediation in VA Mental Health Rehabilitation Settings	
Principal Investigator: Yash Joshi, M.D., Ph.D.	
VA Facility: VA San Diego Healthcare System (VASDHS)	PATIENT CONSENT
Participant Name :	Date:

STUDY SUMMARY

You are being asked to participate in a research study. This section summarizes key information about this study to assist you, or your legally authorized representative, in understanding the reasons why you may or may not want to participate in the research. Your participation is voluntary. You may refuse to participate or withdraw at any time. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer. Carefully review this section and the detailed information that follows before you agree to participate.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is about helping Veterans with mental illness succeed in aspects of their life such as work, school, and living independently in the community. Veterans recruited from any VASDHS's Psychosocial Rehabilitation & Recovery Centers (PRRC), mental health Residential Rehabilitation Treatment Programs (RRTPs), inpatient mental health treatment, outpatient mental health treatment facility or Substance Abuse Residential Rehabilitation Treatment Program (SARRTP) will be assessed on EEG measures and performance on a one hour "brain training" exercise. This study will test whether an EEG or brain wave test can be used to better match the Veteran to the "right" cognitive remediation treatment. It is being funded by the Department of Veterans Affairs by a Career Development Award (CDA) to the Principal Investigator. By doing this study, we hope to learn how to apply a personalized approach towards cognitive rehabilitation for Veterans with mental illness.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

You will be asked to participate in one visit followed by brief monthly assessments for three months. In the first visit you will be interviewed about your medical and psychiatric history, current problems you may be having and how you are getting along in life. You will also complete some problem-solving tasks, some of which will be done on a computer. You will also do an EEG or brain wave test, complete a computer-administered "brain training" exercise and then tell us about your experiences with these tasks. This visit will take about 7 hours and will be done at an EEG lab at UCSD in Hillcrest. In the follow-up visits you will be asked about activities of daily living, how you have been feeling and any symptoms you may have. These visits will take about 30 minutes.

Your participation in this research will last about 4 months. After the 3rd follow-up visit you will be asked for permission to contact you every 4 months for 12 months to assess how you are doing over the phone and review your medical information through the VA Computerized Medical Record System (CPRS). These assessments will take less than 30 minutes. If you agree, your total participation will be approximately one year and four months.

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WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are no direct anticipated benefits to you beyond the benefit of the services you already receive but the researchers hope to learn to better match cognitive interventions to Veterans with mental illness to aid with rehabilitation programming and to improve your ability to live independently in the community.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The most important reasons/risk(s) why a participant may NOT want to volunteer for this study include potential 1) loss of confidentiality; 2) emotional distress during the assessments due to discussing or thinking about emotional or uncomfortable topics; and 3) short-term anxiety or discomfort due to EEG biomarker assessment (hearing tones in earphones) and performing exercises on cognitive remediation exercise.

A complete description of risks is included in the Research Details Study Risks section.

Participation is voluntary and the only alternative is to not participate.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Yash Joshi, M.D., Ph.D. of the VA San Diego Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study he may be contacted at (619) 316-6242.

RESEARCH DETAILS

WHO IS CONDUCTING THIS RESEARCH AND WHY?

Yash Joshi, M.D., Ph.D. and Gregory Light, Ph.D. are asking for your consent to this research. They are conducting this study in collaboration with Michael Thomas, Ph.D. from Colorado State University and the University of California San Diego (UCSD). This study is being sponsored by a VA Career Development Award (CDA) awarded to Dr. Joshi.

No members of the research team have a significant financial interest and/or a conflict of interest related to the research. Unrelated to this study, Dr. Light has been a consultant to Astellas, Heptares and Neurosig and has stock in Neuroverse.

The purpose of the research is to test whether an EEG or brain wave test can be used to better match the Veteran to the “right” cognitive remediation treatment, regardless of their specific mental health diagnosis, among Veterans in VASDHS Mental Health Residential Rehabilitation Treatment Programs (RRTP), Psychosocial Rehabilitation and Recovery Centers (PRRC), inpatient mental health treatment, outpatient mental health treatment facilities or Substance Abuse Residential Rehabilitation Treatment Program (SARRTP). You are being asked to participate because you are a Veteran who is engaged in or within 6 weeks of discharge from a VA Mental Health Residential Rehabilitation Treatment Program (RRTC), Psychosocial Rehabilitation and Recovery

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Center (PRRC), VASDHS inpatient or outpatient facility or VASDHS's Substance Abuse Residential Rehabilitation Treatment Program (SARRTP). Approximately 104 people will take part in this research at the VASDHS facility.

