Cover Page for ClinicalTrials.govs

Official Title of the Study:

Acceptance and Mindfulness Based Exposure Therapy For Survivors Of Sudden Cardiac Arrest

NCT Number:

NCT04596891

Principal Investigator:

Yuval Neria, PhD

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646-774-8041

Date of Document:

09/30/2022

Statistical Analysis Plan

Study analyses will employ SPSS Statistics version 28.0. This feasibility study was not powered to detect treatment effects. Separate repeated measures ANOVAs will be conducted for CAPS-5 and HAM-D scores over time will explore treatment effects on psychiatric symptoms. For completers, paired sample *t*-tests will compare symptoms at baseline, posttreatment, and 3-month follow-up using all available data. Cohen's *d* will be computed to determine effect sizes. Descriptive statistics will describe the proportion of patients achieving PTSD remission (defined *a priori* as no longer meeting PTSD diagnostic criteria and CAPS-5 score≤23) or clinically significant response (≥30% reduction from pretreatment CAPS-5). To classify HamD-17 depression severity, we will follow recommendations of Zimmerman et al.: not depressed (0–7), mild (8–16), moderate (17–23), and severe depression (≥24).

The first recorded 7200 minutes of Fitbit actigraphy use (confirmed by pulse recording) post account activation will define the baseline and will be compared to final treatment week in separate paired samples t-tests for average daily steps, sedentary minutes, and minutes asleep. Analyses will exclude patients lacking 7200 minutes of final week active wear.

Protocol Title:
ACCEPTANCE AND MINDFULNESS BASED EXPOSURE THERAPY FOR SURVIVORS OF SUDDEN CARDIAC ARREST

Version Date:
09/30/2022

Protocol Number:
8017

First Approval:
09/04/2020

Research Area:
Anxiety, Mood, Eating & Related Disorders
Division:
Anxiety/PTSD/OCD

Expiration Date:
07/19/2023

Contact Principal Investigator:
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Co-Investigator(s):
John Markowitz, MD
Maja Bergman
Doron Amsalem

Research Chief:
Helen Simpson, MD

Department & Unaffiliated Personnel

Department

What Department does the PI belong to?
Anxiety Disorders Clinic
Within the department, what Center or group are you affiliated with, if any?
PTSD Team

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.
PTSD Team

Amendment

Describe the change(s) being made
Clarifying language has been added to the Methods to Protect Confidentiality to explain that identifiable

data will be kept on secure, password-protected NYSPI, while some completely deidentified data may be stored on secure, password-protected CUIMC servers.
Provide the rationale for the change(s)
This will allow our collaborators at the Roybal Center for Fearless Behavioral Change at Columbia University, the study sponsor, to assist with data analysis.
Comment on the extent to which the proposed change(s) alter or affect risks/benefits to subjects
N/A
Comment on if the proposed change(s) require a modification to the Consent Form (CF)
N/A

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

✓ Audio or Videotaping
✓ Internet-based Data Collection or Transmission
✓ Psychotherapy Trial

Population

Indicate which of the following populations will be included in this research

✓ Adults
✓ Adults over 50

Protocol Title:
ACCEPTANCE AND MINDFULNESS BASED EXPOSURE THERAPY FOR SURVIVORS OF SUDDEN CARDIAC ARREST

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Cover Sheet

Choose ONE option from the following that is applicable to your study
If you are creating a new protocol, select "I am submitting a new protocol." As 5 Year Renewals are no longer required, this option remains for historical purposes.
I am submitting an annual continuation without modifications

Department & Unaffiliated Personnel

Department

What Department does the PI belong to?
Anxiety Disorders Clinic
Within the department, what Center or group are you affiliated with, if any?
PTSD Team

Unaffiliated Personnel

List investigators, if any, who will be participating in this protocol but are not affiliated with New York State Psychiatric Institute or Columbia University. Provide: Full Name, Degrees and Affiliation.
Ian Kronish, MD, Columbia University
Sachin Agarwal, MD, Columbia University
Donald Edmondson, PhD, Columbia University
Jeff Birk, PhD, Columbia University
Alexandra Sullivan, Columbia University
David Lopez-Veneros, Columbia University
Robin Cumella, Columbia University
Gaspar Cruz, Columbia University
Jennifer Mizhquiri Barbecho, Columbia University
Maria Serafini, Columbia University
Ammie Jurado, Columbia University
Brooke Morgan, Columbia University
Tyla Yurgel, Columbia University
Lee Sung, Columbia University
Cara McMurry, Columbia University
Datla Raju, Columbia University
Kaitlin Shaw, Columbia University
Kristal Quispe, Columbia University
Faith Parsons, Columbia University

Application for Continuation of Research

Status

Current Status of Study:
All research interventions were completed. Only data analysis is ongoing.

Summary of Experiences to Date

Please provide a summary of scientific progress of the study and the experience of research participants, to date. This requirement is designed to allow for the investigator and the IRB to reassess the study's risks and benefits in terms of developments in the field, changing practice patterns, and new IRB policies and procedures.
To date we have enrolled 11 participants (7 female and 4 male). Ten participants completed the intervention, while 1 participant decided to discontinue study involvement. No serious adverse events have occurred, and all interventions have been well tolerated. There have not been any study findings, recent literature, or untoward events in the past year which might affect the analysis of the safety, risks, or benefits of study participation.

