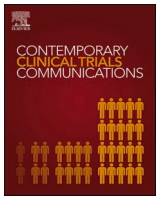
Contemporary Clinical Trials Communications 43 (2025) 101426

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc



A mind-body resilience intervention for emotional distress in cardiac arrest survivors and their informal caregivers – Recovering together after cardiac arrest: Protocol for an open pilot trial

Danielle La Camera [a], Jonathan Elmer [b], Sarah M. Perman [c], Michael W. Donnino [d,e], Ona Wu [f,g], Robert A. Parker [h], Ana-Maria Vranceanu [a,i], Alexander M. Presciutti [a,i,*]

[a] Center for Health Outcomes and Interdisciplinary Research, Department of Psychiatry, Massachusetts General Hospital, United States
[b] Departments of Emergency Medicine, Critical Care Medicine, and Neurology, University of Pittsburgh School of Medicine, United States
[c] Department of Emergency Medicine, Yale School of Medicine, United States
[d] Center for Resuscitation Science, Department of Emergency Medicine, Beth Israel Deaconess Medical Center, United States
[e] Division of Pulmonary, Critical Care, and Sleep Medicine, Beth Israel Deaconess Medical Center, United States
[f] Athinoula A. Martinos Center for Biomedical Imaging, Massachusetts General Hospital, United States
[g] Department of Radiology, Harvard Medical School, United States
[h] Department of Medicine, Harvard Medical School, United States
[i] Department of Psychiatry, Harvard Medical School, United States

ARTICLE INFO

Keywords:
Cardiac arrest
Psychosocial intervention
Dyads
Caregivers
Mindfulness
Resilience
Mixed methods

ABSTRACT

Background: Chronic emotional distress among cardiac arrest (CA) survivors and their caregivers is prevalent and worsens quality of life and recovery. Interventions to prevent chronic distress post-CA are needed. We developed *Recovering Together after Cardiac Arrest* (RT-CA), an intervention to increase resiliency in CA survivor-caregiver dyads (pairs).

Method: We will conduct an open pilot clinical trial of RT-CA to examine preliminary feasibility and refine the intervention based on participant feedback. We will enroll at least 7 CA survivor-caregiver dyads during their hospitalization at a single academic medical center. We will identify eligible survivors by screening admission reports and through referrals from medical staff. *Inclusion criteria*: Survivors - sufficient cognitive status to meaningfully participate (Short Form of the Mini Mental State Exam ≥5). Dyads - English-speakers; one member must have clinically significant distress (≥8 on either Hospital Anxiety and Depression Scale subscale). *Procedure:* dyads will participate in 6, 30–45 min sessions with a study clinician. Sessions will include mind-body coping skills training and provision of anticipatory guidance and resources to navigate CA-survivorship. Dyads will complete pre- and post-test measures of emotional distress and treatment targets. We will calculate frequencies and proportions of our primary outcomes (feasibility - recruitment, assessments, adherence, therapist fidelity and acceptability/credibility). After completing post-test assessments, dyads will provide feedback via exit interviews. We will integrate qualitative and quantitative data using explanatory-sequential mixed-methods.

Discussion: We will use our findings to refine RT-CA content and study procedures. If successful, RT-CA has potential to significantly improve quality of survivorship for CA survivors and their caregivers.

1. Introduction

Cardiac arrest (CA), the complete cessation of the heart's mechanical activity and circulatory blood flow [1], is an unexpected and catastrophic event for both survivors and their caregivers [2–5]. CA survivors and caregivers frequently endorse emotional distress [4,5], often exacerbated by feeling unprepared to manage challenges associated with post-acute survivorship (e.g., chronic physical, emotional, and cognitive symptoms resulting from the CA) [6,7]. If left untreated, post-CA distress can become chronic and have lasting effects, including poor quality of life, major adverse medical events, and early death [8–13].

