

# Acceptance and Mindfulness-Based Exposure Therapy for PTSD After Cardiac Arrest:

## An Open Feasibility Trial

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### Abstract

**Background:** Posttraumatic stress disorder (PTSD) is prevalent after surviving sudden cardiac arrest (SCA). SCA-induced PTSD is associated with increased mortality and cardiovascular risk, yet no psychotherapeutic treatment has been developed and tested for this population. Exposure therapy is standard treatment for PTSD, but its safety and efficacy remain unconfirmed for SCA survivors: current protocols do not address their specific disease course and have high attrition. Mindfulness-based interventions are typically well-tolerated and have shown promise in reducing PTSD symptoms from other traumas.

**Objective:** This study sought to determine feasibility, safety, and preliminary efficacy of acceptance

and mindfulness-based exposure therapy (AMBET), a novel SCA-specific psychotherapy protocol combining mindfulness and exposure-based interventions with cardiac focused psychoeducation to reduce symptoms and improve health behaviors in patients with post-SCA PTSD.

**Methods:** We conducted an open feasibility pilot study from January 2021 to April 2022 with a small sample (N=11) of SCA survivors meeting DSM-5 PTSD criteria. AMBET comprised eight 90-minute remotely delivered individual sessions. Clinical evaluators assessed PTSD symptoms using the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) at baseline, midpoint, posttreatment, and 3-month follow-up.

**Results:** Ten (91%) of 11 enrolled patients completed treatment.

Satisfaction was high and patients reported no adverse events. PTSD symptoms significantly improved statistically ( $P<.001$ ) and clinically with large effect sizes ( $g=1.34-2.21$ ) and treatment gains sustained at 3-month follow-up. Posttreatment, 80% of completers (n=8) showed significant treatment response, 70% (n=7) with PTSD diagnostic remission. No patient reported symptom increases.

**Conclusions:** This initial trial found AMBET feasible, safe, and potentially efficacious in reducing PTSD following SCA. These encouraging pilot results warrant further research.

**Trial Registration:** ClinicalTrials.gov identifier: NCT04596891

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Sudden cardiac arrest (SCA) is a leading cause of death in the United States. With survival rates around 10%, American hospitals discharge approximately 75,000 survivors annually.<sup>1</sup> Life after clinical death is frequently accompanied by psychological distress, as patients live with the knowledge that their bodies have fatally failed them once and could do so again. Having fortuitously survived, they often face a new reality, needing to adapt to unexpected, frightening medical status and limitations. Interviewed survivors have described SCA as a traumatic event.<sup>2</sup> Symptoms of what we today call posttraumatic stress disorder (PTSD) have been reported since the invention of cardiopulmonary resuscitation.<sup>2</sup>

At hospital discharge, 1 in 3 survivors screens positive for likely PTSD by self-report.<sup>3</sup> Like Lazarus, who reportedly never smiled in his 30 years post resurrection,<sup>4</sup> the SCA population needs a focused intervention.

Beyond emotional suffering, elevated PTSD symptoms following SCA are associated with increased risk for future adverse cardiac events and mortality.<sup>5</sup> Although this linkage is likely multifactorial, PTSD induced by non-cardiac events also carries elevated cardiovascular disease risk. This well-established relationship has been hypothesized<sup>6</sup> to reflect 2 main pathways: chronically activated physiological stress responses and impaired cardiovascular health behaviors

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## Clinical Points

- PTSD following sudden cardiac arrest is common, but no psychotherapeutic treatment has been tested for this population, and little is known about safety and efficacy of interventions.
- Acceptance and mindfulness-based exposure therapy, a brief and targeted treatment combining mindfulness and exposure interventions, was found helpful in reducing PTSD symptoms following cardiac arrest survival.

such as avoiding physical and social activities. Despite calls to identify effective treatments for cardiac-induced PTSD,<sup>3,7,8</sup> no trials have been published.