Funding

Have there been any changes in funding status since the prior approval?
No
Have the principal investigator and other investigators made all required disclosures of financial interest in the study sponsor/product?
Yes

Summary

Have there been any study findings, recent literature, or untoward events occuring here or at other sites in the past year which might affect the analysis of the safety, risks or benefits of study participation?
No
Have there been any serious adverse events (serious and/or unanticipated problems involving risks to subjects or others at this site which occured in the past year)?
No
Have all study staff with a significant role in the design or implementation of the human subject components of this study received required training in human research subject protections?
Yes
Is the study covered by a certificate of confidentiality?
No

Overall Progress

Approved sample size
14
Total number of participants enrolled to date
11
Number of participants who have completed the study to date
10
Have there been any significant deviations from the anticipated study recruitment, retention or completion estimates?
No
Comments / additional information

Sample Demographics

Specify population
Survivors of Sudden Cardiac Arrest with PTSD
Total number of participants enrolled from this population to date
11
Gender, Racial and Ethnic Breakdown

Gender:
Female: 7 (64%)

Male: 4 (36%)

Race:
White: 10 (91%)
Black: 1 (9%)
Native American: 0 (0%)
Asian or Pacific Islander: 0 (0%)
Other: 0 (0%)

Ethnicity:
Of Hispanic or Latinx descent: 0 (0%)
Not of Hispanic of Latinx descent: 11 (100%)

Summary of Current Year's Enrollment and Drop-out

Number of participants who signed consent in the past year
6
Did the investigator withdraw participants from the study?
No
Did participants decide to discontinue study involvement?
No

Procedures

To create the protocol summary form, first indicate if this research will include any of the following procedures

✓ Audio or Videotaping
✓ Internet-based Data Collection or Transmission
✓ Psychotherapy Trial

Population

Indicate which of the following populations will be included in this research

✓ Adults
✓ Adults over 50

Research Support/Funding

Will an existing internal account be used to support the project?
No
Is the project externally funded or is external funding planned?
Yes
Select the number of external sources of funding that will be applicable to this study

Funding Source #1

Is the PI of the grant/contract the same as the PI of the IRB protocol?
Yes
Select one of the following
The grant/contract application is a pending review or a funding decision
Source of Funding
Other
Sponsor
Roybal Center for Fearless Behavior Change at Columbia University
Select one of the following
Single Site
Business Office
RFMH
Does the grant/contract involve a subcontract?
No

Study Location

Indicate if the research is/will be conducted at any of the following
✓ NYSPI
✓ Other Columbia University Medical Center Facilities
This protocol describes research conducted by the PI at other facilities/locations
No

Lay Summary of Proposed Research

Lay Summary of Proposed Research

This pilot trial seeks to examine feasibility, acceptability, safety, and preliminary efficacy of a new behavioral treatment for survivors of sudden cardiac arrest with clinically elevated symptoms of post traumatic stress disorder (PTSD). While several well-studied, validated treatments for PTSD exist, to date, there is no evidence-based treatment for PTSD in cardiac arrest survivors. Standard PTSD interventions targeting fear extinction and threat perception in the context of current safety pose a problem in a population that is living with an actual ongoing cardiac threat. Thus, we will be developing a *de novo* protocol for an Acceptance and Mindfulness-Based Exposure Therapy (AMBET) intervention that targets increased discriminatory perception through mindful interoceptive attention and adaptive threat responding. To assess

whether patients' medication adherence and physical activity are improved over the course of treatment, participants will be provided with a wearable device (Fitbit wristband) to monitor their physical activity.

The specific aims of this study are to: (1) develop an acceptable protocol for an AMBET intervention for survivors of sudden cardiac arrest with elevated PTSD symptoms (2) examine its safety and feasibility in a small sample of 14 patients (3) investigate acceptability and feasibility of the measurements including a physical activity monitoring device.

The subject population will consist of cardiac arrest survivors with clinically diagnosed PTSD (n=14; CAPS-5 $\geq$ 23). In Phase 1 (interview phase), with the aim to develop a treatment manual, 14 SCA survivors will be interviewed about their symptoms and evaluated for baseline assessment. In Phase 2 (treatment phase) the same participants will be treated with eight sessions of AMBET. Participants will be evaluated at baseline, at treatment mid-point (week 4), and at the end of treatment.

Background, Significance and Rationale

Background, Significance and Rationale
Clinically elevated levels of posttraumatic stress disorder (PTSD) symptoms occur in approximately 1 in 3 cardiac arrest survivors with intact cognitive function, and are associated with increased risk for future cardiac events and mortality(1),(2). Elevated PTSD symptoms have been associated with low adherence to physical activity and medication adherence in patients with elevated PTSD symptoms after other types of cardiovascular events(3),(4),(5), in part because medications and physical activity can serve as traumatic reminders, and nonadherence to cardioprotective health behaviors may explain the association between cardiac arrest-induced PTSD and poor prognosis. Given the lack of evidence-based psychological therapies for cardiac arrest survivors with PTSD, the development and testing of an acceptance and mindfulness-based exposure therapy (AMBET) protocol may be beneficial to survivors of cardiac arrest. Our long-term goal is to determine the effectiveness of this therapy on reducing psychological distress, reducing aversive associations with secondary prevention behaviors, and improving quality of life and cardiovascular outcomes.

