Title

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Study protocol for a hybrid 1 effectiveness-implementation trial of Brief Skills Training in Affective and Interpersonal Regulation (Brief STAIR) and web-administered STAIR (webSTAIR) for posttraumatic stress disorder in integrated primary care

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Abstract

Background: Posttraumatic stress disorder (PTSD) disproportionally affects low-income, racial and ethnic minoritized communities, where prevalence is high, yet access to evidence-based

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

treatments (EBTs) is low. As such, there is a need to identify effective, feasible, and scalable interventions for PTSD. Stepped care approaches that include brief, low-intensity treatments are one approach to improving access yet have not been developed for adults with PTSD. Our study aims to test the effectiveness of a step one PTSD treatment in primary care while gathering information on implementation to maximize sustainability in the setting.

Methods: This study will be conducted in integrated primary care in the largest safety net hospital in New England using a hybrid type 1 effectiveness-implementation design. Eligible trial participants are adult primary care patients who meet full or subthreshold criteria for PTSD. Interventions include Brief clinician-administered Skills Training in Affective and Interpersonal Regulation (Brief STAIR) versus web-administered STAIR (webSTAIR) during a 15-week active treatment period. Participants complete assessments at baseline (pre-treatment), 15 weeks (post-treatment), and 9 months (follow-up) post-randomization. We will assess feasibility and acceptability post-trial using surveys and interviews with patients, study therapists, and other key informants, and will assess the preliminary effectiveness of interventions in terms of PTSD symptom change and functioning.

Conclusion: This study will provide evidence for the feasibility, acceptability, and preliminary effectiveness of brief, low-intensity interventions in safety net integrated primary care, with the aim of including these interventions in a future stepped care approach to PTSD treatment.

Clinical Trial Number: NCT04937504

Keywords

posttraumatic stress disorder; effectiveness; implementation; hybrid; stepped care

1. Introduction

Violence is a rapidly growing crisis in the United States and is concentrated in low-income, racial and ethnic minoritized communities,[1,2] where rates of violence exposure are as high as 94%.[2] Consequentially, PTSD prevalence in these communities is up to 50%,[3] compared to 6% in the general population.[4] Although trauma exposure and PTSD prevalence is well-documented, the treatment gap is large, with only 13% of patients with PTSD receiving any mental health treatment,[5] and only 57% of whom receive a minimally adequate dose of therapy.[6]

Multi-level barriers drive racial and socioeconomic disparities in access to evidence-based treatments (EBTs) for PTSD. Despite strong evidence for their efficacy, current first-line EBTs for PTSD such as cognitive processing therapy (CPT)[7] and prolonged exposure (PE)[8] are burdensome on healthcare systems, often making them unsustainable in usual care.[9–11] This is particularly the case in low-resource settings where there are few mental health specialists and limited access to EBT trainings.[12–15] At the patient-level, medical mistrust due to historical and ongoing maltreatment (including discrimination) in healthcare settings,[16,17] low mental health literacy, and stigma[18–21] contribute to under-engagement in mental health treatment. Although racially minoritized patients can equally benefit from EBTs,[22] these patients are at 30% lower odds of achieving meaningful improvement[23] and are less likely to complete treatment.[22,24] Differences in treatment engagement and

outcomes underscore the potential need to adapt interventions and address system inequities that drive large treatment gaps. For example, preparing interventions for implementation in less stigmatized settings (primary care),[12] evaluating the need for cultural adaptation (e.g., consideration of race-based stress and trauma within treatment models),[25,26] or considering the need for adjunctive structural (social needs) interventions.