Multiple efficacious PTSD treatments exist, with exposure-based cognitive behavioral therapy (CBT) treatments showing the greatest evidence.<sup>9</sup> Some aspects of existing protocols may not suit SCA survivors, however. First, psychopathology following events occurring while unconscious and without explicit memory were not recognized as PTSD symptoms before *DSM-5*, and such presentations require substantial adaptation of most exposure protocols. Some studies have found brain injury and neurogenic amnesia, frequent post-SCA sequelae, associated with greater attrition and less benefit from standard PTSD treatments,<sup>10</sup> whereas other studies have not.<sup>11</sup> Furthermore, standard treatments are generally designed for administration in the context of current safety, whereas SCA survivors typically live with ongoing cardiac threat and recurrence risk.<sup>1</sup> Many survivors bear implanted resuscitation devices that constantly remind them of this. As enduring cardiac threat is central to maintaining fear and hypervigilance for acute cardiac event survivors,<sup>7</sup> interventions targeting cognitive distortions and challenging beliefs may less suit a population whose negative illness appraisals and threat perception may be realistic.

Second, even using the best-supported PTSD treatments, many patients do not recover,<sup>12</sup> dropout is considerable,<sup>13–15</sup> and hyperarousal symptoms and sleep disturbance remain common even among treatment responders.<sup>16</sup> These limitations and needs for increased accessibility and efficiency have yielded widespread acknowledgment<sup>13,17–19</sup> of the need for novel interventions to improve treatment engagement and outcomes.

Mindfulness- and acceptance-based treatments constitute one innovative line of PTSD therapies. Large randomized controlled trials are scarce, but promising findings from general PTSD samples indicate reduced symptoms with medium to large effect sizes and low attrition.<sup>20</sup> Adding mindfulness components to exposure therapy purportedly enhances both willingness to engage in exposure and consequent outcomes.<sup>21</sup> Importantly for

cardiac patients, mindfulness-based approaches have normalized cortisol levels and reduced inflammatory biomarkers in PTSD patients, physiological processes linking PTSD and cardiovascular risk.<sup>22,23</sup> Mindfulness may also provide a form of exposure to aversive internal experiences and reduce distress from attempts to control thoughts and emotions.<sup>24</sup> Furthermore, contrasting with associations found between hypervigilant interoceptive awareness and psychopathology, mindful attention to interoceptive cues has been linked to adaptive, resilience-enhancing behaviors.<sup>25</sup>

This novel pilot study developed and tested the feasibility, safety, and preliminary efficacy of acceptance and mindfulness-based exposure therapy (AMBET), the first targeted protocol for SCA-induced PTSD, combining exposure interventions with mindfulness and cardiac-specific psychoeducation to reduce PTSD symptom burden and enhance adaptive fear-response. We further explored AMBET effects on cardioprotective health behaviors including daily step counts, sedentary behavior, and sleep duration.

## METHODS

### Intervention

Treatment development drew on reviews of the treatment literature and study team experience in delivering evidence-based PTSD and mindfulness interventions. Reviews of evidence-based CBT-spectrum PTSD treatments suggest that the shared active components of successful treatments are psychoeducation, emotion regulation, cognitive processing, and meaning making.<sup>26</sup> Our draft manual, theoretically anchored in behavioral therapy principles, incorporated interventions and strategies targeting these areas using acceptance and mindfulness-based interventions. Exposures followed the inhibitory learning model.<sup>27</sup> A patient-centered approach based on qualitative data from SCA survivor interviews refined the protocol to ensure that treatment addressed domains patients deemed relevant. We hypothesized that AMBET would (1) reduce PTSD symptoms, including hypervigilance to internal bodily stimuli (interoceptive bias), and (2) improve cardiovascular health behaviors (physical activity, sleep) post cardiac arrest.

AMBET comprised eight 90-minute weekly sessions. Developed during the COVID-19 pandemic, this individual teletherapy is delivered via synchronous video session (Zoom), with weekly assigned home practice.

Following psychoeducation about PTSD and cardioprotective health behaviors, therapists introduce patients to mindfulness practices for emotion regulation, stress reduction, and exposure to internal stimuli. These are followed by individually tailored in vivo exposures that evoke fear responses (eg, hearing sirens, reading about SCA deaths, physical activity) to reduce avoidance responses; imaginal exposure (eg, reviewing memories

