Recovery Bridge: A Peer Facilitated Intervention to help bridge the transition from psychiatric inpatient hospitalized to living in the community

NCT05758376

October 31, 2023

Department of Veterans Affairs

Research Consent Form

Participant Name: _____ Date: _____

Title of Study: Recovery Bridge: A Peer facilitated intervention to help bridge the transition from psychiatric inpatient hospitalization to living in the community

Principal Investigator: [redacted] Facility: VA Maryland Health Care System

IRB Study Number: HP-00098903
Sponsor: VA Health Services Research and Development

INTRODUCTION: You are being asked to participate in a research study that is being done at the VA Maryland Health Care System (VAMHCS). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

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

CONCISE SUMMARY

The purpose of this research study is to learn more about an intervention called, Recovery Bridge that is designed to help Veterans reduce the likelihood of being re-admitted to the hospital for mental health services. The intervention is also designed to help Veterans connect to outpatient mental health services and improve outcomes such as a sense of hope and quality of life. Recovery Bridge is a web-based program that helps Veterans focus on daily wellness, managing triggers and early warning signs, and develop plans for what to do when things breakdown. VA Peer Specialists are used to help Veterans use Recovery Bridge. Participants will be asked to enroll during their inpatient mental health hospitalization and work with a VA Peer Specialist to use the Recovery Bridge tool during and after leaving the hospital over approximately five, 30-75 minute sessions. Additionally, participants will be asked to complete a set of brief 30-45-minute questionnaires before the intervention sessions start and after the intervention sessions have ended. Sessions may be audio or video recorded. When participants complete the last set of questionnaires, they will also be asked to participate in a 30-60-minute, audio-recorded interview to understand their experience participating in the intervention. Participation will last a total of two months and participants will receive a total of $60 if all questionnaires and interviews are completed.

The greatest risks of this study include boredom, embarrassment, and potential loss of

confidentiality. The potential benefit is that participants may learn skills and strategies to use as they transition from inpatient psychiatric hospitalization to community living. Study participation is voluntary.

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

RESEARCH DETAILS

PURPOSE OF THE STUDY

- The time following discharge from mental health inpatient hospitalization is a high-risk period and has been associated with a range of negative outcomes including high rates of hospital readmission. The purpose of this research study is to learn more about a Peer-Specialist-administered intervention, called Recovery Bridge, designed to decrease inpatient readmission rates and improve Veterans' hope, recovery orientation, and quality of life after being discharged from a psychiatric inpatient unit.
- You are being invited to participate in this study because: a) you are currently hospitalized in the Baltimore VAMC psychiatric inpatient unit and b) you are scheduled to be discharged back into the community
- A total of 15 Veterans will be asked to participate in all study procedures. Your participation is voluntary.

STUDY PROCEDURES:

- The first study visit will take place on the Baltimore VAMC inpatient unit. All other study visits will take place in a private space at the VAMHCS Annex Building (209 W Fayette Street, Baltimore, MD), in the Baltimore VA Hospital, at the Perry Point VA, over the phone, or via video appointment depending on your preference. If you are completing sessions over the phone or via video, research staff will conduct all procedures in a private, secure space and will ask you questions to ensure that you are also in a private space in order to protect your privacy.
- Participants will first meet with a study staff member to complete a set of questionnaires that ask about hope, recovery orientation, and quality of life. This visit will last 30-45 minutes, and participants will receive $25.
- All participants will then be scheduled to meet with a Peer Specialist to receive approximately five, one-on-one Recovery Bridge intervention sessions. Each session will last 30-75 minutes.

Sessions may be audio or video recorded for fidelity purposes. If you refuse to be recorded, you will no be able to partake in this study.

- Within seven days after the last Recovery Bridge intervention session, participants will again meet with a study staff member to complete the same questionnaires as at the beginning of the study. These questionnaires will take 30-45 minutes to complete. At the same visit, participants will also complete a 30-75-minute, recorded interview so we can better understand their experience participating in the intervention. Participants will receive $35 for this visit.
- It will take approximately two months to complete all study procedures.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

- Clinically relevant research results will be disclosed to participants and their providers, as applicable to well-being.
- You may request the overall results of this study when the study is complete.