Stepped care for PTSD may make treatments more patient-centered, accessible, and equitable by establishing a continuum of options that balance clinical effectiveness, patient preferences, and implementation feasibility.[27] Stepped care approaches typically begin with interventions that are low-intensity (step one), and progress to more intensive care (step two) if indicated. Step one interventions may be less burdensome on the care setting, more appealing for patients not yet ready to engage in high-intensity therapies that require emotional or cognitive reprocessing of the trauma memory or reminders, and delivery in non-specialty settings (e.g., primary care, web-administered) may promote engagement for patients facing stigma-related barriers to care. Yet, stepped care models for PTSD have not been developed for adults.[28]

In this paper, we describe the study protocol for the "Implementing a Skills Training Evidence-Based Treatment for PTSD" (I-STEP) study that takes place in a safety net hospital setting. Safety net hospitals provide health care services regardless of patients' ability to pay and primarily serve racially minoritized and low-income patients.[29] The I-STEP study will pilot two candidate "step one" interventions for PTSD in primary care: Clinician-administered Brief Skills Training in Affective and Interpersonal Regulation (Brief STAIR)[30,31] and web-administered STAIR (webSTAIR).[32]

STAIR is a transdiagnostic empirically supported cognitive behavioral therapy that has demonstrated effectiveness in a variety of contexts, including safety net settings.[30,33–36] STAIR focuses on improving psychosocial functioning through emotion management and social skills and does not require recounting the trauma memory, making it highly tolerable. Further, the focus on functional improvement (rather than psychopathology) may be more acceptable to patients experiencing high mental health stigma. Brief STAIR maintains the same goals as the longer version of STAIR, adapted for brief (5-session) delivery in primary care (also called STAIR-PC).[31] WebSTAIR contains the same core components of Brief STAIR in a web-administered, self-directed platform.[37] Both synchronous Brief STAIR and asynchronous webSTAIR have shown similar effect sizes in PTSD. STAIR and Brief STAIR have been shown to reduce PTSD and improve psychosocial functioning in two randomized controlled trials (RCT)[31,38] and three open trials,[36,39,40] with PTSD outcomes consistently exceeding effect sizes of .80. A peer-delivered format of Brief STAIR has been tested in an open trial in our setting.[40] WebSTAIR has been tested in 5 studies including 2 open trials,[37,41] 1 comparative trial[42] and one randomized controlled trial,[43] with pre-to-post PTSD effect sizes ranging from .53 to 1.04. The low-intensity, low system-burden, and demonstrated effectiveness of each modality suggests either may be suitable step one interventions. To date, testing of Brief STAIR and webSTAIR has been limited to Veteran Health Administration (VHA) settings, and implementation outcomes of each modality have not been compared in an RCT. Given the unique challenges of treatment implementation in low-resource settings, there is a need to optimize and test these treatments. Our hybrid

type 1 effectiveness-implementation trial design[44] will allow us to assess the feasibility, acceptability, and preliminary effectiveness (PTSD symptoms, functioning) while gathering information on implementation of both modalities.

2. Methods

2.1 Setting

The I-STEP study takes place in primary care clinics at the largest safety net hospital in New England, serving approximately 50,000 patients. Most patients are people with low-income, over 60% identify as people from racial or ethnic minoritized groups, and 70% are insured by Medicaid. To accommodate the high demand for behavioral health services, primary care utilizes an integrated behavioral health (IBH) model, which relies on collaboration, communication, and colocation of primary care physicians and behavioral health specialists. IBH prioritizes brief, effective, low-intensity interventions, and utilizes a stepped-care approach in which patients are offered least-intensive treatments first, then referred to higher levels of care when needed, making IBH an ideal setting for testing of a step one intervention for PTSD. Since the Covid-19 pandemic, referral volume has increased by 80% and show rates have increased by 62%, underscoring the urgent need for effective, scalable interventions.