**Table 1.**  
**Treatment Overview**

Module	Clinical target	Clinical focus
<b>Session 1: Introduction and Assessment</b>	Information/consent, case formulation, and goal setting	Psychoeducation, normalization, treatment planning, rapport building
<b>Sessions 2 and 3: Mindfulness and Acceptance</b>	Distress tolerance and symptom discrimination	Emotion regulation and interoceptive awareness
<b>Sessions 4 and 5: Approach and Activation</b>	Heart-healthy behaviors	Values-based exposure and clarification
<b>Sessions 6 and 7: Trauma Narrative</b>	Adaptive meaning-making	Cognitive processing and defusion
<b>Session 8: Conclusion</b>	Relapse prevention	Coping skills and tracking

**Table 2.**  
**Demographic Data**

Participant characteristics	Value <sup>a</sup>
<b>Age, mean ± SD, y</b>	51.55 ± 9.1
<b>Gender, female</b>	7 (64)
<b>Race-ethnicity</b>	
Hispanic	0 (0)
Non-Hispanic White	10 (91)
Non-Hispanic Black	1 (9)
Non-Hispanic Asian	0 (0)
Native American/Pacific Islander	0 (0)
Other	0 (0)
<b>Employment status</b>	
Employed full-time	5 (46)
Employed part-time	3 (27)
Unemployed	2 (18)
Disabled	1 (9)
<b>Marital status</b>	
Married	8 (73)
Living with partner	1 (9)
Divorced	1 (9)
Never married	1 (9)
<b>Level of education</b>	
High school	2 (18)
College degree (2- or 4-year)	5 (45)
Graduate degree	4 (36)
<b>Diagnosis</b>	
Posttraumatic stress disorder	11 (100)
Major depressive disorder	9 (84)
<b>Prior trauma exposure</b>	6 (54)

<sup>a</sup>Values expressed as n (%) unless otherwise noted.

from waking in hospital or medical interventions); and composing a trauma narrative that patient and therapist process for adaptive meaning-making. Table 1 describes session content and focus. The AMBET manual outlines specific session activities, clinical management guidelines, and SCA information and includes handouts and worksheets for home practice.

Study therapists were 2 master's-level clinicians (M.B., E.E.-M.) with 14 and 8 years, respectively, of psychotherapy experience, including exposure-

based CBT and treatment of PTSD. Both trained in recognizing and responding to acute cardiovascular events. One clinician treated 7 of the cases; the other, 4. A psychiatrist extensively experienced in psychotherapy trials provided weekly supervision. All treatment sessions were recorded for supervision and fidelity checks.

## Study Design

This open trial assessed preliminary AMBET feasibility, safety, and patient acceptance. The New York State Psychiatric Institute (NYSPI) institutional review board approved the study, which was registered on ClinicalTrials.gov (NCT04596891) and conducted between January 2021 and April 2022.

## Eligibility

Patients were adult US residents meeting *DSM-5* PTSD criteria assessed by the Clinician-Administered PTSD Scale for *DSM-5* (CAPS-5,<sup>26</sup> cued to SCA) > 3 months following SCA survival. Exclusion criteria included lack of English fluency; current psychosis; bipolar disorder; acute suicidal risk; recent (< 3 months) psychotropic medication change; severe substance use disorder; severe cognitive impairment (Mini Mental State Examination<sup>28</sup> < 23); and severe heart failure (ejection fraction < 25%) or other medical condition with < 1 year life expectancy. Demographic data and medical and psychiatric history (Table 2) were collected during initial phone screen and baseline clinical interview.

## Measures

Recruitment and retention feasibilities were defined a priori as (a) > 75% of eligible participants electing to enroll in the study and (b) ≥ 10 completed treatments from a maximum recruitment of 14 eligible participants. This maximum of 14 was selected to reflect attrition rates comparable to gold-standard PTSD treatments.

Treatment tolerability was further assessed using the patient-rated Client Satisfaction Questionnaire (CSQ-3). The CSQ-3 has shown good internal consistency and test-retest reliability for psychotherapy patients. Internal reliability for this study was acceptable ( $\alpha = .68$ ). Responses

rated on a 4-point scale yield total scores ranging from 4 to 12; higher scores indicate greater satisfaction. Responses have correlated significantly with attrition, session attendance, and self-reported symptom change.<sup>29</sup>

Any patient-reported injury, problem, or unfavorable experience, elicited by open-ended clinician inquiry or spontaneously volunteered, was recorded following each patient encounter.

