



Study protocol: A multimethod psychophysiological randomized controlled trial of a couple therapy for post-traumatic stress disorder

Ilil Zaks^{a,*}, Rachel Dekel^b, Yael Shoval Zuckerman^b, Danny Horesh^{a,c}

^a Bar-Ilan University, Department of Psychology, Ramat Gan 590002, Israel

^b Bar-Ilan University School of Social Work, Ramat Gan 590002, Israel

^c Grossman School of Medicine, Department of Psychiatry, New York University, 550 First Avenue, New York, NY 10016, USA

ARTICLE INFO

Keywords:

#PTSD
Couples therapy
Autonomic nervous system
Randomized controlled trial
Physiological synchrony
Telepsychology

ABSTRACT

Posttraumatic stress disorder (PTSD) sequelae often have ripple effects on victims' families and spouses. Yet there has been a lag in the development and study of couple therapy for PTSD. To fill this gap, we present here a protocol for a study examining the efficacy of Cognitive Behavioral Conjoint Therapy (CBCT), a 15-session couple therapy protocol meant to alleviate PTSD and improve relationship satisfaction, in the Israeli context. The study will be a randomized controlled trial examining outcomes and processes of change via self-report questionnaires, qualitative interviews, and physiological measures (e.g., both partners' heart rate variability and electrodermal activity). We will employ a modified remote treatment protocol via video conferencing. The study will examine whether there is a reduction in couples' levels of symptomatic, emotional, and behavioral difficulties following CBCT and whether relationship satisfaction and couples' physiological synchrony increases. The study will also examine physiological and psychological change mechanisms in CBCT. Sixty Israeli couples ($n = 120$) will be randomly assigned to either a CBCT group or a wait-list control group. Outcomes will be assessed at four timepoints: before treatment, during treatment, post-treatment, and four months after treatment. The proposed study has the potential to shed light on the unique psychological and physiological mechanisms underlying CBCT and will be the first RCT study to employ this unique methodology in CBCT research, particularly in a video conferencing setting. This study may increase our ability to offer effective, cost-efficient, and attainable treatments for patients with PTSD and their spouses.

1. Introduction

Individuals who develop posttraumatic stress disorder (PTSD) following exposure to trauma often experience ongoing significant functional and social impairment, affecting their professional life, home life, and social life [1,2]. PTSD is characterized by four main symptom clusters: re-experiencing, avoidance, negative alterations of condition or mood, and alterations in arousal and reactivity [3]. It is often associated with other comorbidities, mainly depression [4].

Posttraumatic stress disorder often has a ripple effect on close others, including survivors' partners and children. Partners of individuals with PTSD in various cultures constitute a high-risk population [5,6], reporting high levels of emotional distress including anxiety and depression, as well as marital problems ([7]), such as low levels of intimacy and marital satisfaction [8], and exposure to domestic violence [9]. Despite the extensive knowledge on the effects of PTSD on couple

relations, and findings showing that individual interventions do not necessarily improve family functioning [10–12], there has been a major lag in the development and study of couple interventions in the context of PTSD [13]. Currently, there are only a few couple-based interventions for PTSD, one of which, Cognitive Behavioral Conjoint Intervention [CBCT, 14] has the most empirical support in the widest variety of populations [15,16].

CBCT for PTSD is a 15-session, manualized therapy developed by Monson and Fredman [14], designed to simultaneously improve PTSD symptoms and enhance relationship functioning. Studies on CBCT indicate improvements in both PTSD symptoms and relationship satisfaction across a range of relationship distress levels, traumatic events, and a variety of couple types (i.e., married, cohabitating, same sex) [9,15,17]. Additionally, studies have shown that following CBCT, partners experienced improvement in their individual mental health symptoms, psychological distress, and patients' posttraumatic growth

* Corresponding author.

E-mail addresses: ililzaks@gmail.com (I. Zaks), Rachel.Dekel@biu.ac.il (R. Dekel), yael.shoval@biu.ac.il (Y.S. Zuckerman), Danny.Horesh@biu.ac.il (D. Horesh).

<https://doi.org/10.1016/j.cct.2023.107280>

Received 3 February 2023; Received in revised form 25 June 2023; Accepted 3 July 2023

Available online 5 July 2023

1551-7144/© 2023 Elsevier Inc. All rights reserved.

[15,18,19].