FUTURE USE OF DATA INCLUDING FOR PARTICIPANT RE-CONTACT

- Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we cannot ask for your additional consent.
- Any hard copies of data will be kept in a locked cabinet in a locked room in the MIRECC suite located on the 7th floor of the Baltimore Annex ([redacted]). All electronic data will be password-protected and stored on the MIRECC Share Drive. Audio and video recordings will be kept on the MIRECC Restricted Share Drive and both drives are located behind the VA firewall. Materials will only be available to project staff as needed.

- The investigators may want to contact you after the study has finished in order to understand more about your experience participating in this research study. Do you give us permission to contact you in the future, after this study is closed? Please initial below.

_____ YES, I permit Dr. Goldberg and his team to contact me in the future.

_____ NO, I do not permit [redacted] and his team to contact me in the future.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, your responsibilities will include:

- Showing respect for study staff in and outside of study appointments.
- Plan to attend all scheduled study appointments and call research staff if you will be late or need to cancel or reschedule an appointment.

POTENTIAL RISKS/DISCOMFORTS:

- The tasks that you will be asked to complete during this study have been used in many other research studies.
- You may feel embarrassed or uncomfortable discussing personal topics such as your feelings of hope and recovery during assessment and Recovery Bridge intervention sessions or while being recorded during your sessions and interview. However, most people get used to the situation and relax after a few minutes. You are free to not answer any questions that make you uncomfortable. Additionally, you may feel bored or tired while completing assessments. You have the option of taking a break at any time during your study participation.
- Other unlikely risks include a loss of confidentiality, when research records are accidently disclosed to people who are not authorized to see the information. We have several procedures in place for minimizing these privacy risks. Any electronic research documents that include your name will be password -protected and securely stored behind the VA firewall. All electronic research data including audio or video recordings will be labeled by code; this means they will not have your name on them and will be stored on a password protected secure VA network that only research project personnel will have access to. All project staff will be thoroughly trained in issues relating to confidentiality. Statistical analyses will be based on group data; no individual data will be reported.
- There may be other risks associated with this study which are not yet known.

POTENTIAL BENEFITS

- Participation in this study may provide no direct benefits to participants. However, Veteran participants may learn skills and strategies to use as they transition from inpatient psychiatric hospitalization to community living.
- Your participation will also help determine if Recovery Bridge is an intervention that can be used for other Veterans who are transitioning from psychiatric hospitalization to community living.

Participant Name: _____ Date: _____

Title of Study: Recovery Bridge: A Peer facilitated intervention to help bridge the transition from psychiatric inpatient hospitalization to living in the community

Principal Investigator: [redacted] Facility: VA Maryland Health Care System

ALTERNATIVES TO PARTICIPATION

- Study participation is voluntary. You may choose to not participate in this study.
- Your healthcare at the VA Maryland Health Care System (VAMHCS) will not be affected regardless of your decision to participate in the study.

COSTS TO PARTICIPANTS

- It will not cost you anything to take part in this study.
- You will not be charged for any treatments or procedures that are performed for research purposes in this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

PAYMENT/REIMBURSEMENT TO PARTICIPANTS

- You can earn up $60 for participating in this study, depending upon how many study components are completed, and as detailed below:
  - $25 for completing the first set up questionnaires at your first study visit
  - $35 for completing the second set of questionnaires and audio-recoded interview at your last study visit.
- You will not be paid for attending Recovery Bridge intervention sessions.
- You will be paid by VA Voucher.
- There are times, during your participation in this study, when we may run into problems with having vouchers available at the completion of your scheduled study visits. The end of the fiscal year is a time when this problem may arise because the release of VA research funds can be put on hold. We do not anticipate this to happen often. We will notify you before your visit should this problem come up. If at the time of your appointment we do not have access to funds in order to pay you, we will pay you as soon as possible following your appointment,. We will give you the payment in person (at your next appointment with us), or we can mail you the payment for your convenience, if you are being paid with a voucher.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

- The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85). Every reasonable safety measure will be used to protect your well-being. If you are injured as a result of taking part in this study, the VAMHCS will provide

necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. This care may be limited by local or federal law.

