Research paper

Feasibility of a remote heart rate variability biofeedback intervention for reducing anxiety in cardiac arrest survivors: A pilot trial

Jeffrey L. Birk [a,*], Robin Cumella [a], David Lopez-Veneros [a], Sachin Agarwal [b], Ian M. Kronish [a]

[a] Center for Behavioral Cardiovascular Health, Department of Medicine, Columbia University Irving Medical Center, 622 West 168th Street, New York, 10032, United States
[b] Department of Neurology, Division of Critical Care & Hospitalist Neurology, Columbia University Irving Medical Center, 177 Fort Washington Avenue, Milstein Hospital, 8GS-300, New York, 10032, United States

A B S T R A C T

Background: Heart rate variability biofeedback (HRVB) is a promising non-pharmacologic approach for reducing anxiety. This intervention's feasibility needs testing in psychologically distressed cardiac patients for whom heart-related anxiety is a core concern. To enhance scalability and convenience, remote delivery of HRVB also needs to be assessed. Accordingly, we evaluated the feasibility of remote HRVB in survivors of cardiac arrest (CA) with elevated CA-related psychological distress.
Methods: The intervention was comprised of daily sessions of diaphragmatic paced breathing and real-time monitoring of cardiac activity guided by a smartphone app and heart rate monitor. This single-arm feasibility trial assessed the percentage of eligible contacted patients who consented and engaged in the study and the self-reported acceptability, feasibility, appropriateness, and usability of the intervention. Exploratory analyses assessed pre-to-post changes in trait anxiety, negative affect, cardiac-related interoceptive fear, and resting-state HRV.
Results: Of 12 eligible CA survivors contacted, 10 enrolled. All 10 patients completed the virtual study visits and the majority (>50 %) of prescribed training sessions. Ninety percent reported good scores for intervention acceptability and feasibility, and 80 % reported good scores for its appropriateness and usability for reducing fear. Trait anxiety decreased significantly pre-to-post intervention. There were no changes in negative affect, interoceptive fear, or resting state HRV.
Conclusion: A remotely delivered HRVB intervention was acceptable, feasible, and useable for cardiac patients with CA-related psychological distress. A phase 2 randomized controlled trial evaluating the efficacy of HRVB on cardiac patients' psychological distress, health behaviors, and autonomic dysfunction may be warranted.

1. Introduction

Sudden, life-threatening cardiac events, including cardiac arrest (CA), induce high levels of psychological distress (e.g., cardiac-specific anxiety, post-traumatic stress disorder (PTSD) symptoms) in a subset of patients [1,2]. This distress can linger for years after the event, thereby disrupting patients' lives and interfering with their ability to engage in recommended behaviors to improve their heart health (e.g., regular physical activity, adequate adherence to prescribed medication regimens) [2]. Traditional approaches to addressing distress after life-threatening medical events such as cognitive behavioral therapy are time-consuming for clinical research staff, require a willingness to be

emotionally vulnerable for patients, and can have high attrition [3]. A self-guided breathing intervention that can be practiced by patients after a single training session with interventionists could be a beneficial alternative approach.

A growing body of research shows that heart rate variability biofeedback (HRVB) is an intervention that increases heart rate variability (HRV) and reduces anxiety with a large standardized effect size in a meta-analysis of 24 studies [4,5]. HRVB has been shown to reduce PTSD symptoms in trauma-exposed people [6] and reduce generalized anxiety in patients undergoing cardiac surgery [7]. These results are in line with the reliable finding that higher HRV has been associated with lower negative affect, even after controlling for respiration rate,

demographic characteristics, exercise, smoking, and medications that affect cardiac activity [8].

HRVB is believed to work by stimulating the parasympathetic branch of the autonomic nervous system by making use of the resonance frequency of the cardiorespiratory system [9,10]. By breathing at a rate near the system's resonant frequency, the intervention creates high-amplitude oscillations in momentary heart rate [10]. This, in turn, increases activity in the vagus nerve and strengthens autonomic reflexes, such as the baroreflex [9], which serves to maintain homeostasis by lowering heart rate when blood pressure increases [11,12]. Stimulation of vagal afferent pathways can also influence brain areas (e.g., amygdala, insula, hippocampus) involved in affect and mood regulation [10]. Indeed, in a general adult sample, HRVB has been shown to increase functional connectivity at rest in brain regions associated with emotion regulation (e.g., enhanced connectivity between the medial prefrontal cortex and amygdala) [13]. Furthermore, resonant-frequency breathing, the hallmark of HRVB, increases baroreflex sensitivity [14], which is inversely associated with anxiety in the general population and in cardiac patients [15,16].