Nevertheless, there remain gaps in our knowledge about CBCT. First, CBCT studies have mainly been implemented in North America; thus, knowledge about CBCT's efficacy in other family contexts and cultures is very limited. The Israeli culture differs from the North American one in various ways. Military service is compulsory for men and women and the security situation in Israel is far less stable and includes frequent wars and terrorist attacks which range close to the border and the cities. This situation leads to widespread exposure of citizens to potentially traumatic events. In addition, Israel is a more traditional and family-oriented society as people marry more, divorce less, and the fertility rate is higher [20,21]. Second, the efficacy of CBCT has been studied using mainly a face-to-face format. Preliminary results on brief CBCT showed that brief CBCT via videoconferencing was equally effective as face-to-face brief CBCT [22] and studies of individual videoconferencing treatments for PTSD have shown positive effects in treating PTSD [23–25]. Yet following COVID-19 and the growing use of Telehealth more research on this format's efficacy in CBCT is needed. Finally, there have been only a few randomized controlled trials (RCTs) of this intervention, with those that do exist employing only self-report questionnaires, neglecting the study of physiological changes during and after CBCT in both spouses.

Along with psychological and emotional distress, PTSD is characterized by significant physiological arousal and reactivity. Irregularities in the autonomic nervous system (ANS), characterized by a hyperactive sympathetic nervous system (SNS) and a hypoactive parasympathetic nervous system (PNS), have been documented among individuals with PTSD in numerous studies [26]. Such irregularities manifest as higher heart rate, higher blood pressure, lower skin conductance, and lower heart rate variability [27]. Spouses of individuals with PTSD have also been found to exhibit similar physiological responses [28,29]. Yet there is meager research on the reciprocal interpersonal physiological synchrony between individuals with PTSD and their spouses. Studies on synchrony among couples in general have shown mixed results that present a complicated and dynamic picture.

To fill these gaps, the proposed study will examine the efficacy of CBCT among Israeli couples in which one spouse suffers from PTSD. Following previous calls for further research [30] we will employ an RCT design to examine both outcomes and processes of change via multiple methods of assessment, including self-report questionnaires, qualitative interviews, and physiological synchrony measures. The primary outcome measures to assess CBCT efficacy will be PTSD symptom severity level and relationship satisfaction level.

Qualitative interviews will allow for an in-depth examination of the experience of the therapeutic process and its effects [31]. Physiological assessments before, after, and throughout the sessions will enable an understanding of the development and change in synchrony between spouses, increasing our knowledge regarding the effects of PTSD on couple dynamics and the association between these measures and emotional and behavioral regulation. Finally, given the ongoing nature of COVID-19, the intervention will be delivered remotely, via videoconferencing, and for the first time the full protocols' efficacy in this format will be examined.

2. Design & method

2.1. Aims and hypotheses

The **first aim** of this study is to examine the efficacy of CBCT using multiple methods in an RCT design in the Israeli context delivered via videoconferencing. The primary outcome measures for this aim will be PTSD symptoms and relationship satisfaction. The secondary outcome measures will be anger, guilt, depression, anxiety, relationship aggression, and posttraumatic growth. The following hypotheses related to treatment efficacy will be examined.

Psychological main effect.

1. We expect that the CBCT group will show a larger decrease in

partners' level of PTSD symptoms and a decrease in depression, anger, guilt and relationship aggression among both partners in comparison to wait-list (WL) controls at the end of the 15- sessions treatment. Post-traumatic growth and relationship satisfaction of both partners is expected to increase. These results are expected to be maintained at the follow-up measurement, 4 months post treatment.

Physiological main effect.

2. We expect that partners with PTSD will show an increase in HRV and a decrease in electrodermal activity (EDA) following CBCT, compared to WL controls at the end of the 15- sessions treatment.

Exploratory hypothesis:

The efficacy of CBCT via videoconferencing will be tested as an exploratory hypothesis due to lack of previous research on this matter.

3. Second aim

The second aim of the study is to understand change processes and mechanisms specific to CBCT. The following hypotheses will be examined.

Psychological mechanisms of change.

1. We hypothesize that the positive effect of CBCT on PTSD symptoms and relationship satisfaction will be mediated by accommodation and emotion regulation: Namely, compared to the WL group, the CBCT group will report higher levels of these factors at mid-treatment, and mid-treatment scores will, in turn, be associated with better outcomes (e.g., PTSD symptoms, depression, relationship satisfaction) post-treatment, at the end of the 15- sessions.