Rationale for Intervention: Survivors of acute cardiovascular events (e.g., cardiac arrest, acute coronary syndrome) are typically encouraged to monitor for somatic cues of cardiovascular activity that might indicate recurrent events. However, threat-related attention bias is a common sequela of trauma. In cardiac patients, this hypervigilant attention to interoceptive cues of danger may serve to maintain threat perception, as arousal amplifies awareness of internal stimuli(6). PTSD symptoms have been associated with attempts to avoid distressing internal symptoms as well as to negatively influence engagement in health behaviors in both cardiac and non-cardiac populations(7),(8),(9),(10),(11).

Treatments aimed at reducing fear of interoceptive sensations in patients with various anxiety disorders are, however, not necessarily applicable to a cardiac population where negative illness appraisals and threat perception might be realistic. Furthermore, elements of interoceptive exposure frequently utilized in these treatments such as hyperventilation may not be recommended for some cardiac patients as they may provoke arrhythmias common among cardiac arrest patients. While no evidence-based treatments for

cardiac disease induced-PTSD currently exist, initial evidence has been published to suggest the safety, and potential efficacy of, imaginal exposure in cardiac patients to reduce PTSD symptoms.(12) Among PTSD treatments, exposure therapy is the most widely recommended. However, even among the most well-supported treatments for PTSD, the efficacy is moderate, and high dropout rates are well documented(13-15). The need for novel and adjunctive interventions that will improve treatment engagement and outcomes has been widely acknowledged(16), (17).

One innovative line of PTSD therapies can be found among mindfulness- and acceptance-based treatments. Although large scale RCTs are still limited, there are promising findings of treatment effects on reduced PTSD symptoms, with medium to large effect sizes(18),(19). Reported dropout rates have been low across treatments, indicating a high degree of treatment acceptability. The addition of mindfulness components to exposure therapy has been proposed to enhance the effects of exposure as well as the willingness to engage in them(20). Of particular interest for cardiac patients are findings that mindfulness-based approaches have normalized cortisol levels and reduced inflammatory biomarkers in PTSD patients, as these are physiological processes that have been implicated in the links between PTSD and cardiovascular risk(21),(22),(23). Several mechanisms have been posited to underlie the efficacy of mindfulness-based approaches including increased metacognitive awareness of interoceptive sensations and mind-body connections(24),(25). Mindfulness may additionally function as a form of exposure to aversive internal experiences and reduce distress from attempts to control thoughts and emotions(26), (27), (28). Furthermore, and contrary to the associations found between hypervigilant interoceptive awareness and psychopathology, mindful attention to interoceptive cues has been linked with adaptive, resilience-enhancing behaviors(29).

The goals of the AMBET treatment will be to reduce PSTD symptoms and hypervigilance to internal stimuli (i.e., interoceptive bias), and increase cardiovascular health behaviors (medication adherence, physical activity) following cardiac arrest. Following psychoeducation about PTSD and cardiovascular disease (CVD) related health behaviors, participants will be engaged in in vivo and imaginal exposure exercises to reduce avoidance responses. Participants will be introduced to acceptance and mindfulness-based strategies that will be practiced in session and as homework assignments. Sessions will be delivered to patients individually through HIPAA-compliant zoom-hosted video visits. A meta-analysis of remote (e.g., telepsychiatry; video-based) treatments for PTSD found these treatments superior to waitlist conditions. Compared to face-to-face treatments, videoconferencing CBT treatments did not result in significantly different PTSD outcomes at post-treatment(30).

Specific Aims and Hypotheses

Specific Aims and Hypotheses
The specific aims of this study are to: (1) develop an acceptable protocol for an AMBET intervention for survivors of sudden cardiac arrest with PTSD; (2) examine its safety and feasibility in a small sample of 14 patients; (3) investigate acceptability and feasibility of the measurements including **a** physical activity monitoring device.

Hypothesis 1: The AMBET intervention will demonstrate preliminary tolerability (<20% dropout)

Hypothesis 2: The AMBET intervention will demonstrate efficacy (pre/post decrements on psychological distress) and the recruitment goal (n=14) will be met.

Hypothesis 3: Participants will find the health behavior monitoring technology acceptable and comply with study procedures (wearing Fitbit device daily and during sleep.)

Description of Subject Population

Sample #1

Specify subject population
Survivors of sudden cardiac arrest with clinically diagnosed PTSD (CAPS-5 =23)
Number of completers required to accomplish study aims
10
Projected number of subjects who will be enrolled to obtain required number of completers
14
Age range of subject population
18-85

Gender, Racial and Ethnic Breakdown

Gender:

50% female (N:5-7)
50% male (N:5-7)

Ethnicity:
25% Hispanic
45% White
30% African-American
Description of subject population

All participants will be adult survivors of cardiac arrest who present with clinically elevated PTSD or acute stress disorder (ASD) symptoms. Patients will be evaluated at the Anxiety Disorders Clinic for potential inclusion in the study. The expected ethnicity distributions are based on population data from the CANOE patient registry. The study aims to enroll an equal number of males and females.

