Implementing a Skills Training Evidence-Based Treatment for Posttraumatic Stress Disorder (I-STEP)

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1 List of Abbreviations

PTSD = Posttraumatic stress disorder; STAIR = Skills training in affective and interpersonal regulation; EBT = Evidence-based treatment; CPT = Cognitive processing therapy; PE = Prolonged exposure; VHA = Veterans health administration; I-STEP = Implementing a skills training evidence-based treatment for PTSD; IBH = Integrated behavioral health; RCT = Randomized control trial; DSM-5 = Diagnostic and Statistical Manual of Mental Disorders, 5th edition; LEC-5 = Life events checklist for the DSM-5; PCL-5 = PTSD checklist for the DSM-5; RA = Research assistant; CAB = Community advisory board; PI = Principal investigator; CSQ-8 = Client satisfaction questionnaire, 8-item; ISEL-12 = Interpersonal support evaluation list, 12-item; BSI-18 = Brief symptom inventory, 18-item; CFIR = Consolidated framework for implementation research; LIM = Level of integration measure; ICS = Implementation climate scale; EBPAS-15 = Evidence-based practice attitude scale, 15-item; ORCA = Organizational readiness to change assessment; PCIS = Perceived characteristics of intervention scale

2 Protocol Summary

Title:	Implementing a Skills Training Evidence-Based Treatment for Posttraumatic Stress Disorder (ISTEP)
Population:	Adult primary care patients with posttraumatic stress disorder symptoms, N=60
Intervention:	Behavioral health interventions, including web-administered and clinician administered brief Skills Training in Affective and Interpersonal Regulation (STAIR) for PTSD
Objectives:	Hybrid type 1 effectiveness-implementation trial to assess the feasibility, acceptability, and preliminary effectiveness of web- versus clinician-administered brief STAIR (primary outcome: PTSD symptoms, secondary outcome: functioning) while gathering information on implementation of both modalities. Findings will inform a full stepped-care approach to PTSD treatment that spans primary care and specialty care.
Design/Methodology:	60 patients were randomized, 30 in each condition (webSTAIR v. Brief STAIR). Participants completed study survey assessments at baseline (0 weeks), 15 weeks (active treatment), and 9-months post-randomization. To ensure consistency in timing of data collection, assessments are not linked to condition or amount of content completed.
Subject Participation Duration:	9 months

3 Background/Rationale & Purpose

3.1 Background Information

Provide background information, study rationale, and purpose / study objective(s) and/or hypotheses for this study. PTSD is a significant public health challenge that disproportionately affects individuals receiving care safety net hospitals. The lifetime prevalence of exposure to interpersonal violence among patients seen in safety net primary care and behavioral health clinics may be as high as 94%, with current diagnosis of PTSD ranging from 33% to 46%. Despite high rates of trauma and PTSD in these settings, PTSD is vastly under-recognized and under-treated, with only 13% of individuals with PTSD receiving any form of mental health treatment. Of those who do access treatment, only 57% receive a minimally adequate dose of psychotherapy (defined as at least 4 hours of therapist contact).

Racial, ethnic, and socioeconomic disparities in access to and retention in EBTs for PTSD can also be understood in terms of system- and client-level factors. At the system-level, low-income racial and ethnic minority individuals are more likely to live in neighborhoods with few mental health specialists. Further, providers in these settings have less access to specialized training in EBTs for PTSD, thereby rendering EBTs largely unavailable to clients. Clients in resource constricted communities are also more likely to access services through non-specialty primary care setting or community service agencies, and less likely to access specialty outpatient mental health services. These differences may reflect the pragmatic response to the low availability of mental health specialists and perceptions of lower quality of care, as well as consumer preferences for non-traditional mental health service settings. Preferences for informal support and non-specialty care may also be related to experiences of mental illness stigma and negative experiences with prior mental health treatment (including racial discrimination). The unavailability of EBTs for PTSD in usual care and underutilization of outpatient specialty care have led to concerning inequities in quality of care.

Stepped care service delivery models are one approach to making PTSD treatment more accessible, equitable, efficient, and cost-effective. Stepped care approaches usually begin with interventions that are more convenient or acceptable to clients, and, if indicated, progress to more intensive care. By comparison, standard delivery systems often have one mode of treatment that demands intensive therapist time. Despite promise from a recently piloted stepped care approach to treating PTSD in children, stepped care models that include EBTs for PTSD at Step 1 have not been developed for adults. Existing first-line EBTs for PTSD, such as Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE) require specialized and intensive therapist training and consist of 10 to 12 60- or 90-minute sessions. Despite strong support for the effectiveness of these treatments, access to training, supervision, and consultation is largely unavailable to community providers. Implementation trials suggest that the most consistent barrier to implementing EBTs is the lack of time to provide the intervention within their existing clinical system. Given these concerns, clinical researchers in the U.S. have advocated for the development of a stepped care approach that begins with brief, convenient, and patient-centered interventions for PTSD.

This study will be conducted in compliance with the protocol, applicable regulatory requirements, and policies and procedures of the Boston Medical Center and BU Medical Campus Human Research Protection Program.

3.2 Rationale and Purpose

Skills Training in Affective and Interpersonal Regulation (STAIR) is a safe, evidence-based intervention for PTSD that has been tested in specialty care and community-based settings, and has demonstrated effectiveness in improving PTSD symptoms. Both synchronous in-person /telehealth delivery and asynchronous web delivery (webSTAIR) have shown similar effect sizes in PTSD and depression symptom reduction (Bauer et al., in press; Jain et al., 2020).

4 Objectives

4.1 Study Objectives

Our objective is to support the implementation of STAIR in BMC General Internal Medicine and Family Medicine as the new standard of care. The intervention will be delivered by usual care therapists in the integrated behavioral health practice. Participants who enroll in the study will be randomized to either in-person/telehealth STAIR or webSTAIR. Those who do not enroll in the study will still be able to receive STAIR in person or via telehealth as part of usual care. We hypothesize that offering a low intensity treatment for PTSD (i.e., STAIR) through primary care will improve access to and engagement in care for PTSD among BMC's patient population.