This study addressed the question of whether a technology-based HRVB intervention involving slow breathing and attending to real-time heart-related information would be feasible and acceptable to psychologically distressed survivors of CA. We recognized that there may be unique challenges in engaging CA patients in HRVB as they may be especially distressed by an intervention that calls attention to their heart. The study also sought to assess the acceptability and feasibility of delivering such an intervention entirely remotely as it was expected that CA patients might prefer to avoid additional visits to a medical setting. Finally, this study sought to explore the intervention's effects on CA patients' anxiety and other measures of negative affect. Specifically, to test each of these aims, we assessed the following measures: (1) percentage of contacted eligible CA survivors who agreed to participate in the study; (2) percentage of participants who completed all visits and outcome assessments; (3) percentage of participants who completed a majority (≥ 8 of 15) of the requested at-home HRVB sessions; (4) percentage of participants who reported scores ≥ 4 for HRVB's feasibility, (5) acceptability, and (6) appropriateness for reducing anxiety; and (7) percentage of participants who reported total scores ≥ 68 for HRVB's usability. To test the second aim regarding preliminary indications that anxiety or negative affect decreased, we measured pre-to-post-intervention change in trait anxiety, cognitive and somatic anxiety, trait negative and positive affect, and cardiac-related interoceptive fear. We also measured pre-to-post changes in resting-state HRV.

2. Method

2.1. Design

This single-arm pilot trial evaluating the HRVB intervention was an unblinded study. Necessarily, neither the study participants nor the study staff who collected and analyzed the data were blinded to study condition. The study used a remote study design. We aimed to increase the intervention's acceptability by allowing interested CA patients to complete the intervention training sessions at home at self-selected times. Furthermore, we adapted the study design to be entirely remote in response to the initial wave of the COVID-19 pandemic in March 2020. We developed a Zoom-based protocol for the three study visits such that every aspect of the study could be completed virtually by all study participants: eligibility assessment, informed consent process, device delivery, intervention training, participant-led practice sessions, and outcome ascertainment [17].

2.2. Setting

The study was conducted by staff members of the Roybal Center for Fearless Behavior Change at the Center for Behavioral Cardiovascular

Health at Columbia University Irving Medical Center (CUIMC), with CA survivors recruited online nationally and from CUIMC. All study procedures from the informed consent process onward occurred remotely. Recruitment took place between November 23, 2020 and July 23, 2021.

2.3. Eligibility criteria

Participants were included if they: 1) were age 18 years or older; 2) had a CA within the past 6 years as determined by self-report and/or electronic health records; and 3) elevated CA-related PTSD symptoms as measured by a PTSD Checklist for DSM-V [PCL-5] [18] scores ≥ 30 or Acute Stress Disorder Scale [ASDS] [19] scores ≥ 34 (when the event occurred <1 month before measurement). Participants were excluded if 1) they were not fluent in English, 2) did not own a smartphone, or 3) were unable to complete the study protocol due to a physical (e.g., breathing disorder that precluded paced breathing, vision or hearing impairment), cognitive (e.g., advanced dementia) or psychiatric reason (e.g., serious mental illness, active substance use disorder).

2.4. Recruitment and consent

Potential participants were identified in two ways. First, patients who had been recruited into the Cardiac Arrest Neuropsychological Outcome Evaluation (CANOE) study, a cohort of CA survivors hospitalized at CUIMC who met eligibility criteria were invited by phone to consent to screen for the study. Second, the study was advertised by the Sudden Cardiac Arrest Foundation (SCAF) via its website and an email distributed to its members, with links to an online consent to screen for the study and a screening questionnaire. Survey respondents were informed of their eligibility status upon survey completion. The study team contacted eligible patients to schedule their first study visit. Regardless of the recruitment method, all accrued participants provided informed verbal consent during the first study visit. The study team ensured that only the patients who had sufficient mental capacity should complete the process of informed consent. Additionally, multiple aspects of the eligibility criteria listed above ensured that patients with limited mental capacity were not enrolled in the study (e.g., age 18 years or older, no major cognitive impairment).

