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Protocol for RCT comparing Brief Peer Supported webSTAIR vs. Waitlist Study NCT04286165

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(1.) Principal Investigator
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(2.) Project Title and Abstract

A Randomized Controlled Trial Comparing Brief Peer Supported webSTAIR to Waitlist

This study will enroll 350 Veterans at a 2:1 ratio where 200 Veterans will be enrolled into a brief peer supported webSTAIR (BPS webSTAIR) and 100 will be supported into Waitlist. The purpose of the study is to assess the efficacy BPS webSTAIR in regard to four outcomes: reduction in PTSD and depression symptoms (measured by the PCL-5 and PHQ-8, respectively) and improvement in emotion regulation and work and social adjustment (measured by the DERS-16 and WSAS, respectively). The active treatment is a 6-session modular treatment that focuses on learning emotion management skills where Veterans will have 10 weeks to complete the treatment. Assessments will occur three times for those in webSTAIR: baseline, post-treatment (10 weeks after randomization) and 8-week follow-up. and twice for those on waitlist (baseline and 10 weeks after randomization). It is hypothesized that BPS WebSTAIR will be superior to WL on all four outcomes. Mixed Effects Models will be used to evaluate the outcomes.

(3.) Purpose.

The purpose of this randomized controlled trial is to assess the efficacy of a brief version of webSTAIR (BPS webSTAIR) supported by peers compared to a waitlist condition (WL). Brief peer supported (BPS) webSTAIR is a 6-modulen web-based transdiagnostic program that provides skills training in emotion regulation; participants in this condition will be able to contact a Veteran peer trained in the program to obtain general support plus guidance about program use and application of skills.

(4.) Scientific Rationale

An 11-module version of webSTAIR with therapist coaching (Ortigo & Cloitre, 2018) has provided pilot data that the program is effective in reducing symptoms of posttraumatic stress disorder (PTSD) and depression as well as improving emotion regulation and work and social adjustment. Pilot data indicate that initial gains are made in the first 6 sessions. In addition, qualitative interviews with Veterans who have completed the program indicate high satisfaction with these modules. This study will assess whether a shorter version of the treatment (6 rather than 11 modules) and with peer rather than professional coaching will be effective compared to a waitlist condition. The BPS webSTAIR program was developed with the aim of providing a treatment for trauma-related symptoms that is effective, brief, engaging and likely to be completed by the user. The reduction of the number of modules creates a briefer treatment than our current web-based program. In addition, data indicated that integrating Veteran peers into mental health programs leads to better engagement and greater retention (Koenig et al., 2016), providing the rationale for including Veteran peers rather than therapists (e.g., psychologists, social workers). Given the absence of findings that a brief, peer-supported version of webSTAIR provides improvement in the above symptoms, we followed recommendations for the development and testing of psychotherapies and used a waitlist control as an initial test of efficacy.

(5.) Focus

(a) Specific research question(s).

Aim 1: To establish the efficacy of BPS webSTAIR in improving symptoms of PTSD and depression, emotion regulation problems and work and social adjustment compared to a Waitlist Control.

Hypothesis 1a: Compared to WL, BPS webSTAIR will provide greater improvement in PTSD symptoms as measured by the PCL5 (primary outcome) and depression as measured by the PHQ-8 (secondary outcome). Assessments will be made at pre-treatment, post-treatment, and 8-week follow-up for webSTAIR participants and pre and post-treatment (or 10 weeks from randomization) for WL.

Hypothesis 1b: Compared to WL, BPS webSTAIR will provide greater improvement in emotion regulation as measured by the DERS-16 and overall functioning as measured by the work and social adjustment scale (WSAS) (secondary outcomes). Assessments will be made at pre-treatment, post-treatment and 8-week follow-up for webSTAIR participants and pre and post-treatment (or 10 weeks after randomization) for WL.

(c) Product.
It is proposed that the brief online therapy programs will be made available for free to Veterans through the Vets Prevail platform.

(6.) Anticipated Impact.
We anticipate that Veterans and other individuals with symptoms of PTSD and depression could potentially benefit in several ways by participating in this study. These benefits may include reduced symptoms of depression and PTSD and improved emotion regulation and work and social adjustment.

(7.) Methods

(a) Study design and approach
This is a two-condition randomized controlled trial comparing BPS webSTAIR to WL. Participants will be enrolled in a 2:1 ratio (BPS webSTAIR vs. WL). Participants will be recruited from among users of the Vets Prevail website. A special effort will be made to enroll women Veterans via relevant ads on Facebook and other social media. Vets Prevail is responsible for enrolling 300 Veterans (200 into webSTAIR, 100 into WL). As noted in the study contract, enrollment is defined as the number of participants who have been accepted into the study and randomized into a treatment condition. Vets Prevail is responsible for recruiting and screening veterans and alerting NCPTSD RA to make phone contact with Veteran at all relevant assessment periods (baseline, post-tx and follow-up). The NCPTSD RA will facilitate completion of verbal informed consent, describe program including goal of completing program in 10 weeks answer questions about the study and motivate engagement in the program. The NCPTSD RA will then read through the baseline questions and document the answers. At the end of the call, the RA will recommend to the Veteran that they enter the Welcome Module and provide guidance to them at that time if they are ready to begin program.

