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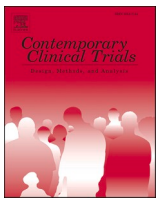

Supporter-focused early intervention for recent sexual assault survivors: Study protocol for a pilot randomized clinical trial

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ABSTRACT

Introduction: Sexual assault is a common form of trauma that is associated with elevated risk for negative psychosocial outcomes. Although survivors' social relationships could serve as a major protective factor against negative outcomes, survivors' supporters often lack knowledge regarding effective responses and may inadvertently respond in ways that are detrimental to healing. Communication and Recovery Enhancement (CARE) is a 2-session early intervention for survivors of a past-10-week sexual assault and their supporters that aims to improve supporters' ability to respond effectively.

Objective: In this paper, we present a study protocol for a pilot randomized clinical trial of CARE (NCT05345405). The goal of this pilot trial is to understand the feasibility, acceptability, and preliminary efficacy of two versions of CARE: a version in which survivors and supporters attend sessions together (dyadic version) and a version in which supporters attend sessions alone (supporter-only version).

Methods: Survivors aged 14+ with elevated posttraumatic stress will enroll with a supporter of their choosing. Dyads will be randomized to dyadic CARE, supporter-only CARE, or waitlist control, and will complete self-report assessments at baseline, post-session-1, and follow-ups (1, 2, and 3 months post-baseline). We will use descriptive statistics, effect sizes, and exploratory statistical tests to characterize the acceptability of both CARE versions, impact on knowledge change from baseline to 1 month, impact on disclosure experiences at 1 month, and impact on functional outcomes at 3 months.

Discussion: Results will be used to inform future changes to CARE and determine whether a fully-powered randomized controlled trial is warranted.

Sexual assault is a common form of trauma: approximately 36% of women, 17% of men, and 34–47% of transgender and gender diverse individuals are sexually assaulted in their lifetime [24,25,28]. Survivors of sexual assault have high risk for psychopathology [9,13,16]. Three quarters of survivors have elevated symptoms of posttraumatic stress disorder (PTSD) one month after sexual assault [15]. Natural recovery of PTSD symptoms is common, but 41% of survivors still have PTSD 12 months later [15].

Given these harms, it is important to test preventative interventions that facilitate natural recovery. There is evidence that early interventions—those delivered within 3 months of trauma—are effective [19,20,22]. Early interventions have reduced PTSD severity among sexual assault survivors [26].

Existing early interventions focus only on sexual assault survivors and do not target the social contexts in which survivors' recovery occurs. However, these social contexts are important to recovery [9,17,29].

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Nearly all survivors seek help from supporters (e.g., friends, family, romantic partners) [30,32], often soon after assault [2]. Unfortunately, most survivors receive negative reactions when they seek help, and these reactions increase risk for psychopathology [14].

Importantly, supporters do not necessarily respond in negative ways with malicious intent, but instead due to a lack of knowledge about effective responses, a lack of knowledge about survivors' preferences, or difficulty managing their emotional reactions [1]. Unfortunately, though, even well-intentioned negative reactions may increase survivors' risk for psychopathology. Indeed, the reactions that are most strongly associated with psychopathology—controlling survivors' decisions and distracting survivors [14]—may be offered with the intention of helping survivors.

To our knowledge, one prior preventative intervention has aimed to improve responses to disclosures. Supporting Survivors and Selves trained groups of undergraduate students in support skills in anticipation of receiving a future disclosure of interpersonal violence [18]. In a randomized clinical trial, this intervention led to improvements in intended responses but did not change actual responses among those who prospectively received a disclosure [18]. Intervening with supporters who are currently in a support role with a survivor, rather than individuals who might be a supporter in the future, could potentially increase the impact of supporter-focused interventions. However, there is currently no empirically-supported intervention to improve supporters' ability to respond effectively to survivors in the immediate aftermath of sexual assault and thereby improve survivors' downstream outcomes.

