STUDY INFORMATION:

Study Title: Cognitive remediation for cognitive control and decision-making deficits in Veterans at risk for suicide

Principal Investigator (Head Researcher): Erin Hazlett, PhD

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SUMMARY OF THIS RESEARCH STUDY:

A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this pilot research study is to examine a new treatment for depression. It is called "Cognitive Remediation for Executive Functioning Deficits." Participants in this study will be provided a novel bi-weekly group therapy (two times per week for 10 weeks) that focuses on improving their thinking skills (e.g., trouble concentrating, becoming distracted by persistent negative thoughts, difficulty making helpful decisions or devising strategies to manage daily problems) that may be getting in the way of their daily functioning. The intervention includes exercises to improve their attention, decision-making, and problem-solving skills. The treatment lasts for 10 weeks and will include education and support. It will also include use of computer programs. This is an "add-on" treatment to your ongoing care.

If you choose to participate, you will be asked to complete:

- Self-report questionnaires
- Interviews
- Cognitive tests that measure your thinking process
- The Cognitive Remediation Executive Functioning Treatment that will last for 10 weeks (group format; 2 times each week, each session lasting for 90 minutes)

The main risks to you if you choose to participate are feeling distressed or bored during psychological interviews and tests, and discomfort with the group-based treatment. In rare cases, the assessments may cause some emotional distress or an increase in suicidal thinking or urges. Should you become suicidal during the assessment procedure, one of the study doctors will evaluate you and you may be

escorted to the emergency room at Mount Sinai for a more detailed examination. There may also be unforeseeable or unknown risks to participation.

It is also possible that you may still experience suicidal thinking and urges even with participation in this treatment. The research team has developed a safety management plan for the emergence of suicidal thoughts, urges or acts that occur during the treatment. The research team physician, Dr. M. Mehmet Haznedar, MD, will be available to perform a suicide assessment at any point if you are experiencing negative thoughts. He will ask questions regarding suicidal ideation and suicide plan and arrange for your transfer to the psychiatric emergency room if necessary.

This study is not designed to benefit you personally, but it is possible you may also benefit from participation in this research if the Cognitive Remediation for Executive Functioning Deficits 10-week treatment helps you better manage depressive symptoms and suicidal feelings, thoughts, and urges.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all of the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you had previously qualified to participate in a VA study entitled, “Neurobiology of Affectivity Instability of Veterans at Low- and High-Risk for Suicide,” and meet diagnostic criteria for Major Depressive Disorder.

Funds for conducting this research are provided by VISN 2 MIRECC at the James J Peters VA Medical Center.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 20 appointments that occur for 90 minutes twice per week over the course of 10 weeks. There will also be two 90-minute appointments, one prior to the 20 intervention appointments and one following the intervention, during which you will be asked to complete measures of depression, suicidal thinking, and decision-making and also participate in a battery of cognitive assessments that assess attention and decision-making skills. The number of people expected to take part in this research study is 24.

DESCRIPTION OF WHAT’S INVOLVED:

If you agree to participate in this research study, the following information describes what is involved.

All of the following interviews, assessments, and interventions will be completed by trained research staff through online telehealth video platforms like HIPAA-compliant Zoom, online survey applications such as REDCap, and websites that run online computerized measures at Mount Sinai.

This study involves 22 visits. One telehealth initial visit at the time of enrollment (for 90 minutes), 20 telehealth sessions (twice per week for 10 weeks, each lasting 90 minutes for a total of 30 hours), and one telehealth visit following the completion of the 20 visits (for 90 minutes). We will work with you to find a convenient visit schedule. Visits will involve the following procedures:

- Clinical Assessments: These interviews ask targeted questions about your mental health. You will also be asked to complete questionnaires about your mental health. This will take 45 minutes and be administered via HIPAA-compliant Zoom at baseline and via HIPAA-compliant Zoom at the follow-up appointment post-intervention.
- Computerized Assessments: These assessments will assess your attention and problem-solving skills. This will take 45 minutes and be administered via HIPAA-compliant Zoom at baseline and via HIPAA-compliant Zoom at the follow-up appointment post-intervention.
- The Cognitive Remediation for Executive Functioning Deficits Intervention: This intervention will last for 10 weeks, 2 times each week, and each session will be 90 minutes and conducted via HIPAA-compliant Zoom. The session will consist of computerized games/exercises (40 minutes) followed by a 4-person group therapy session (45 minutes) that focuses on improving thinking skills (e.g., trouble concentrating, becoming distracted by persistent negative thoughts, difficulty making helpful decisions or devising strategies to manage daily problems) that may be getting in the way of daily functioning. To ensure privacy and safety of those assigned to each Cognitive Remediation group, group members are asked to join the HIPAA-compliant Zoom session when they are in a private area without others around. Before joining their first Cognitive Remediation session, the PI will call the participant to verbally review the group telehealth agreement, which is standard clinical practice for groups conducted over HIPAA-compliant Zoom and explains the risks and consequences of group telehealth sessions. This acknowledge will be documented in participants medical records.