Recruitment Procedures

Describe settings where recruitment will occur
Referrals will be done by Dr. Sachin Agarwal's team. Dr. Agarwal is a neurointensivist and founder of the

Neuro Cardiac Comprehensive Care Clinic (N4C) at New York Presbyterian Hospital/Columbia University Irving Medical Center (CUIMC). Patients will be recruited from the Cardiac Arrest Neuropsychological Outcomes Evaluation (CANOE) study (CUIMC IRB- AAAR8497), an observational, prospective cohort study of cardiac arrest survivors discharged from CUIMC who have consented to being contacted about future studies. CANOE participants who are currently seen in-person by the CANOE team at the hospital will be provided with an IRB approved flyer by a CANOE team member informing them of the study and how to contact the study coordinator. Additionally, the study will be advertised via the Sudden Cardiac Arrest Foundation's network, other patient support and interest groups (i.e Facebook groups), and local cardiology departments informing potential study participants to contact the study team if they are interested in participation. Posting of the flyer in online support groups will be done by respective group administrators.
How and by whom will subjects be approached and/or recruited?
Potential patients already enrolled in the CANOE protocol will be asked by Dr. Agarwal's team to contact the study research assistant who will schedule a phonescreen with the patient. If patient is potentially eligible, a clinical evaluation will be conducted by the PTSD program clinicians.
How will the study be advertised/publicized?
The study will be advertised via the included recruitment flyer.
Do you have ads/recruitment material requiring review at this time?
Yes
Does this study involve a clinical trial?
Yes
Please provide the NCT Registration Number
NCT04596891

Concurrent Research Studies

Will subjects in this study participate in or be recruited from other studies?
Yes
Describe concurrent research involvement

Subjects will be recruited from CUIMC/CANOE protocol AAAR8497. No identifiable or de-identified data will be shared back with the CANOE study team.

Inclusion/Exclusion Criteria

Name the subject group/sub sample
Adult survivors of sudden cardiac arrest
Create or insert table to describe the inclusion criteria and methods to ascertain them

Criteria	Method of ascertainment

1. Males or females between the age of 18-85	Medical records demographic information
2. A PCL-5 score of ≥ 33 at screening and a CAPS-5 score ≥ 23 at intake assessment	PCL-5, CAPS-5
3. Hospitalization for cardiac arrest with cardiac etiology at any time in the past.	Medical records review

Create or insert table to describe the exclusion criteria and methods to ascertain them

Exclusion Criteria	Method of ascertainment
1. Heart failure with severe systolic dysfunction (ejection fracture ≤ 25%)	Medical records review Rationale: Patients with severe systolic dysfunction are unlikely to be able to comply with study procedures.
2. Terminal non-cardiovascular illness with life expectancy of <1 year	Medical records review and/or clinical interview Rationale: Patients with terminal non-cardiovascular illness with life expectancy <1 year are unlikely to be able to comply with study procedures due to severe limitations.
3. History of psychiatric diagnosis of psychotic episode, psychotic disorder, schizophrenia, schizoaffective disorder	SCID and clinical evaluation Rationale: Such disorders are considered to have a more chronic trajectory and there is a lack of evidence to support the use of exposure therapy and remote treatments for this population.
4. Current *severe* depression determined by a) a score of >25 on the Hamilton Rating Scale for Depression (HAM-D-17-item), and b) clinical assessment	SCID, HAM-D and clinical evaluation. Rationale: Patients with severe depression are less responsive to exposure therapy and severely depressed patients may be better served by treatments that target these symptoms first.
5. Significant cognitive impairment Defined by Cerebral Performance Category Score ≥3, and/or MMSE score of <24 neurological impairment precluding ability to complete study questionnaires	Review of medical records: Cerebral Performance Category Scale MMSE (conducted at intake) Rationale: Cognitive impairments at this level is likely to impact patient ability to complete study questionnaires and other activities as well as comprehension of study procedures required for informed consent.

6. Active suicidal ideation or behavior	Clinical interview; score of > 2 on item 3 of the Hamilton Rating Scale for Depression (HAM-D-17-item). Rationale: To ensure safety of participants, active suicidal patients will be referred to psychiatric care.
7. Current primary diagnosis of bipolar disorder	SCID and clinical evaluation. Rationale: Patients with bipolar illness are less responsive to exposure therapy and may be better served by treatments that target these symptoms first.
8. Current unstable or untreated medical illness	Clinical evaluation and medical history. Rationale: Patient safety.
9. Current drug or alcohol misuse: severe alcohol/cannabis or any other substance use disorder (except nicotine)	SCID and clinical interview. Rationale: Severe substance abuse issues should be addressed with evidence-based treatment targeting these symptoms and behaviors that are otherwise likely to interfere with treatment and ability to comply with study procedures.
10. Recent psychotropic medication change or initiation within the last 3 months	Clinical interview regarding current medication and treatment history. Rationale: to ensure safety and stability of management.
11. Initiation of other psychotherapy within the last 3 months	Clinical interview regarding current psychotherapeutic treatment history.
12. Patient resides in a state that does not permit remote research therapies to be conducted out-of-state.	Phonescreen

Waiver of Consent/Authorization

Indicate if you are requesting any of the following consent waivers
Waiver of consent for use of records that include protected health information (a HIPAA waiver of Authorization)
No
Waiver or alteration of consent
No