We created CARE (Communication and Recovery Enhancement) to address the lack of early interventions to improve supporters' responses. CARE is intended for survivors of past-10-week sexual assault and a support person of their choice. It involves two telehealth sessions with a clinician and a supporter, with the survivor present (dyadic version) or without the survivor present (supporter-only version). Either supporters or survivors may initiate CARE services, although in all cases, the survivor must be screened and consent to both parties' enrollment. The first session provides psychoeducation and skills aiming to encourage assault-related conversations and improve supporters' responses (Table 1). Between sessions, both parties complete a workbook together, which involves reviewing all session content, practicing skills, and clarifying the survivor's support needs. The second session involves reviewing and troubleshooting skills practice. The same content is delivered in the dyadic and supporter-only versions. In the supporter-only version, the content is delivered solely as part of private workbook completion with the supporter rather than also during appointments with the clinician. As a preventative intervention, CARE aims to prevent common problems stemming from sexual assault before they become established, thereby reducing the need for higher-burden treatments and ultimately reducing the impact of assault on survivors and service systems.

Table 1
CARE session content.

Content Area	Session 1	Session 2
Opening	Introductions and icebreaker	Review of workbook practice
Understanding reactions to sexual assault	Psychoeducation and discussion of experiences	Review of Session 1 psychoeducation and discussion of skills practice
Coping with reactions to sexual assault	Psychoeducation and discussion of how skills could apply to clients	
Starting conversations	Psychoeducation and discussion of preferences	
Supporters' responses in conversations	Psychoeducation, discussion of preferences, and supporter roleplay with clinician (if supporter only) or survivor (if dyadic)	
Giving supporters feedback about responses	Psychoeducation and discussion of preferences	
Closing	Discussion, recap, and planning skills practice	Discussion and planning skills practice

CARE was created by adapting a 2-session dyadic early intervention for patients following hospitalization for illness or injury [10]. The prior intervention reduced PTSD and negative supporter reactions relative to assessment-only control at 24-month follow-up [7,12]. The creators of the prior intervention and the principal investigator of the current trial revised the intervention for sexual assault survivors. These revisions included decreasing focus on bidirectional disclosure, expanding content on negative reactions, and adding a supporter-only option to allow CARE to be delivered to supporters concurrently with survivors' service system contact and reduce burden on survivors.

Then, to increase inclusivity across intersections of client identity (e.g., gender, race/ethnicity, religion, age, relationship with supporter), CARE materials were reviewed and revised by an Inclusivity Advisory Board, comprised of four experts in cultural adaptations of related interventions. Changes included adding culturally-relevant content (e.g., examples of bodily experiences of emotion), prompts for clients to share relevant aspects of their identity (e.g., cultural norms around talking about difficult thoughts and emotions), and discussion prompts to help clients tailor skills to their needs and values.

Finally, we conducted 12 feedback sessions with survivor-supporter dyads in which the intervention was role-played with dyads and feedback was elicited. Materials were iteratively revised following sessions. Revisions included removing content on how supporters can get their needs met from survivors, adding concrete suggestions and roleplays to the section on positive reactions, and clarifying confusing wording.

The goal of this protocol is to describe our methods for a pilot randomized clinical trial of dyadic and supporter-only CARE. Our goals are to understand feasibility, acceptability, and preliminarily characterize efficacy. We hypothesize:

H1: Dyadic and supporter-only CARE will be rated as acceptable by survivors and supporters at 1-month follow-up.

H2: Dyadic and supporter-only CARE will lead to increases in survivor and supporter knowledge from baseline to 1-month follow-up.

H3: Dyadic and supporter-only CARE will improve disclosure experiences (i.e., increasing survivor disclosure frequency, reducing supporter negative reactions, increasing supporter responsiveness) at 1-month follow-up compared to waitlist.

H4: Dyadic CARE and supporter-only CARE will improve functional outcomes among survivors (i.e., PTSD, stress, relationship quality) and supporters (i.e., stress, relationship quality) at 3-month follow-up compared to waitlist.

We will conduct exploratory follow-up tests for each hypothesis to compare the dyadic and supporter-only versions of the intervention.

1. Methods

This trial has been reviewed by the University of Washington Institutional Review Board and registered with ClinicalTrials.gov (NCT05345405).

1.1. Trial design

This pilot randomized clinical trial uses a unmasked, prospective, parallel group, superiority design. See Fig. 1 for a participant flow diagram. Participants will be allocated 1:1:1 (unstratified) to dyadic CARE, supporter-only CARE, or waitlist control. Assessments will be completed via self-report at baseline, post session 1, and 1, 2, and 3 months post-baseline.