All sessions were videorecorded, with 10% of sessions randomly selected and rated using a structured fidelity form. Eight items assessed on a 7-point scale covered completing session activities, homework assignment and review, use of behavioral theory in psychoeducation and rationale, absence of proscribed elements (eg, psychodynamic or cognitive interventions targeting increased control rather than acceptance), and overarching manualized therapy factors: eg, establishing a therapeutic alliance, fostering autonomy and independence, and maintaining an accepting and nonjudgmental stance. Two independent raters without other study involvement reviewed each recording.

## Outcomes

Clinical evaluators assessed PTSD diagnosis and symptom severity at baseline, midpoint (following session 4), posttreatment (following session 8), and 3 months posttreatment by CAPS-5, the canonical PTSD assessment. The well-validated, reliable CAPS-5 shows good sensitivity to change,<sup>30</sup> with good internal reliability in this study ( $\alpha = 0.81\text{--}0.86$  across administrations). The 17-item Hamilton Depression Rating Scale (HAM-D-17),<sup>31</sup> a standard measure with well-established psychometric properties,<sup>32</sup> measured depressive symptoms. Study internal consistency was acceptable ( $\alpha = 0.68$ ). The Structured Clinical Interview for *DSM-5* (SCID-5)<sup>33</sup> determined comorbid diagnoses. Clinic assessors routinely underwent interrater reliability checks on these instruments. CAPS-5 intraclass correlation coefficient (ICC) ratings for the 4 study raters was 0.97 (95% CI = 0.92–0.99), with  $k = 1$  for PTSD diagnosis.

At all assessment points and before each weekly session, patients completed the PTSD Checklist for *DSM-5* (PCL-5),<sup>34</sup> cued to SCA, and the Beck Depression Inventory-II (BDI-II).<sup>35</sup>

The Multidimensional Assessment of Interoceptive Awareness (MAIA-2)<sup>36</sup> measured interoceptive attention style. This self-report measures regulatory aspects of interoceptive processing and differentiates between anxiety/hypervigilance-driven interoceptive attention and acceptance/mindfulness-based attention. The MAIA-2 comprises 37 items across 8 scales, with higher scores more adaptive. Interoceptive threat bias was measured using the 3 Anxiety Sensitivity Index (ASI)<sup>37</sup> physical subscale cardiac items, with higher scores indicating greater cardiac-related anxiety.

The study provided a wrist-worn Fitbit HR Inspire device to continuously measure activity and sleep. Patients were instructed to wear it throughout, removing it only for recharging and weekly syncing.

## Procedure

Adult US SCA survivors were recruited through outreach calls to patients enrolled in an observational cohort study at a large metropolitan hospital and by recruitment flyer distributed via the Sudden Cardiac Arrest Foundation newsletter. Figure 1 presents the enrollment process. The first 16 callers were offered a phone screen. Those who met initial eligibility (PCL-5  $\geq 33$ ) were offered clinical assessment to determine PTSD diagnosis and inclusion/exclusion criteria.

Four trained clinical assessors had at minimum master's degrees. Due to study budget limitations, 2 assessors were study clinicians but did not assess their own patients. Patients received compensation for completing assessments (maximum \$250).