Physiological mechanisms of change.

1. We hypothesize that the positive effect of CBCT on PTSD symptoms and relationship satisfaction will be mediated by physiological synchrony. We expect that among the CBCT group, there will be a change in physiological synchrony levels post-treatment at the end of the 15- sessions (as measured by HRV and EDA co-variation at the mid-point measurement), and that these in turn will be associated with more improvement in outcome measures.

2. Physiological synchrony hypotheses will be examined in more detail regarding different types of synchronization (SNS/PNS). This hypothesis will be exploratory in nature, as types of physiological synchrony have not previously been examined in a population of individuals with PTSD and their partners.

4. Procedures

All potential participants will undergo screening sessions using self-report questionnaires [32–39] as elaborated in Fig. 1. Data will be collected through Qualtrics, an online data-reporting tool. Participants excluded will be referred to appropriate treatment venues. Couples found to be eligible will be allocated to treatment or wait-list conditions randomly as elaborated in Fig. 2.

4.1. Physiological assessment

The autonomic nervous system (ANS) of each partner will be examined in physiological assessments before, during and after the intervention. Each partner's physiological responses will be assessed as a secondary outcome measure and the couple's interpersonal physiological synchrony will be assessed as a mechanism measure. Physiological synchrony is defined as the spontaneous temporal coordination of physiological processes between two or more individuals [40].

A. Physiological assessment before and after the intervention: Communication lab interaction.

Before and after the intervention we will utilize an adapted videotaped dyadic interaction task [41]. The pre-treatment assessment will be used as the baseline, and the post-treatment assessment will be used to