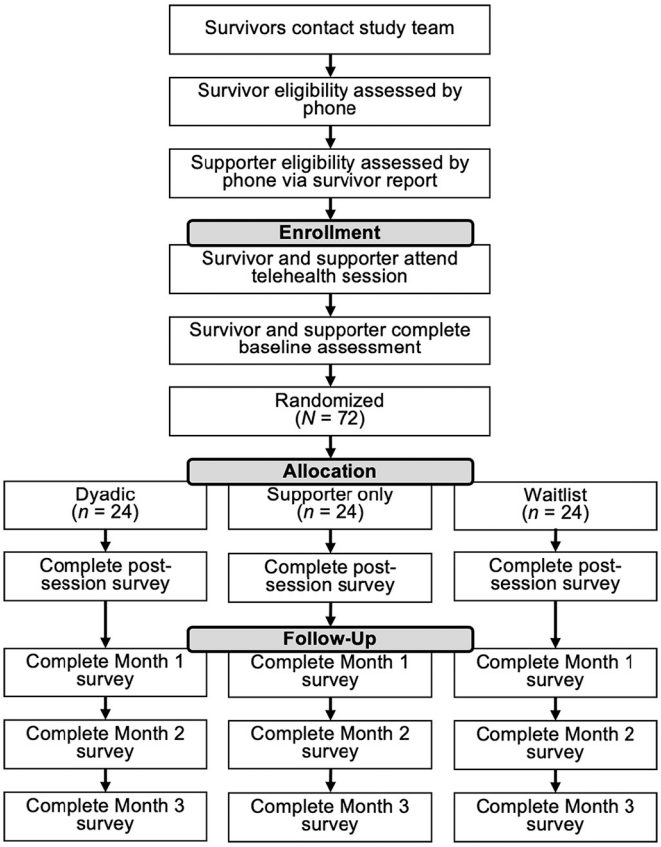

Fig. 1. Participant flow diagram.

1.2. Advisory boards

We formed a Researcher-Practitioner Advisory Board to ensure that methods reflect best research and clinical practices. Practitioner members of the board include staff from recruitment sites and experts in responses to sexual assault and/or trauma. Researcher members include experts in dyadic research, clinical trials of trauma interventions, and sexual assault recovery. Meetings involve monitoring adherence, troubleshooting challenges, and interpreting results.

We also formed a Survivor Advisory Board to ensure that the study reflects survivor needs and preferences. The Survivor Advisory Board currently has 4 members; members will be added over the course of the study. Meetings involve providing feedback on study materials, methodological decisions, and study results.

1.3. Spanish translation

Our partner sites identified providing services to non-English-speaking survivors as a key area of need. Thus, we will enroll individuals who speak either English or Spanish. The intervention and study materials were translated into Latin American Spanish by credentialed translators and reviewed for accuracy by native Spanish speakers, as recommended [5]. The intervention will be delivered in Spanish by a study staff member who is a native Spanish speaker.

1.4. Participants

Participants will be 72 survivors of a past-10-week sexual assault and their supporters (e.g., friends, family, romantic partners) (total $N = 144$). As this is a pilot trial, the sample size was selected primarily for feasibility rather than significance testing.

Survivor inclusion criteria are:

1. Age 14+ years
2. Can speak/read English or Spanish
3. Have access to a Zoom-capable device
4. Screened for eligibility within 10 weeks of sexual assault, defined as any unwanted, distressing sexual contact (e.g., unwanted touching, coerced sexual activity, rape)
5. Able to attend first study session within 2 weeks of screening
6. Elevated PTSD symptoms at screening as operationalized by a Primary Care PTSD Screen [27] score of 2/5 or above
7. Able to identify an eligible supporter
8. Able to receive and complete surveys privately
9. Located in the US

Inclusion criteria for supporters are assessed via survivor report and include:

1. Age 14+ years
2. Can speak/read English or Spanish
3. Have access to a Zoom-capable device
4. Able to attend first study session within 2 weeks of survivor's screening
5. Are in contact with the survivor at least once a week
6. In the opinion of the survivor, are able to make an independent decision about whether or not to participate in the study
7. Able to receive and complete surveys privately
8. Located in the US

Exclusion criteria for survivors are:

1. Active psychosis
2. Active suicidal intent

Exclusion criteria for supporters are assessed via survivor report and include:

1. Perpetrated the sexual assault
2. Engaged in severe past-year violence or abuse (as defined by the survivor) against the survivor
3. The survivor has not told the supporter about the sexual assault at the time of screening and was not already planning to tell the supporter
4. In the opinion of the survivor, relational conflict exists between the survivor and supporter that could be exacerbated by participation
5. In a primarily professional, paid, time-limited role with the survivor (e.g., therapist)

1.5. Recruitment

Participants will be recruited nationally, primarily via survivor-serving sites, with supplemental social media and community advertisements. Clinical staff will present flyers to survivors or their supporters. Survivors or their supporters may enter their contact information in an online form or contact the study team directly. If supporters contact the study, we will answer their questions and discuss how to refer the survivor while minimizing coercion.

1.6. Procedures

Survivors will be screened by phone. Following verbal consent, survivor eligibility criteria will be assessed, and supporter eligibility criteria will be assessed via survivor report. Eligible survivors will be scheduled for a telehealth appointment within two weeks of screening and will be instructed to invite their supporter.

Survivors and supporters will attend the telehealth appointment together. The clinician will send electronic consent forms to both parties and review forms orally. Both members of the dyad will be required to consent for the dyad to participate. Following consent, participants will

complete baseline questionnaires. If dyads are in the same location, we will instruct them to go to separate rooms and not discuss responses with each other.

Following baseline, the dyad will be randomized via computer algorithm. Participants randomized to waitlist will schedule their session for 3 months later. Participants randomized to dyadic or supporter-only CARE will start session 1 immediately. Survivors in dyads randomized to supporter-only CARE will leave the appointment and will be instructed to go to a different room if they are in the same location as the supporter.

1.7. Intervention delivery

The intervention will be delivered by either the first author (a licensed clinical psychologist) or a staff member trained by the first author. Both telehealth sessions will be 90 min and will be delivered using a slide deck and a script. Sessions will be audiorecorded for supervision and fidelity tracking. Clients will be sent an electronic and/or paper workbook following session 1. The clinician will complete a clinical note regarding content coverage and clinical observations. In session 2, the note will document attendance, homework completion, and skills practice. We will also assess homework completion and skills practice via survivor and supporter self-report at 1-month follow-up.

1.8. Post-session & follow-up assessments

All assessments will occur via online self-report surveys. Survey invitations and reminders will be sent via email or text message. Participants will complete follow-up questionnaires after session 1 and at 1, 2, and 3 months post-baseline to assess changes in knowledge, disclosure, and symptoms. We selected these time points because recovery occurs most rapidly within the first 3 months post-assault [15].

Survivors and supporters will be paid $10, $10, $20, $30, and $40 for baseline, post-session-1, 1-month, 2-month, and 3-month assessments, respectively (total possible per person: $110). Participants may choose to be paid via preloaded debit card or emailed gift card and will be provided with referrals.

1.9. Measures

1.9.1. Acceptability

1.9.1.1. Survivor and supporter preferred version of CARE at baseline. We will ask both participants which version of the program they prefer to receive (dyadic, supporter-only, no preference).

1.9.1.2. Survivor and supporter satisfaction with received version of CARE at Month 1. Among survivors and supporters randomized to dyadic or supporter-only CARE, we will assess satisfaction using the 8-item Client Satisfaction Questionnaire [4] at the Month 1. Items are rated on a 1 to 4 scale. This measure has high internal consistency (α = 0.91) and convergent validity [4].

1.9.2. Impact on knowledge at Month 1

We will use brief assessments created for this study to assess self-reported comprehension of CARE concepts. The survivor knowledge scale will include 8 items and the supporter knowledge scale will include 9 items.

We will assess supporter confusion about helping behavior via supporter self-report using the 6-item Confusion subscale of the Impact on Friends scale [1]. This measure has adequate internal consistency (α = 0.84) [1]. We will also assess survivor confusion about help-seeking behavior via survivor self-report using a 4-item measure created for this study to parallel the supporter confusion subscale. Items are scored on a 1 (Strongly disagree) to 5 (Strongly agree) scale.

1.9.3. Impact on disclosure experiences at month 1

CARE's proximal goal is to increase disclosure of thoughts or emotions related to the sexual assault and improve supporter responses in these conversations. Because the need for these conversations is expected to decrease over time, we will evaluate impact on these outcomes at Month 1.