## Data Analysis

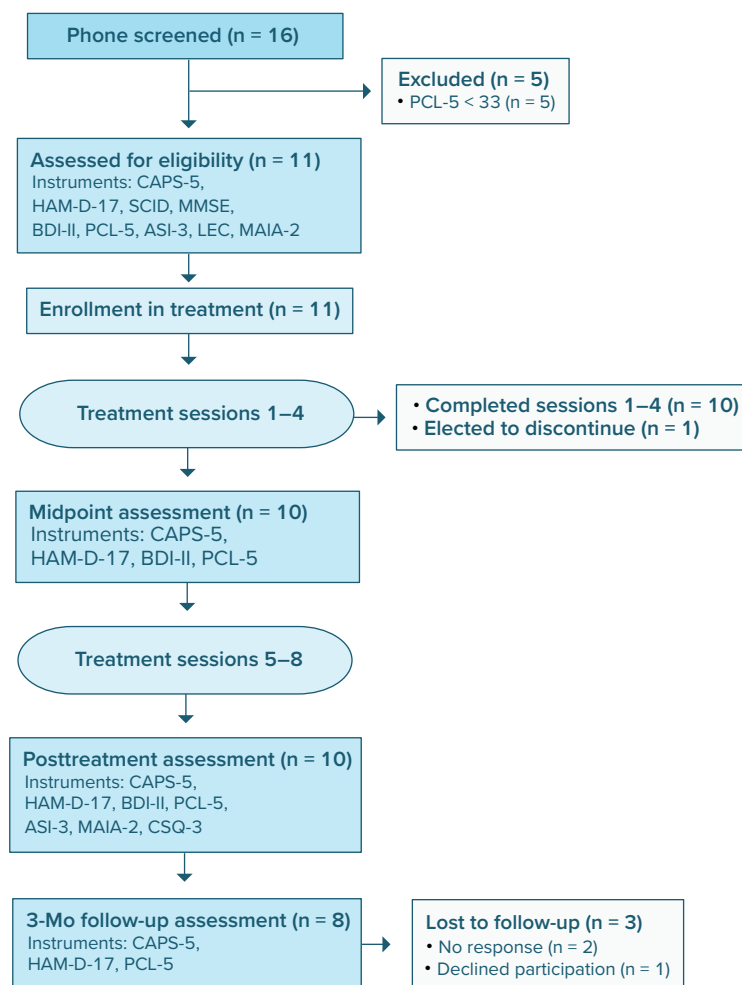
Study analyses employed SPSS Statistics version 28.0. This feasibility study was not powered to detect treatment effects.<sup>38</sup> Separate repeated-measures analyses of variance (ANOVAs) conducted for CAPS-5 and HAM-D scores over time explored treatment effects on psychiatric symptoms. For completers, paired sample *t* tests compared symptoms at baseline, posttreatment, and 3-month follow-up using all available data. Hedges' *g* was computed to determine effect sizes. Descriptive statistics described the proportion of patients achieving PTSD remission (defined a priori as no longer meeting PTSD diagnostic criteria and CAPS-5 score  $\leq 23$ ) or clinically significant response ( $\geq 30\%$  reduction from pretreatment CAPS-5).<sup>18,39–41</sup> To classify HAM-D-17 depression severity, we followed recommendations of Zimmerman et al<sup>42</sup>: not depressed (0–7) and mild (8–16), moderate (17–23), and severe ( $\geq 24$ ) depression.

We compared the first recorded 7,200 minutes of Fitbit actigraphy use (confirmed by pulse recording) post account activation, which defined baseline, to final treatment week 7,200 minutes in separate paired samples *t* tests for average daily steps, sedentary minutes, and minutes asleep ( $n = 6$ ). Analyses excluded patients lacking 7,200 minutes of final week active wear ( $n = 4$ ).

## RESULTS

Table 2 presents patient baseline characteristics. Seven women and 4 men aged 36 to 65 enrolled. Ethnoracial composition was 91% non-Hispanic White, 9% non-Hispanic Black. Time since SCA ranged from 10 to 71 months (mean = 29.5; SD = 21.0). Of 7 patients fitted with implantable cardioverter-defibrillators post-SCA, 3 subsequently experienced either repeated SCA or shocks from their devices. Six reported other, pre-SCA

Figure 1.

**Enrollment Flowchart: Steps to Enrollment, Assessment Points, and Instruments<sup>a</sup>**

<sup>a</sup>Total pool of patients expressing interest: N=74.

Abbreviations: ASI-3=Anxiety Sensitivity Index-3, BDI-II=Beck Depression Inventory-II, CAPS-5=Clinician-Administered PTSD Scale for *DSM-5*, CSQ-3=Client Satisfaction Questionnaire, HAM-D-17=Hamilton Depression Rating Scale, 17-item, LEC=Life Events Checklist, MAIA-2=Multidimensional Assessment of Interoceptive Awareness, MMSE=Mini Mental State Examination, PCL-5=PTSD Checklist for *DSM-5*, SCID=Structured Clinical Interview for *DSM-5*.

trauma exposure but met PTSD criteria based on SCA. One reported past PTSD with pre-SCA recovery. All patients reported PTSD symptoms starting within 6 months post-SCA. Nine (82%) patients met criteria for comorbid current major depressive disorder (MDD). Six had previously attended post-SCA psychotherapy without PTSD symptom remission. Three had previously taken antidepressant medication, but none received psychotropic medication within 3 months of or during the study. Mean baseline CAPS-5 score was 36.7 (SD = 7.4).

