RESEARCH CONSENT FORM

Basic Information

Title of Project:
Implementing a Skills Training Evidence-based Treatment (EBT) for Posttraumatic Stress Disorder (PTSD)

Short Title: "I-STEP at BMC Study"

NCT04937504

IRB Number: H-41323

Principal Investigator: Sarah Valentine, PhD
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You can reach study staff including the Principal Investigator by phone or text message at (857) 264-1102 or by email at ISTEPBMC@gmail.com

Overview

We are asking you to be in a research study because you may be experiencing symptoms of posttraumatic stress disorder (PTSD) and your primary care provider is at Boston Medical Center (BMC).

A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study, and your decision will have no impact on that care that you receive at BMC. Your treatment plan will not be impacted by being in this study.

We aim to evaluate a treatment for PTSD provided by your Integrated Behavioral Health therapist. The treatment provided will be a new standard of care. No experimental therapies will be given.

If you agree to participate in the study, you will either receive the therapy during regular in-person or telehealth visits with your therapist or via a self-paced web program. In either case, your IBH therapist will be responsible for monitoring your treatment progress. You will have access to the therapy in-person or via telehealth from your IBH therapist regardless of whether you choose to participate in the study, however, only those who enroll in the study will have access to the self-paced web program.

If you agree to participate in the study, you will be asked to complete assessments about your clinical care at three time points. You will complete assessments at baseline (before treatment start), at 15 weeks from your

baseline date, and at 9 months from your baseline date. We will also check in by phone every two weeks to collect information about your treatment progress.

The total time required to complete all of the assessments is approximately 3 hours across the 3 visits. You will find more information about what will happen in this study later in this form.

The main risks of being in the study are potential discomfort in answering some personal questions and loss of confidentiality. You will find more information about risks later in this form.

Your therapist may also be engaged in this research study. Being engaged in research means your therapist is working with both you and our study team, using and sharing your health information and our research data. You may want to get another opinion about being in the study. You can do so now or at any time during the study. A therapist who is not part of this study could give you their opinion about being in the study. You do not have to agree to be in this study even though it is offered by your therapist.

Purpose

Primary care clinics at BMC offer multiple treatment options and are always trying new ones to see what is most effective. The goal of this study is to evaluate a standard PTSD treatment offered in primary care clinics. In this study you will either receive the therapy administered by your clinician **in person or via telehealth** or via a **self-paced online program**. Both formats of the therapy involve the same content.

During this study, therapists will receive training and supervision in the PTSD treatment from the study principal investigator (Dr. Valentine). We will learn from your therapists about the advantages and disadvantages of the two formats of the program.

What Will Happen in This Research Study

Assessments in this study involve answering questions about your emotional health, current stressors, and your experiences with a PTSD treatment in primary care. Some measures are for clinical practices, while some measures are for research only. The two measures that are for clinical practice will be documented in your medical chart, these include measures of trauma exposure and PTSD symptoms.

The therapy program available in primary care is called Skills Training in Affective and Interpersonal Regulation (STAIR) for PTSD. STAIR is an established treatment that is helpful for people who are struggling with the after effects of trauma. STAIR helps by teaching skills that improve coping with one's emotions and navigating interpersonal relationships.

If you choose to participate, you will be one of approximately 60 patients to complete study assessments while receiving PTSD treatment in primary care clinics at Boston Medical Center (BMC).

In this study, 30 patients will receive will receive the therapy during in-person or telehealth visits ("STAIR") and 30 patients will receive the web-based therapy ("webSTAIR").

Participants will be randomized at the end of the baseline assessment. Randomization means being assigned to one of the ways we can deliver STAIR by a flip of the coin.

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STAIR involves five 30-minute sessions of therapy scheduled weekly or every other week with your therapist, whereas webSTAIR is completed at your own pace and the timing is not linked to therapist appointments.

If you are randomized to STAIR, we will direct you back to your therapist to schedule Session 1.

If you are randomized to webSTAIR, we will provide you with a link to the website and your own unique username and password. The sessions can be completed at our own pace, with the goal of completing within 12 weeks. You can call or text the I-STEP study team Monday through Friday from 9 AM to 5 PM to resolve any technical issues: (857) 264-1102. We will inform your therapist that you were assigned to this condition, and the therapist will be available to you if you have any questions about the therapy.

You may receive STAIR for PTSD in-person or via telehealth whether or not you choose to participate in this research study, although webSTAIR format is only available to those who enroll in the study.

The total time that you will be involved in the study is approximately 3 hours, to complete assessments.

The duration of time you will be in the study will be 9 months from baseline.