2.2 Formative Work

Our I-STEP interventions and implementation blueprint were tailored to the local setting using participatory methods. During the trial planning period, integrated primary care leadership was presented with multiple first-line EBTs for PTSD (including CPT-C and PE). Brief STAIR was selected as an ideal candidate step one intervention due to its brevity, low-intensity, and demonstrated effectiveness in VHA primary care.[31] We conducted a developmental formative evaluation (Oct 2018-Jan 2020) to tailor Brief STAIR to the local setting and worked closely with patient and provider community advisory boards (CAB) to prepare for the trial.[45,46] We conducted a second developmental formative evaluation (Oct 2020-Feb 2021) to refine the intervention and implementation blueprint due to Covid-19-related changes to the setting and increased attention on the role of racism in PTSD treatment implementation.[47,48] Our study redesign (due to Covid-19) yielded the addition of webSTAIR (which requires no therapist time) as a comparator for its potential in alleviating provider burden while maximizing access. The local setting was not receptive to randomizing patients to a true control condition. Full detail of our formative work and CAB engagement is published elsewhere.[45–48]

2.3 Trial Design

I-STEP is a single site, unmasked, hybrid type 1 effectiveness-implementation[44] trial assessing the feasibility, acceptability, and preliminary effectiveness of Brief STAIR and webSTAIR while gathering data on implementation. We aim to randomize 60 patients (30 in each condition). Participants 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. This trial is conducted in accordance with government regulation, has been approved by Institutional Review Board, and is pre-registered at clinicaltrials.gov [NCT04937504].

2.4 Clinical Trial Procedures

See Table 1 for full eligibility criteria. Generally, eligible patients are adults seen in primary care who may benefit from PTSD treatment, including those who meet full or subthreshold criteria for PTSD based on the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5).[49] That is, patients must endorse a Criterion A trauma exposure assessed on the Life Events Checklist for the DSM-5 (LEC-5)[50] and meet full or subthreshold criteria for PTSD using the PTSD Checklist for the DSM-5 (PCL-5).[51] Full PTSD criteria is defined as endorsement of (score ≥2) of at least 1 Criterion B item (questions 1-5), 1 Criterion C item (questions 6-7), 2 Criterion D items (questions 8-14), and 2 Criterion E items (questions 15-20). Subthreshold PTSD is defined as endorsement of 2-3 B-E criteria.[52] Given that the IBH setting is designed to provide care to those with mild-moderate symptom severity—and the potential transdiagnostic benefit of STAIR on depressive symptoms, we included patients with subthreshold PTSD. The research assistant (RA) will administer the LEC-5 and PCL-5 to assess eligibility. To reduce inflation of symptoms reported due to general distress, the RA will be trained to ensure participants anchor symptoms to the Criterion A event.[53]

Per local setting preference, all recruitment is therapist-mediated. If a therapist determines PTSD treatment may be appropriate, they present all treatment options for PTSD, including Brief STAIR and webSTAIR. If the patient is interested, the therapist obtains patient permission to be contacted by study staff. Then, the RA calls the patient to describe the study, determine eligibility, and obtain informed consent via electronic signature. Those who do not enroll in the study will receive standard of care from their therapist, which may include Brief STAIR. However, at this stage, webSTAIR is only available to study participants. We aim to expand access to webSTAIR to all patients in the local setting via contracting with the vendor.

After completion of the baseline, patients are randomized to Brief STAIR or webSTAIR in a 1:1 ratio using a computer-generated sequence developed by a biostatistician not involved in recruitment or intervention assignment. Randomization is stratified by full vs. subthreshold PTSD to ensure equal assignment across diagnostic groups. Upon randomization, all participants are assigned a study therapist responsible either for delivery of Brief STAIR or treatment oversight for webSTAIR (“clinician on record”). The RA communicates assignments to the patient and therapist, and the patient begins the active treatment period (week 0-15). During the active treatment period, the RA conducts biweekly check-ins (via phone/text), which include collection of PTSD symptoms (PCL-5) and webSTAIR engagement (time spent, modules completed). The RA documents this information in the electronic medical record for the therapist to view. At the end of the active treatment

period (week 15), patients complete an assessment and the therapist determines a plan for follow-up care. The final assessment takes place 9 months post-randomization. Patients are compensated $20 for completion of each study assessments but are not compensated for therapy visits.

As another IRB approved sub-study, the RA will offer participants who have reached the 9-month assessment participation in an optional 30-minute exit interview, and will obtain abbreviated verbal consent. We aim to recruit 30 patients to complete the exit interview, including 20 engagers (10 per condition) and 10 non-engagers (5 per condition). Participants will receive an additional $20 for completion of the interview.