2.5. Study visit procedures

All study visits were conducted remotely via the Zoom platform. In visit 1, participants provided verbal consent and completed a questionnaire assessing demographic characteristics. Participants also downloaded the Elite HRV app on their phones with guidance from the study team. In visit 2 (after participants received study devices), they completed baseline measures (including resting-state HRV) and received HRVB training. In visit 3, participants completed post-intervention outcome assessments (including resting-state HRV). Visit 3 occurred three weeks after visit 2. Participants were debriefed at the end of visit 3. Participants were compensated for the completion of video visits 1, 2, and 3.

2.6. Intervention

The HRVB intervention consisted of (1) supervised training that was conducted during a single remote session after devices had been delivered to patients followed by (2) unsupervised at-home HRVB sessions that were self-administered over the course of the subsequent three weeks. HRVB supervised training was administered consistently in four sequential steps during visit 2. In advance of this session, participants had downloaded the Elite HRV app onto their smartphone during visit 1, and they had received the Polar H10 heart rate monitor (Polar Electro Oy, Kempele, Finland), which is an easy-to-apply chest strap with an adequately high sampling rate for assessing HRV. This monitor has demonstrated valid measurement of HRV in resting positions and

specifically when used together with the Elite HRV app [20]. Throughout the session, the trainer used the share screen function to visualize instructions and the Elite HRV app to participants. First, participants were trained in the method of relaxed "belly breathing" (i.e., abdominal breathing with minimal involvement of the upper chest). Participants were told to place one hand on their stomach to feel its rising and falling as they breathed in a relaxed way. Second, participants were trained to apply this relaxed breathing style to a regularly paced respiratory pattern. In this portion, participants followed the visual pacer stimulus in the Elite HRV app and practiced breathing at the slow rate of 0.1 Hz (i.e., one full breath cycle every 10 s with 5-s inhalation and 5-s exhalation). They were instructed to breathe in as the pacer expanded in size and to breathe out as it shrank in size. Third, participants practiced HRV biofeedback in which they watched momentary oscillations in heart rate on the visual display of the app while they continued to engage in relaxed, paced breathing. They were told that their goal was to maximize the amount that their heart rates went up and down with their inhalations and exhalations. Finally, the training concluded with instructions for continuing at-home HRVB sessions for the subsequent 3 weeks. Participants were instructed to practice HRVB on their own at least 5 times a week for 10 min at a time over the next three weeks. Participants were told that they could do these practice sessions at whatever times were preferable to them, and that they would receive brief reminders via text, email, or phone call, depending on their preference, twice each week to complete these sessions. Instructions for the heart rate monitor and for the intervention were mailed to participants, who were reminded to refer to these instructions for their unsupervised HRVB sessions (see online supplementary material for these instructions).

The HRVB training was delivered by three study team members, who were not required to have any prior clinical training [21] but were taught the key procedures of HRVB. Overall, the training took approximately 45 min to deliver. Intervention fidelity was assessed by a checklist (see Appendix A) that was created for this protocol with the key components of HRVB from in-person studies [22]. One staff member administered the checklist during the HRVB training session as the other staff member interacted with the participant.

2.7. Measures

In all visits, self-report measures were displayed on the shared screen via Zoom. The outcome assessor read questions aloud and entered participants' responses into the surveys. The pre-specified primary outcomes were assessed post-intervention (visit 3). The pre-specified secondary outcomes were assessed at pre- (visit 2) and post-intervention (visit 3).

2.8. Feasibility outcomes

The primary feasibility outcome was the percentage of contacted eligible patients who agreed to participate in the study after hearing a description of the intervention. This number was computed across the multiple recruitment methods in the study. The denominator of contacted eligible patients was the total number of CA survivors who: (1) made contact either via the internet (Qualtrics survey) or via telephone or email directly with a study team member, (2) completed the full set of questions needed to determine eligibility, and (3) were deemed to be eligible at the conclusion of that process. The numerator was the number of patients who gave verbal consent to participate in the pilot study.

Other important feasibility outcomes included the percentage of participants who completed all three virtual study visits and the percentage of participants who completed a majority (≥8 over 3 weeks) of the assigned at-home unsupervised HRVB sessions. This latter metric of compliance was determined objectively by assessing the total number of recorded data files on the Elite HRV app during the three-week study timeframe—*not* including ones generated during the video visits.

