The Development and Implementation of a Peer-Led Diet and Exercise Intervention in Older Urban Dwelling Veterans with Dysmobility

NCT04994938

July 25, 2023

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Subject Name:	**Informed Consent Date:**
Protocol # or IRBNet ID #: 1639690 **Principal Investigator: Dr. Erin Hazlett, Ph.D.**	**VAMC: James J Peters**
Title of Study: A Novel Cognitive Remediation Intervention Targeting Poor Decision-Making and Depression in Veterans at High Risk for Suicide: A Safe, Telehealth Approach During the COVID-19 Pandemic	

This page for research staff only
****If consenting in person skip to page 2 of consent****

Research Staff: *Hello, my name is _____ from the James J. Peters VAMC. I am calling with one other staff member, _____, about a potential research opportunity that you may be interested in called Cognitive Remediation for Executive Functioning Deficits. Are you interested in learning more about it?* **Wait for any response.** *If you are interested, I can go over the consent for the study with _____ as the witness and you can ask us any questions that come up. Make sure you have the mailed copy of the electronically sent version of the informed consent form to follow along.*

Research staff goes over every part of the consent form with the Veteran.

1. **Purpose of study and how long it will last:**

You are being asked to participate in a research study. This pilot study aims to examine a new treatment for suicidal Veterans who have been diagnosed with Major Depressive Disorder or Psychosis. It is called **"Cognitive Remediation for Executive Functioning Deficits."** You will be provided this treatment. You qualify for participation in this study because you are a Veteran with a history of suicidal thinking or behavior. Participants in this study will be provided a novel bi-weekly group therapy (two times per week for 10 weeks) that focuses on improving your 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 your daily functioning. The intervention includes exercises to improve your 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. We will work closely with your current outpatient mental health team and seek their opinions regarding whether this treatment was helpful to you.

As this is a new treatment approach, this study will examine how well the treatment is in affecting change and whether Veterans and clinicians find the treatment to be helpful. Your participation will last for approximately 4 months, which includes the Cognitive Remediation for Executive Functioning Deficits treatment and three assessments.

We plan to enroll 36 Veterans in this project.

2. **Description of the Study Including Procedures to be Used:**

If you consent to participate in this research study, the Cognitive Remediation for Executive Functioning Deficits treatment will last for 10 weeks (2 times each week), and each session will last for 90 minutes. You will be asked to complete clinical assessments about how you are feeling (paper/pencil and clinician based) and other cognitive assessments that look at

attention and decision-making skills, three times: at baseline, Week 10, and Week 20 (e.g., immediately after the treatment is finished).

We estimate these assessments will last approximately two hours each. We are interested in determining whether Cognitive Remediation for Executive Functioning Deficits impact any of your depressive or cognitive symptoms (e.g., trouble concentrating or trouble distancing negative thoughts). All assessments for this project will take place at the James J. Peters VAMC (JJPVAMC) in the Mental Health Outpatient Clinic or the Mental Illness Research, Education and Clinical Center (MIRECC).

The intervention for this project will take place through VVC or Webex. Patient research participants will also continue their current treatment plan. To ensure privacy and safety of all participants, all participants are asked to join the VVC/Webex when in a private area without others around. Before joining the first session, the clinician will call each participant to verbally review the group telehealth agreement, which is standard clinical practice at the VA for groups conducted over VVC/Webex and explains the risks and consequence of group telehealth sessions. This acknowledgement will be documented in each of the participant's medical records. Reminders for how to troubleshoot technology problems that may arise will also be provided.

All participants as part of the Cognitive Remediation for Executive Functioning Deficits study will be asked to provide an emergency contact, local emergency resources, current phone number, and current address at the start of every treatment session to ensure safety.