2.3 Treatment Conditions

2.3.1 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.[30,31] 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).[54] 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.

2.3.2 Web-administered 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 use audio, video, and text delivery of psychoeducation and therapy components, and interactive exercises to assist in skills practice.[32] 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).

2.4 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[30] 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) happens 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.

2.5 Provider Assessment Procedures

Post-trial (or, upon completion of study participation), study therapists and key informants complete surveys and a semi-structured interview with the PI to assess implementation outcomes of feasibility and acceptability. Key informants (N=15) are hospital employees in the integrated primary care setting who are not responsible for delivering Brief STAIR, including primary care physicians and leadership. Therapists and key informants are compensated $20 for the completion of post-trial assessments.

3. Outcomes (Table 2)

3.1 Feasibility

Feasibility, defined as the extent to which the intervention can be implemented as intended, is measured as patient retention (e.g., recruitment rates, assessment completion rates, engagement in content), therapist fidelity to Brief STAIR (benchmark adherence rating of 75%+ and overall competency score of 4+), and synthesis of interview data with patients, study therapists, and key informants.

3.2 Provider Acceptability

Acceptability is defined as the tolerability of the intervention in the real-world setting. The PI, a clinical psychologist in the local setting with expertise in implementation

and interviewing techniques, conducts post-trial interviews with study therapists and key informants to elicit qualitative information on provider acceptability. Questions include implementation considerations (e.g., recommendations to promote sustainability and uptake in the setting) and study therapists are asked to describe their experience delivering Brief STAIR (e.g., observed outcomes, challenges, the potential need for cultural adaptations to the intervention). See Table 3 for interview guide.

3.5 Patient Satisfaction (Acceptability)

The Client Satisfaction Questionnaire (CSQ-8)[55] assesses patient acceptability of the intervention. The CSQ-8 consists of 8 items scored on a 1 to 4 Likert scale, with higher scores indicating greater satisfaction. For those who opt-in, exit interviews will qualitatively assess patient acceptability (satisfaction). See interview guide in Table 3.

3.4 Preliminary Effectiveness

3.4.1. PTSD Symptoms (Primary outcome)—We use the PCL-5[51] 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.[56]

3.4.2 Functioning (Secondary outcome)—We use the Interpersonal Support Evaluation List (ISEL-12)[57] to assess social functioning and the Brief Symptom Inventory (BSI-18)[58] to assess general mental health functioning.

3.4 Implementation Process

Provider-completed surveys follow constructs outlined by the Consolidated Framework for Implementation Research (CFIR)[59] to assess indicators relevant to implementation success. Measures include the Level of Integration Measure (LIM)[60] to assess perceptions of integrated care in the setting, and the Implementation climate scale (ICS)[61] to assess level of support for EBT implementation. Study therapists complete the Evidence-Based Practice Attitude Scale (EBPAS-15)[62] to assess attitudes towards EBTs, Organizational Readiness to Change Assessment (ORCA)[63] to assess readiness for implementation in the setting, and the Perceived Characteristics of Intervention Scale (PCIS)[64] to assess attitudes towards Brief STAIR.

3.5 Exploratory outcome

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.

3.6 Covariates and Predictors of Engagement

Patient survey data elicits information on covariates and predictors of engagement, including demographic information (e.g., self-identified gender, sexual orientation, age, education,

marital status, race, ethnicity, family income), exposure to new traumatic events, stress responses related to Covid-19, stress responses related to experiences of racism, stigma, and help-seeking attitudes. See Table 2 for full list of measures.