This study will also allow us to compare the feasibility of two modes of treatment delivery (inperson/ telehealth v. webSTAIR), while gathering further evidence of the effectiveness of the intervention in our local setting. We hypothesize that both formats will be effective in reducing mental health symptoms, while webSTAIR may have some advantages in regard to uptake and long-term sustainability in usual care.

4.2 Study Outcome Measures

Our evaluation will include a collection of both process measures to understand feasibility, acceptability, and satisfaction to help us make iterative improvements, and outcome measures to understand whether the treatment is improving patient PTSD symptoms, other mental health symptoms, and overall functioning as expected. Our evaluation will also rely on medical record data to evaluate healthcare utilization. All participants will be given a code that will be used on all data collection tools. The master key that connects participant codes to name, date of birth (DOB), contact information, MRN, and scheduled appointment date and time will be kept in a password protected word file saved on the password protected BMC Psychiatry network drive. The list will only be accessible to Dr. Valentine and study team staff.

Participants' medical records will be accessed to obtain information about session scheduling, information about ongoing treatment at BMC, and other healthcare utilization data from 6 months pre-enrollment to 9 months from baseline. Participants will be asked to sign a medical release form in the case that they move out of the area during the study or attend visits at a different hospital, so that we may obtain medical records from their new hospital/doctor. In addition, we will obtain the list of EPIC encounters of each enrolled patient in order to keep track of number of scheduled/attended/no-showed appointments. In total, the following information will be extracted from participant medical records: MRN, Name, DOB, problems lists, and encounter data (date and time of scheduled appointments, and date and time of unscheduled care [i.e., emergency department visits, urgent care visits, Boston

Emergency Services Team (BEST) safety evaluations, records of hospitalization]). Participants will be informed of this extraction during the informed consent process.

4.2.1 Primary Outcome Measures

Feasibility and Acceptability. We operationalized feasibility as participant retention and provider adherence to the protocol. Retention was calculated as the proportion of content for the assigned intervention that the participant completed (e.g., number of sessions [Brief STAIR] or number of modules [webSTAIR] completed / total number of sessions [5] or modules [10]). We utilized a researcher-developed fidelity checklist, adapted from the Brief STAIR fidelity checklist (Cloitre et al., 2002) to assess adherence to the intervention. Adherence is reported as percentage of session components delivered per protocol. Overall study fidelity was calculated at study completion based on adherence scores from a random 20% of Brief STAIR sessions. Fidelity was assessed by two raters. We assessed client acceptability (satisfaction) using The Client Satisfaction Questionnaire (CSQ-8, Larsen et al., 1979), an eight item self-report measure. Each item is scored on a 4-point Likert scale from 1 "poor" to 4 "excellent" to indicate level of satisfaction with services. Higher scores indicate greater satisfaction with services.

Preliminary Effectiveness, PTSD Symptoms. We use the PCL-5[42] to assess PTSD symptoms. The PCL-5 includes 20 items, which map onto DSM-5 criteria for PTSD. Items are scored on a 5-point Likert scale to indicate symptom severity (0 – not at all to 4 – extremely), with a possible total score of 0-80. A score ≥ 33 is considered clinically elevated.

4.2.2 Secondary Outcome Measures

Social and Emotional Functioning (Secondary outcome): We use the Interpersonal Support Evaluation List (ISEL-12)[48] to assess social functioning and the Brief Symptom Inventory (BSI-18)[49] to assess general mental health functioning.

4.2.3 Exploratory Outcome Measures

Changes in patterns of healthcare utilization is assessed via chart review from 6 months pre-treatment to 6 months post-treatment. We extract variables from the medical record including number of visits, visit types/departments, no-shows, etc. to characterize healthcare utilization.

5 Study Design

I-STEP is a single site, unmasked, hybrid type 1 effectiveness-implementation[36] trial which will assess the feasibility, acceptability, and preliminary effectiveness of Brief STAIR and webSTAIR while gathering data on implementation. We will randomize 60 patients (30 in each condition). Participants will complete study survey assessments at baseline (0 weeks), 15 weeks (active treatment), and 9-months post-randomization (follow-up; see Figure 1). To ensure consistency in timing of data collection, assessments are not linked to condition or amount of content completed. We hypothesize that: 1) Brief STAIR and webSTAIR will be effective in reducing PTSD symptoms (primary effectiveness aim) and mental health symptoms (secondary effectiveness aim); 2) Brief STAIR (clinician-administered) will have advantages

over webSTAIR (self-directed) in terms of treatment completion; and 3) webSTAIR will evidence advantages over Brief STAIR in regard to scalability and sustainability. Outcomes will be assessed using survey data and chart extraction.

Self-report measures that have been shown to have excellent psychometric properties will be used to assess mental health and general well-being for each of the three study assessments (baseline, 15 week, and 9-month). This will include the LEC-5 and PCL-5 to assess trauma exposure (historical at the baseline study visit and any new traumatic events at the post-treatment and follow-up assessments) and current PTSD symptoms; the Difficulties in Emotion Regulation Scale (DERS) to assess emotion regulation; the Interpersonal Support Evaluation List (ISEL-12); the Posttraumatic Cognition Inventory (PTCI-9) to assess cognitions associated with PTSD; and the Brief Symptom Inventory (BSI-18) to assess for general mental health issues. Patients will also complete the Coronavirus Stressor Screener, the Everyday Discrimination Scale (EDS), and the Traumatic Symptoms of Discrimination Scale (TSDS) to understand stress response related to Covid-19 and racism. During the baseline assessment, patients will also be asked to complete a demographic questionnaire to collect data on gender, sexual orientation, age, education, marital status, ethnicity, and family income. During the baseline and 15-week assessments, participants will also be asked to complete the Consumer Experiences of Stigma Questionnaire (CESQ) to assess for perceived mental health stigma, the Attitude Toward Seeking Professional Help (ATPHS) to assess attitudes towards help-seeking, and the International Trauma Questionnaire (ITQ) to track their own symptoms. During the 15-week assessment only, participants will be asked to complete the Client Satisfaction Questionnaire (CSQ-8) to assess intervention acceptability. The 15-week assessment also includes an open text box where participants can provide suggestions and recommendations for how to improve STAIR.