1.9.3.1. Survivor disclosure frequency. Survivor disclosure frequency will be assessed via survivor self-report using the item: "In the past month, about how many separate times did you have a conversation with your supporter about the *[preferred term for sexual assault]* or its effects on your life?" Supporters will respond to a parallel item as an informant report.

1.9.3.2. Supporter reactions. Supporter past-month negative reactions will be assessed via informant (i.e., survivor) report using the Social Reactions Questionnaire- Shortened [31]. We will assess supporters' overtly hostile negative reactions (i.e., blame, stigma, infantilization) via the 6-item Unsupportive Acknowledgement subscale. We will assess supporters' subtle unsupportive reactions (i.e., distraction, controlling decisions, egocentric reactions) via the 6-item Turning Against subscale. Supporters will respond to a parallel version of this measure regarding their own behavior.

Supporter responsiveness will be assessed via survivor report using the 8-item Partner Responsiveness Inventory [11]. This scale has strong convergent and predictive validity, and strong internal consistency (α = 0.88–0.93) [11].

1.9.4. Impact on functional outcomes at month 3

We expect that short-term increases in disclosure and supportive responses will have longer-term benefits. We will thus assess mental health and relational outcomes at Month 3.

1.9.4.1. Survivor PTSD. We will use the Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) to assess survivor PTSD symptom severity and survivor provisional PTSD diagnostic status via survivor self-report [6]. The PCL-5 includes 20 items assessing past-month DSM-5 criteria for PTSD and has scoring rules to assign a provisional diagnosis. The PCL-5 has demonstrated strong internal consistency (α = 0.94), test-retest reliability, and convergent and discriminant validity [6].

1.9.4.2. Survivor and supporter stress. We will use the 7-item Stress subscale of the Depression, Anxiety, and Stress Scales [3] to assess survivor stress (via survivor self-report) and supporter stress (via supporter self-report). This subscale has strong internal consistency (α = 0.91) and convergent validity [3].

1.9.4.3. Survivor & supporter perceived relationship quality. We will assess survivor perceived relationship quality and supporter perceived relationship quality via each participant's self-report using the 7-item Relationship Assessment Scale [21]. This scale has strong criterion-related and convergent validity [34] and has internal consistency of α = 0.86.

1.10. Ethical considerations

Participants may be as young as 14, which raises ethical considerations around capacity to consent. We obtained a waiver of parental consent given that this study involves few risks, the intervention could reduce risk for negative outcomes, and notifying parents could have greater risks than the consent process (e.g., if the parent did not know that the participant was assaulted). In addition, the age of consent for mental health treatment is 13 in the state where the study is based.

Participants might find it difficult to decline participation if they perceive the study to be part of clinical services or if they are directly

asked to participate by a clinician. Thus, we will emphasize throughout participant contacts that the study is separate from clinical services. To further reduce real or perceived pressure, we have made every effort to mask patients' decisions about participation from clinical staff.

Supporters might find it difficult to decline participation when asked to participate by a survivor. To reduce this risk, we will discuss with the survivor during phone screening whether their supporter would be able to make a free decision to participate, and encourage them to choose someone else if not. Further, we emphasize the importance of making an independent decision to participate and check with each participant privately before enrolling. Finally, although both the survivor and supporter must consent to enroll and thus consent decisions will not be private, either individual may withdraw without affecting the other's eligibility.

We have taken precautions to protect privacy. First, direct identifiers will be stored separately from research data and linked only with an identity key. Second, participants will be told that they can decline to answer any questions. Third, data will be stored in secure, restricted-access servers. Fourth, this study is covered by a Department of Justice privacy certificate. Fifth, we will check that surveys are sent to a device and account not accessible by their dyadic partner.

1.11. Analyses

Analyses will be conducted with the intent-to-treat sample. As this study is not powered to detect statistical significance, we will examine the direction and magnitude of effects to preliminarily understand efficacy and test significance in an exploratory manner only. Within-group *d*s will be calculated as the mean-level difference in scores from baseline to follow-up for each condition divided by the standard deviation of change scores. Between-group *d*s will represent relative change between conditions and will be calculated as the difference between within-group *d*s.

1.11.1. Acceptability (H1)

We will use descriptive statistics to summarize acceptability ratings among dyads randomized to dyadic or supporter-only CARE. We will use independent-samples *t*-tests and between-group *d*s to compare acceptability by condition.