The 4-item versions of the Acceptability of Intervention Measure (AIM), the Feasibility of Intervention Measure (FIM), and the Intervention Appropriateness Measure (IAM) were used to assess participant perceptions of the acceptability, feasibility, and appropriateness of the HRVB intervention [23]. Participants were instructed to rate the extent to which they agreed with a series of statements on a 5-point scale ranging from *Completely disagree* (1) to *Completely agree* (5). The items' wordings were adjusted to fit the intervention and its goals. Participants were instructed as follows: "For each statement below, 'the HRV training' always refers to the combination of the Elite HRV app together with the Polar H10 heart rate monitor" (e.g., "The HRV training meets my approval" [AIM], "The HRV training seems doable" [FIM], "The HRV training seems fitting for reducing fear" [IAM]). A mean score of 4 or greater for each scale satisfied the feasibility goal.

Usability of the intervention was assessed with the 10-item System Usability Scale (SUS) [24]. Participants were asked to report their level of agreement for each item on a 5-point scale ranging from *Strongly disagree* (1) to *Strongly agree* (5) (e.g., "I would imagine that most people would learn to use the HRV training very quickly"). After recording of items and reverse-scoring of half the items, the individual items are summed and multiplied by a factor of 2.5 such that the total possible score ranges from 0 to 100, with higher total scores indicating higher perceived usability. A score of ≥68 is considered adequate system usability.

2.9. Psychological and HRV outcomes

Trait anxiety was measured by the 20-item trait version of the State-Trait Anxiety Inventory [25], one of the most common measures of trait anxiety in the general population [26]. Participants are asked to indicate how they generally feel on a 4-point scale ranging from *Almost never* (1) to *Almost always* (4) (e.g., "I feel nervous and restless"). The total scale score ranges from 20 to 80 points, with higher scores indicating greater anxiety.

Cognitive and somatic anxiety were measured using the 21-item State-Trait Inventory of Cognitive and Somatic Anxiety (STICSA) [27]. These anxiety measures were included to capture specific facets of trait anxiety because the STAI has been shown to be a measure of general negative affectivity that is not entirely specific to trait anxiety [26] and because the STICSA has been shown to correlate more strongly with other measures of anxiety and less strongly with measures of depression, relative to the STAI [27]. Participants indicate how often they have felt a variety of symptoms over the past week on a 4-point scale ranging from *Not at all* (1) to *Very much so* (4) (e.g., cognitive: "I feel agonized over my problems; " somatic: "My breathing is fast and shallow"). The total possible score ranges from 10 to 40 points for the cognitive subscale and 11 to 44 points for the somatic subscale, with higher scores indicating higher symptoms of anxiety.

Negative as well as positive affect were measured by the 20-item Positive and Negative Affect Schedule (PANAS) [28]. For a variety of emotion-related words participants indicated the extent to which they generally felt that affective experience. Examples of negative items included "upset," "scared," and "nervous," whereas examples of positive items included "enthusiastic," "strong," and "inspired." The total possible score for the negative and positive subscales each ranged from 10 to 50 points.

Cardiac-related interoceptive fear was measured by the four cardiac items drawn from the physical subscale of the Anxiety Sensitivity Index–3 [29]. Participants were asked to indicate the extent to which they agreed with each item based on their own experiences on a 5-point scale ranging from *Very little* (0) to *Very much* (4) (e.g., "It scares me when my heart beats rapidly").

Resting-state HRV was measured by the root mean square of the successive difference between heartbeats (RMSSD). This measure was computed using the exported RR intervals collected by the Elite HRV app during the resting state task in video visits 2 and 3. Before computing

RMSSD via the standard formula, RR intervals that differed by more than 300 ms from the previous interval were removed from the time series because they likely reflect artifacts (e.g., ectopic beats) that are known to reduce the accuracy of this and other HRV metrics [30]. The RMSSD measure was transformed due to a non-normal distribution by taking the natural log (ln RMSSD), a typical transformation for this measure [31]. The unit of measurement was milliseconds.

2.10. Other measures

Demographic characteristics (age, race, ethnicity, sex at birth, gender, sexual orientation, education, language, health insurance coverage, and partner status) and medical characteristics (implanted cardiac devices, prescribed beta-blocker or antiarrhythmic medications) were elicited via self-report.