Patients may complete the questionnaires over REDCap, in which case the RA will email the participant a participant-specific link to the REDCap surveys using a secure BMC email address. This data will be collected on REDCap with no identifying patient information but the research staff at the clinic will hold the screen ID for eligible and interested patients to link the screening form to the patient. Participants will be given the option to complete the questionnaires inperson on paper-and-pencil (depending on COVID-related clinical and research guidance from the institution), or to have them administered verbally (in-person or by phone) by study staff. Regardless of the mode of data collection, study staff will be available to answer any questions that arise. All data will be entered into REDCap.

6 Potential Risks and Benefits

6.1 Risks

Foreseeable risks or discomforts to subjects as a result of their participation in this study include: a) personal discomfort answering questions about trauma and other psychological symptoms, and b) confidentiality risks.

Mitigation of Study Assessment Risks

The risk of discomfort with answering questions about trauma and other psychological symptoms is expected to be short term. To minimize potential discomfort, surveys will be conducted in a private, comfortable setting (or in location of participant's choosing if engaging in telehealth STAIR delivery or

webSTAIR). Participants will be assured that their participation is completely confidential and that neither their name nor any identifying information will be connected with their responses. If the participant feels upset or uncomfortable with any question, they will be free to refuse to answer the question without jeopardizing their study status or any regular clinical treatment received at BMC. They will be informed that they may end their study participation at any time for any reason without negative consequences.

Additionally, all staff will be trained in how to manage distress related to answering questions regarding mental health symptoms, and the study PI is a BMC-credentialed and licensed Clinical Psychologist that can help study staff manage distressed participants. Participants who express severe distress will be referred for evaluation and treatment. If the participant expresses significant distress (but no suicidal or homicidal intent), the PI will make a collaborative plan with the participant in order to address their needs (e.g., brief support, referral, additional phone check ins).

If the participant expresses suicidal or homicidal intent with a plan, standard protocol to assure safety will be followed (i.e., call the IBH clinical social worker on call, send patient to the emergency department, contact BEST). Information obtained from participants will indicate if they are at risk of self-harm. Therefore, we have a suicide safety protocol in place to mitigate this risk. Using the Red Alert function on REDCap, study staff will be automatically notified when a participant indicates they are at risk for suicide (>0 on item 12 of the Brief Symptom Inventory-18 [BSI-19], administered at baseline, 15-week, and 9-month assessments). Study staff will notify the principal investigator and the participants' clinician of the participant's elevated risk for suicide. The principal investigator will evaluate the participant's risk and connect them with appropriate resources and follow-up care (including scheduling a visit with their behavioral health providers in integrated care, referral to other BMC providers, or sending participants to the emergency department if necessary). The treatment follow-up plan will also be communicated to the participant's clinician. If for some reason the participant's safety cannot be assessed, the Boston Emergency Services hotline will be called to evaluate participant safety. In extreme situations, 911 may be called to ensure participant safety.

In the case that suicidality is indicated during the participant's sessions with an IBH clinicians, the IBH clinician will follow the standard safety procedures used in IBH. This process involves clinician assessment of patient safety and negotiating appropriate follow-up care for the patient (including but not limited to: paging the Integrated Behavioral Health team, scheduling a followup visit, referral to outpatient psychiatry, calling the BEST hotline, sending patient to the emergency department). IBH clinicians will report any safety assessments and treatment followup plans related to patients participating in the study to the study team. The suicidality protocol (Psychiatric Emergencies) is the same for all conditions. Specifically, a person could disclose thoughts of harm to self or others in the context of a clinical appointment, through study measures, or during a study visit or check-in with study staff. Participants are not able to disclose this information during webSTAIR sessions because only the user has access to item-level information. We will inform participants in all conditions to reach out to their clinicians, the study team, call 911, and/or present to the ED if they are having a psychiatric emergency.

Mitigation of Confidentiality Risk

Breach of confidentiality is always a concern when participating in a research study. Additionally, the switch to remote data collection due to COVID-19 has created a research standard practice that is

inherently more vulnerable to confidentiality breaches than using paper and pencil. If hospital administration allows research to be conducted in person, we will offer this option to patients. However, we believe that the likelihood of a breach of confidentiality is low given the steps we have put into place to decrease this risk. Specifically, all participant information will be assigned a Study ID and this will be the only way to identify them in the data. Physical study documents with information about participants will be stored in a locked cabinet within a locked office at BMC. Electronic data (e.g., session audio-recordings, webSTAIR data) will be stored on a secure, private, password-protected BMC network server that can only be accessed by members of the study team and will be labeled only with their Study ID.

The webSTAIR site is protected by a data security assurance, ensuring that all content is password-protected, item-level and written content is not viewable outside of an individual account, and all information on the site is maintained in a confidential and secure. Survey data will be stored on REDCap, a HIPAAcompliant, password-protected, access-restricted electronic database. One list of names and Study IDs will be kept on a private, password-protected computer separate from the coded data and accessible only to the study team. Documents with participant information on them (i.e., consent form) will be kept separate from their other data. Any data transmission will take place in pooled form and participants will be identified only by a Study ID. Though therapists will be able to use the STAIR program with all patients, the online program will only be offered to study participants. Training all site staff in using these programs and ensuring that the system runs smoothly for each participant would place a large burden on clinic staff. Furthermore, the program is encrypted to protect the privacy of patients and limit access to the program developers and key study staff. Since site staff cannot support the implementation of the online program without the involvement of study staff, the online program cannot be offered to all patients and will be limited to study participants.