Waiver of documentation of consent
No
Waiver of parental consent
No

Consent Procedures

Is eligibility screening for this study conducted under a different IRB protocol?
Yes
Indicate NYSPI IRB #
7094R
Describe Study Consent Procedures
Patients will first give verbal consent for the telephone screen with a screener who has at minimum a bachelor's degree. Preliminary phone screen will be conducted as approved under Anxiety Disorders Clinic IRB #7094R. Patients who are found eligible for an intake evaluation will then be emailed a link to a REDCap e-consent. NYSPI REDCap is a HIPAA approved platform hosted on secure NYSPI servers. Patients will be informed not to sign the consent until the form is reviewed with a person that is authorized to discuss and document consent (see section "Persons Designed to Discuss and Document Consent") and who has at minimum a master's degree. After patient reads the consent form the clinician will go over the form with the patient and answer all the patient's questions. After answering all the patient's questions by the clinician patient will sign the study consent. The signed consent form is available to the study team immediately upon submission by the participant in REDCap. Throughout this process, the patient will be told that they are free to refuse to participate in the research and that participation or non-participation in research has no effect on their ability to continue to receive clinical care or services.
Indicate which of the following are employed as a part of screening or main study consent procedures
✓ Consent Form

Persons designated to discuss and document consent

Select the names of persons designated to obtain consent/assent
Amsalem, Doron
Bergman, Maja
Campeas, Raphael, MD
Eder-Moreau, Elizabeth
Neria, Yuval, PHD
Sanchez-Lacay, jose, MD
Type in the name(s) not found in the above list

Study Procedures

Describe the procedures required for this study

As shown in the study overview flow chart below, the study comprises the following procedures: 1) Eligibility assessment; 2) Baseline assessment with an independent evaluator (IE); 3) Intake interview; 4) Treatment (during which there will a separate (additional) meeting with the IE at week 4); 3) End of treatment assessment; **6**) Three-month follow-up assessment posttreatment.

The protocol will be carried out remotely. Video-visits and assessments will be conducted over HIPAA-compliant Zoom (utilizing licensed NYSPI accounts), a password protected and HIPAA compliant electronic platform. For consent forms and self-report measures, NYSPI REDCap will be utilized to gather signatures and information from patients. Patients will receive an email with a weblink to complete these on this HIPAA compliant platform and the data will be stored on secure NYSPI servers.

Approximately 7-10 days after completion of intake interview, participants will receive a package from the study team that will include the Fitbit required for study participation, along with instructions for how to use this device. Participants will be provided with a commercially available Fitbit Inspire HR, equipped with a highly sensitive accelerometer to track activity as well as sleep quantity and sleep quality characteristics (This product has previously been approved by the CUIMC IRB and used successfully in studies conducted by Center for Behavioral Cardiovascular Health). The Fitbit will be registered with a study ID and password and participants will be instructed to download the FitBit app to their phone to sync. Participants will be asked to continuously wear the Fitbit throughout the study period, including regularly charging the Fitbit once per week and wearing the device during sleep. The participant will receive push notifications to recharge the Fitbit if its battery is running low or if the Fitbit disconnects for a prolonged period of time (>24 hours).

Flow Chart of Study Procedures:

Visit 0: Eligibility Assessment (Review of medical records and phone screening). Potential patients will be asked by Dr. Agarwal's team to contact the study research assistant who will schedule a phonescreen with the patient. Alternatively, participants who respond to the flyer may also self-refer to the study by contacting the research assistant listed on the advertisement. If patient is potentially eligible after completing the phonescreen, a clinical evaluation will be conducted by the PTSD program clinicians.

Meeting 1: Consent for study participation, baseline assessment, and intake interview. Baseline assessment: Participants will meet over a HIPAA-compliant zoom video call with a trained research clinician who will administer the Clinician-Administered PTSD scale (CAPS-5) MMSE and HRSD-17. Participants will also fill out self-report measures (LEC-5, HADS, CAQ, and MAIA, the Morisky Medication Adherence Scale [MMAS-8], and four cardiac items from the Anxiety Sensitivity Index [ASI-3]) delivered to them through a weblink to a REDCap survey. Participants will then meet with the study clinician who will conduct a qualitative clinical interview (interview guide attached) regarding participant’s experience with PTSD symptoms reported in CAPS-5.

Following meeting 1, eligible participants will be mailed the study devices and instructions for how to use them.

Meeting 2-9
Once weekly AMBET sessions. These visits will last 90 minutes and will be conducted remotely over HIPAA-compliant zoom video call. Treatment content described below.

Midpoint Assessment: Between treatment session 4 and 5 a visit with an IE will take place over HIPAA-compliant zoom video call at which participants will complete self-ratings via REDCap survey and the IE will administer clinical measures (CAPS-5, HamD-17, CGI).

Visit 9: End of treatment arm and posttreatment evaluation. Following the final treatment session, participants will meet with IE over HIPAA-compliant zoom video call for clinical measures (CAPS-5, HamD-17, CGI) and given an opportunity to provide feedback on the treatment. Participants will also fill out self-report measures.

Visit 10: Participants will once again meet with IE at three months posttreatment for forty-five minutes over HIPAA-compliant zoom video call for a clinical assessment (CAPS-5, HamD-17, CGI). Participants will also fill out self-report measures (PCL-5, ASI-3, HADS).

Treatment:
Treatment sessions will be carried out virtually over a zoom video call. Treatment sessions will be video recorded to ensure integrity and treatment fidelity.