4. Data Analysis

4.1 Quantitative Data

In terms of feasibility, fidelity and treatment progress is evaluated using researcher-completed checklists for Brief STAIR and website behavioral data for webSTAIR. For retention, we will estimate rates of recruitment, assessment completion, and attendance/engagement, and provide standard errors based on the binomial distribution. All survey data is stored in REDCap, a HIPAA-compliant, password-protected, electronic database and analyses will be conducted using SPSS. Prior to analysis, variables will be checked for inconsistent/missing values, and adjusted for normality. Following intention-to-treat principles, data from all randomized participants will be included and multiple imputation will account for missing data in participants lost to follow-up. Quantitative longitudinal analysis will examine changes in effectiveness outcomes, PTSD symptoms and functioning, across three time points as a function of condition. Statistical tests will compare changes in outcomes over time (t-test, Wilcoxon rank sum) and between conditions (ANOVAs, linear regression). Tests will employ two-tailed p-values (alpha = .05). T-tests will compare healthcare utilization across 6 months pre-treatment and 6 months post-treatment.

An N of 60 provides statistical power necessary to compare means between groups, and to test for mediators and covariates utilizing regression analyses. Our patient recruitment timeline was estimated based on referral numbers and patient needs in IBH during the trial-planning period. We expect at least 20% of the over 500 referrals to IBH monthly may meet our inclusion criteria. Due to therapist capacity, we conservatively estimate enrollment of 1 patient per week, for 18 months.

4.2 Qualitative Data

Interviews will be audio-recorded and immediately transferred onto a password protected network drive only accessible by the study team. Interviews will be transcribed verbatim (except for identifiable information). We will use NVIVO 10 to organize and manage data analyzed using a directed content analysis approach[65] of post-study interviews. Our codebook for these analyses will align with the implementation outcomes outlined by Proctor's Taxonomy.[66] We will additionally collect recommendations on intervention adaptations to promote uptake and sustainability, including considerations of cultural adaptations to content.[25]

4.3 Data Integration

A mixed-methods summative evaluation[67] post-trial will integrate quantitative and qualitative data on effectiveness and implementation outcomes. Drawing on the deductive and inductive codes identified through the directed content analysis approach, we will draw comparisons across intervention modality and data sources and assess for recurring themes and trends relating to appropriateness, acceptability, feasibility, and sustainability.[65,68]

Quantitative data will be embedded within qualitative data to build upon and strengthen findings, and integration will provide a richer understanding of implementation factors and outcomes in the setting. The CABs will assist with interpretation of findings and further adaptation, maintenance, and evolution of interventions in this setting.

5. Discussion

Stepped care approaches to PTSD treatment are one public health solution to improve access and engagement to EBTs for PTSD, yet how to best sequence interventions has not been developed for adults with PTSD. This study aims to test the delivery of brief, low-intensity step one interventions in an integrated primary care setting. Our use of a hybrid type 1 design[44] will allow us to assess feasibility, acceptability, and preliminary effectiveness of two modalities of the intervention, while gathering information on important implementation factors. Implementation process data will inform iterative refinement of the interventions and an implementation blueprint. The trial will also contribute to knowledge on translation of EBTs to low-resource communities historically excluded from research, and will lay the foundation for development of stepped care approaches to PTSD treatment that spans primary care and specialty care settings. Future studies may also tease apart best strategies for embedding web-administered interventions, either as stand-alone/self-directed or in adjunct to therapy.

The study design is not without limitations. The study does not utilize a true control condition and is not sufficiently powered to assess comparative effectiveness. We chose to compare Brief STAIR and webSTAIR without a true control condition to maximize treatment access, as the local setting was not receptive to randomizing patients to treatment-as-usual or other type of control. Recruitment for the study relies on clinician-mediated referral, which may limit the generalizability of results. For example, it is possible that this recruitment strategy (versus universal screening) may lead to a sample in the higher range of PTSD symptom severity. In addition, representativeness our sample is limited due to the exclusion of non-English speakers at this developmental phase. Language adaptations are planned post-trial. Rather than gold standard clinician-administered assessment of PTSD, [69] this study relies on the PCL-5, a validated self-report measure that a) may be more readily adopted in the setting due to its short administration time (5min v. 45-60min), and b) may be more sustainable within measurement-based care in the local setting.

