Prevention of Suicide in Veterans Through Brief Intervention and Contact (VA-BIC)

NCT04446468

February 6, 2025

Title of study: Prevention of suicide in Veterans through brief intervention and contact (VA-BIC)
IRBNet #: [redacted]
Researcher name: [redacted]
Researcher Phone #: [redacted]

Key Information Section

What am I being asked to do?

You are being asked to take part in a research study. Research is different from standard medical care, and is done to learn something new.

You are being asked to be in this study because because you are currently admitted to the WRJ VA inpatient mental health unit ([redacted] and there are some concerns about your possible risk of self-harm. Research studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

The purpose of this research is to evaluate a suicide prevention program called Prevention of Suicide: Education, Awareness, Connection, and Engagement, or the PEACE intervention. The PEACE intervention includes two parts that work together to prevent suicide after hospital discharge: 1) a manual-based intervention that is delivered by a study therapist regularly for three months after discharge and promotes engagement in care, and 2) a mobile Health app, called My3, which aims to improve social connectedness after hospital discharge. The PEACE intervention is considered experimental for United States Veterans.

If you choose to be in this study, you will be assigned by chance (50/50, like a flip of a coin) to receive our PEACE intervention along with your regular care OR to receive regular care only. If you are assigned to receive our PEACE intervention, the study therapist will call or meet you in person eight times to check on you and help you stay connected to your treatment providers after you are discharged. You will also complete four assessment visits throughout the study, for a total of twelve visits. The study therapist will also set you up with the My3 app on your phone and encourage you to use it. The My3 app is described in further detail under the "What does this study involve" section of this form.

All study participants will complete 4 study interviews which are described under the "Study Surveys" section of this form. You have the option of attending the study visits by phone, VA VideoConnect or in-person. You could be in this study for 6 months.

There are a few risks involved in taking part in this study. You may experience feelings of embarrassment, nervousness, boredom or discomfort when being asked to answer study questions about the problems that you might be struggling with.

Voluntary Participation
You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, you will not lose any services, benefits or rights you now have.

What are reasons you might choose to volunteer for this study?
We cannot promise any direct benefit to you for participating in this study. With your participation, we hope to find information that may help Veterans in the future. You do not have to be in this study to receive mental health care at the VA.

What are reasons you might choose not to volunteer for this study?

You may not want to be in this study if you are unable to take the extra time off from work or from other personal commitments to attend the study visits.

For a complete description of risks, refer to the Detailed Information Section.

What are my other choices if I decide not to be in this study?
Instead of being in this study you could choose among the options listed below.

- The usual plan of medical care for people with your condition, which is described under the "Group B: Standard hospital discharge care" section of this form.
- You could also decide to enroll in other research studies aimed at evaluating suicide prevention strategies after psychiatric hospitalization. We are not aware of any such research studies currently being tested at the White River Junction VA Medical Center, but such studies may exist at other VA facilities or in the private sector.

What if you have questions, suggestions or concerns?

The person in charge of the study is [redacted]. If you have questions, suggestions, or concerns about this study or you want to withdraw from the study, her contact information is

[redacted]

Detailed Information Section

This is a single-site study conducted at the WRJ VA Medical Center. [redacted] is the recipient of a VA Clinical Science Research and Development (CSR&D) Career Development Award that is funding this study. We expect up to 160 people to be in this study.

What does this study involve?

If you decide to join this study, you would be in this research for up to six months and participate in 4 or 12 study visits depending on which group you are assigned to. If you decide to join this study, you will be assigined by chance (50/50, like a flip of a coin) to one of the groups listed below.

Group A: PEACE intervention plus standard psychiatric hospital discharge care

For this group of people, the study activities include, in addition to receiving the standard care provided to all Veterans at the time of discharge from [redacted] (please see the detailed description of standard discharge care listed for Group B):