* Corresponding author. Center for Health Outcomes and Interdisciplinary Research 1 Bowdoin Sq, Suite 100, Boston, MA, 02114, United States.
E-mail address: apresciutti@mgh.harvard.edu (A.M. Presciutti).

https://doi.org/10.1016/j.conctc.2024.101426
Received 16 September 2024; Received in revised form 30 December 2024; Accepted 31 December 2024
Available online 2 January 2025

Substantial research suggests that the psychological needs of critically ill patients and caregivers are interdependent and thus should be treated in tandem [14–19]. A dyadic intervention can address the needs of both CA survivors and their caregivers and produce synergistic effects [20–23]. However, to date, there are no dyadic psychosocial interventions routinely offered to survivors and caregivers aimed toward managing CA-related stressors [6]. Indeed, such interventions can address acute and chronic stressors specific to CA. First, unlike in other life-threatening conditions (e.g., stroke, myocardial infarction, cancer), CA lacks established post-discharge care pathways for supporting post-CA management [6]. Thus, dyadic interventions that provide psychoeducation on post-CA sequelae and anticipatory guidance of future challenges can address feelings of unpreparedness widely reported by both CA survivors and caregivers. Second, CA is a complete mind-body-heart disruption that is continuously traumatic, perpetuating feelings of uncertainty in both the survivor and the caregiver. Specifically, CA survivors experience *enduring somatic threats* (recurring, bodily, traumatic reminders of their event), including the sensation of their implantable cardioverter defibrillator (ICD) inside their chest, invasive electrical shocks discharged from the ICD, pain from rescue interventions, chronic fatigue, and other changes in physical and motor functioning [7,24,25]. These somatic experiences contribute to a feedback loop of heightened cardiac sensitivity, hypervigilance, fear of future cardiac events, and existential distress [7,24–26]. Informal caregivers, instead, may have witnessed the CA event, graphic rescue interventions, intensive care unit (ICU) admission, and/or the lengthy, slow recovery, any of which can contribute to trauma and ongoing uncertainty [5,6]. Based on dyadic interdependence theory, the distress experienced by survivors exacerbates the distress experienced by caregivers, and vice-versa, further contributing to this feedback loop [14,21,22]. Resilience is also interdependent, however, thus building resilient coping skills in survivors can improve coping in caregivers, and vice-versa [14,21,22].

To address the need to improve emotional distress post-CA, we developed *Recovering-Together after Cardiac Arrest* (RT-CA) following the National Center for Complementary and Integrative Health Research Framework for mind-body intervention development (Fig. 1) [27]. In a prior study, we interviewed CA survivor-caregiver dyads shortly after CA and queried them on their acute stressors and intervention needs [28]. We then elicited their feedback on preliminary RT-CA content, which was adapted from *Recovering Together* (RT), an evidence-based mind-body intervention to prevent emotional distress in patient-caregiver dyads admitted to the Neuroscience Intensive Care Unit [23]. During these interviews, dyads expressed a need for coping skills training, as well as anticipatory guidance and resources to manage CA-related stressors [28]. Based on this feedback, we refined RT-CA to its current iteration.

Here we describe our protocol for a small single-arm open pilot trial which aims to 1) examine preliminary feasibility and acceptability of RT-CA, and 2) gather user-feedback of the intervention and study procedures. We will use our findings to further refine RT-CA prior to testing definitive feasibility in a randomized control trial comparing RT-CA to minimally enhanced usual care.

2. Methods

2.1. Study design and setting

We will conduct a single-arm open pilot clinical trial of RT-CA. We will enroll at least 7 CA survivor-caregiver dyads (14 participants total), a similar sample to other open pilot trials that explored initial feasibility and acceptability and gathered feedback from the end-user prior to definitive feasibility testing [29,30].

RT-CA study staff will recruit and enroll CA survivors from intensive care units (ICUs) and stepdown floors at a single academic medical center. We outline study flow in Fig. 2.

3. Ethics Approval

The local institutional review board has approved this open pilot trial (#2024P001877).

3.1. Recruitment

3.1.1. Screening and enrollment

Textbox 1 describes our inclusion and exclusion criteria for participation.

3.1.2. Recruitment methods

We will identify potentially eligible survivors via two methods: 1) nursing and social work referrals and 2) review of ICU admission rosters. Study staff will conduct daily monitoring of identified CA survivors' neurological exams in the electronic medical record (EMR). Once an identified survivor has documented recovery of gross neurological function (e.g., awake, alert, and oriented), an RA will contact the patient's care team to remind them of the study, confirm the survivor's mental status, and ask for permission to approach the survivor. If the RA is granted permission, they will then coordinate with the bedside nurse to identify an optimal time to approach the survivor.