There are three assessments that will take place over the course of 9 months. For all assessments, you will have the choice to complete questionnaires online, over the phone, or in-person.

> **Baseline:** This assessment will happen before you start STAIR. At the end of this assessment, you will find out which format you will receive.
>
> **15 weeks (post-treatment):** This assessment will happen 15 weeks from the date you completed the baseline assessments. You have the choice to complete these assessments in-person with a member of our research staff, over the phone, or online.
>
> **9 months:** This assessment will happen 9 months after your baseline date.

During these assessments, you will be asked for demographic information, your opinions on mental health treatment and current social supports, and information on your past experiences of trauma. You will also be asked about your ability to manage emotions and your current mental health symptoms, including posttraumatic stress symptoms, depression, and anxiety symptoms. The 15-week assessment will also include a survey to assess how satisfied you are with the services you receive in treatment for PTSD and an open text box so that you can let us know any suggestions or recommendations you have.

During treatment, we will contact you ever other week for 12 weeks to assess your PTSD symptoms and therapy progress (5 minutes). This information will be entered by study staff into the electronic medical record (EMR), so that your therapist can monitor your symptoms and treatment progress in real-time. This also means that other providers directly involved in your care will have access to this information and will know that you are receiving STAIR or webSTAIR. As standard of care, your therapist will also reference STAIR in your treatment plan and therapy notes in the EMR.

Specifically, we will be entering the following information into the EMR for the purposes of clinical practice:

1. We will send a message via the medical record to notify your primary care team that you are enrolled in this study and which format of STAIR you will be receiving.
2. We will enter two surveys into the chart, which document what types of trauma events you have experienced and your current level or PTSD symptom. We enter your PTSD symptom measure so that your team can monitor your treatment progress.
3. If you receive webSTAIR, we will also update your primary care team every two weeks on how many modules you have completed.

Please ask us if you have any questions about what information will be included in your medical records.

We will also collect information from your medical records about your diagnoses and visits, as well as your therapy notes, in order to track your use of healthcare services. We will collect your health care use information from the following timeframe: 6 months before you started PTSD treatment to 9 months after baseline. Our access to your medical records is only for the purpose of this evaluation. If you begin receiving care at a different hospital, we will ask you to sign a medical release form so that we can continue to access your medical records.

The ways we will protect your privacy and confidentiality are described later in this form.

For STAIR in-person and telehealth sessions: Sessions will be audio-recorded and reviewed by study staff and the Principal Investigator. Audio files will be reviewed for two reasons: (1) so that we can provide feedback to your therapist on their performance, and (2) so that study staff can track what types of skills your therapist uses in each session.

For webSTAIR sessions: The webSTAIR program collects information on the amount of time you spend engaging with various therapy modules and skills, as well the optional self-assessment tools. This information allows us monitor therapy progress and completion. webSTAIR does not collect item-level data, meaning that anything you type into the program as part of the various exercises is not visible to study staff. However, item-level data will be visible to you throughout the study period. Your webSTAIR access will be discontinued at the end of the study (9 months from baseline).

The study period ends 9 months after baseline. At this point, all research data collection will end and access to webSTAIR will also be terminated. Your clinical care team will be notified of study completion and will continue to provide you with care as needed.

Alternatives

If you do not wish to participate in this study, you can still access any treatment options that are typically available to BMC patients, including in-person or telehealth STAIR. However, webSTAIR is not currently available to patients who are not enrolled in this study. If you are randomized to the webSTAIR condition as part of study participation and you wish to switch to the in-person/telehealth version of STAIR, you may do so at any time by notifying the study staff and your therapist about your decision.

It is important for you to know that this is a research study. If at any point you decide you do not want to be in the research that is fine. You will always have access to services and care at BMC. You can get help for your mental health without participating in this study.

Risks and Discomforts

There are some potential risks associated with participation in the study. These risks are listed below:

Discomfort with answering questions:
One risk is discomfort answering some of the questions we ask you as part of the study. To minimize this discomfort, you can refuse to answer any question that you do not feel comfortable answering. If you are receiving in-person or telehealth STAIR, you can also ask us to stop audio-recording therapy sessions. And you can ask to have any audio-recordings destroyed and not used in the study.

Psychiatric Emergency:
Although it is not expected within this study, if you experience an emergency or sharp decline in your functioning for any reason or if you disclose thoughts of harming yourself or others, we would follow the plan that Integrated Behavioral Health has developed with the Boston Emergency Services Team (BEST). Study staff and therapists will also contact the Principal Investigator, and if needed, the Boston Emergency Services hotline. In extreme situations staff will contact 911. It is important to note that information shared with the study team through REDCap can be used to identify emergencies, but webSTAIR item-level data is completely private to you. If you are having thoughts of hurting yourself or others, please contact your clinician or study staff directly.