- A brief educational visit with the study therapist about suicide prevention, which is designed to address your unique situation. The education visit lasts approximately one hour and will occur prior to your discharge from Ground East.
- During the brief educational visit, the study therapist will help you set-up the My3 app on your phone. Key facts about the My3 app are described below:
  - The app will be provided to you for free in this study.
  - The app includes: 1) A Behavioral Health Coach; 2) A Support Network; 3) Safety Plan; and 4) Educational Materials.
  - The study therapist will act as your Behavioral Health Coach and teach you how to use the My3 app.
  - In some cases, depending in your treatment stage or interest, you might want to add an additional support person to your My3 network. If so, the study therapist will work with you to identify up

to two potential support people (like a friend) to add to your support network.
  - You do not need to add a support person on the My3 app if you do not want to. In this case, the only person included in your support network on the My3 app will be the study therapist.
- You will have a total of eight contact visits (the initial education visit as well as seven follow-up visits at 2 days, 2 weeks, 1 month, 6 weeks, 2 months, 10 weeks, and 3 months after you are discharged) with the study therapist. These visits can be done over the phone, in-person or using VA Video Connect. You can choose which one works best for you. If you choose to participate in any of the study visits over the phone or using VA Video Connect, you should do so in a location where you feel safe and comfortable. We advise against you participating in the visits while you are driving a vehicle. Please note that while you have the choice to complete your visit over the phone or video, none of the visits will be recorded, even if they are in-person, over the phone, or via VA Video Connect.
- At each of these follow-up study visits, you will be asked about how you have been doing since you were discharged and given advice on ways to feel better. These visits will last approximately 15-30 minutes.
- The principal investigator ([redacted] may participate as an observer in one or more of your visits with the study therapist. [redacted] will be observing the study therapist in order to provide the study therapist with feedback on your visit.
- After your complete your final contact visit with the study therapist (visit #8), the study therapist will remove her/himself from your My3 app. However, you may continue to use the app if you wish.
- You will also complete all assessment visits outlined in Group B (including baseline and 1 month, 3 months, and 6 months after discharge). You may continue receiving standard psychiatric discharge care, as described below in Group B.

Group B: Standard psychiatric hospital discharge care

For this group of people, the study activities include the standard care provided to all Veterans at the time of discharge from [redacted] As part of standard psychiatric hospital discharge care, your treatment team will work with you and your outpatient providers to determine the best treatments for your particular mental health condition. The treatment team may also ask you to complete a

safety plan. The treatment team will arrange for you to meet with a mental health provider(s) as an outpatient for a set number of times after discharge. If you are assigned to the High Risk for Suicide List by the inpatient treatment team (or your outpatient providers), the Suicide Prevention Coordinator will ensure that a pop-up flag is placed in your medical record to make providers aware of your mental health needs.

You and the researcher will not be able to control the group to which you are assigned for this study. You will be told about your group assignment. If you are assigned to Group A, the study therapist doing your contact visits will know that you are in Group A. However, the person who conducts the follow-up assessment interviews will not know what group you are in. This is on purpose and we will ask that you please do not tell your interviewer what group you are in.

Screening visit (Visit 1): Baseline assessment before you are discharged (approximately 60 minutes)

- A study member will conduct a brief diagnostic interview with you to determine your current mental health diagnoses.
- The study member will ask you to complete 6 short surveys which ask about how you are feeling, self-harming thoughts and behaviors, level of support, and your feelings about treatment.
- The research team will look in your medical chart to collect demographic information such as your age, gender and race.

Main study visits (Visits 2, 3 and 4): Follow-up study assessments at 1, 3, and 6 months after discharge (approximately 30 minutes)

- The assessments can be completed in-person, over the phone, or using VA Video Connect. If you choose to participate in the visits over the phone or using VA Video Connect, you should choose a location where you feel safe and comfortable. We advise against you participating in the assessments while you are driving a vehicle.
- The study member will ask you to complete 6 short surveys which ask about how you are feeling, self-harming thoughts and behaviors, level of support and your feelings about treatment since your last study visit.
- The study member will ask you about treatments you received after discharge outside of the VA and look in your medical record to collect information about the treatments you received after discharge within the VA system.
- If you are assigned to Group A, the interviewer will also ask you to complete a questionnaire about your use of the My3 app.

Are there risks and discomforts involved in this study?
There could be risks and discomforts involved in this study; however, the risks associated with being in this study are small. We will ask you questions about how you are feeling as well as about self-harming thoughts and behaviors. We will also discuss ways to manage your symptoms. Sometimes people can feel embarrassed, nervous, bored or generally uncomfortable when they are asked to answer these types of questions or talk about the problems that they might be struggling with. If any of the questions make you feel uncomfortable, you should feel free to mention this to the interviewer and have this concern addressed. You can also refuse to answer a question. If you need to take a break, let the interviewer know.