3. Description of any Procedures that may Result in Discomfort or Inconvenience:

The Cognitive Remediation for Executive Functioning Deficits intervention involves testing of aspects of your thinking (e.g., attention/concentration, problem-solving, decision-making) and use of cognitive exercises to improve those aspects of your thinking, which some

Veterans may find uncomfortable. It also includes questionnaires that ask about depressive symptoms and suicidal thoughts, and the treatment itself is group-based, all of which some Veterans also may find to be uncomfortable. You may find the content distressing and may not want to share details of your clinical condition or symptoms with other group members. Group members are not required to disclose the contents of safety plans to others and are never required to speak in sessions. We will work closely with you to help you with these concerns. We will alert your primary mental health provider through CPRS that you completed these assessments and exercises in the case that you need additional support. Any specific concerns about your reactions may be shared with your psychiatrist and mental health case manager.

4. Expected Risks of Study:

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 physicians (Dr. Marianne Goodman, MD and 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. They will ask questions regarding suicidal ideation and suicide plan and initiate the standard protocol employed by outpatient psychiatry at the JJPVAMC, which includes contacting the JJPVA Suicide Prevention Team initially and, if necessary, calling 911 should imminent suicidal behavior be expressed. If you become suicidal during this study, your participation in the study may need to be terminated.

You may feel bored when you complete some of the assessments or cognitive exercises and, in rare cases, the assessments or cognitive exercises 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, if you are an outpatient, you may be escorted to the emergency room for a more detailed examination and your participation in the study may be terminated. There may also be unforeseeable or unknown risks to participation.

5. Expected Benefits of the Study:

The assessment you receive as part of your participation in this study may not be of direct benefit to you, but the knowledge gained will help us design and implement more effective treatments for Veterans at risk for suicide.

There are possible benefits by taking part in this study. It is possible that participation in the Cognitive Remediation for Executive Functioning Deficits 10-week treatment will improve your thinking skills, including improvement of your concentration skills, improvement of your ability to control persistent negative thoughts, and improvement of your decision-making and problem-solving skills, which may help you better manage the depressive symptoms and suicidal feelings, thoughts, and urges.

6. Other Treatments Available:

It is entirely up to you to participate in this study. If you choose not to participate, this will not affect any of your options for treatment at the VA. You qualify for this study because you are a Veteran currently receiving outpatient treatment for mental health at the VA. The treatment provided in this study is adjunctive or additive to the current outpatient treatment you are currently receiving in outpatient psychiatry at the VA.

7. Use of Research Results:

You will be assigned a unique study identification number (ID) and the linking documents will be stored in password-protected areas with limited access. Therefore, participant identifiable information such as names, or other demographic information will never appear anywhere (e.g., future publications). Data, questionnaires, forms and other materials generated from this study will be stored by subject identification number in locked cabinets located in research office space at the JJPVAMC. Access to the VA intranet is granted only after background security clearances are completed by VA police and HR departments.

Only the Principal Investigator, Erin Hazlett, PhD, and those designated on the research team, will have access to this VA-sensitive data.

We will let you and your VA physician know of any significant new findings made during this study, which may affect your willingness to participate in this study. Specifically, the research team may collaborate and share information, such as significant concerns of suicide, with your primary mental health treatment team.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, recognizable photograph, or any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

In order to comply with federal regulations, research records identifying you may be reviewed by the following: Representatives of the sponsor or sponsors of this study. Authorized representatives of the Bronx VAMC (e.g., Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Office of Inspector General (OIG), and the Office for Human Research Protections (OHRP).

Your medical records will be retained according to National Archives and Records Administration, in accordance with Records Schedule RCS-10-1.

Do you give the researchers permission to contact you in the future to collect additional information about you, or to discuss possible participation in another research project? Please initial your choice:

Yes _____ No _____

If consenting over the phone, staff members initial below:

Your initials as the study team member obtaining consent on this form indicates that you provided information about future contact and you initialed Yes/No to indicate the participants response.

Yes _____ No _____

Your initials as the witness on this form indicates that the study member obtaining consent provided information about future contact and you too initialed Yes/No to indicate the participants response.

Yes _____ No _____

Otherwise, your de-identified information may **not** be used for future research without additional consent.

8. Special Circumstances:

A copy of your signed informed consent form and signed HIPPA authorization will be placed in your medical record.

9. Compensation and/or Treatment in the Event of Injury:

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The VA must provide necessary medical treatment in accordance with applicable federal regulations to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Further information about compensation and medical treatment may be obtained from the medical administration service at this VA medical center.