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

[redacted]

- The VA does not normally provide any other form of compensation for injury. However, by signing this form, you have not waived any legal rights or released the VAMHCS or its agents from liability for negligence.

CONFIDENTIALITY AND ACCESS TO RECORDS

- All information collected during the study will be kept confidential to the fullest extent permitted by law. However, if the research staff hears about or sees that you intend to harm yourself or someone else, s/he will need to tell your treatment provider or some other authority so that you can get help, even if that means telling them without your permission. In this situation, research staff would only disclose information that would prevent harm to you or other people that might be in danger. If we hear about or see something that would immediately endanger you or others, such as child abuse, we will seek help to protect the child. In addition, we must follow legal requirements concerning child abuse and neglect. If you tell us information about child abuse, we must disclose this information to the appropriate individuals and/or authorities.
- This study will involve confidential information. We have several procedures in place to help protect your confidentiality. Your name will not be included on the collected data. Instead, a code number will be placed on the data, and through an identification key, the researchers will be able to link your survey to your identity. Only the researchers will have access to the identification key. The information we collect from you will be stored at the VAMHCS in a locked cabinet in a locked room in the MIRECC suite located on the 7th floor of the Baltimore Annex ([redacted]. Electronic files with your information will be kept in secure computers in a locked room. The electronic data files with your information will be password protected. All audio or video recordings will be stored electronically, behind the VA firewall and labeled by code. Coded information will only be accessible to members of the research team and individuals involved in our data management process.

- We will include information about your study participation in your medical record. Your medical and research records will be kept strictly confidential to the fullest extent permitted by law.
- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the University of Maryland Institutional Review Board (IRB), the VAMHCS Office of Research Compliance and other representatives of this organization. The study records can also be reviewed by federal agencies, VA Office of Research & Development (ORD), VA Office of Research Oversight (ORO), VA Office of Inspector General (OIG), and Office of Human Research Protections (OHRP). The monitors, auditors, and the IRB, will be granted direct access to your medical records for verification of the research procedures and date. By signing this document, you are authorizing this access.
- A description of this clinical trial will be available on http://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.
- Your research records and/or identifiers will be retained in accordance with the VA records control schedule. The "records control schedule" is a set of rules set by the federal government that states when federal agencies are allowed to dispose of records. The VA and VHA must follow these rules.
- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information at the VAMHCS will work to keep your personal information confidential. Your personal information will not be given out unless required by law or authorized by you in the VAMHCS "HIPAA Authorization to Obtain, Use and Disclose Protected Health Information for Research". However, if your information is disclosed to other entities, the VAMHCS no longer has control of that information. Please see the HIPAA Authorization for this study for further details.

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 working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, suicide safety plan, and information from your medical records such as information about receipt of VA mental health services.
- 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 Institutional Review Board, Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).
- Your health information disclosed pursuant to 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 must write to the Release of Information Office 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 his 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.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

- Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we cannot ask for your additional consent.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the

study will involve no penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect the way you now pay for medical care at the VAMHCS.

- If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator [redacted]
- There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.
- If you withdraw from this study, already collected data may not be removed from the study database.
- You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff or if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

The VA Maryland Health Care System (VAMHCS) has designated the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to review this research study.

If you wish to confirm that this study is in fact IRB approved and is being conducted at the VAMHCS, or if you have any questions, concerns, complaints, you may contact:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

You may also contact the VAMHCS Human and Animal Research Protections Officer (HARPO).

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VAMHCS Human and Animal Research Protections Officer
Baltimore VA Medical Center
10 North Greene Street, Mail Stop 151
Baltimore, MD 21201
410-605-7000, extension 56582 or 56568

The VAMHCS Human and Animal Research Protections Officer may contact you in the future to ask you about your experiences with this research study.

Department of Veterans Affairs

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Your signature indicates that the research team member obtaining consent has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

Furthermore, by signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Date

_____ Person Obtaining Consent (Print)	_____ Consenter's Signature	_____ Date