Time Point	Clinical Assessments	Cognitive Assessments	Cognitive Remediation Intervention	Total
Baseline	45 minutes	45 minutes	--	90 minutes
Group Therapy Sessions	--	--	90 min, 2x per week, 10 weeks	30 hours
3 months	45 minutes	45 minutes	--	90 minutes

COVID-19 Precautions:

During the COVID-19 pandemic, the study will be conducted remotely (i.e. NOT in person), and you must have access to a desktop or laptop computer with Internet access in order to participate in it. The clinical and computerized assessments will be completed via the telehealth video platform HIPAA-compliant Zoom for Healthcare at the baseline and follow-up appointments (2 appointments in total, each of which is 90 minutes in duration). The Cognitive Remediation Intervention will be conducted through HIPAA-compliant Zoom for Healthcare. During the baseline appointment, you will be taught how to access and use the programs needed for the Cognitive Remediation Intervention.

USE OF YOUR DATA:

In the future, your identifiable information will be removed from the private information that is collected as part of this research. After this removal, the information will be used for future research studies or shared with other research teams for future research studies. You will not be informed of the details of specific research that is done with your data. That means that a research project might be done that you would not consent to if provided with the details of that research project. While we will remove your identifying information before sharing the information there will be code attached to the information. That code will remain at Mount Sinai. In addition, we may contact you in the future to discuss the possibility of participating in other research studies.

To do more powerful research, it is helpful for researchers to combine data with other studies by putting it into one or more scientific databases, where it is stored along with information from other studies. A data repository is a large database where information from many studies is stored and managed. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information will be placed into one or more scientific databases for future research. There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai, James J Peters VA Medical Center, or another institution. A researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

You may decide later that you do not want to share your information. If so, contact the researchers who conducted this study, and they will stop using this information.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things:

1) Attending 22 telehealth visits through HIPAA-compliant Zoom over a 10-week period and allowing contact during this time.

2) Completing the Cognitive Remediation for Executive Functioning Deficits treatment, which focuses on improving your thinking skills.
3) Answering questions about your personal health and doing cognitive assessments.
4) Agree for data that has your name, date of birth, address, and phone number removed, to be used for future research.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you for your time and effort. You will be offered financial compensation of $30 for each completed clinical and cognitive assessment battery completed pre-intervention and then a second time post-intervention. You will be offered financial compensation of $15 (two times a week) for each completed intervention session. Total reimbursement for participation in the study will be $360. Checks require some time to be prepared and will be given to you once processed and available.

	Number of Appointments	Amount
Baseline Assessment	1	$30
Intervention Sessions	20	$15
Post Intervention Assessment	1	$30
Total	22	$360

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, the information collected in this study m ay help us better understand the cognitive deficits associated with depression, suicidal feelings, thoughts, and urges, and help us better understand how to address them.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Risks of clinical assessments: During clinical interviews and surveys, you will be asked personal questions. Participants sometimes find this uncomfortable, and occasionally become emotionally distressed or an increase in suicidal thinking or urges. You may stop and/or postpone the assessment if needed.

Risks of cognitive assessments: Sometimes participants find cognitive testing to be boring or tedious and may become distressed. There are breaks during the testing session to minimize these potential risks. You may stop and/or postpone the assessment if needed.

Risk of treatment: It is also possible that you may still experience suicidal thinking and urges even with participation in this treatment. The research team has developed a safety management plan for

the emergence of suicidal thoughts, urges or acts that occur during the treatment. The research team physician, Dr. M. Mehmet Haznedar, MD, will be available to perform a suicide assessment at any point if you are experiencing a change in your suicidality. In addition, the Cognitive Remediation intervention is a group-based intervention, which some participants may find uncomfortable. Participants may find the content distressing and may not want to share details of their clinical condition or symptoms with their group members. We will work closely with you to help you with these concerns.

Risk of loss of private information: this risk always exists, but there are procedures in place to minimize the risk.

Legal risk: You may interact with a professional who is a mandatory reporter of child abuse and neglect, so there is a risk of being reported for child abuse or neglect if you disclose this information.

Risks of Data Sharing:

Group Risks: Although we will not give other researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

Privacy Risks: Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or VA hospitals or receive any benefits to which you are otherwise entitled.

Instead of being in this research study, your choices may include obtaining assistance in finding clinical treatment if you wish. Your choice not to participate in this study will in no way compromise your access to treatment.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator, Dr. Erin Hazlett (800 718-584-9000 x3701 or 212-535-0847.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals, VA hospitals, or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff.

If you decide you do not want your data to be used for research anymore, you must contact the Principal Investigator in writing (Erin Hazlett, PhD, Department of Psychiatry, One Gustave L. Levy Place, Box 1230 New York, NY 20019) and ask to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data and specimens have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator, Dr. Erin Hazlett at phone number 212-535-0847 or at the VA Hospital: (718) 584-9000 x3701 or x5869.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions

regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, date of birth, SSN, address, telephone number, and email. The medical records number will be recorded only if you receive medical care at the Mount Sinai Campus. During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing mental health records but only if held on the EPIC system at the Mount Sinai Health System or VHA CPRS Health System; the aim of reviewing your records is to confirm and supplement information supplied during the interviews with regards to psychiatric care and medication.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System and VA Health System.

The research team and other authorized members of The Mount Sinai Health System (“Mount Sinai”) workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School’s Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need

your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: James J Peters VA Medical Center
- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: VISN 2 MIRECC

In all disclosures outside of Mount Sinai and the JJPVAMC, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?
Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

In almost all disclosures outside of Mount Sinai and the JJPVAMC, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

ADULT PARTICIPANT:
Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____
Signature of Study Participant	Printed Name of Participant	Date

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date

WITNESS SECTION:
When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____	_____	_____
Signature of Witness	Printed Name of Witness	Date