While in this study, you can continue to receive the mental healthcare treatment that you and your healthcare providers have decided is the best plan for you.

If I decide to be in this study, what activities are only done for research purposes?
If you join this study, the activities listed below will be done only for research purposes:

- Participation in baseline and follow-up assessments listed under "What does this study involve"
- If assigned to Group A, brief suicide prevention education, use of the My3 app and 8 study intervention contact visits (Brief Education Visit as well as 7 follow-up contacts) as described under "What does this study involve"

Can I withdraw from the study?
You can choose to stop being in this study at any time by notifying a member of the research team. If you decide to stop, it will not affect the quality of your mental health care. It is possible the study may be terminated early, thereby ending your participation. Your mental health provider may choose to terminate your participation in the study without your consent if they feel it is in your best interest.

Are there other reasons why I might stop being in the study?
Yes. The study doctor may take you off this study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You are not able to follow the instructions for the study.

- The study may be stopped at any time by the Institutional Review Board (IRB) or study sponsor. The study sponsor is the organization that is responsible for the study. An IRB is responsible for protecting people who volunteer to join studies.

Will I receive any results from this research?
If you present an imminent suicidal risk during the research procedures, you will be informed.

Will I be told new information related to this study?
We will tell you about new scientific findings related to this research as they become known. You can then decide again if you want to continue being in this study.

What are the costs to me if I take part in this study?
You will not be charged for any treatments or procedures that are part of this study, such as the intervention contacts for Group A or the assessment visits for Group A/Group B. If you usually pay co-payments for VA care and medications (as part of your standard psychiatric discharge care), you will still pay these co-payments for VA care and medications that are not part of this study.

Will I be paid to participate in this study?
Yes. You will be paid a total of **$250** for your time and effort. The payment will be provided to you as a direct deposit into your bank account. We listed the schedule of payments below.

- Baseline Assessment Visit: **$25**
- Follow-up Assessment Visit at 1 month: **$50**
- Follow-up Assessment Visit at 3 months: **$75**
- Follow-up Assessment Visit at 6 months: **$100**

You will receive each payment after completing the study visit or receive a lump sum at the end of the study, depending on your preference.

Your name, address, and social security number, and bank information will be given to the VA Fiscal Department so they can make your study payments to your bank account via direct deposit.

What will happen if I am sick or injured because I am in the study?
VA Policy: If you have an injury or illness as a result of being in this study, the VA will provide emergency treatment and medical care at no cost to you. No

additional payments by the VA are planned. By signing this form, you do not lose any of your legal rights or release the VA Medical Center from its duty to provide proper medical care.

If you believe you have injury, illness, or a bad reaction related to the study activities, please let the researcher know as soon as possible. You can call the researcher at [redacted] during the day or the on-call VA doctor at [redacted] after business hours. If you receive emergency medical care in a private hospital because you are unable to come to the VA Medical Center, please have a family member or friend let the study staff know. The VA Medical Center can then work with the private hospital to support your medical care.

More information about medical care and payments for medical services in the event of a study related injury or illness is available from the VA Medical Center's Business Office at [redacted] extension [redacted]. You may also call the VA Medical Center's Patient Advocate at [redacted] extension [redacted]

How will my privacy and the confidentiality of the information collected for the study be protected?

This study uses the same practices as a medical clinic to protect your privacy, such as using non-public spaces for physical exams and interviews.

What is Protected Health Information and how will it be used in the study?

The study team will collect or create Protected Health Information meaning your:

- name,
- initials,
- address,
- phone number
- gender,
- age/date of birth,
- medical record number
- medication status
- medical history
- mental health clinical notes
- discharge summary
- survey and questionnaire responses

- drug abuse information
- alcohol use and abuse information

How is the confidentiality of study information protected?
The rules of VA Record Control Schedule apply to the information collected and created for this research. We also have made careful plans to protect the identities of the people who are in the study and the confidentiality of the information collected about them for this study.

Careful efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study, such as:

- Any written research materials will be kept on the White River Junction VA Medical Center Grounds in a locked cabinet located in a locked room in a locked building.
- Data will also be stored on a local, secure computer research server. To gain access to the server, the investigator must use a password protected computer. The computer is located in a locked building on the White River Junction VA Medical Center grounds.