Current Study Status

The I-STEP trial began June 30th 2021. At the time of this submission, 58 of 60 participants have been randomized.

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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

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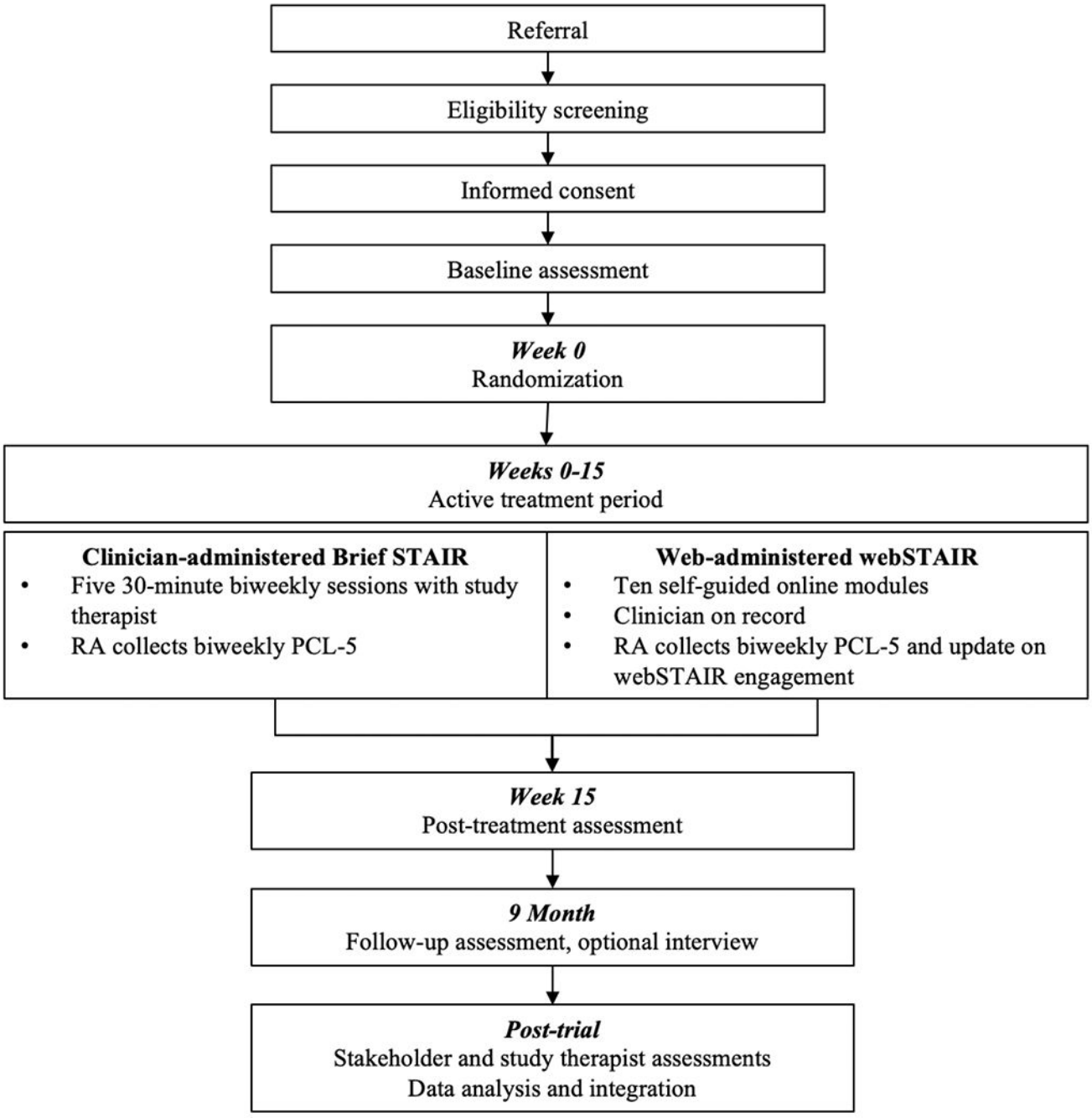

Figure 1. I-STEP Timeline

Note. Timeline illustrating I-STEP study participation.