6.2 Potential Benefits

There is no direct benefit to participants from taking part in this study. However, patients experiencing symptoms of PTSD may benefit from the findings of the study. Specifically, this study is meant to understand if STAIR is helpful, feasible, and acceptable to patients seen in BMC primary care.

6.3 Analysis of Risks in Relation to Benefits

This study advances our ability to assess if PTSD treatment offered in IBH is actually helping reduce mental health outcomes and healthcare utilization as expected and will provide important information from patients about what might need to change in order to be more effectively implemented in this clinic. We believe the risks to participate are reasonable given the importance of direct clinical knowledge that is expected to result from the study.

7 Study Subject Selection

7.1 Subject Inclusion Criteria

To participate in research components, patients must endorse having experienced an event on the Life Events Checklist for the DSM-5 (LEC-5) and have elevated PTSD symptoms as measured by the PTSD Checklist for the DSM-5 (PCL-5), defined as reporting at least moderate severity of at least one question

1-5 and 6-7 and at least moderate severity on at least two questions 8-14 and 15-20. Additionally, participants must be over 18 years of age, able to engage in therapy in English.

7.2 Subject Exclusion Criteria

Exclusion Criteria: Participants will be excluded from the study if they (a) do not have reasonable access to the technology needed for both conditions (e.g., phone, computer, internet access), (b) are experiencing bereavement (death of someone close) as primary clinical concern, and is, therefore, not a good fit for a PTSD-specific treatment; (c) are engaged in concurrent cognitive behavioral therapy for PTSD (PE, CPT, or EMDR), or (c) are not appropriate for care in IBH (e.g., need a higher level of care than IBH provides as determined by clinical judgement).

8 Study Intervention

Clinician-administered Brief STAIR

Participants randomized to Brief STAIR complete five 30-minute sessions with a study therapist via telemedicine or in-person based on patient preference and Covid-19 restrictions in the setting. Brief STAIR is five sessions and includes all core elements of traditional 10-session STAIR.[33,34,44] Each session begins with review of the patients' most recent PCL-5 score (documented in the medical record by the RA). Session 1 provides psychoeducation around the impact of trauma on emotions and relationships, an introduction to the treatment program structure, and a focused breathing exercise. Sessions 2-4 focus on emotion regulation skills across the body, thought, and behavior channels (i.e., the cognitive behavioral therapy triad).[45] These include emotion regulation techniques such as focused breathing and emotion surfing to down-regulate symptoms of over-activation (e.g.,, anxiety, hyperarousal) and techniques such as behavioral activation and pleasurable activities planning to up-regulate individuals when they are in a depressive or dysthymic state. Session 5 focuses on compassion, strategies for improving social engagement and sustaining relationships (e.g., conflict resolution), review of treatment progress, and a plan to continue use of skills.

Web-administered STAIR (webSTAIR)

Participants randomized to webSTAIR complete the program at their own pace. WebSTAIR includes the same content as Brief STAIR in ten online modules, which include audio, video, and text delivery of psychoeducation and therapy components, with interactive exercises to assist in skills practice.[35] All webSTAIR participants will have a therapist on record for treatment oversight (in case higher-level of care is needed) and for treatment planning purposes. In some cases, webSTAIR participants will have access to their study therapists for sessions outside of this treatment, i.e., support that is not PTSD-specific. This may include regular therapy sessions (which typically occur every 4-6 weeks in usual care), but *not* Brief STAIR or other trauma-focused therapies during the treatment window. The RA provides patients with unique login information, technology support, and lightly encourages engagement through biweekly reminder phone calls/texts. The principal investigator (PI) and RA have access to administrator-level login, which allows them to access behavioral data on participant progress (time spent, modules completed). To protect patient privacy, open text fields within webSTAIR (e.g., personal written answers to exercises and modules) are not viewable by study staff. Patients have access to the program for all 9 months of study participation, though progress is only reported back to study therapists during the active treatment phase (weeks 0-15).

Study Therapists: Training, Fidelity, and Supervision

Study therapists (N=10) are behavioral health specialists in integrated primary care, including Master's-level social workers and doctorate-level psychologists. The PI, a nationally certified trainer in Brief STAIR, leads a 4-hour didactic training available to all therapists. Study therapists receive the Brief STAIR manual developed by Drs. Cloitre, Ortigo, & Gupta, and tailored to the local setting by the PI and CAB. Post-training, the study team sends a follow-up email to determine interest in research participation. Therapist participation in the study is voluntary. To account for therapist turnover and maximize uptake in usual care, trainings are ongoing as new hires and trainees join the clinic. During the trial, the PI provides ongoing supervision to study therapists through biweekly group consultation and individual written feedback on each session of the first two training cases. Consultation includes case review and discussion of real-time barriers/facilitators to implementation. All Brief STAIR sessions are audio-recorded to allow for fidelity assessment. Fidelity checklists (developed by Dr. Cloitre[33] and adapted for our version of the manual) assess adherence, defined as completion of all session components (0 = not implemented, 1 = implemented, N/A = unable to complete), and competency, defined as how skillfully each component was delivered from 0 (not completed) to 7 (excellent). Average adherence and competency scores are calculated for each session. Fidelity monitoring for the purposes of training (written feedback on two training cases) will happen in real-time. Overall fidelity will be calculated at study completion based on 20% of Brief STAIR sessions selected at random. Fidelity will be assessed by two raters.