3.2. Enrollment

After obtaining permission to approach, study staff will meet with identified survivors at their bedside to introduce the study. If the survivor shows interest in participating, staff will ask them to confirm whether they have a caregiver. For interested and potentially eligible

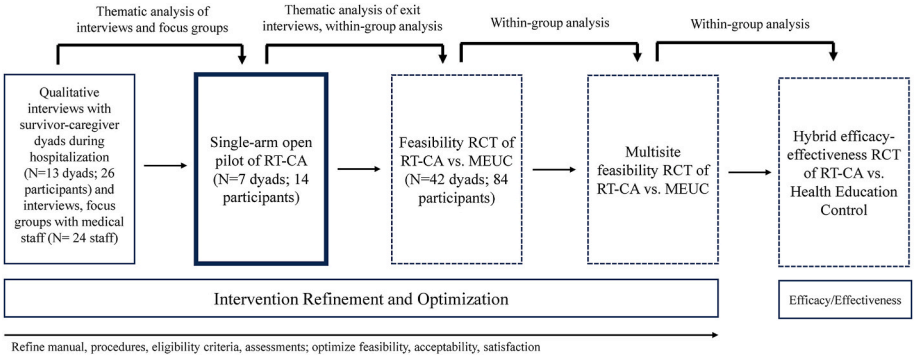


Fig. 1. Iterative development of a dyadic mind-body intervention for CA survivor-caregiver dyads following the NCCIH Research Framework. The protocol described here is the open pilot trial.
CA: cardiac Arrest; RT-CA: Recovering Together after Cardiac Arrest; RCT: randomized control trial; MEUC: minimally enhanced usual control.

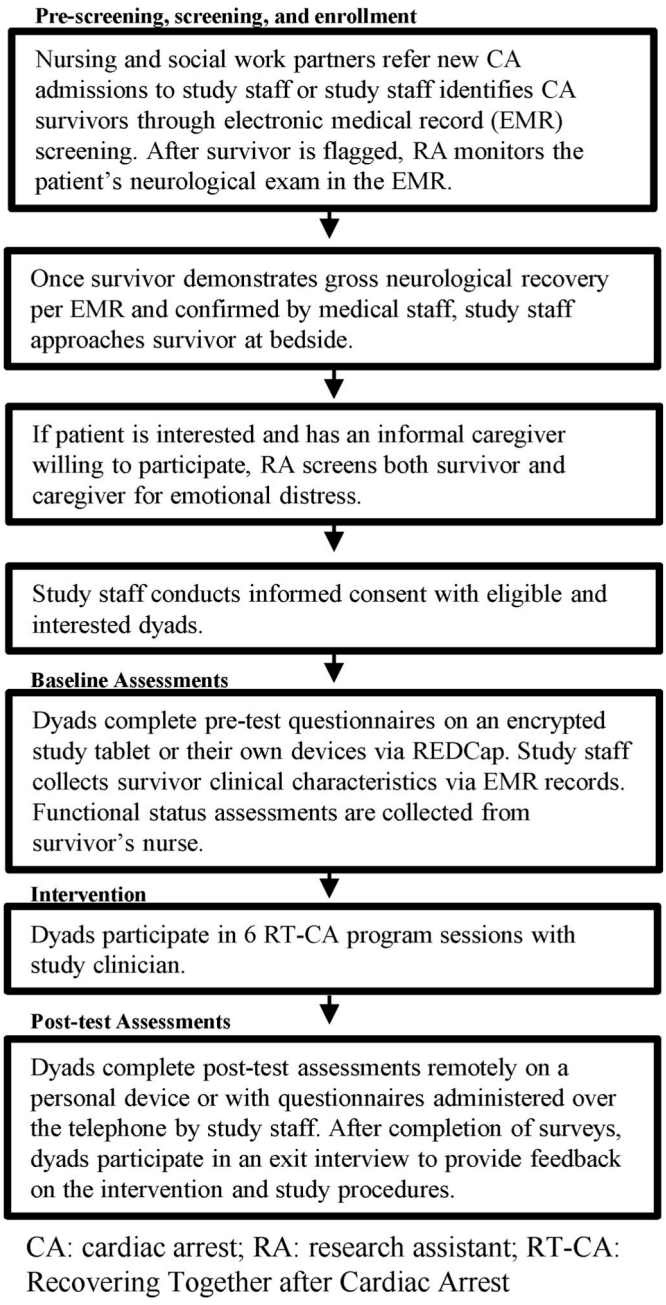


Fig. 2. Study flow.

survivors, an RA will conduct cognitive screening using the Short Form of the Mini Mental State Exam [35]. Potential survivors scoring ≥5 will be considered cognitively able to meaningfully participate and potentially eligible for inclusion. An RA will then screen each dyad member for emotional distress using the Hospital Anxiety and Depression Scale (HADS) [34]. At least one dyad member must score ≥8 on either HADS subscale to be considered eligible. A RA will consent eligible survivors and caregivers. Enrollment will require both individuals to consent to participation. After signing consent, survivors and caregivers will each complete their own self-report questionnaires (baseline assessments; Table 1) hosted by Research Electronic Data Capture (REDCap).We will compensate each participant $60 ($20 for completion of baseline assessments and $40 for post-intervention assessments) or $120 for the dyad.