This study is about helping Veterans engaged in PRRC, RRTP outpatient programming or discharged from VASDHS inpatient programs within the last 6 weeks succeed in aspects of their life such as employment, school, and living independently in the community. Veterans recruited currently engaged or within 6 weeks from discharge from VASDHS's PRRC, RRTP, inpatient or outpatients or SARRTP programs will be assessed on EEG measures and performance on a one-hour cognitive remediation or "brain training" exercise. This study will test whether an EEG or brain wave test can be used to better match the Veteran to the "right" cognitive remediation treatment. Information gained from this study will help establish a personalized approach towards cognitive rehabilitation for Veterans with mental illness.

FOR HOW LONG WILL I BE IN THE STUDY?

Your individual participation will take last about 4 months. You will be asked to participate in one visit followed by brief monthly assessments for three months. In the first visit you will be interviewed about your medical and psychiatric history, current problems you may be having and how you are getting along in life. You will complete some problem-solving tasks, some of which will be done on a computer. You will also do an EEG or brain wave test, complete a computer-administered cognitive or "brain training" exercise and then tell us about your experiences with these tasks. Visit 1 will take about 7 hours and will be done at an EEG lab at UCSD in Hillcrest. In the follow-up visits you will be asked about activities of daily living, how you have been feeling and any symptoms you may have. These visits will take about 30 minutes and will be done over the telephone. After the 3rd follow-up visit you will be asked for permission to contact you every 4 months for 12 months to assess how you are doing over the phone and review your CPRS data. These assessments will take less than 30 minutes. If you agree, your total participation will be approximately one year and four months.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

Visit 1

1. We will ask you for some basic demographic information about yourself, such as age, gender, education and marital status (25 minutes)
2. You will provide a specimen of urine to test for the presence of drug use. We will test for methamphetamine, opiates, PCP, benzodiazepines, barbiturates, amphetamine, cocaine, and THC. If the test is positive, you will not be able to participate in the study (5 minutes).
3. You will be interviewed about your medical and psychiatric history. You will be asked specific questions about problems or difficulties you might have had as well as how you think and act in a variety of situations. You can refuse to answer any question that makes you uncomfortable and you may stop the interview at any time. The interview will last no longer than one hour.
4. You will complete a series of problem-solving tests which are administered via computer. These tests will take approximately one hour.

5. You will be asked about activities of daily living such as mobility, self-care, getting along with people, and life activities, which will take about 15 minutes.
6. A cap with sensors will be placed on your head so that your brain waves (EEG) can be measured. Additional sensors will be placed next to each eye on your nose and behind your ears. You will be asked to listen to a series of brief tones for a total of approximately 50 minutes. The total time for EEG data collection, including electrode placement, preparation and clean up, is about 80 minutes.
7. You will also do a task in which you sit in front of a computer and listen to pairs of tones and press a button whenever the two sounds are the same or different. This task takes approximately 75 minutes, including three five-minute breaks.
8. You will be interviewed about your attitudes about the EEG test and the computer-administered cognitive "brain training" exercise you just completed, including your interest/enjoyment, usefulness of these tests as well as any improvements you feel should be made. This interview will take about 25 minutes. In addition, we will audio-record interviews for later review to avoid taking detailed notes during the interview.

This visit will take place in Dr. Light's laboratory at the UCSD Medical Center in Hillcrest and will take approximately 7 hours.

Optional Activity Tracker – As part of this study you have the option to wear a Fitbit activity tracker over the course of the study. We would like you to wear the Fitbit as much as possible, including when sleeping. If you agree you will receive additional payment and will keep the Fitbit at the end of the study.

☐ **Yes, I would like to hear about the optional activity tracker** _____ (initial)

☐ **No, I do not wish to hear about the optional activity tracker** _____ (initial)

Monthly Assessments

There will be three monthly assessments in which the following will happen:

1. You will be asked about activities of daily living such as mobility, self-care, getting along with people, and life activities, which will take about 15 minutes.
2. You will be briefly interviewed about how you have been feeling and any symptoms you may have, which will take approximately 15 minutes.
3. You can refuse to answer any question that makes you uncomfortable and you may stop the interview at any time.
4. These assessments will take approximately 30 minutes and will be done over the telephone.