Recruitment and retention goals were achieved (Figure 1): 10 of 11 patients completed all AMBET sessions and posttreatment evaluation. One (9%) dropped out before

session 4. Eight patients completed the 3-month follow-up assessment. Patients lacking posttreatment (n = 1) or follow-up data (n = 2) did not significantly differ from completers on age, gender, ethnicity, or baseline symptom severity. Patients reported no adverse study events. CSQ-3 showed very high treatment satisfaction (mean = 10.9/12; n = 10). Treatment fidelity was high (mean = 51/56) with good interrater reliability ( $k = 0.80$ ). Fidelity ratings and outcomes did not significantly differ by clinician.

Table 3 presents mean clinical symptom scores and effect sizes over the 4 time points, showing decrease across all measures. Table 4 describes clinically significant symptom levels over time. Repeated-



Table 3.

**Clinical Symptoms: Means, Standard Deviations, Effect Sizes**

	Baseline (n = 10)		Midpoint (n = 10)		Posttreatment (n = 10)			3-Month follow-up (n = 8)		
	Mean	SD	Mean	SD	Mean	SD	$g^a$	Mean	SD	$g^a$
<b>CAPS-5<sup>b,c,d</sup></b>	37.00	7.05	25.90	9.15	16.20	10.84	1.59	12.12	7.24	1.79
<b>PCL-5<sup>b,c,d</sup></b>	43.72	10.49	30.11	14.69	23.35	14.18	1.29	15.5	12.68	1.98
<b>HAM-D<sup>d</sup></b>	17.27	6.36	13.50	4.50	10.10	7.23	0.61	5.00	1.92	1.23
<b>BDI-II<sup>e</sup></b>	23.6	6.58	18.90	8.22	13.30	8.34	1.08	NA	NA	NA

<sup>a</sup>Effect sizes are calculated compared to baseline.

<sup>b</sup>Significant difference between pretreatment–midpoint ( $P < .05$ ).

<sup>c</sup>Significant difference between pretreatment–posttreatment ( $P < .05$ ).

<sup>d</sup>Significant difference between pretreatment–follow-up ( $P < .05$ ).

Abbreviations: BDI-II = Beck Depression Inventory-II, CAPS-5 = Clinically Administered PTSD Scale for *DSM-5*, HDRS = Hamilton Depression Rating Scale, NA = not applicable, PCL-5 = PTSD Checklist for *DSM-5*.

Table 4.

**Percentages of Patients With Clinically Significant Symptoms**

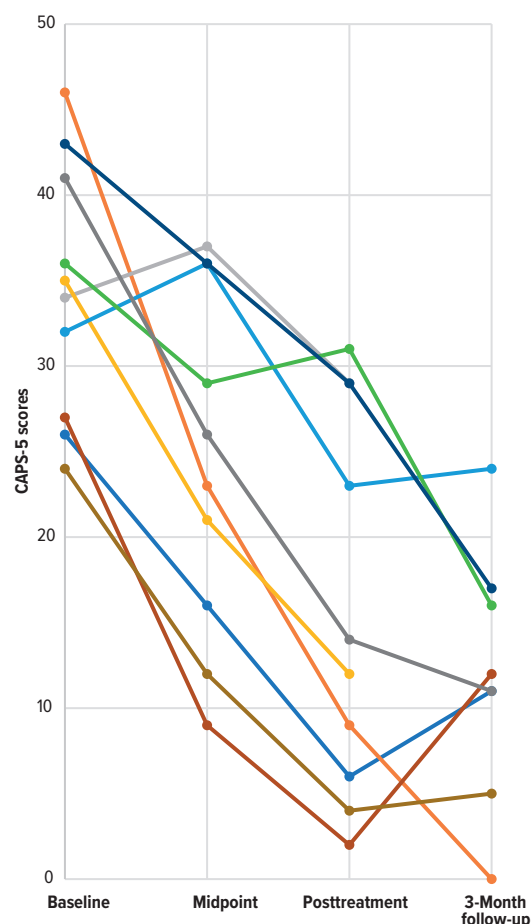
	Baseline (N = 11)	Posttreatment (N = 10)	3-Month follow-up (N = 8)
<b>PTSD</b>	100	30	0
<b>Current major depressive episode</b>	81.8	50	12.5
Severe	27.2	0	0
Moderate	36.4	20	0
Mild	18.2	30	12.5