Acceptance and Mindfulness Based Exposure Therapy (AMBET)
A manual will be developed to provide clear structure for the course of treatment and will be forwarded to the IRB when a more complete draft has been finalized. All study therapists conducting the AMBET sessions will be trained clinicians at master's or PhD level who have completed training in the protocol and who have experience delivering exposure therapy to treat traumatic stress. Study therapists will be supervised by a licensed psychiatrist. The clinician will first provide psychoeducation regarding PTSD symptoms that can ensue after medical trauma and then introduce the rationale for the treatment. The principal treatment content can be summarized as: explore personal values and impact of avoidance behaviors on well-being, increase functional interoceptive awareness and cardiovascular symptom discrimination through mindfulness and defusion exercises, approach feared events and activities through values-based exposure, and create meaning and cohesion through flexible perspective taking. The protocol will primarily target:

1. Maladaptive behavioral responses related to fear (particularly avoidance)
2. Hypervigilant interoceptive attention and catastrophic bias
3. Engagement in heart-healthy behaviors such as physical activity and medical adherence.

The specific interventions are:

A) Mindfulness exercises to increase functional interoceptive awareness and discrimination of benign/malign symptoms for more accurate threat perception and adaptive responding.

B) Exposure exercises to physical sensations that are similar to cardiac symptoms (e.g., palpitations due to

physical activity or anxious arousal) to reduce symptom-related hypervigilance and increase adaptive threat responding. Values exploration to increase motivation for engagement in in-vivo, imaginal, and interoceptive exposure exercises.

C) Increased physical activity to reduce depressive symptoms and improve cardiovascular health.

Therapist adherence to protocol: All sessions will be videotaped and reviewed for adherence to the treatment protocol.

You can upload charts or diagrams if any

Criteria for Early Discontinuation

Criteria for Early Discontinuation
Principal Investigator and/or Co-Principal Investigators, will review (at minimum) all currently enrolled patients in a weekly meeting.
1. Requests to withdraw from the study.
2. Elevated level of distress, for PTSD patients demonstrated by a score of 6 or higher on the weekly CGI for two consecutive weeks, unless the distress is due to an acute transient event (to be evaluated by treating clinician, PI, and study psychiatrist). The CGI will be administered to consider both PTSD and Depression symptomatology.
3. Significant suicidal ideation, as assessed by the study therapist and/or by the HAM-D-Item 3 and/or the BDI-II suicide item
4. Clear-cut deterioration in social or occupational functioning as assessed by the clinician.
5. Non-compliance with protocol requirements.
6. New or inter-current illness that prevents the patient from complying with the protocol.

In the event discontinuation criteria are met, the treating clinician will meet with the patient to explain the necessity of termination, provide appropriate referrals, and assist in patient transfer as needed.

Treatment via IRB #8017 will continue until such time as a referral is complete.

Assessment Instruments

Create a table or give a brief description of the instruments that will be used for assessment

Treatment credibility will be measured immediately after the first therapy session with the Treatment Expectancy Questionnaire (TEQ)(31). This measure contains 4 items scored using a 10-point Likert scale (0 “No expectancy/credibility” to 9 “Very strong expectancy/credibility”) concerning how logical the treatment seems, participant confidence in undergoing the treatment and recommending it to others, and

their expectations for the treatment's success. The TEQ has good internal consistency and test-retest reliability.

Satisfaction with AMBET intervention will be assessed using the Client Satisfaction Questionnaire (CSQ-3)(32). The CSQ-3 has good test-retest reliability, internal consistency, and sensitivity to treatment.

Fear Related Mechanisms: 1) Interoceptive Attention Style will be measured by the Multidimensional Assessment of Interoceptive Awareness (MAIA)(33). The MAIA is a self-report measure that assesses regulatory aspects of interoceptive processing and differentiates between anxiety/hypervigilance driven interoceptive attention and acceptance/mindfulness-based attention. 2) Cardiac Anxiety will be assessed using the Cardiac Anxiety Questionnaire (CAQ)(34). The CAQ is an 18-item self-report measure that assesses heart-focused anxiety across the three subscales fear, avoidance, and attention. 3. Interoceptive threat bias will be measured using the four selected cardiac-related items from the physical subscale of the Anxiety Sensitivity Index.(35)

Psychological Distress: 1) PTSD will be measured using the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5)(36) at intake and post treatment. PCL-5 will be used for screening and prior to weekly sessions during treatment. 2) Self-reported depression and general anxiety will be measured by Hospital anxiety and depression scale (HADS)(37) at intake and post-treatment. A clinician will also assess depressive symptoms using Hamilton Rating Scale for Depression (HRDS-17)(38) at these time points, and Beck Depression Inventory (BDI-II)(39) will be used as a symptom measure prior to each session.

Health behaviors: Adherence to a representative CVD medication (typically, beta-blocker) will be assessed using Morisky Medication Adherence Scale (MMAS-8) (40). Physical activity will be measured continuously for 3-months using a wrist-worn Fitbit Charge accelerometer. The Fitbit device has been chosen because it has been validated for physical activity and its heart rate monitor performed well against ECG for heart rate changes at relatively low levels of physical activity (41), (42).

Prior trauma exposure will be measured using the Life Events Checklist (LEC-5)(43).

Clinical severity and change will be measured using the Clinical Global Impression Scale (CGI)(44).

Psychiatric history will be assessed using the Structured Clinical Interview for DSM Disorders (SCID).(45).