Time Schedule	Visit	Study Events	Length of Visit

Week 1	Visit 1	Basic demographic Interview Problem solving tests Assessment of everyday task EEG Brain Training Exercise Your Feedback	7 hours
One month later	Monthly Assessment 1	Interview by telephone	30 minutes
One month later	Monthly Assessment 2	Interview by telephone	30 minutes
One month later	Monthly Assessment 3	Interview by telephone	30 minutes

WHICH PROCEDURE/S OR TREATMENT/S ARE DONE FOR RESEARCH?

The entire protocol can be considered experimental and not part of your routine care; therefore, all procedures will be done specifically for research purposes.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Potential risks in this study include the following:

1) You may experience emotional distress during the assessments and interviews due to discussing or thinking about emotional or uncomfortable topics. Some people become uncomfortable at being asked questions about their life problems, symptoms and difficulties. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.
2) You may feel short-term anxiety or discomfort due to EEG testing (hearing tones in earphones) and performing exercises on cognitive remediation exercise.
3) You might experience some fatigue, restlessness, or concern that you are not performing well during the EEG, brain training and problem-solving tests.
4) The EEG procedure involves cleaning areas on the scalp and around the eyes for placement of the sensors that can result in minor skin abrasion. Participants usually do not find these cleaning procedures to be uncomfortable.
5) There is the possibility of skin irritation from contact with the saline electrode paste, however, this is unlikely, as the salt concentration of the paste is very similar to that of human sweat.
6) There is the risk of boredom from the testing procedures including the 1 hour of brain training exercise.
7) Other risks may include increased symptoms, or decreased treatment engagement in your program. You will be closely monitored for potential negative response to assessment instruments, EEG assessment and brain training exercises.

8) There is the possibility of loss of confidentiality. All data will be collected for research purposes and treated in a confidential manner. Loss of confidentiality is a risk of participating in research, although it is rare given appropriate procedures. There is a very small risk that sensitive information (e.g., diagnosis) could become known outside the research setting. Significant efforts relating to data security keep this risk low.
9) While information derived from this research will be kept confidential and will not be entered into your clinical chart, it is possible that positive drug screen results may become known outside of the research setting. If this information was disclosed, it could be potentially damaging to your employability or insurance.

There are no known legal risks associated with engaging in this study.

There is always a chance that any procedure can harm you. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. 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.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize voice recording(s) to be made of you by the study team while you are participating in this study. The said voice recording is intended for the following purposes: In Visit 2, you will be interviewed about your attitudes about the EEG testing and computer administered brain training exercise you just completed, including your interest/enjoyment, usefulness of these tests as well as any improvements you feel should be made. We will audio-record interviews for later review to avoid taking detailed notes during the interview. These notes will be used to help optimize future studies of cognitive remediation for Veterans in PRRC/RRTP and other VASDHS rehabilitative programs.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.

If you refuse to grant consent to be audio recorded, sign and date below. You can still be an active participant in the study.

Subject's Signature: _____ Date: _____

Signature of Legally Authorized Representative: _____ Date: _____

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your conditions.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS RESEARCH STUDY?

This is not a treatment study so that the alternate to participating in this study is not to participate.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance, but no additional compensation is available.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:
Dr. Yash Joshi at (619) 316-6242.

AFTER HOURS:

Call VA San Diego Medical Center at (858) 552-8585 and ask the operator to page the on-call psychiatrist.

DO I HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

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

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Your participation might be terminated by the investigator without regard to your consent if the Investigator feels it is in your best interest, such as you are having increased symptoms, an increase in suicidal feelings, decreased participation in your program or experience a decline in functioning. Dr. Joshi will closely monitor Veterans who appear to be distressed and refer participants to any additional needed services.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact Dr. Joshi.

Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

WHAT COMPENSATION WILL I RECEIVE IF I TAKE PART IN THIS STUDY?

You will receive $225 for completing Visit 1.
You will receive $25 for each of the follow up visits, for a final compensation of up to $300.
If you complete only a portion of the visit, payment will be prorated based on the amount of time spent. You will receive no further payments.

Payment will be by VA electronic funds transfer. This payment will be made directly to your bank account using electronic funds transfer. If you currently have a debt to the Federal Government, your debt may be subtracted from your funds transfer payment for study participation.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, or concerns about the research or other related matters, you may contact Dr. Joshi at (619) 316-6242.