Abbreviation: PTSD = posttraumatic stress disorder.

measures ANOVA revealed significant CAPS-5 score improvement over time ( $F_{3,21} = 20.62$ ,  $P < .001$ ). Pairwise comparison using Bonferroni correction found that CAPS-5 mean significantly decreased between baseline and midpoint ( $P = .006$ , 95% CI = 4.67–19.58), baseline and posttreatment ( $P = .002$ , 95% CI = 11.60–32.65), and baseline to 3-month follow-up ( $P < .001$ , 95% CI = 14.01–36.24). Follow-up paired samples  $t$  tests showed PTSD symptoms significantly decreased posttreatment on both clinician-rated (CAPS-5  $t = 5.2$ ,  $P < .001$ ,  $g = 1.59$ ) and self-reported (PCL-5  $t = 4.24$ ,  $P = .002$ ,  $g = 1.29$ ) assessments, with continued decrease at 3-month follow-up ( $n = 8$ ) on both CAPS-5 ( $t = 5.3$ ,  $P < .001$ ,  $g = 1.79$ ) and PCL-5 ( $t = 5.91$ ,  $P < .001$ ,  $g = 1.98$ ). Figure 2 shows individual score change over time.

Posttreatment, 80% ( $n = 8/10$ ) of completers showed clinically meaningful improvement: 70% remitted and another 10% met response criteria ( $> 30\%$  symptom reduction). Of 2 patients with clinically insignificant posttreatment reductions, 1 declined 3-month follow-up evaluation; the other reported PTSD remission. At 3-month follow-up ( $n = 8$ ), no patient met CAPS-5 PTSD criteria. No patient symptomatically worsened, including the patient who discontinued.

Figure 2.

**Individual PTSD Symptom Severity Scores Across Assessment Timepoints**

Abbreviations: CAPS-5 = Clinician-Administered PTSD Scale for *DSM-5*, PTSD = posttraumatic stress disorder.

Repeated-measures ANOVA of HAM-D-17 scores over time also reached significance ( $F_{3,21} = 8.46, P < .001$ ). Pairwise comparisons of baseline symptoms and subsequent time points showed significant differences between baseline and 3-month follow-up ( $P < .001, CI = 14.3-22.1$ ). Depression symptoms decreased significantly from baseline to 3-month posttreatment follow-up ( $t = 3.68, P = .008, g = 1.23$ ). At posttreatment, mean scores decreased by 41%; the number of patients with severe depression scores (HAM-D  $\geq 24$ ) decreased from 3 to zero, and moderate range patients decreased from 4 to 2. Only 1 of these 2 patients attended follow-up assessment, scoring in the mild range; the remaining 7 remitted (HAM-D  $\leq 7$ ). Three-month follow-up did not assess depression self-report, but BDI-II scores significantly declined by paired samples  $t$  test from pre- to posttreatment ( $t = 3.59, P = .006, g = 1.08$ ).

Patient scores significantly increased baseline/posttreatment on the MAIA-2 subscales measuring emotional awareness (mean = 12.7/14.5; SD = 3.3/4;  $P = .004; g = -1.30$ ), self-regulation (mean = 6.9/8.6; SD = 2.9/2.6;  $P = .005; g = -1.20$ ), and body listening (mean = 4.7/6.8; SD = 2.8/2.2;  $P = .025; g = -0.87$ ). ASI-3 scores significantly decreased from mean = 9.9 (SD = 2.33) to 6.8 (SD = 2.90) ( $P = .004, g = 1.16$ ).

Daily average steps significantly increased with large effect sizes on paired samples  $t$  test, from 7,110 (SD = 5,378) to 9,297 (SD = 5,600) ( $t = -3.12, P = .026, g = -1.2$ ), whereas mean daily sedentary minutes decreased from 692 to 553 ( $t = -3.36, P = .02, g = 1.2$ ). Baseline mean sleep duration remained within normal range without meaningful change.