Clinician Administered PTSD Scale (CAPS-5) (30 Minutes)
Beck Depression Inventory (10 minutes)
Clinical Global Impression – Severity Scale (CGI-S) (5 minutes)
Clinical Global Impression – Change Scale (CGI-S) (5 minutes)
PTSD Checklist (PCL-5) (5 minutes)
Hamilton Depression Rating Scale (HDRS-17) (10 minutes)
Client Satisfaction Questionnaire (CSQ-3) (2 minutes)
TEQ (2 minutes)
Life Events Checklist (LEC) (5 minutes)
CSQ-3 (5 minutes)
MAIA (5 minutes)

CAQ (5 minutes)
HADS (5 minutes)
SCID (30 minutes)
MMSE (20 minutes)
MMAS-8 (5-minutes)
ASI-3 (2 minutes)

Please attach copies, unless standard instruments are used

Research Related Delay to Treatment

Will research procedures result in a delay to treatment?
Yes
Maximum duration of delay to any treatment
All effort will be made to arrange an intake as soon as possible, within a few days of initial contact if possible. Clinical staff will meet weekly to discuss new intakes, and disposition to active treatment will be made as soon as patients have been found eligible and have signed informed written consent. We expect that patients should enter treatment within two weeks of initial intake date. This allows time to review the qualitative information from the initial intake interview to develop individualized treatment plans within the scope of the treatment protocol as well as for delivery of Fitbit device and HIPAA-compliant zoom video call training. The patient will have immediate access to the intake clinician and study-team psychiatrist if he or she presents with an emergent clinical issue.
Maximum duration of delay to standard care or treatment of known efficacy
The maximum delay before active treatment of known efficacy is offered will be 12 weeks from baseline assessment. However, we are not excluding survivors who are currently in other treatment (provided there has been no change in treatment in previous three months) so for these there will be no delay in treatment.
Treatment to be provided at the end of the study
Participants will be referred for further treatment as needed. The types of referrals offered may include general referrals to other treatment clinics and centers in the tri-state area, or more specifically referrals may be offered as preferred to trauma-focused therapists, low-cost therapists and clinics, or to veteran specific services.

Clinical Treatment Alternatives

Clinical treatment alternatives
Patients who do not participate in research will be referred to treatments for PTSD in the community, such as cognitive behavioral therapy, prolonged exposure therapy, interpersonal psychotherapy for PTSD, or psychopharmacology depending on the clinical evaluation and their expressed preferences.

Risks/Discomforts/Inconveniences

Risks that could be encountered during the study period
Cardiovascular Risk: Physical activity following cardiac arrest is generally recommended and will be included in the treatment plan only if approval is obtained from the patient's treating physician. To ensure patient safety during sessions, participants will be required to confirm the address where they are located at the start of each remote session as well as to provide the study team with the telephone number to an emergency contact should any medical emergency occur during the remote procedures. Additionally, patients will sign a release of information form between the study team and patient's treating physician. The study team includes an internist and a neurologist who can both be called upon to determine if urgent medical attention is needed, and advise for the necessary action (e.g., calling an ambulance). Sessions and assessments will be scheduled during times when at least one of the study team MD's are available to be contacted for urgent consultation according to a rolling schedule of on-call responsibilities. Clinicians and research staff will have a phone available during sessions and patient meetings to be able to call for back-up while remaining in the HIPAA-compliant zoom session, and the MD can join the zoom call via either weblink or phone. Before enrolling any patients, all research and clinical team members who do not hold an MD will receive training in when to contact a study doctor for medical consultations and common symptoms of cardiovascular events such as stroke or myocardial infarctions warranting immediate 911 call. This training will be provided by Dr. Ian Kronish over HIPAA-compliant zoom and will be recorded for asynchronous viewing to ensure all team members are adequately trained.

Psychological Distress: Exposure treatments pose some risk of psychological discomfort. Participants may find that discussing trauma related memories or facing feared situations may increase emotional distress. The treatment protocol will start with introduction to grounding techniques such as diaphragmatic breathing and mindfulness-based techniques for distress management and emotion regulation, and participants will practice these in session with clinician. Patients will also be informed that they can contact their clinician between sessions for support and to troubleshoot homework exercises. The treatment will be delivered by a clinician with experience in treating PTSD with exposure therapy. Additionally, as with any time-limited treatment, patients may feel uncomfortable when treatment ends. This is an issue that patients will be encouraged to discuss with their therapist, and treatment will be provided by a clinician experienced in delivering short-term treatments.

Loss of Confidentiality: A potential risk from this study is the violation of the participant's privacy, since patient medical information will be used as a source of data. Special protections against this risk are provided (see below).

Identification of Severe Mental Illness: There is the possibility that we will discover during screening that participants have significant cognitive or alcohol/drug impairments that disqualify them from participating in the study. It may be discovered during screening or during assessment that a participant has severe depression that warrants immediate treatment. Should the subject express suicidal ideation at any time during the assessment or treatment, the study clinician will be contacted immediately to assess the subject and to determine the appropriate course of action.

During intake, treatment and assessment, participants will be required to confirm the address where they are located at the start of each remote session as well as to provide the study team with the telephone number to an emergency contact. Participants will be required to provide a response to suicidality item on BDI-II prior to each session. If a patient would endorse suicidal thoughts, clinician or assessor would further assess risk.