3.3. RT-CA intervention content

After completion of baseline assessments, dyads will partake in 6, 30–45 min weekly intervention sessions with the study clinician (clinical psychologist). We will encourage dyads to engage in session 1 in-person, while the remaining sessions will be delivered at bedside (if the survivor is still admitted), or remotely over Zoom or phone call.

RT-CA sessions provide coping skills training (mind-body and resilience skills), anticipatory guidance of CA-related challenges, and resources to manage CA-related challenges (see Table 2 for full intervention outline). The first two sessions focus on managing uncertainty post-CA through relaxation, mindfulness (staying in the present), and dialectics (introducing mental flexibility by acknowledging contradictory thoughts and emotions, such as attending to both positive and negative aspects of the arrest). At the end of session 1, the clinician reviews CA survivorship resources with the dyad and revisits the resources as needed throughout the program. Sessions 3 and 4 focus on building the dyad's problem solving (using acceptance and change) and communication skills. Sessions 5 and 6 are forward-looking, focusing on living with meaning and according to one's values, as well as developing a "Cope Ahead" plan for future CA-related challenges.

3.4. Feasibility and acceptability outcomes

Primary outcomes are feasibility and acceptability markers. We present our benchmarks in Table 3. With 7 dyads, it will be possible to examine whether we reach the benchmarks of >70 % (good; at least 5 of 7 dyads) or >80 % (excellent; at least 6 of 7 dyads) on each of our feasibility measures.

3.5. Assessments

Each dyad member will complete their own self-report measures of emotional distress and treatment mechanisms (mindfulness, coping, social support; see Table 1 for full list) before and after completing the intervention. Study staff will also gather clinical CA characteristics of the survivor from the EMR (e.g., initial rhythm, arrest location, time to return of spontaneous circulation).

3.6. Exit interview procedures

Following completion of post-test assessments, dyads will participate in an exit interview. During the interview, study staff will ask for feedback on RT-CA content, study procedures, manuals, intervention delivery format (remote versus in-person), and timing. Study staff will also ask participants about feasibility and acceptability metrics (e.g., Recruitment – "what aspects of the program did you consider before deciding to participate?; Adherence – "what aspects of the program contributed to you attending all sessions?"), and their responses on pre- and post-questionnaires (e.g., If there is a change in depression scores - "over the course of the program, why do you think your mood went up (or down)?"). Exit interviews will last 10–30 min and be audio-recorded and transcribed for qualitative analysis.

3.7. Data analysis

The primary objective of this small, single-arm open pilot trial, is to explore preliminary feasibility, gather qualitative feedback from the end-user (CA survivor-caregiver dyads) on their experience of the intervention and study procedures, and use this information to refine the intervention as needed prior to definitive feasibility testing by way of a feasibility randomized trial.

To do this, we will conduct explanatory-sequential mixed methods. First, we will calculate frequencies and proportions of our primary feasibility and acceptability benchmarks. We will then explore pre-test and post-test changes in emotional distress and treatment mechanisms

Textbox 1
Inclusion and exclusion criteria for an open pilot trial of *Recovering Together after Cardiac Arrest*, a mind-body resilience intervention for CA survivors and their informal caregivers.