9 Recruitment and Retention Procedures

9.1.1 Recruitment Procedures

As a standard practice of care, IBH therapists determine who might benefit from PTSD treatment according to clinician appraisal for PTSD during their intake assessment. This a standard evaluation is already in place. If the patient screens positive on the PC-PTSD-5 or it is otherwise determined that PTSD treatment is appropriate, the therapist will ask permission to be contacted by study staff. The study RA will then contact the patient to provide information about STAIR and the research study, and to administer a study eligibility screener. Those who are not eligible or choose not to enroll in the study components will still receive standard of care from their IBH therapists. Study staff will go over the Brief Screening Agreement with the potential participant before administering the study eligibility screener. If the participant is ineligible or not interested in participating, the results of the study eligibility screener will be immediately destroyed.

All recruitment will be clinician-mediated - meaning that IBH therapists will present patients with all treatment options for PTSD, including STAIR. If patient is interested in STAIR for PTSD, then the IBH therapist will briefly describe the study and ask the patient for permission for the study team to contact. The therapist will inform study staff that a patient is interested in participating. Once a patient has been introduced or referred to the study team, recruitment/screening will occur in a private exam room in the primary care clinic or our research center (dependent on institutional safety policies surrounding COVID-19), or over the phone. If study staff or patient is not immediately available, study staff will reach out to the patient over the phone to tell them more information about the study, complete screening (if not assessed by clinician), and, if eligible, schedule a time for the patient to complete informed consent with study staff prior to their next appointment in IBH. The Recruitment Script may be used for in-person and over the phone recruitment, only in cases where the clinician has gained permission from patient for study staff to contact. If the patient qualifies for the study and completes informed consent, screening data will be retained. Due to the unacceptability and burden of conducting full screening

consent, conducting consent immediately after screening, or destroying screening data after assessing eligibility (justification detailed above), we are requesting a waiver of HIPAA authorization language so that we can retain screening data without full screening consent or immediate informed consent. If the patient does not qualify for the study or does not complete informed consent, screening results will not be retained by the research team, with the exception of overall count data. Written informed consent, completed in person or over REDCap via electronic signature, will be obtained prior to baseline assessment and treatment sessions, and includes notification that the study team will retain screening data if the participant agrees to participate and completes consent.

For those determined eligible after screening, full written informed consent will be obtained as soon as possible (see justification to retain screening data without full screening consent or immediate informed consent). Study staff will complete the Informed Consent Form and subsequent assessments with interested patients. Study staff will inform the referring therapist of the patient's decision on participation in the research components, so that the referring therapist can facilitate referral to PTSD treatment if necessary (either within IBH, in outpatient psychiatry, or in community-based clinics). Patients will be informed that they may receive treatment without participating in the research component, either within IBH clinic or via referral to outpatient psychiatry or community-based clinics.

9.1.2 Retention Procedures

Our team will make every attempt to support participant retention, including use of multiple methods for contacting participants (phone call, text message, messaging through the medical record, email, home address), send visit reminders, and provide incentives for visit attendance).

10 Screening Procedures

Screening will occur in two steps. If a patient screens positive for PTSD on the PC-PTSD-5 and/or is deemed a good fit for PTSD treatment by clinician judgment, the IBH therapist will refer the patient to the study team for study eligibility screening. Study staff will conduct screening in person in a private exam room (dependent on institutional safety policies surrounding COVID-19) or over the phone. Study staff will go over the Brief Screening Agreement with the potential participant before administering the screening questions. If the participant is ineligible or not interested in participating, the results will be immediately destroyed. If the Brief Screening Agreement is completed and the patient is still interested, study staff will set up a time to obtain written informed consent. The patient will complete the Informed Consent Form and subsequent assessments with study staff via REDCap prior to baseline assessment and treatment sessions. Patients may also be offered to complete these measures in person with study staff if hospital COVID-19 policies permit. Additionally, eligibility screening data assessed by researchers will be communicated to clinicians and may be added to chart by study staff or clinicians only for those who have provided informed consent to participate in the study (we have included necessary CoC language in the informed consent form).

If the patient qualifies for the study and completes informed consent, screening data will be retained (we have provided justification to request a waiver of HIPAA Authorization language above; our Informed Consent Form and Brief Screening Agreement includes language notifying the participant that we will retain screening data if they are eligible and provide consent). If the patient does not qualify for the study or does not complete informed consent, screening results will not be retained by the research team, with the exception of overall count data. We will retain a running list of patient names that have

already been screened that will contain only their name, date of screen, and outcome (enrolled, ineligible, not interested), so that we can create a recruitment flow chart as well as not inadvertently approach the same patient twice regarding the study. Reasons for ineligibility will be kept in a separate list not linked to patient names. These lists will be kept in a secure private, password-protected drive that can only be accessed by members of the study team. After the study is completed and the recruitment flow chart is created, this list will be destroyed.

11 Consent Procedures

For patients who do not sign an informed consent form, no patient data will be retained. For patients who do sign the informed consent form and agree to participate, study eligibility screening data will be retained. Participants will be made aware prior to screening and during the consent process that data collected prior to informed consent will be retained and used as study data.

When study staff complete screening, a Brief Screening Agreement is used before administering questionnaires. Language has been added to the Brief Screening Agreement to explicitly state that screening data will be retained if the participant is eligible and completes informed consent. Written informed consent, completed over REDCap via electronic signature (process explained in 17.1), will be obtained prior to baseline assessment and treatment sessions, and the informed consent form also includes notification that the study team will retain screening data if the participant qualifies and completes consent.