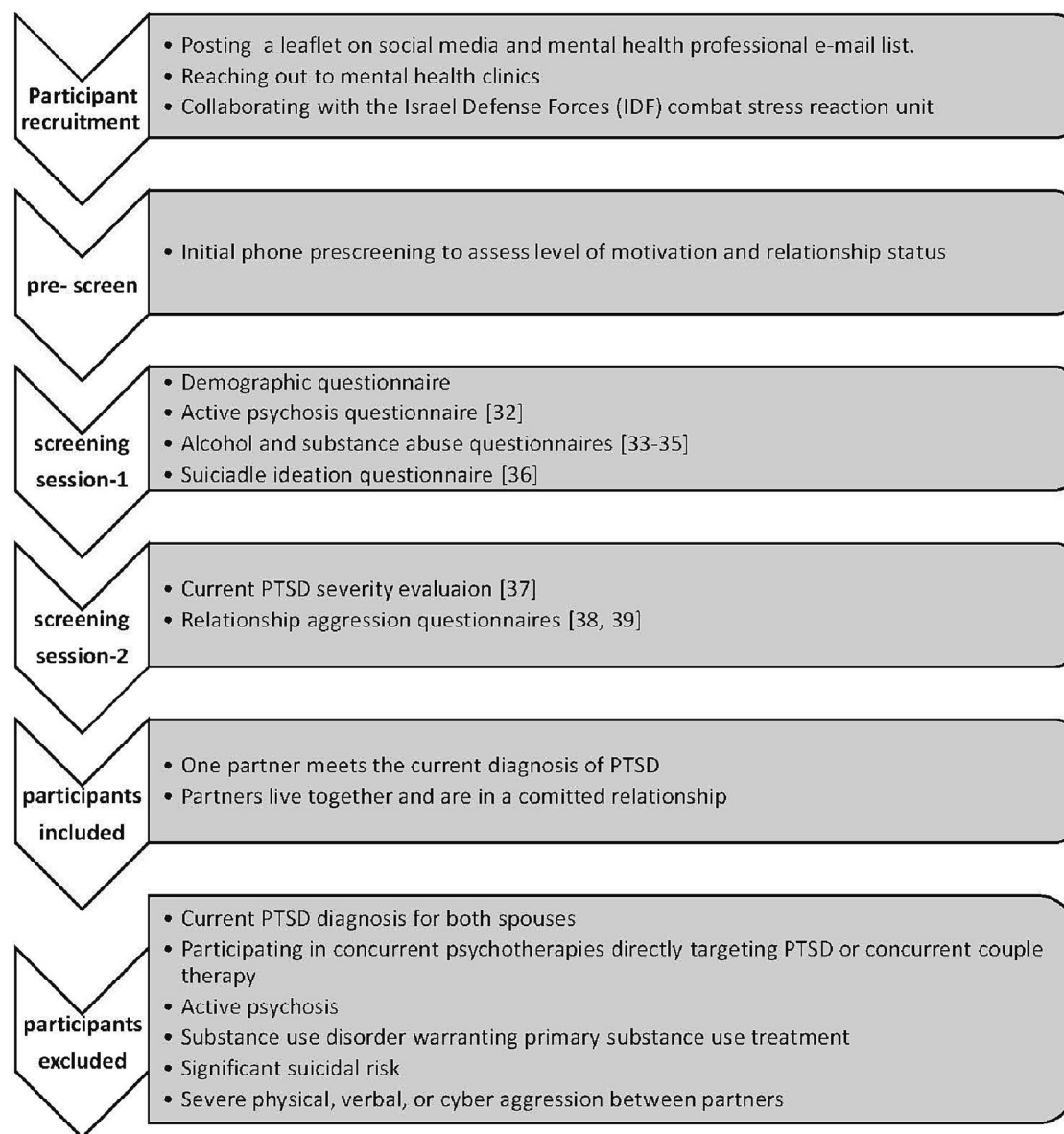


Fig. 1. Recruitment and screening procedure flow chart.

assess the intervention's effect. In the assessments, couples will first sit in silence for five minutes, so that each partner's baseline can be assessed. Afterwards, they will share and discuss both a negative (the effects of the PTSD on their relationship) and a positive (a shared positive experience) context with the partners alternating subject matter. The order of speaking will be pre-determined randomly. During this task, their physiological response will be recorded through MindWare stationary recorders. MindWare is a well-validated and specialized hardware and software system aimed at monitoring autonomic balance, cardiac performance, and respiratory measures. Both spouses will be fitted with specialized electrodes to conduct an electrocardiogram/ECG (which allows for the derivation of HRV) and galvanic skin response/GSR (which allows for the derivation of EDA). They will be videotaped, allowing full visibility of both interacting partners. The following measures will be assessed:

1. Heart rate variability (HRV) represents the dynamic time-series of intervals between consecutive heartbeats, serves as a cumulative measure of neuro-regulative output of the heart. Increased HRV at

rest is considered to be a marker of adaptive regulation, whereas reductions in HRV are expected during stressogenic states [42].

2. Electrodermal activity (EDA) is considered a proxy for the state of sweat glands in the skin. As sweating is modulated by the sympathetic nervous system [43], EDA is considered a biomarker indicative of physiological arousal. When the sympathetic branch is aroused, sweat gland activity also increases, which in turn increases EDA level. In this way, skin conductance can serve as a measure of emotional and sympathetic responses [44].
3. Cardiac impedance is a measurement of the mechanical activation of the heart. By recording cardiac impedance in conjunction with the electrical activation of the heart, the electrocardiogram (ECG), we can gain insight into sympathetic nervous system activity. When combined with heart rate variability (HRV) analysis, we will be able to obtain a clearer picture of autonomic balance.

B. Physiological assessment during the intervention.

Physiological monitoring of both partners will be conducted throughout the treatment, measured every third session throughout the