PCL-5 = PTSD checklist for the DSM-5. RA = research assistant.

Table 1.

Patient Eligibility Criteria

Inclusion Criteria	Exclusion Criteria
1. Over 18 years of age	1. Does not have reasonable access to technology needed for both conditions (smartphone, tablet, laptop/computer, internet access) *
2. Able to receive therapy in English and read English at a 5th grade reading level	2. Experiencing bereavement as primary clinical concern (not a good fit for PTSD-specific treatment)
3. Trauma exposure (LEC-5)	3. Engaged in concurrent cognitive-behavioral therapy for PTSD
4. Full or subthreshold criteria for PTSD (PCL-5)	4. Is not appropriate for care in IBH (in need of higher level of care)

PTSD = posttraumatic stress disorder, LEC-5 = Life Events Checklist for the DSM-5, PCL-5 = PTSD checklist for the DSM-5, IBH = integrated behavioral health

* Note. In the case that a patient does not have access to a smartphone, tablet, or laptop/computer, and internet access, the RA troubleshoots ways to connect the patient with access (rather than exclusion from the study), which may include providing the patient with technology devices at the institution if needed.

Table 2.

List of Outcomes and Measures

Outcome	Data Source	Time Point
Feasibility		
Retention: Recruitment, assessment completion, and engagement rates	Patient	Post-trial analyses
Fidelity: Audio review of Brief STAIR sessions	Study therapist	Post-trial analyses
Semi-structured interview	Patient Study therapist, Key informant	T3 Post-trial
Acceptability		
Patient satisfaction: CSQ-8	Patient	T2, T3
Semi-structured interview	Patient Study therapist, Key informant	T3 Post-trial
Preliminary Effectiveness		
PTSD symptoms: PCL-5*	Patient	T1, T2, T3
Functioning		
Interpersonal Support: ISEL-12	Patient	T1, T2, T3
Comorbidities: BSI-18	Patient	T1, T2, T3
Implementation Process		
ICS	Study therapist, Key informant	Post-trial
LIM	Study therapist, Key informant	Post-trial
EBPAS-15	Study therapist	Post-trial
PCIS	Study therapist	Post-trial
ORCA	Study therapist	Post-trial
Exploratory Outcome		
Healthcare utilization: Medical record review from 6 months pre- and post-enrollment	Patient	Post-trial analyses
Covariates & Predictors of Engagement		
Demographics	Patient	T1
Exposure to new traumatic events: LEC-5	Patient	T1, T2, T3
Stress response related to Covid-19: Coronavirus stressor screener	Patient	T1
Stress response related to racism:		
EDS	Patient	T1
TSDS	Patient	T1, T2, T3
Stigma: CESQ	Patient	T1, T2
Help-seeking attitudes: ATSPPH-SF	Patient	T1, T2

Note. T1 = baseline (pre-treatment), T2 = week 15 (post-treatment), T3 = 9 months (follow-up)

*The PCL-5 is also collected biweekly during the 15-week treatment period.

PCL-5 = PTSD Checklist for the DSM-5, ISEL-12 = Interpersonal Support Evaluation List 12-item, BSI-18 = Brief Symptom Inventory 18-item, CSQ-8 = Client Satisfaction Questionnaire 8-item, ICS = Implementation Climate Scale, LIM = Level of Integration Measure, EBPAS-15 = Evidence-based Practice Attitudes Scale 15-item, PCIS = Perceived Characteristics of Intervention Scale, ORCA = Organizational Readiness to Change Assessment, LEC-5 = Life Events Checklist for the DSM-5, EDS = Everyday Discrimination Scale, TSDS = Trauma Symptoms of Discrimination Scale, CESQ = Consumer Experiences of Stigma Questionnaire, ATSPPH-SF = Attitudes Towards Seeking Professional Psychological Help Short-Form

Table 3.