Inclusion Criteria:
Survivors:

- •Adults (18 years or older)
- •English speakers
- •Out-of-hospital or in-hospital cardiac arrest survivors with new diagnosis of "cardiac arrest" in electronic medical record and documented loss of pulse
- •Must have an informal caregiver (identified by the survivor as the primary family or friend involved in their care)
- •Scores ≥5 on Short Form of the Mini Mental State Exam for sufficient cognitive function for meaningful participation [26]
- •Ability and willingness to participate in in-person, live video, or phone intervention

Caregivers:

- •Adults (18 years or older)
- •English speakers
- •As identified by the survivor, caregiver must be primary family or friend involved in the survivor's care
- •Ability and willingness to participate in in-person, live video, or phone intervention

Either Dyad Member:

- •At least one member of the dyad screens for clinically significant emotional distress (≥8 on either Hospital Anxiety and Depression Scale subscale) [34]

Exclusion Criteria:

- •Active psychosis, mania, substance dependence, or suicidal intent or plan
- •Caregiver must not be a cardiac arrest survivor

(mindfulness, coping, perceived social support) using paired samples t-tests. We will calculate Cohen's d of change scores to explore effect sizes when assessing changes.

We will analyze our qualitative exit interview transcripts via hybrid deductive-inductive thematic analysis, following the Framework Method [50]. As discussed above, our exit interviews will explicitly ask participants about their feasibility and acceptability metrics, as well as their responses on pre- and post-test measures, providing them with an opportunity to elaborate on these outcomes. We will then integrate our quantitative and qualitative results and use our findings to refine RT-CA.

In addition to these analyses, we will also explore qualitative differences between dyads of out-of-hospital and in-hospital cardiac arrest survivors in terms of their exit interview feedback, due to their different phenotypes (out-of-hospital arrests are sudden and unexpected; in-hospital arrests occur in those who are already sick).

4. Discussion

Roughly 1 in 3 CA survivors and caregivers endorse clinically significant emotional distress [4,5] and many feel unprepared to manage CA challenges [6,7,31], however these needs are often unaddressed in standard post-CA care [5–7,28,31,32]. RT-CA will fill this gap for CA survivor-caregiver dyads by providing them with tailored resources and coping skills training.

Our open pilot trial design of RT-CA has several strengths. First, the intervention will be delivered to dyads early (during hospitalization), enabling them to utilize the intervention's resources and skills to prevent the common post-CA "downward spiral," that is: acute, untreated

Table 1
Measures administered at pre- and post-intervention timepoints.

Emotional Distress
Hospital Anxiety and Depression Scale – assesses anxiety and depression symptoms [34]
Post-Traumatic Stress Disorder Checklist – 5– assess post-traumatic stress symptoms [36]
Cognitive and Functional Status
Modified Rankin Scale– measures functional status [37]
Short Form of Mini Mental State Exam– assesses cognitive function for meaningful participation [26]
Mindfulness, Coping, and Resiliency
Cognitive and Affective Mindfulness Scale-Revised – measures dispositional mindfulness [38]
Enhancing Recovery in Coronary Heart Disease Social Support Inventory – measures perceived social support [39]
Measure of Current Status Part A – measures adaptive coping skills [40]
Mental Health and CA Resource Usage – investigator created survey that assesses mental health services and CA resource utilization
World Health Quality of Life-Brief – measures perceptions of quality of life including psychological, physical, social, and environmental [41]
Applied Mindfulness Process Scale – measures application of mindfulness skills [42]
Gratitude Questionnaire Six Item Form – measures dispositional gratitude [43]
Meaning in Life Questionnaire (MLQ) – measures degree of presence of and search for meaning in life [44]
Dyadic Interactions
Dyadic Relationship Scale – assesses positive and negative dyadic interactions [45]
Dyadic Coping Inventory – assesses coping abilities when dyad faces stressors [46]
Preparedness for Caregiving Scale – assesses readiness for caregiving responsibilities [47]

Table 2
Session outline for the *Recovering Together after Cardiac Arrest* (RT-CA) intervention.

Session	RT-CA Session Title	RT-CA Session Content
1	Coping with uncertainty part 1	Relaxation response (deep breathing), mindfulness, anticipatory guidance on common post-CA challenges, and provision and initial review of CA informational resources
2	Coping with uncertainty part 2	Dialectics (identifying contradictory thoughts and emotions), staying in the present 24-hour block, review of CA informational resources
3	Adjusting to CA	Acceptance and change coping skills
4	Navigating relationships	Effective communication within the dyad and with social supports
5	Meaning, purpose, and gratitude	Identifying sources of meaning, purpose, and gratitude
6	Cope ahead after CA	Develop individual and dyadic coping plans beyond RT-CA intervention, final review of CA guidance and resources

Notes: 1. The sessions will occur once weekly over 6 weeks. The first session is delivered at bedside unless barriers to caregiver visitation restrict in-person session; following sessions are remote unless survivor is still admitted.
2. Program is dyadic (both the survivor and caregiver participate together).
3. Sessions are 30–45 min.
4. All sessions begin with review of prior content.
5. Dyads will have access to a supplemental website during and after the program with recordings for additional mindfulness exercises.