My3 App Security
If you are assigned to Group A, the study therapist will help you download and set up My3 app on your smart phone. We have described below how the confidentiality of this study information will be protected.

- The My3 App is a free app available for download on Android or iPhone. The My3 App is endorsed by the VA and is owned and maintained by Vibrant Emotional Health, the administrator of the National Suicide Prevention Lifeline.
- In order to work, the My3 App must access your contact list so that you can make a cellular phone call to people in your support network including your support person or the study therapist.
- The My3 app does NOT store any personal health information within the app. The My3 app is also not capable of sending or receiving text messages.
  - You may choose to email your safety plan to one of your support contacts. If you choose to do so, the app will bring you to your default email app on your phone and automatically input your safety plan into a new email message. You will need to manually enter your support person's email address. The app does not store these email addresses or the email itself. It only retrieves information from your phone to more quickly prepare the email.

General Confidentiality and Safety

If you give the research team information about sexual, physical, or other abuse of a child or older person, the research team will report it to authorities. If you make a threat of violence to yourself or others, the study team will evaluate you and take steps to provide appropriate treatment and protection.

Once the research data is no longer being actively collected or analyzed, the research data will be kept (stored as described above) for a minimum of 6 years after study completion in compliance with the VA Records Retention Policy.

We will include information about your study participation in your medical record. While this study is being conducted, you may not have access to your research records.

This will not affect your VA healthcare, including your doctor's ability to see your medical records as part of your usual health care.

The information collected from you for this study, even if information identifying you is removed, will not be used or shared in the future for other research activities

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This certificate means the researchers may not release information that identifies you for any legal action or suit unless you say it is okay. They also may not release research information about you for use as evidence in a legal action unless you agree. The certificate protects against use in federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. As an example of this protection, the researchers could refuse to release research information even in response to a court subpoena.

By providing consent, you are allowing the researchers to release some study information to your treatment team that may be important for your medical care. For example, study staff will write a note in your medical chart at each study visit. This information may be needed by your treating physician in case of an medical emergency. The research team may also contact your medical providers or release research information for your continuing medical care. For example, the research team may contact your mental health provider if your mental health seems to become worse.

Public study information

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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 form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include:

- The VA Clinical Science Research & Development (CSR&D) Data Monitoring Committee.
- The Veterans Institutional Review Board of Northern New England (VINNE) and the Research & Development Committee at the Veterans Affairs Medical Center at White River Junction, VT
- Central VA/VHA offices: Office of Research Oversight (ORO), the Office of Research and Development (ORD), Office of Inspector General, and Office of General Counsel (GAO)
- The Office of Human Research Protection in the U.S. Department of Health and Human Services (OHRP)

You can revoke this HIPAA authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office [redacted] at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization [redacted] and 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.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

Study contact information

If you are having a medical emergency, call 911 or go directly to an emergency room.

For Questions About:	Person or Office	Contact Information
The Study or Research Related Injury during normal business hours	Main Investigator: [redacted]	[redacted]
The Study or Research Related Injury after hours	VA doctor on-call (ask for the psychiatrist on-call)	[redacted]
If you need to contact someone other than the study personnel about a concern or your rights as a research participant	Veteran's Institutional Review Board of Northern New England (VINNE)	[redacted] extension [redacted] during normal business hours.

Your rights and responsibilities

I have read, or someone read to me, the information about this study in this form. The researcher has explained the study to me and answered my questions. I have been told about the possible risks, discomforts, and benefits of the study. I have also been told about the other choices that are available to me instead of being in this study.

If I decide to join this study, I am aware that I am expected to make reasonable efforts to follow the instructions of the researcher and study staff. If I have any health problems while in the study, I agree to report them right away to the researcher.

I am also aware I do not have to join this study. If I decide not to be in the study or change my mind decide to leave it after joining it, no penalty or loss of my VA

or other benefits will happen. My decisions about this study will have no effect on my current or future medical care at the VA.

My signature on this form means that I agree to take part in this study. I will be given a copy of this form after I sign it for my own records.

_____ _____ ____
Signature of study participant Date Time

Initials of study participant after receiving a copy of this consent form _____