Interview Guide

Provider
Key Informants and Study Therapists:
1. How did you think Brief STAIR worked in your clinic? What worked/didn't work?
2. How did Brief STAIR affect the workload of you and your colleagues?
3. How was Brief STAIR received by you and others in IBH?
4. What was the communication like between behavioral health specialists and PCPs during the intervention?
5. What changes should be made to clinic operations to support Brief STAIR in the future?
6. Do you think it would be possible for the clinic to continue using Brief STAIR? Why/why not?
7. Do you think that webSTAIR (a web intervention) is an acceptable treatment for patients?
8. How do you think a web intervention would fit within the IBH model? [e.g., offer to patients on the waitlist, peer-support, hybrid approach]
9. Are there any other thoughts about this PTSD treatment you'd like to share?
Study Therapists only:
10. How did you make decisions about referrals to the study and appropriateness of Brief STAIR? (Brief STAIR-specific):
11. Do you think Brief STAIR is an acceptable treatment for your patients? a. What outcomes are/were you seeing? b. What patient characteristics do you think are best suited for Brief STAIR?
12. Given what you know about this 5-sessino PTSD treatment, what changes do you think should be made to Brief STAIR?
13. What differences, if any, did you notice in delivering Brief STAIR with new vs. existing patients?
14. How did you use Brief STAIR in your usual practice outside of the study?
Cultural Adaptations to Brief STAIR:
15. In what ways did the cultural backgrounds and identities of your patients come up during delivery of Brief STAIR? [e.g., trauma experience, impact on presenting problems/symptoms, need to consider racial trauma, barriers to engagement, etc.]
16. How flexible do you think STAIR was in meeting the needs of patients across different cultural backgrounds? a. Do you think STAIR was applicable and relevant for all patients? How so?
17. What suggestions do you have for changes to Brief STAIR that would make the treatment more culturally responses? [e.g., are there exercises/worksheets you would modify, or additional exercises you would incorporate?]
(WebSTAIR-specific):
18. For patients who were completing webSTAIR, what did you focus on in usual care sessions? a. Did webSTAIR impact their engagement in usual care? How so?
19. What do you think was patients' overall impression of webSTAIR?
20. Do you think webSTAIR is an acceptable treatment for patients? a. What patient characteristics do you think are best suited for webSTAIR? b. Are there changes you would make to how webSTAIR is administered or who would receive it?
Patient
All Participants (Completers and Non-completers)*:*
1. Before you were randomized, did you have a preference for which version of STAIR (clinician-administered Brief STAIR or web-administered webSTAIR) you were hoping to receive? a. Was the version you completed a good fit for your needs? Why or why not?
2. What expectations did you have for treatment? How did the treatment meet or not meet your expectations?
3. How satisfied were you with the treatment you received? In what ways was it useful/not useful? a. What would have made it better?
4. How satisfied were you with your therapist?
5. What challenges did you face in participating in treatment? a. How did you overcome them?

b. What would have made it easier to participate?
c. (webSTAIR): did you experience any technological difficulties with using the program?

6. What would you tell someone else who is thinking about participating in the treatment?

7. Would you recommend the treatment to a family member or friend? Why or why not?

8. What types of mental health services have you engaged in during the follow-up period, and what types of services do you think you will need going forward?

9. Is there anything else we should know about your experience with this treatment?

Completer-Focused:

10. Can you describe what it was like to participate in the treatment? [e.g., what were the best/worst things, what was hard/went well, what did you learn that was helpful]
    a. What was different about [Brief STAIR or webSTAIR] than other therapies you've done?
        i. (webSTAIR): what was it like completing the treatment at your own pace?

11. How did treatment impact your understanding of trauma and PTSD symptoms?

12. How did participating in treatment impact or change you?

13. How did treatment impact the way you think, feel, or behave?

STAIR = skills training in affective and interpersonal regulation, IBH = integrated behavioral health, PCP = primary care physician, PTSD = posttraumatic stress disorder.