If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Institutional Review Board at 858-642-6362. This is the Board that is responsible for overseeing the safety of human participants in this study.

If you have study related questions or concerns you can contact the research team at (619) 316-6242.

WHO COULD PROFIT FROM THE STUDY RESULTS?

This study does not have a commercial sponsor and the Investigators do not have any financial arrangements that could be construed as a potential conflict of interest

FUTURE USE OF DATA AND RE CONTACT

In addition, after the 3rd follow-up visit you will be asked for permission to contact you every 4 months for 12 months to assess how you are doing over the phone and review your CPRS data. These assessments will take less than 30 minutes. You can refuse to answer any question that makes you uncomfortable and you may stop the interview at any time. If you agree, your total participation will be approximately one year and four months. There will be no financial compensation for your participation in these calls.

☐ **Yes, I may be contacted as described**. _____ (initial)

☐ **No, I do not wish to be contacted as described**. _____ (initial)

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After the 3rd follow up visit, you will also be asked if you would like to hear about additional studies.

☐ **Yes, I would like to hear about additional studies** _____ (initial)

☐ **No, I do not wish to hear about additional studies** _____ (initial)

Although identifiers will be removed from your identifiable private information, this information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible.

We will be collecting your Social Security number for CPRS review, payment and tracking purposes. All of your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VA San Diego Health System location, or as files behind the secure VA San Diego Health System computer firewall.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board and federal compliance officers may look at or copy portions of records that identify you.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

Any presentations or publications from this information will not identify you.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

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_____ has explained the study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

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

_____ _____
Participant's Signature Date

_____ _____
Signature of Legally Authorized Representative Date

_____ _____ _____
Signature of Researcher Obtaining Consent Name (print) Date

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this document, you provide your permission called your 'authorization,' for the access, use, and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect and use information learned from the procedures described in this consent form. We may also collect other information including your name, address, date of birth, and information from your medical records such as medical history, allergies, lab results, mental health treatment, drug abuse/substance use history.

The research team may also need to share your health information and the information it collects to other entities as part of the study progress. Other entities may include Veterans Medical Research Foundation; University of California San Diego (UCSD) or other affiliates or collaborators; Institutional Review Board, Office of Research Oversight (ORO), Office of Human Research Protections (OHRP), and the Government Accountability Office (GAO).

Collaborators include researchers at Colorado State University, UCSD, and the University of California, Los Angeles, who will assist with statistics and data analysis.

Your health information disclosed outside the VA as described in this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may (a) write to the Release of Information Office at this facility; (b) ask a member of the research team to give you a form to revoke the authorization; or (c) send your written request to the Principal Investigator for this study at the following address:

Yash Joshi, MD, PhD
3350 La Jolla Village Dr.
San Diego, CA 92161

If you revoke this authorization, Dr. Joshi and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

While this study is being conducted you will not have access to your research-related health records.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization.

Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose

your information will expire at the end of this research study; any study information that has been placed into a repository to be used for future research will not expire.

AGREEMENT TO AUTHORIZE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

By signing this document below, I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this document. This authorization has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint. I will be given a signed copy of this document for my records.

_____	_____	_____
Participant's Signature	Last 4 of SSN	Date

A copy of this document will be provided to the research participant.

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_____ _____
Signature of Legally Authorized Representative Date

A copy of this document will be provided to the research participant.

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EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in medical research. You have the right to know:

1) The nature and purpose of the study.
2) The procedures in the study and any drug or device to be used.
3) Discomforts and risks reasonably to be expected from the study.
4) Benefits reasonably to be expected from the study.
5) Alternative procedures, drugs, or devices that might be helpful to you and their risks and benefits.
6) Availability of medical treatment should complications occur.
7) You may ask questions about the study or the procedure.
8) You may quit the study at any time without affecting your future care at the VA.
9) You should be given a copy of the signed and dated written consent form for the study.
10) Your consent to participate must be given freely, without being obtained through deceit, force, or coercion.

If you have any questions or concerns about your rights as a research subject, please contact the VASDHS Research Compliance Officer at (858) 642-3817 or RCO@vapop.ucsd.edu. You may leave an anonymous comment at the VASDHS research compliance hotline at 858-642-6311.

REF: California HSC 24170-24179.5