2.10.1. Sample size determination

The sample size for this pilot study was guided by the need to enroll enough participants who survived CA to examine the feasibility of conducting a stage II efficacy randomized controlled trial (RCT) of our HRVB intervention in this patient population. The goal was to determine whether it would be possible to recruit, retain, and ascertain outcomes as well as implement the desired intervention with good fidelity and good participant compliance with unsupervised HRVB sessions. It was determined that recruiting 10 participants would be sufficient to gain a preliminary understanding of these metrics.

2.11. Statistical analysis

The data were analyzed using SPSS version 28.0. Descriptive statistics were used to describe the feasibility, acceptability, appropriateness, usability, and compliance outcomes. Two-tailed paired-samples *t*-tests were used to assess pre-to-post intervention changes in psychological and HRV outcomes.

3. Results

Fig. 1 presents the participant flow showing screening, enrollment, treatment adherence, follow-up, and analysis. Of 103 CA survivors contacted (online or by phone or email), 73 completed the initial eligibility screening. Sixty-one patients were excluded for not meeting eligibility criteria ($n = 60$) or for declining to participate ($n = 1$). A total of 12 contacted participants were deemed to be eligible for the study. Of these 12 patients, 10 (83 %) ultimately enrolled. One eligible patient who did not enroll was initially unavailable for immediate scheduling due to an upcoming surgery, and then the study's enrollment target was met before scheduling could occur; the other completed eligibility screening after the study's enrollment target had been met. Of the 10 enrolled participants, 3 were recruited locally from the CANOE registry, and 7 were recruited nationally from advertising via SCAF. There were no missing data; all enrolled participants completed the study procedures at all three study visits. The intervention training (visit 2) for all 10 participants (100 %) achieved perfect fidelity scores (13/13 total possible points distributed across four sections: Relaxed breathing, Paced breathing, Biofeedback, and Practice sessions; see Appendix A).

Table 1 shows the baseline characteristics of the sample. They were mostly men, highly educated, not Hispanic, heterosexual, and generally partnered or married. Patients were rather diverse in age ($M_{age} = 58.20$ years [$SD = 15.73$]) and race (50 % White, 20 % Black, 10 % American Indian or Alaska Native, 10 % unknown or not reported). As is common for CA survivors, many patients had implanted cardiac devices, and most were taking beta-blockers (see Discussion).

Critically, none of the 12 eligible patients who completed screening declined to participate in the intervention study. Ten out of those 12 eligible patients (83.33 %) enrolled in the study and were allocated to the intervention. (As noted above, two of the approached eligible patients were not enrolled because the enrollment target had been met.) Ten (100 %) of the enrolled participants completed all three study visits, and ten (100 %) participants completed a majority of the assigned 15 at-home unsupervised, self-led HRVB sessions after they had been trained
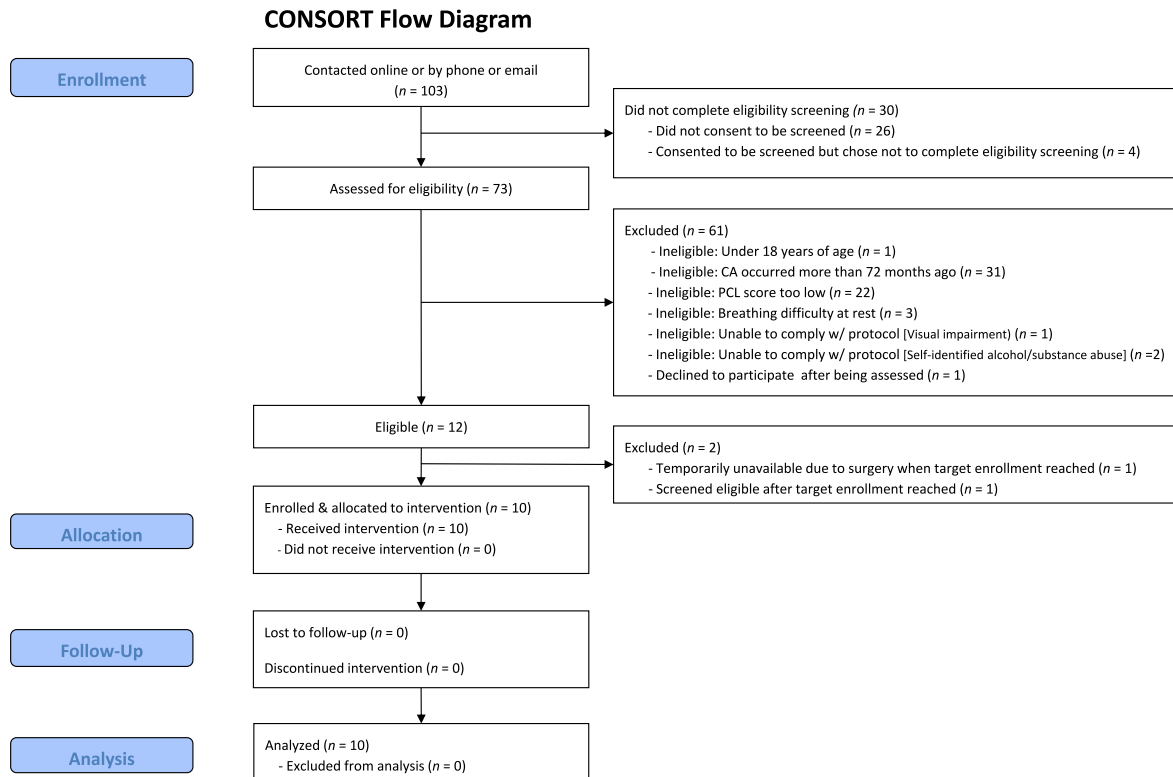
CONSORT Flow Diagram