If you have any questions about this medical care, talk to the principal investigator for this study, Erin Hazlett, PhD at 718-584-9000 ext 3701.

10. Voluntary Participation:

You are not required to take part in this study. Your participation is entirely voluntary. You can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled. This will not interfere with your regular medical treatment, if you are a patient.

You can refuse to participate now or you can withdraw from the study at any time by speaking to the research team.

Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study. Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately. Also, a signed copy of this consent form will be given to you.

11. Termination of Participation:

There are no consequences if you choose to withdraw from this study.

For subjects that withdraw from the treatment trial, our research team will work closely with the suicide prevention team to establish contact, assess reasons for discontinuing treatment and attempt to address concerns. The suicide prevention team and this research

team will ask for emergency contact numbers and an emergency contact person that may assist us if you drop from treatment or an emergency occurs.

Adhere to Protocol: If you do not follow through with this assessment program and do not regularly keep your appointments, we will reach out to your treatment team; in some cases you may be discontinued from the study.

12. Costs and Reimbursements:

You will not incur any costs for participation in this study nor be required to pay extra for the Cognitive Remediation for Executive Functioning Deficits treatment. For Veterans who are required to pay co-payments for medical care and services provided by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this study.

Time-points	Amount
Baseline Appointment: • Consenting/Clinical Interview Screening • Cognitive Assessments • Self-reports • State-based clinical interview	Total: $150 $30 $60 $30 $30
10-Week Assessment	$170
20-Week Assessment	$200
Total	$520

It may take 6-8 weeks for you to receive your reimbursements for your study participation.

13. Contact Person(s):

To obtain answers to questions about the research, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following – Erin Hazlett Ph.D. at 718-584-9000, hospital extension 3701, Office 4B-46 in the MIRECC.

If you need to speak to someone after hours, (Co-PI) Marianne Goodman, M.D., (646) 245-7071. You may also call 718-584-9000 and ask the operator to connect you to the Psychiatry Resident on call or call the Suicide Prevention Hotline at 1-800-273-8255.

I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D. ACOS/R&D Program by requesting an appointment at (718) 741-4228 hospital extension 4228, first floor in the research building, room 1F-01 if I have questions, concerns and/or complaints or to offer input.

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above. Dr. Erin Hazlett or her delegate has explained the study to me and answered all of my questions. 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 understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law. This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature	Date	Time

Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page)	Signature of Person Obtaining Informed Consent	Date

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this page for research staff only
****only use if consenting over the phone –**
Otherwise skip**

Research Staff: After going over the consent. *Do you have any questions so far that have not been answered?*
Participant Answer: YES☐ NO☐

CONSENT: *I am now going to ask you if you consent to participate in this study. Only say yes if you have understood the information I have told you, you voluntarily agree to participate, and you are 18 years of age or older. If you have any questions or there is something you do not understand, please ask before responding.*

Do you consent to participate in this research study?
Participant Answer: YES☐ NO☐

If you just agreed to consent in the study, please sign and date the consent in your possession with which you have been following along.

Informed consent signed by patient not retained due to_____.
Please see attestations below.

How was consent obtained:_____

Witness:
Your signature on this form indicates that you were present as the study team member explained the research study to the patient named on this form. You heard the study team member review all information provided in this consent form, made sure the participant understood the information, and answered the participant's questions to the best of their ability. Your signature also indicates that the participant agreed to participate in the study

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and agreed to all informed consent and that you, as the one witness, agree to be contacted by parties including the IRB with any questions.

Study Team Member:
Your signature on this form indicates you provided information about the aforementioned research study to the patient named on this form. You reviewed all information provided in this consent form, made sure the participant understood the information, and answered the participant's questions to the best of your ability. Your signature also indicates the participant agreed to participate in the study and agreed to all informed consent and that you, as the one obtaining informed consent, agree to be contacted by parties including the IRB with any questions.

_____

Witness 1 Print Name and Signature Date Time

_____

Person Obtaining Informed Consent Print Name and Signature Date Time