Table 3
Feasibility and acceptability benchmarks for the open pilot trial of *Recovering Together after Cardiac Arrest*, a mind-body and resiliency intervention for CA survivor-caregiver dyads.

Outcome	Definition
Feasibility (>70 % Acceptable; >80 % Excellent)	
Recruitment	Percentage of eligible dyads who participate
Assessments	Percentage of dyads with no measures missing
Adherence	Percentage of dyads that complete 4/6 sessions
Therapist Fidelity	After randomly selecting 20 % of audio-recorded sessions, percentage of selected sessions with 100 % adherence to session content
Acceptability (>70 % Acceptable; >80 % Excellent)	
Treatment Acceptability	Percentage of dyads that score above the midpoint on the Client Satisfaction Questionnaire-3 [48]
Credibility and Expectancy	Percentage of dyads that score above the midpoint on the Credibility and Expectancy Questionnaire [49]
Adverse Events	Minimal adverse events (<1) related to the study

distress, followed by discharge without direction/follow-up care, leading to persistent, untreated cognitive and physical symptoms, which exacerbate and perpetuate distress [6]. Second, we will offer flexible delivery (i.e., in person, over video call, or over audio call) to increase access and reach, and to account for dyads' multiple transition points (e.g., preferred delivery can change depending on whether the dyad is in ICU, stepdown, inpatient rehabilitation, or home). Third, the intervention is intentionally low burden (6 brief, 30-45-min sessions) to account for fatigue, competing time commitments, and low cognitive bandwidth [28,35]. Relatedly, content in initial sessions is simple and practical to allow for easier comprehension for survivors experiencing ongoing cognitive recovery. Fourth, RT-CA skills are evidence-based (adapted from an efficacious intervention for neurocritical ill patients and their caregivers [23]), transdiagnostic (address multiple psychopathologies), and are tailored to CA-specific stressors.

Notable limitations of our pilot trial are the small sample size and single-site recruitment pool, both of which reduce generalizability. However, we will expand our catchment areas in our future multi-site feasibility and efficacies studies, in line with the NCCIH Research Framework for mind-body intervention development (Fig. 1) [27]. Moreover, our small open pilot sample size is consistent with the NCCIH's recommendations [33] as the goal is initial feasibility and refinement, and not maximizing external validity. Second, our recruitment is restricted to English-speaking dyads, survivors with good cognitive recovery, and caregivers of those who survived the CA. In future iterations we will adapt RT-CA for dyads in which the survivor has more severe cognitive impairments, and for bereaved caregivers; we also plan to culturally tailor it to other ethnolinguistic populations. Third, while offering different delivery modalities may introduce error variance, offering remote options can increase access to care. Indeed, flexibility in delivery modality was a priority for dyads in our prior qualitative interviews [28]. Finally, over the course of 6 weeks dyads' stressors may differ from session to session depending on the survivor's current setting (i.e., in hospital, in rehab, at home), and the study clinician will tailor intervention content based on stressors related to each setting. In a future fully powered clinical trial of RT-CA, we will examine the impact of discharge disposition as an effect modifier.

5. Conclusions

Our findings from this open pilot trial of our mind-body intervention for CA survivor-caregiver dyads, RT-CA, will inform the next iteration of our intervention as we prepare for feasibility testing, and ultimately an efficacy/effectiveness RCT.

CRediT authorship contribution statement

Danielle La Camera: Writing – original draft, Visualization, Project administration. **Jonathan Elmer:** Writing – review & editing, Conceptualization. **Sarah M. Perman:** Writing – review & editing, Conceptualization. **Michael W. Donnino:** Writing – review & editing, Conceptualization. **Ona Wu:** Writing – review & editing, Conceptualization. **Robert A. Parker:** Validation, Conceptualization. **Ana-Maria Vranceanu:** Writing – review & editing, Conceptualization. **Alexander M. Presciutti:** Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: AMP and SMP are both volunteer scientific advisors of the Cardiac Arrest Survivor Alliance.

Acknowledgements

Alexander M. Presciutti receives salary support and project funds for this project from the National Center for Complementary and Integrative Health (Grant Numbers: K23AT012487 and L30AT012564).

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