Individuals accepted into the study will either be provided with access to BPS webSTAIR or placed on waitlist. Participants in BPS webSTAIR will complete a posttreatment assessment and 2-month follow-up. Participants in the WL condition will

complete a second assessment at 10th week, conclude their involvement in the study and be offered the Vets Prevail coping program including the use of webSTAIR.

In the BPS webSTAIR condition, participants will first complete a welcome module to orient them to the program. After randomization, participants will have 10 weeks to complete the 6 modules. Every time the Veteran logs on they will have the opportunity to engage with a Veteran peer for support through the web program. Contacts can last for up to an hour. Veterans will receive a series of automated reminders and engagement emails that the Vets Prevail program sends at various points in the program.

(b) Population and sample, including control group, if applicable.
Participants will be 350 Veterans, where after attrition from baseline assessment we expect to enroll per condition (200 in BPS webSTAIR and 100 in Waitlist) across all gender identities who meet the following criteria:

Inclusion Criteria

1. Age 21 or older
2. Able to read/write English
3. Internet connection allowing stable access to VetsPrevail website
4. Have experienced at least one traumatic event as indicated in the PC-PTSD-5
5. A score greater than or equal to 3 on the PC-PTSD-5 **OR** greater than or equal to 2 on the PHQ2 on the screen.
6. Enrollment into the webSTAIR study must be completed within two weeks of completing screener/eligibility based on symptoms.

Exclusion Criteria

1. Currently receiving a trauma-focused intervention (PE, CPT, EMDR, WET) assessed during baseline
2. Being unlikely to benefit from therapy or Telemental health, for example:
   -Cognitive difficulties as indicated during baseline assessment.
   - Active psychosis as indicated during baseline assessment.

(c) Measures and Assessment Schedule

Measure	Items	Purpose	Time	Screen	Base Line	Sessions	Post-Tx	2M FU
Sociodems	19	Baseline Sample Characterization	5min	X				
LEC-5	16	Baseline Sample Characterization	5min	X				
PC-PTSD-5	5	PTSD Inclusion/Exclusion Criteria	2min	X				
PHQ-2	2	Depression Incl/Exclusion Criteria	1min	X				
PCL-5	20	Primary Outcome – PTSD	7min		X		X	X
PHQ-8	8	Secondary Outcome – Depression	5min		X		X	X
DERS-16	16	Secondary Outcome – Emotion Regulation	10min		X		X	X
WSAS	24	Secondary Outcome -work and social functioning	15min		X		X	X
DERS-6	6	Weekly Feedback	2min			X		

Web Metrics *(example constructs/data)*

Construct	Explanation
Module Completion	Per module; options of yes, no, partial
Time on Each Module	Time in minutes user spent in each module
Total Time in Entire Program	Time in minutes
NEW: Brief 6-item DERS Score at the beginning of each module	Sum of six items
Frequency of Accessing Each Skill	Frequency of each skill accessed/practiced outside of module
Time Spent on Each Skill	Time in minutes user spent in each skill
Frequency of requesting chat	Number of requests
Duration of average chat	Minutes
Total Time Spent in Chat	Minutes

(d) Analysis Plan.

Overview: The equivalence of the treatment conditions on baseline variables demographics and psychological variables) will be assessed and controlled (if necessary) in the final analyses. Other preliminary analyses will include examination of distributional properties of the measures. We will use transformations to improve distributions when necessary. Missing data patterns (from missed assessments and from dropout) will be examined and compared between conditions. Mixed Effects Models (MEMs) will be used to evaluate differences between the two treatments over time with time as a main effect and treatment-by-time as an interaction term. Participants will be random.

(8.) Duration/Resources

Proposed Duration of Study: The probable duration of the study will be approximately 24 months. We expect that it will take approximately 3 months to build and test the webSTAIR program, obtain IRB approval and hire and train staff, 17 months to recruit the participants and approximately 5 additional months to finish collecting the data (last cohort of participants which will take a maximum of 18 weeks to complete), and approximately 3 months to clean, analyze data and prepare reports.

Monthly Gantt Chart – Timeline for tasks and participant

Tasks	*M01-03*	*M04-06*	*M07-09*	*M10-12*	*M13-15*	*M16-19*	*M20-23*	*M24-26*	*M27-29*
Build & Pilot test webSTAIR	*3Mo*								
IRB Approval	*3Mo*								
Hire and Train Staff	*3Mo*								
Enroll Participants		*17Mo*							
Final Follow-Up Data								*5Mo*	
Data Analysis and Reports									

Funding: Internal NCPTSD funds will be used to cover the costs of participant reimbursement. Participants will be reimbursed $40 for the baseline assessment, $60 for the post assessment and $60 for the 2-month follow-up.

(9.) References.

Ortigo, K. M., & Cloitre, M. (2018, November). webSTAIR VA enterprise-wide initiative: A skills-based web program with coaching support targeting MST for rural veterans. Presented in Symposium (Chair: A. Edwards Stewart), *Technology for mental health in military and veteran populations*, at Association of Behavioral & Cognitive Psychotherapy Annual Conference, Washington, D.C.

Koenig, C. J., Abraham, T., Zamora, K. A., Hill, C., Kelly, P. A., Uddo, M., ... & Seal, K. H. (2016). Pre-Implementation strategies to adapt and implement a Veteran Peer Coaching intervention to improve mental health treatment engagement among rural veterans. *The Journal of Rural Health*, *32*(4), 418-428.