For those determined eligible after screening, full written informed consent, completed over REDCap via electronic signature (or on pencil and paper), will be obtained by study staff either at the time of screening or at another scheduled time before participant completes study assessments or attends the first treatment session. The full written informed consent includes HIPAA authorization language to allow us to collect PHI and abstract the medical record, as well as a consent statement to allow for collection of evaluation data. The consent also notifies participants that if they agree to participate, we will retain their screening data. Patients will be informed that they may receive treatment without participating in the research component, either within IBH or via referral to outpatient psychiatry or community-based behavioral health clinics. Individuals obtaining consent will be study staff who are well trained in obtaining informed consent. Before the verbal consent, the RA will email the participant a participant-specific link to the consent form in REDCap using a secure BMC email address. The informed consent process will be administered by the RA. During the consent process, the RA will introduce the patient to the consent form and summarize its content. Participants will be given sufficient time to review the consent and ask any questions necessary in order to aid in their decision to participate. The participant will follow the link, read through the form (which has already been summarized by the RA) and will electronically sign it in REDCap. Paper copies of the informed consent will be used during in-person informed consent process. After reviewing paper copies with the RA, the participant will be provided a REDCap link to sign electronically before proceeding to surveys. Participants will be able to keep the printed copy and/or have an electronic copy of the consent form sent to them.

12 Study Procedures

The **standard of care** in Primary Care is to provide options for screening and treating posttraumatic stress disorder (PTSD) and related mental health disorders to all patients. Patients

have several options for mental health treatment, including treatment with Integrated Behavioral Health (IBH) therapists, referral to behavioral health specialists in outpatient psychiatry, or referral to community-based behavioral health clinicians. This treatment is not research and takes place regardless of participation in the research components. Specifically, all embedded IBH therapists that work in Primary Care will have the opportunity to receive training and consultation in the STAIR intervention prior to start of the study and will be able to offer this treatment to any patient, regardless of a patient's decision to participate in research components, as a new standard of care. We will also train additional therapists in outpatient psychiatry at BMC in the intervention in case IBH therapists experience issues with capacity in their caseloads. However, the online, self-paced version of the therapy (webSTAIR) will only be provided to research participants for the time being.

Clinic population: IBH provides mental/behavioral health treatment to patients in Primary Care who are experiencing a range of mental/behavioral health disorders and symptoms who would like the option of seeing a therapist for these issues through the Primary Care clinic. The Primary Care team includes Primary Care Providers, Nurses and Nurse Practitioners, Community Health Workers, and IBH therapists. IBH therapists include social workers, psychologists, and trainees receiving supervision.

This project will evaluate the intervention for PTSD that is being used in IBH and use the data to iteratively improve the treatment and to explore how effectively the intervention is working in the primary care clinics. We will compare the relative advantages and disadvantages of the in - person/telehealth and web-administered versions of STAIR to better understand and improve the quality of care in IBH.

Eligibility: IBH patients with PTSD treatment needs (based on clinical screening or clinical judgment) may be appropriate for STAIR. The IBH clinician will ask patients for their permission to be contacted by the study team. The study RA will then contact the patient to provide information about STAIR and the research study, and to complete a study eligibility screener. Those who are not eligible or choose not to enroll in the study components will still receive standard of care from their IBH therapists, which may include in-person or telehealth STAIR.

Inclusion Criteria: To participate in research components, patients must endorse having experienced an event on the Life Events Checklist for the DSM-5 (LEC-5) and have elevated PTSD symptoms as measured by the PTSD Checklist for the DSM-5 (PCL-5), defined as reporting at least moderate severity of at least one question 1-5 and 6-7 and at least moderate severity on at least two questions 8-14 and 15-20. Additionally, participants must be over 18 years of age, able to engage in therapy in English.

Exclusion Criteria: Participants will be excluded from the study if they (a) do not have reasonable access to the technology needed for both conditions (e.g., phone, computer, internet access), (b) are experiencing bereavement (death of someone close) as primary clinical concern, and is therefore not a good fit for a PTSD-specific treatment; (c) are engaged in concurrent cognitive behavioral therapy for PTSD (PE, CPT, or EMDR), or (c) are not appropriate for care in IBH (e.g., need a higher level of care than IBH provides as determined by clinical judgement). With patient permission obtained from IBH therapist first, study staff will reach out to patients to go over the Brief Screening Agreement before administering the study eligibility screening questions assessing for other inclusion and exclusion criteria. If the participant is ineligible or not interested in participating, the results of the study eligibility screener will be immediately destroyed.

Adding HIPAA authorization language to our screening process would not be acceptable to our participant population, as evidenced by other researchers' previous experience in conducting full screening consent with participants over the phone and conversations with our community determining patient eligibility, we would have to repeat the measure with other baseline assessments, causing undue patient burden. Therefore, we are requesting a waiver of authorization language in order to keep screening data of participants who are eligible for and interested in participating in the study and have set up a time to meet with research staff either in person or over telehealth to conduct the informed consent process. Language in the Brief Screening Agreement informs patients that we will retain their screening data if they enroll. Patients in the webSTAIR condition will provide email addresses to study staff. Study staff will then email a unique login username and temporary password to each participant for use on the webSTAIR website. See the webSTAIR Website: **https://www.webstair.org/**

Evaluation Data Collection: This is a QI project with an evaluation; data is used to iteratively improve the intervention and to explore whether and how the treatment is working. Our evaluation will include a collection of both process measures to understand feasibility, acceptability, and satisfaction to help us make iterative improvements, and outcome measures to understand whether the treatment is improving patient PTSD symptoms, other mental health symptoms, and overall functioning as expected. Our evaluation will also rely on medical record data to evaluate healthcare utilization. All participants will be given a code that will be used on all data collection tools. The master key that connects participant codes to name, date of birth (DOB), contact information, MRN, and scheduled appointment date and time will be kept in a password protected word file saved on the password protected BMC Psychiatry network drive. The list will only be accessible to Dr. Valentine and study team staff.