Fig. 1. Participant flow diagram.

Table 1

Baseline characteristics of participants.

Characteristic	Intervention ($n = 10$)
Age (mean, *SD*, in years)	58.20 (15.73)
Sex	
Female	3 (30.00 %)
Male	7 (70.00 %)
Ethnicity	
Hispanic	1 (10.00 %)
Not Hispanic	8 (80.00 %)
Unknown or not reported	1 (10.00 %)
Race	
American Indian or Alaska Native	1 (10.00 %)
Black	2 (20.00 %)
White	5 (50.00 %)
Unknown or not reported	2 (20.00 %)
Sexual orientation	
Straight or heterosexual	10 (100.00 %)
Partner status	
Single	1 (10.00 %)
Partner/spouse	6 (60.00 %)
Separated	1 (10.00 %)
Divorced	2 (20.00 %)
Education	
Some college	2 (20.00 %)
College graduate	3 (30.00 %)
Graduate school/professional school	5 (50.00 %)
Implanted cardiac device type	
No cardiac device	2 (20.00 %)
Unpaced cardiac monitor	1 (10.00 %)
Implantable cardioverter defibrillator	4 (40.00 %)
Pacemaker	2 (20.00 %)
Unknown or not reported	1 (10.00 %)
Beta blocker or antiarrhythmic medication	
Beta blockers	6 (60.00 %)
Neither beta blockers nor antiarrhythmics	1 (10.00 %)
Unknown or Not Reported	3 (30.00 %)

Note. Unless otherwise indicated, values are number (percentage) of participants.

Table 2

Feasibility outcomes.

Compliance measure	Procedures		
Study visits completed, mean (*SD*)	3.00 visits (0.00)		
At-home HRVB sessions completed, mean (SD)	15.80 sessions (3.36)		
Participant-reported feasibility measure	Pre-Intervention	Post-Intervention	
Feasibility	N/A	4.65 (0.58)	
Acceptability	N/A	4.45 (0.45)	
Appropriateness for reducing anxiety	N/A	4.05 (0.54)	
Usability	N/A	87.00 (11.41)	
Psychological outcomes	Pre-Intervention	Post-Intervention	P-value
Cardiac-related interoceptive fear (ASI-3)	10.10 (6.12)	8.60 (5.85)	.15 _
Trait anxiety (STAI-T)	46.90 (13.30)	40.70 (13.53)	.03 *
Negative affect (PANAS)	23.80 (6.27)	21.90 (7.42)	.32 _
Positive affect (PANAS)	31.90 (7.85)	35.00 (6.20)	.11 _
Somatic anxiety (STICSA)	17.40 (2.12)	16.80 (2.78)	.43 _
Cognitive anxiety (STICSA)	15.80 (5.20)	16.20 (4.10)	.75 _
Physiological outcome	Pre-Intervention	Post-Intervention	P-value
HRV at rest (ln RMSSD)	2.40 ms (1.24)	1.82 ms (0.88)	.11 _