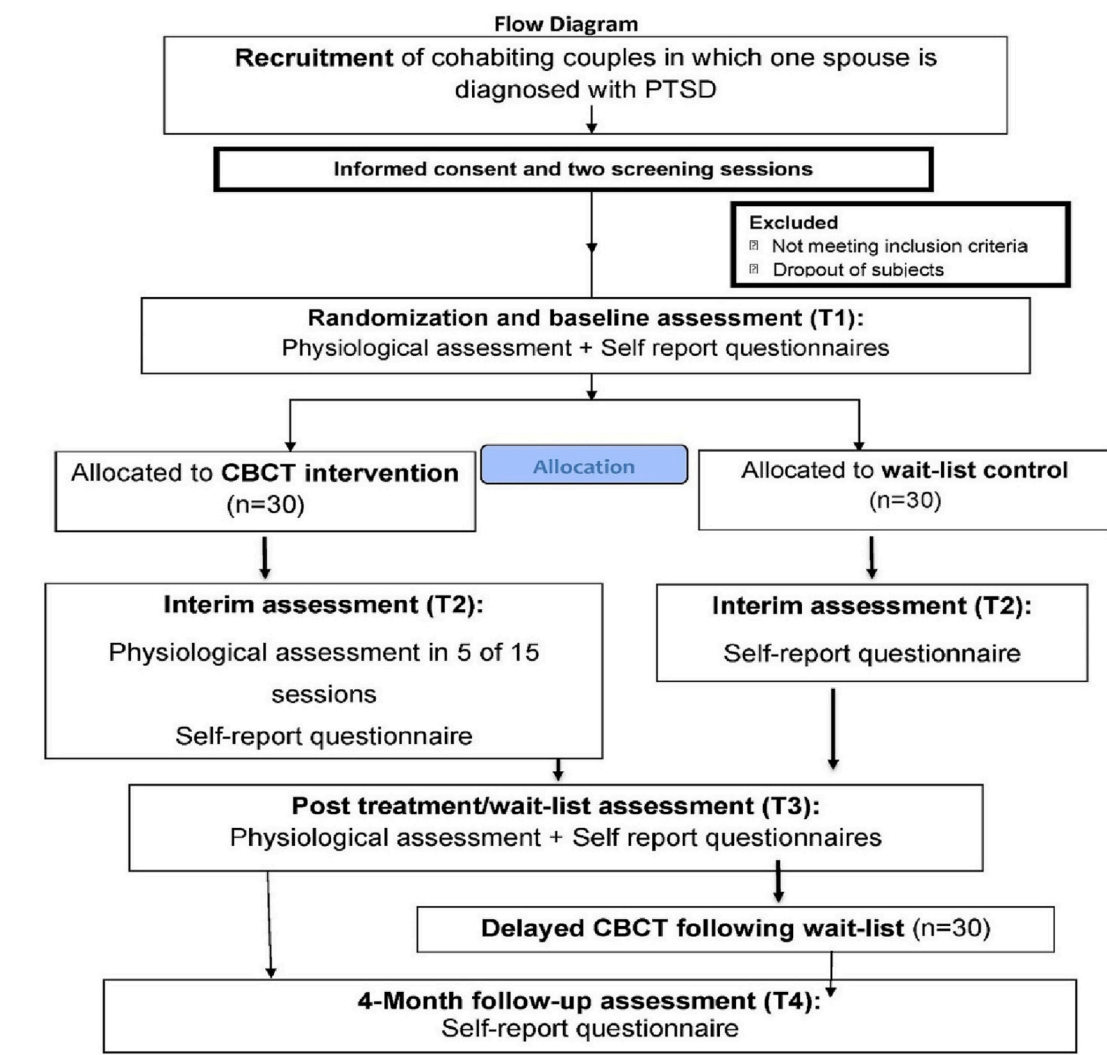


Fig. 2. Randomized controlled trial flow chart.

entire session using the “Empatica” E4 wristbands [45,46]. The E4 is equipped with sensors designed to gather high-quality data. It combines EDA and photoplethysmography (PPG) sensors, simultaneously enabling the measurement of sympathetic nervous system activity, heart rate and HRV. During the session participants will use the “E4 Real Time” application, which will synchronize and upload the data to a secure cloud in real time. This process will enable an understanding of the development and change in each partner’s physiological response and in their shared physiological synchrony during CBCT sessions.

4.2. Primary outcome questionnaires

Clinician-Administered PTSD Scale for DSM-5 [CAPS-5; [37]. The CAPS-5 is the gold standard for PTSD assessment [47]. It will be used to determine eligibility to participate in the study by assessing whether participants meet the DSM-5 diagnostic rule. In addition, this CAPS-5 assessment severity score will serve as a baseline for the severity of PTSD pre-treatment, while the post-treatment CAPS-5 assessment severity score will serve as a primary outcome measure of the treatment effect on PTSD symptoms. The assessment will be conducted via videoconferencing (i.e., ZOOM). Each question on the CAPS-5 corresponds to a DSM-5 criterion for PTSD. Each symptom has a scale ranging from 0 (absent) to 4 (extreme), and the severity score cutoff is 2 (moderate/threshold) or higher. The number of symptoms that meet the cutoff within each subscale is then compared against diagnostic criteria

to determine whether a PTSD diagnosis is appropriate. We will assess both partners to ascertain that one spouse indeed meets the diagnostic criteria for PTSD while the other does not.