Medical Chart Extraction Data: Participants' medical records will be accessed to obtain information about session scheduling, information about ongoing treatment at BMC, and other healthcare utilization data from 6 months pre-enrollment to 9 months from baseline. Participants will be asked to sign a medical release form in the case that they move out of the area during the study or attend visits at a different hospital, so that we may obtain medical records from their new hospital/doctor. In addition, we will obtain the list of EPIC encounters of each enrolled patient in order to keep track of number of scheduled/attended/no-showed appointments. In total, the following information will be extracted from participant medical records: MRN, Name, DOB, problems lists, and encounter data (date and time of scheduled appointments, and date and time of unscheduled care [i.e., emergency department visits, urgent care visits, Boston Emergency Services Team (BEST) safety evaluations, records of hospitalization]). Participants will be informed of this extraction during the informed consent process.

Surveys for participants: Self-report measures that have been shown to have excellent psychometric properties will be used to assess mental health and general well-being for each of the three study assessments (baseline, 15 week, and 9-month). This will include the LEC-5 and PCL-5 to assess trauma exposure (historical at the baseline study visit and any new traumatic events at the post-treatment and follow-up assessments) and current PTSD symptoms; the Difficulties in Emotion Regulation Scale (DERS) to assess emotion regulation; the Interpersonal Support Evaluation List (ISEL-12); the Posttraumatic Cognition Inventory (PTCI-9) to assess cognitions associated with PTSD; and the Brief Symptom Inventory (BSI-18) to assess for general mental health issues. Patients will also complete the Coronavirus Stressor Screener, the Everyday Discrimination Scale (EDS), and the Traumatic Symptoms of Discrimination Scale (TSDS) to understand stress response related to Covid-19 and racism. During the baseline assessment, patients will also be asked to complete a demographic questionnaire to collect

data on gender, sexual orientation, age, education, marital status, ethnicity, and family income. During the baseline and 15-week assessments, participants will also be asked to complete the Consumer Experiences of Stigma Questionnaire (CESQ) to assess for perceived symptoms. During the 15-week assessment only, participants will be asked to complete the Client Satisfaction Questionnaire (CSQ-8) to assess intervention acceptability. The 15-week assessment also includes an open text box where participants can provide suggestions and recommendations for how to improve STAIR.

Patients may complete the questionnaires over REDCap, in which case the RA will email the participant a participant-specific link to the REDCap surveys using a secure BMC email address. This data will be collected on REDCap with no identifying patient information but the research staff at the clinic will hold the screen ID for eligible and interested patients to link the screening form to the patient. Participants will be given the option to complete the questionnaires inperson on paper-and-pencil (depending on COVID-related clinical and research guidance from the institution), or to have them administered verbally (in-person or by phone) by study staff. Regardless of the mode of data collection, study staff will be available to answer any questions that arise. All data will be entered into REDCap.

Fidelity to the treatment:

For in-person/telehealth STAIR, patients will be asked to consent to audio-recording of treatment sessions to ensure that fidelity and adherence to the intervention can be evaluated. Research staff will listen to 20% of audio-recorded STAIR sessions and complete a checklist of expected treatment components. Fidelity monitoring will happen in near real-time to assist with therapist training. **For webSTAIR,** study staff will monitor treatment progress via information collected by webSTAIR. This includes behavioral data on module completion, time in each module, total time in program, and the frequency and time spent access each therapy skill. IBH clinicians will also have access to the webSTAIR dashboard so they can monitor their patients' progression through the treatment. The dashboard will be reviewed in consultation meetings.

Randomization procedure: Participants will be randomized through a randomization software. Each patient will receive a unique study ID at the time of referral to the study that is not connected to identifiable data. Before randomization, the referred patient will complete the following enrollment procedures: (1) each referred patient will complete a clinical intake at with their IBH therapist, and (for those with PTSD treatment needs) give permission for study team to contact, (2) each referred patient will complete an assessment with study staff to determine eligibility for the study, (3) each referred patient will give study staff consent to participate in the study, and (4) each referred patient will complete the baseline assessments. Once a participant gives consent to enroll in the study, they will be provided with a unique ID number and this ID number will be connected to their identifiable data (access to identifiable data will be limited). Once all four steps of enrollment (clinical intake, eligibility assessment, consent, and baseline assessment) are completed, the participant will be randomized. Study design schedule: This evaluation is designed so that all patients who may benefit from PTSD treatment will be offered STAIR through in-person/telehealth format. Only those who enroll in the study are are randomized to webSTAIR will have access to the webSTAIR format. Group assignment will therefore be randomized for all eligible participants. We also acknowledge that, because clinic practices cannot change overnight, after STAIR is rolled-out, some patients still may not be provided STAIR, due to their treatment preference or their therapist's preference not to complete STAIR training. Therefore, even therapists who do not complete the STAIR training will be instructed to offer STAIR as an option that may be delivered by a different IBH therapist.

We will collect participant data for 9 months from baseline. Treatment plans will continue to be determined by usual care providers, the study has no involvement in any decisions regarding care. This means that a participant's IBH therapist can continue the therapy, offer a different treatment option, or refer to other services at any time in the study and after the study is completed. At any time, patients can also choose to change their treatment plans, for example from webSTAIR to in-person/telehealth STAIR, or to another treatment option in the clinic. Access to webSTAIR will be discontinued at 9 months.

13 Assessment of Safety and Data Safety Monitoring Plan (DSMP)

13.1 Definitions for Safety Assessment

The following definitions will be used in the assessment of safety:

Adverse Event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Event (SAE) is any adverse event that

(1) results in death;
(2) is life-threatening;
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

Life-threatening means that the event places the subject at immediate risk of death from the event as it occurred.

Unanticipated Problem is defined as an event, experience or outcome that meets **all three** of the following criteria:

- is unexpected; AND
- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research

Unexpected means the nature, severity, or frequency of the event is not consistent with either:

- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol–related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
- the expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

13.2 Safety Review

This study is not greater than minimal risk. Unanticipated Problems, Adverse Events, and protocol deviations will be reported to the IRB as required by IRB policies.