Note. Values are means (standard deviations) across participants at each indicated study timepoint. ASI-3-C = Sum of cardiac-related items from the physical subscale of the Anxiety Sensitivity Index-3. HRV = Heart rate variability. ln RMSSD = natural log of the root mean square of the successive difference. STAI-T = Trait version of the State-Trait Anxiety Inventory. PANAS = Positive and Negative Affect Schedule. STICSA = State-Trait Inventory of Cognitive and Somatic Anxiety. *P*-values are for two-tailed paired-samples *t*-tests comparing pre- to post-intervention assessments. *$p < .05$.

in the HRVB steps by study staff. The mean number of completed sessions was 15.80 (*SD* = 3.36, range: 13–24).

Table 2 shows the study's self-reported feasibility outcomes as well the psychological outcomes and the HRV outcome. Most participants rated the intervention procedures as highly feasible and acceptable. Specifically, 90 % rated the feasibility and acceptability of the intervention as at least 4 out of 5. Furthermore, 80 % rated the appropriateness of the intervention for reducing anxiety as at least 4 out of 5. Trait anxiety decreased pre- (*M* = 46.90 points, *SD* = 13.30) to post-intervention (*M* = 40.70 points, *SD* = 13.53), *p* = .031. The other psychological outcomes and HRV did not change significantly.

4. Discussion

The remote delivery of HRVB training to CA survivors with subsequent unsupervised HRVB sessions showed evidence of being feasible for testing in a larger future trial. Most participants rated the intervention acceptable and were highly compliant in completing all study procedures and at home HRVB sessions. The findings extend the prior research on HRVB for anxiety to a specific medical population experiencing ongoing distress up to six years after a potentially traumatic and life-threatening sudden cardiac event.

Although this pilot feasibility study was not intended to address the underlying theory of the intervention's mechanisms of action, we found suggestive evidence consistent with the notion that HRVB may be efficacious for reducing trait anxiety. There were no trends for pre-to-post reductions in other measures of psychological distress. Interestingly, reductions in trait anxiety occurred in the absence of pre-post-differences in resting-state HRV as has been shown in trials of HRVB conducted in other patient populations. It was not surprising that resting-state HRV was not altered in this small study because most

participants had been prescribed beta blockers and some had actively paced heartbeats, both of which factors greatly reduce HRV. However, it should be emphasized that this study had no control group and was underpowered to detect pre-to-post differences in psychological or HRV outcomes, and these findings should be viewed as exploratory.

Overall, these pilot study findings suggest that many distressed CA survivors are interested in the HRVB intervention. Partnering with SCAF enabled the achievement of recruitment goals and increased geographic diversity. Furthermore, most CA survivors who tried the intervention found it acceptable and believed it was appropriate for lowering feelings of anxiety. At a behavioral level, the results suggest that CA patients may be willing to complete virtual study sessions and at-home HRVB sessions in future research. These favorable feasibility findings occurred for at-home sessions that were unscheduled and unsupervised, although it should be noted that participants did receive reminders twice per week to complete sessions.

The study has several limitations. First, by necessity, neither participants nor study personnel was blinded to the assignment to the intervention, nor were they blinded to the intended psychological benefits of the intervention. Second, the fidelity of the HRVB sessions could not be assessed because those sessions were self-administered. Nevertheless, the study team instructed participants systematically during the HRVB training session and answered all questions. High fidelity in delivering the HRVB intervention was demonstrated according to key principles [22]. Third, the study population was limited to a subset of distressed CA survivors with smartphone access. Therefore, the feasibility results may be restricted to patients who are comfortable using smartphone technology and have the financial means to afford it. Nevertheless, we did not restrict eligibility to people who were comfortable using Bluetooth-reliant wearable devices, and yet all participants were able to connect their devices with the study team's guidance. Furthermore, remote delivery enabled recruitment nationally and facilitated enrollment target achievement. Fourth, most patients were prescribed beta-blockers or had paced heart rhythms, which likely interfered with HRVB's mechanisms. Future research is needed to

understand the impact of these factors on anxiety reduction.