Loss of confidentiality:
This is when someone outside of the study team accesses your personal health information from the study. Maintaining your confidentiality is important for the study team. Many measures are put in place to minimize this risk as much as possible. Participant numbers/codes will be used instead of names, and all study data will be identified by a study ID code only. The link between participant names and ID numbers will be kept separately in password protected BMC servers. Study data can only be accessed by approved study staff. Data collected by webSTAIR can only be linked to your other study data by study staff. All hard copies of study data will be stored in locked cabinets or rooms that are only accessible by trained study staff. All information from questionnaires and audio files will be stored in a secure, password-protected server that can only be accessed by study staff members. The study staff and therapists have been trained in how to maintain the confidentiality of participants. All audio files will be transferred off of recorders onto a password-protected drive immediately after each therapy session.

Potential Benefits

You will receive no direct benefit from being in this study. Your being in this study may help the investigators learn how a PTSD treatment is working in primary care.

Costs

Items and services done only for study purposes will be provided at no cost to you. They won't be billed to your health insurance either.

You or your health insurance will be billed for all costs that are part of your normal medical care, which include all behavioral health visits at Boston Medical Center (BMC) primary care. These costs include co-payments and deductibles. You will only be billed for in-person or telehealth therapy visits.

You can ask any questions now about insurance coverage for this study or about the research activities paid for by the study. You can also ask the investigator later, using the number on the first page of this form.

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Payment

You will receive the following payments for each assessment:

- Baseline = $20
- 15-week = $20
- 9-month = $20
- You will not receive payment for PTSD treatment or symptom monitoring calls as these will be provided as part of ongoing treatment in primary care.

You will be compensated through a BMC payment system called ClinCard.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

It is important for you to know that if you agree to participate and sign this consent form, we will retain your responses to the screening questions about trauma exposure and symptoms your clinician or our study team asked you previously. We keep this data because they are a part of the Baseline Assessment and we want to respect your time by limiting the amount of repeated surveys we give you. If you agree to participate and sign this form, your participation in the study as well as your responses about trauma exposure and symptoms will be communicated to your behavioral health provider in primary care and added to your medical record. This communication and documentation is a part of usual care practices in Boston Medical Center (BMC) primary care clinics.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

We will record information from two measures from this study in your medical record, which are directly related to your medical care. These measures include information on trauma exposure and PTSD symptoms. Please ask us if you have any questions about what information will be included in your medical records. You should know that once information has been put into your medical records, it is not covered by the CoC. However, information in your medical records is protected in other ways.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.

- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- People who see your medical records. Please ask us if you have any questions about what information will be included in your medical records.
- Any people who you give us separate permission to share your information.

You should know that we are required to report information about child abuse or neglect; elder abuse; specific reportable diseases; or risk of harm to others. These procedures are in line with standard reporting conducted by the Primary Care team.

If you are in immediate danger of hurting yourself or others at any time in the study, the study team will work with you and your clinician to coming up with a plan to keep you safe. Because study staff will be trying to protect you, it is possible that your information will be shared with others as part of a plan for safety.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

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.

Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. This includes symptoms, treatment notes, and other information commonly added to a patient's medical record. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- The health information specifically includes:
  - Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.

- To comply with laws and regulations. This includes safety-related information. As we explained above, we also have to share any information from you about child abuse or neglect, elder abuse, specific reportable diseases, or risk of harm to others.
- To protect you. As we explained above, if you are in immediate danger of hurting yourself, it is possible that your information will be shared with others as part of a plan for safety.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from Boston Medical Center (BMC), Boston University, and/or other organizations
- Other people within Boston Medical Center (BMC) and Boston University (BU) who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- Public health and safety authorities who receive our reports about child abuse or neglect; elder abuse; specific reportable diseases; or risk of harm to others.
- Other care providers and public safety authorities who may be involved in helping to protect you if you express thoughts about hurting yourself.

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center (BMC) at DG-privacyofficer@bmc.org

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes_____No You may contact me again to ask for additional information related to this study

____Yes_____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact study staff by phone at (857) 264-1102 or ISTEPBMC@gmail.com.

Also call if you need to report an injury while being in this research.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center (BMC) and Boston University Medical Campus (BUMC) IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

By agreeing to be in this research, you are indicating that you have read this form, that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described, including your health information.

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

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