13.3 Reporting Plans

The Principal Investigator at BMC/BU Medical Campus will report Unanticipated Problems, safety monitors' reports, and Adverse Events to the BMC/BU Medical Center IRB in accordance with IRB policies:

- Unanticipated Problems occurring at BMC/BU Medical Campus will be reported to the BMC/BU Medical Campus IRB within 7 days of the investigator learning of the event.
- Adverse Events (including Serious Adverse Events) will be reported in summary at the time of continuing review, along with a statement that the pattern of adverse events, in total, does not suggest that the research places subjects or others at a greater risk of harm than was previously known.

13.4 Stopping Rules

The study has no pre-defined stopping rules.

14 Data Handling and Record Keeping

14.1 Confidentiality

We will make every attempt to protect confidentiality. All participants will be assigned a study ID and questionnaires, and audio files will only have that study ID without other identifiable information. REDCap will be used to enter coded study data. Only coded data will be included in REDCap. Study staff may enter data from paper forms or from patient phone calls into REDCap or participants may complete surveys directly into REDCap. All paper data files will be kept in a locked file cabinet in a locked office. In person and telehealth intervention sessions will be audio-recorded. The recordings will be saved on a password protected BMC network drive that can only be accessed by members of the study team and labeled only with their Study ID. After the recording is saved on the password protected BMC network drive, the recording will be deleted from the audio-recording device. WebSTAIR (operated by the Veteran's Health Administration) is protected by a data security assurance, ensuring that all content is

password-protected, item-level and written content is not viewable outside of an individual account, and all information on the site is maintained in a confidential and secure manner. The VHA is not engaged in the same research project and will not have access to any study data collected by BMC (via RedCAP) for purposes of this study. They will not be able to link data gathered by webSTAIR to our data, as only BMC study team will know the link between webSTAIR usernames and Study ID numbers, and only the BMC study team will have access to data collected during study visits. webSTAIR is a password-protected website. For this study, we have been allocated a set of 30 patient-level accounts (with unique usernames and passwords) to distribute to study participants. In addition, the program manager has created four administrator-level account (2 for BMC study staff, including PI and RA; and 2 for VA collaborators). The administrator-level account allows study staff to see patient engagement information such as the date, time, and duration of accessing various modules on the website and optional self-assessments so patients can track their progress. The website does not collect item-level information (e.g., fillable text boxes within the modules and worksheets), this information is only available to patients via their unique login. The webSTAIR website does not communicate with the EMR. Because we will contact patients over the course of the study and will access patients' medical records, we will record their contact information, their date of birth, and their MRN. One list of names and contact information and Study IDs will be kept on a private password protected BMC network drive separate from any data collection tools and will only be accessible to the study team. All identifiable information will be transmitted, stored, analyzed, or otherwise exist only on HIPAA-compliant electronic systems that meet the standards for protection of PHI established by Boston Medical Center. As an extra layer of protection, we have a Certificate of Confidentiality because this project is NIH-funded.

15 Statistical Plan

15.1 Study Hypotheses

Hypotheses:

A. Brief STAIR will lead to significant change PTSD symptoms between baseline and 3 months.
B. WebSTAIR will lead to significant change PTSD symptoms between baseline and 3 months.
C. There will be no group differences in change in PTSD across conditions.

15.2 Sample Size Determination

Taking into account the quasi-experimental study design in the pilot of a comparison between pre- and post-implementation of the intervention, I based the power calculation on a recent but simple method proposed by Viechtbauer et al.109 suggesting a sample size of 60 as adequate. True probability is unknown, and therefore the lower bound of the probability will be considered in the context of the proposed study. Caution proposed by Kraemer is also considered, where clinical significance is the focus.110,111

15.3 Statistical Methods

Analyses were conducted in SPSS version 29. All continuous outcome variables were evaluated for and met the assumptions of normality (using both the Shapiro-Wilk test and the test statistics for skewness and kurtosis) and homogeneity of variance (using Levene's test; Hahs-Vaughn & Lomax, 2020). Chi-square tests and independent samples t-tests were used to examine differences in study variables between participants assigned to STAIR and webSTAIR conditions. Paired samples t-tests were used to

examine pre to post differences and pre to follow-up differences; effect sizes were calculated using cohen's d. Participant retention, measured by percent of intervention content completed, did not meet the assumption for normality. To compare differences in engagement between STAIR and webSTAIR, we used the Kruskal-Wallis test, a non-parametric test that does not assume distributions between groups are similar. Linear mixed models with repeated measurements nested within patients were used to examine changes in study outcomes across time points and between groups. We used the restricted maximum likelihood estimator and unstructured covariance matrices for residuals. We examined fixed effects of time, treatment group, and time by treatment group interactions for all study outcomes. In post hoc analyses, we used Spearman's correlations to examine the correlation between engagement and baseline trauma symptoms of discrimination, stigma, and attitudes toward help seeking. Post hoc LMMs examined primary outcomes only (PTSD symptoms, mental health symptoms, and depression symptoms) and included two indicators of engagement, percent of assigned intervention completed and additional contact hours (count of behavioral health encounters documented in the electronic medical records).

16 Ethics/Protection of Human Subjects

This study is to be conducted according to applicable US federal regulations and institutional policies (which are based in federal regulations, guidance, and ICH Good Clinical Practice guidelines).

This protocol and any amendments will be submitted to the Boston Medical Center and Boston University Medical Campus for formal approval of the study conduct. The decision of the IRB concerning the conduct of the study will be made in writing to the investigator.

All subjects for this study will be provided a consent form describing this study and providing sufficient information for subjects to make an informed decision about their participation in this study. The consent form will be submitted with the protocol for review and approval by the IRB. The consent of a subject, using the IRB-approved consent form, must be obtained before that subject is submitted to any study procedure. Consent will be documented as required by the IRB.

17 Literature References

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