Clinicians in our clinic are well trained and experienced in conducting suicide assessments and have additional completed the Comprehensive Suicide Risk Assessment online training course through the Center for Practice Innovations. Research assistants have access to clinician backup during all scheduled interactions with research participants and are instructed to immediately contact a clinician if there are endorsements or disclosures of suicidal ideation for further assessment. In case of active suicidal ideation or increased risk, clinicians will alert supervising psychiatrist immediately over phone while remaining on HIPAA-compliant zoom meeting with patient for further action (safety planning and/or contacting emergency services as appropriate). In cases of acute risk, clinician will call 911 while remaining on HIPAA-compliant zoom meeting with patient and additionally alert the supervising psychiatrist. Clinician may contact 911 with or without patient as needed. Patient will be informed of these procedures and exemptions to confidentiality in such situations during the informed consent procedures. Other options for addressing suicidal ideation will include safety planning with clinician, referring for urgent (same day) evaluation and treatment in an outpatient clinic, or emergency room evaluation and hospitalization. Similar practices will be used for other emergencies, including but not limited to psychosis, homicidal or violent thoughts, or an acute change in a subject's physical status.

There are no known long-term risks from any study activities.

Interviews/assessments: Some subjects may find the interviews and assessments anxiety provoking or upsetting. Subjects will be informed that they may choose not to answer specific questions and may stop the interview at any time if they are feeling uncomfortable. Trained evaluators will be sensitive to patient vulnerabilities, and every effort will be made to ensure patients' comfort.

Exposure Therapy: (1) Patients may become distressed by the discussion of sensitive or painful material or by the experience of strong emotions during treatment. Some patients may find psychotherapy embarrassing or anxiety-provoking, whether or not the treatment presses them to confront reminders of past traumas. A risk of this treatment is that it may be ineffective and that patients may not improve or even worsen. Therapists experienced in treating PTSD patients will assess this distress continually as part of treatment and will ask for additional evaluations or PI intervention when clinically appropriate. Every effort will be made to ensure patients' comfort during treatment, and patients will be withdrawn if needed.

Video recording: Some patients may feel uncomfortable about the treatments being video recorded (necessary for supervision and treatment integrity checks). However, this will be a required procedure. The purpose of the videotaping will be explained, confidentiality will be respected, and tapes will be erased after the spot checks or following supervision. Informed consent for recording will be obtained. Patients will be informed that they can withdraw their consent at any time, upon which time the recordings will be erased. Recordings will be made using HIPAA-compliant software through Zoom and stored on password protected NYSPI servers.

Audio recording: Some patients may feel uncomfortable about the treatment sessions being audio recorded (necessary for supervision and treatment integrity checks). However, this will be a required procedure. The purpose of the audiotaping will be explained, confidentiality will be respected, and tapes will be erased after the spot checks or following supervision. Informed consent for taping will be obtained. Patients will be informed that they can withdraw their consent at any time, at which point the recordings will be erased.

Recordings will be made using HIPAA-compliant software through Zoom and stored on password protected NYSPI servers.

Describe procedures for minimizing risks

Other Procedures for Minimizing Risk:

1) Careful medical and psychiatric screening to identify patients for whom risk for potential adverse effects are elevated. Such patients will be excluded from the study. As an example, an actively suicidal patient would be excluded from study participation as per the exclusionary criteria and appropriate clinical treatment provided.

2) Patients with any of the following will be removed from research and treated openly or as clinically indicated: a) the occurrence of assaultive or illegal behavior; b) the occurrence of active suicidal ideation at any point during the trial as assessed by clinical interview; c) behaviors while intoxicated that are a danger to him/herself or others.

3) Inclusion of psychoeducation about PTSD, the treatment process and memory triggers within the therapeutic framework and in-session practice of emotion regulation techniques.

4) Careful monitoring of patients during pretreatment and study participation by experienced clinicians. Patients will see the same clinician for each of their treatment visits.

6) Ability to remove any patient from the study who evidences significant clinical deterioration during treatment. Provisions will be made for appropriate clinical care of such patients.

7) All data will be coded and stored on secure servers and password protected drives to ensure confidentiality. All assessment and session procedures will be conducted remotely, using HIPAA compliant platforms (NYSPI REDCap and licensed Zoom accounts).

Methods to Protect Confidentiality

Describe methods to protect confidentiality
All data collected will be kept confidential and used for research purposes only. Patient charts will be kept on secure and password protected servers. **Identifiable data will be limited to secure, password-protected NYSPI servers. Some completely deidentified data may be stored on secure, password-protected CUIMC servers.** Access to research records is restricted to research staff and Federal, State, and Institutional regulatory authorities. No subject's identifying data will be published. All assessment and session procedures will be conducted on HIPAA compliant platforms (NYSPI REDCap and licensed Zoom accounts). No data (identifiable or de-identified) will be shared with the CANOE study team.
Will the study be conducted under a certificate of confidentiality?
No

Direct Benefits to Subjects

Direct Benefits to Subjects

This study is not designed to benefit participants directly.

Compensation and/or Reimbursement

Will compensation or reimbursement for expenses be offered to subjects?
Yes
Please describe and indicate total amount and schedule of payment(s).
Include justification for compensation amounts and indicate if there are bonus payments.

Participants will be reimbursed for their time participating in the study. Participants will receive $70 for completing the initial interview and assessment and $50 for completing the midpoint assessment. At the end of treatment, participants will be paid $50 for completing the post-treatment evaluation and up to $80 for completing all session survey ($10 for each session survey). Participants will receive an additional $20 for completing the three-months posttreatment follow-up assessment. Participants will only be compensated for the tasks and surveys that have been completed. The maximum compensation that can be received for participation and completion of all study tasks is $270. Pre-loaded PayCards will be delivered individually within four weeks following each compensation point by mail, in non-identifying manila envelopes. Participants will be permitted to keep the Fitbit at the end of the study, at which point they can set it up with their own account.

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