1.11.2. Efficacy (H2–4)

We will calculate within- and between-group *d*s to represent mean changes on focal outcomes. We will use the reliable change index to quantify whether change is unlikely to be attributable to measurement error [23], and we will report odds ratios for differences in percent with reliable improvement by condition. We will also report the percent of participants meeting diagnostic criteria based on the PCL at baseline and 3-month follow-up.

Paired sample t-tests will evaluate mean changes from baseline to follow-up. We will test time-by-condition interactions in random-effects models using maximum likelihood estimation to account for missing data. We will test covariates including relationship type, study clinician, participant age, and prior assault history. We will conduct sensitivity analyses with English and Spanish-language participants separately.

2. Results

Enrollment is expected to occur from May 2022 to December 2023. We expect that data collection will be completed by March 2024 and the results will be submitted for publication by late 2024.

3. Discussion

This protocol reflects a 3-arm pilot randomized clinical trial testing CARE, a novel intervention for survivors of past-10-week sexual assault. Although the importance of sexual assault survivors' social contexts in their recovery is well-established [9,17], CARE is the first preventative intervention to directly target these contexts. This trial aims to evaluate the feasibility, acceptability, and preliminary efficacy of CARE to inform future research.

CARE has several strengths. First, its focus on changing survivors' social contexts (rather than survivors themselves) is novel and consistent with both an empowerment focus [33] and suggested strategies for cultural responsiveness in trauma-focused interventions [8]. Second, the CARE adaptation process prioritized survivor feedback and aimed to maximize intersectional inclusivity, which we expect will increase its congruence with participants' needs and values. Third, as a 2-session telehealth intervention, CARE is low burden to survivors and service systems. Fourth, as a preventative intervention, CARE may prevent outcomes of sexual assault before they become chronic, thereby reducing the duration of morbidity and the need for intensive treatments. Fifth, CARE's simple, structured format can be feasibly delivered by individuals without advanced mental health intervention training, which could increase dissemination potential.

However, CARE has a key limitation: it requires the presence of a supporter who is willing to provide support. As a result, it may fail to improve reactions among supporters with the poorest support skills, and cannot improve support among survivors without a supporter who is willing to attend sessions. This may create a ceiling effect: dyads who enroll may already have strong relationships that would have promoted recovery without CARE.

The trial design has strengths and limitations. First, we will examine two versions of CARE: dyadic and supporter-only. Supporter-only CARE represents the first early intervention to intervene primarily with a support person of a trauma survivor. If effective, supporters could be offered CARE while survivors attend healthcare appointments. If both versions are effective, survivors could select their preferred version. However, a limitation of random assignment to CARE versions is that efficacy might be higher (and potentially more reflective of clinical practice) if survivors are able to select their preferred version. Second, we will collect data from both survivors and supporters, which will allow us to understand CARE's impact on both parties and validate relational outcomes (e.g., disclosure frequency) via informant report. However, this introduces complications in interpretation in the case of incongruence between survivor and supporter report. Survivor-reported outcomes will be the primary outcomes of interest.

Our efforts to maximize generalizability introduce strengths and limitations. First, our broad inclusion criteria and inclusion of groups often not reflected in similar research (e.g., adolescents, Spanish speakers) will increase external validity, but this heterogeneity could also obscure effects. Second, our advisory boards will help us ground our approach in needs and preferences of survivors and clinicians. However, the intervention will be delivered by study staff, and so will not be able to establish feasibility and effectiveness when delivered by nurses or non-mental-health specialists. Third, our enrollment of Spanish speakers will allow us to understand the feasibility of a larger trial with this population, but our reliance on translated measures introduces bias. Fourth, the remote design may increase study participation among individuals for whom in-person sessions would have been a barrier and allow us to understand the feasibility of telehealth delivery. However, this may pose barriers for individuals without reliable Internet or smartphone/computer access. In addition, because of the remote design, we elected to exclusively use self-report measures, which could introduce bias.

4. Conclusion

In conclusion, CARE is a promising intervention with high dissemination potential to individuals at elevated risk of negative outcomes. This pilot work will gauge initial feasibility, acceptability, and efficacy to inform adaptations and the need for future testing.

Author note

The authors affirm that they have no competing interests.

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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

No data was used for the research described in the article.

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