## DISCUSSION

This small pilot open trial examined the feasibility, safety, and preliminary clinical efficacy of a novel mindfulness-based exposure therapy protocol for PTSD post cardiac arrest survival. Our findings suggest acceptance and mindfulness-based exposure therapy (AMBET) holds promise for a high-risk patient population lacking prior interventions designed for their idiographic presentation. AMBET appears feasible, safe, and possibly efficacious. We easily attained recruitment goals. AMBET was well-tolerated, with low attrition, high satisfaction ratings, and no reported or observed adverse effects in this small sample. Study protocol delivery appeared feasible, with high therapist fidelity to intervention procedures and high follow-up retention. Patients showed statistically significant, clinically meaningful improvement in PTSD and mood symptoms on both clinician-administered and self-reported measures at 8 weeks posttreatment and 3-month follow-up. Effect size estimates were large, with all but 2 patients no longer meeting PTSD criteria after 8 AMBET sessions.

Consensus is lacking on PTSD remission and response criteria. We utilized diagnostic remission, with additional requirement of CAPS-5 score  $\leq 23$ , although other cutoff points have been employed and suggested. Clinically

significant response was defined as  $\geq 30\%$  reduction from pretreatment CAPS-5, which has been previously utilized,<sup>18,39-41</sup> although with limited theoretical support. A recent study<sup>43</sup> suggested a 12-13 point CAPS-5 reduction as a threshold for identifying clinically meaningful PTSD symptom change, which in our sample yielded a result identical to the  $\geq 30\%$  reduction definition.

Our findings add a new treatment and patient population to the extensive literature supporting exposure therapy interventions for PTSD. The cardiac-specific focus and addition of mindfulness may have helped lower attrition compared to the 29% rate across CBT treatments for PTSD.<sup>13</sup> Although only self-report measures showed statistically significant depressive posttreatment reductions, all patients reported improved depression scores, and all but 1 with baseline comorbid major depression had remitted at follow-up. The lack of clinician-rated depressive statistical significance at posttreatment likely reflects low statistical power. Nonetheless, the reduction in patient perceived depressive symptoms following PTSD treatment is notable in the context of medical illness.<sup>44</sup> One patient received 2 sessions of other psychotherapy between posttreatment and follow-up but chose to discontinue that treatment. This patient reported the only unremitted MDD at follow-up. All others denied posttreatment psychiatric or psychotherapeutic care following AMBET, although 2 had unsuccessfully sought further mental health support.

In targeting health behaviors, we found significantly increased step count and reduced sedentary behavior, identified risks for cardiac disease.<sup>45,46</sup> One might attribute this effect to wearing an activity monitoring device rather than to AMBET. However, studies have found Fitbit devices, even when providing specific activity prompts, have neither increased physical activity nor reduced sedentary behaviors.<sup>47</sup>

The significant improvements in interoceptive attention and threat bias on the ASI-3 and MAIA-2 suggest that 8 weeks of AMBET decreased patient anxiety about cardiac activity and improved coping with and regulating their evoked fear. Both of these interoceptive constructs lacked objective measures, however, and whether such changes reflected specific interventions or nonspecific therapy factors is unclear. Future research should assess the contributions of exposure and mindfulness practices to treatment gains.

At 8 sessions, AMBET is briefer than most evidence-based PTSD treatments. Informal patient feedback suggested that some wanted more sessions. Optimal AMBET treatment length and session number are unknown. As patient adherence predicts outcomes in other exposure therapies,<sup>48</sup> AMBET would benefit from formal assessment beyond session attendance, such as formal measures of homework completion and engagement in exposure and mindfulness practices. Longitudinal studies including health care utilization

data would be required to determine potential impact on mortality and adverse cardiac events.

This novel study produced highly encouraging results, reducing PTSD symptoms and increasing health behaviors in a previously understudied patient group with demonstrated need. While our findings appear extremely promising for SCA survivors, they require cautious interpretation given study limitations. Limited resources required us to use the two therapists as additional assessors. We addressed this limitation as best we could: therapists did not assess their own patients, and patient self-reported symptoms showed comparable reductions. An open trial is appropriate at this initial stage, yet the small sample size, small therapist cohort, and lack of control group preclude assessment of efficacy or comparisons with other treatments.<sup>38,49</sup> Nonetheless, these positive outcomes warrant further research using larger sample size, rigorous randomized design, and credible control condition to investigate outcomes, moderators, and mediators. Such research would elucidate whom this treatment most benefits and mechanisms of action. Given the prevalence and consequences of PTSD in SCA survivors, the need is pressing to advance AMBET to the efficacy testing stage.

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