Future research should apply the fully remote HRVB intervention in an appropriately powered phase 2 efficacy RCT in cardiac patients with elevated psychological distress. We recommend that future research exclude patients who are taking beta-blockers and patients with controlled heartbeats (e.g., pacemaker) or undetectable heartbeats (e.g., left ventricular assist device) so that the proximal target of HRV may be properly modulated via the intervention. We also recommend that the research population be expanded to patients with ongoing psychological distress after other acute medical events, such as ACS or acute exacerbations of chronic obstructive pulmonary disease because these conditions also cause distress [32,33] and have shown some promise with HRVB [21,34]. Future research should test HRVB's effects on health behavior outcomes linked with anxiety (e.g., medication adherence, physical activity) [35,36]. Finally, in line with research on the psychological distress of patients' family members after acute medical events [37,38], future research should consider applying the HRVB intervention to treat not only patients but also their family caregivers.

5. Conclusions

HRVB was a feasible intervention for psychologically distressed survivors of CA to practice independently. Given the relative unacceptability of psychological interventions for many cardiac patients, HRVB may be a more acceptable, more scalable, less time-consuming, and less expensive alternative. Real-time exposure to one's cardiac activity combined with diaphragmatic breathing at a resonant frequency is a promising intervention for patients with cardiac concerns. Efficacy testing of remote HRVB is warranted to test its anxiolytic effects via RCTs in distressed CA survivors. We recommend that the intervention's feasibility and efficacy be tested more broadly among patients suffering from persistent symptoms of psychological distress after a variety of acute medical events.

Author contributions

Jeffrey L. Birk: Conceptualization, Investigation, Supervision, Software, Writing – original draft, Methodology, Writing – review & editing; Robin Cumella: Data curation, Methodology, Project administration, Writing – review & editing, Writing – original draft; David Lopez-Veneros: Data curation, Methodology, Project administration, Writing – review & editing, Writing – original draft. Sachin Agarwal: Writing – review & editing. Ian M. Kronish: Methodology, Project administration, Writing – review & editing.

Trial registration

https://clinicaltrials.gov/ct2/show/NCT04589559 (NCT04589559)

Ethics committee approval

Approval was granted by the Columbia University Irving Medical Center Institutional Review Board (AAAS9001).

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Declaration of competing interest

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

Data availability

The authors do not have permission to share data.

Acknowledgments

Appendix B. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2023.101251.

Appendix A

Subject ID _____ Session _____ Study <u>CALME</u> Date ___/___/___
Intervention Fidelity Checklist
for Heart Rate Variability Biofeedback.

Yes or No	Intervention Component
	Part 1: Relaxed Breathing
	The researcher explained the procedures of diaphragmatic breathing (or "belly breathing").
	The researcher asked the participant to practice diaphragmatic breathing (or "belly breathing").
	Part 2: Paced Breathing
	The researcher instructed the participant about how to follow the breathing pacer stimulus to inhale and exhale at the specified times.
	The researcher allowed *30 s* for the participant to try paced breathing.
	The researcher elicited responses from the participant about their experience with paced breathing and then provided corrective verbal feedback, if needed.
	Regarding inhalation, the researcher instructed the participant not to take in too much air and instead to breathe in a small, continuous stream of air.
	Regarding exhalation, the researcher instructed the participant to relax the belly whenever breathing out.

(*continued*)

Yes or No	Intervention Component
	The researcher instructed the participant to breathe in through the nostrils (if possible) and breathe out through pursed lips (if possible).
	Part 3: Biofeedback
	The researcher instructed the participant about how to watch a visual representation of their heart rate in real time and verified that the participant correctly identified this visual information.
	The researcher explained to the participant that breathing affects the heart's activity.
	The researcher instructed the participant that their goal during practice is to try to *increase* the up-and-down variability of their heart rate.
	The researcher allowed *3 min* for the participant to try the biofeedback (paced breathing while monitoring the rises and falls in their heart rate).
	Part 4: Practice sessions
	At the end of the initial training, the researcher instructed the participant in the frequency of practice (at least 5 per week), the duration of practice (10 min each), and the number of weeks of practice (3 weeks).

This form is to be completed by the researcher present at the CALME training video visit who observes the training led by the other researcher. Indicate whether each of the following intervention components were present for the study participant.

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