PTSD checklist for DSM-5 [PCL-5; [48]. The PCL-5 is a 20-item self-report questionnaire assessing PTSD symptom severity based on DSM-5 criteria. It will be used as an outcome measure in the study. Items are rated on a five-point scale ranging from 0 (not at all) to 4 (extremely) and are summed for a total severity score. The cut-off severity score to indicate PTSD is 33. Subscale severity scores are calculated by summing items in each of the four DSM-5 PTSD symptom clusters: intrusions, avoidance, negative alterations in cognitions and mood, and alterations in arousal and reactivity. The PCL-5 is well validated, with good internal consistency, test-retest reliability, and convergent and discriminant validity [49]. Participants will be asked to answer this questionnaire before and after the intervention (regarding the past month), as well as before each session (regarding the past week).

Dyadic Adjustment Scale [DAS; [50]. The DAS is a 32-item measure of relationship quality and satisfaction. It will be used as an outcome measure in the study. The scale is divided into 4 subscales: dyadic consensus, dyadic satisfaction, dyadic cohesion and affectional expression. The items are rated on a 6-point Likert scale (0 = always disagree, 5 = always agree). Higher scores represent greater relationship satisfaction. The DAS has been shown to have very good internal consistency for each subscale and for the whole scale [51].

4.3. Secondary outcome questionnaires

The Patient Health Questionnaire-9 [PHQ-9; [52]. The PHQ-9 is a 9-item measure of major depression symptoms, parallel with DSM-IV criteria for major depression. It will be used as an outcome measure in the study. Its scores are on a 4-point Likert scale (0 = not at all, to 3 = nearly every day). It can yield either a continuous score, or a probable major depressive disorder diagnosis using a cut-off of 10. The sensitivity and specificity of the PHQ-9 compare favorably with structured psychiatric interviews, and it is well validated, with good internal consistency and test-retest reliability [53].

Brief Symptom Inventory [BSI-18, [54]. The BSI-18 is an 18-item measure of three dimensions of psychiatric disorders: somatization, depression, and anxiety. It will be used as an outcome measure in the study. Each of the three subscales is measured by six items. All BSI-18 items use a 5-point Likert scale (0 = not at all, 4 = extremely). Higher scores indicate greater emotional distress. The BSI-18 has been shown to have high validity and high internal consistency [54].

State-Trait Anger Expression Inventory [STAXI, [55]. The STAXI is a 44-item measure of anger, which comprises six scales and two subscales. It will be used as an outcome measure. The State Anger Scale measures the extent of angry feelings at the specific time of the test. The Trait Anger Scale measures the degree to which an individual is disposed to react in anger. Items are rated on a 4-point Likert scale (1 = not at all, 4 = very great degree) to assess either the intensity of their angry feelings or the frequency with which anger is experienced, expressed, or controlled. The STAXI has been shown to have high validity and high internal consistency [55].

Post Traumatic Growth Inventory [PTGI, [56]. The PTGI is a 21-item measure of the positive psychological changes resulting from the experience of a traumatic event. It will be used as an outcome measure in the study. The 21 items represent five discrete factors: relating to others, spiritual or religious changes, a renewed appreciation of life, personal strength, and new possibilities. Items are rated on a 6-point Likert-type scale (0 = not at all, 5 = very great degree). The PTGI has been shown to have high validity and high internal consistency [56].

Trauma Related Guilt Inventory [TRGI, [57]. The TRGI is a 32-item measure administered to the individual with PTSD only. It will be used as an outcome measure in the study. The TRGI generates three scales (global guilt, distress, and guilt cognitions) and three subscales (hindsight bias, wrongdoing, and lack of justification). Items are rated on a 4-point Likert scale (0 = not at all true, 4 = extremely true). The TRGI has been shown to have high validity and high internal consistency for all three scales [57].

Conflict Tactic Scale [CTS-2; [38] - a 42 item measure of psychological and physical aggression, currently or in the past year. In the proposed study it will be used both for screening and as an outcome variable. The CTS-2 contains 5 subscales: negotiation, psychological aggression, physical assault, sexual coercion and physical injury. Each item is filled from a perpetration and victimization perspective. The items are rated on an 8-point Likert frequency scale (0 = never, 7 = more than 20 times). The CTS-2 provides rates of chronicity and severity of spousal conflict. CTS-2 has been shown to have high validity and good internal consistency for each sub-scale [38].

4.4. Mechanism questionnaire

Difficulties in Emotion Regulation [DERS-18, [58]. The DERS is an 18-item measure of awareness of emotions and emotional reactions. It will be used as a mechanism measure in the study. The items are rated on a 5-point Likert scale (1 = almost never, 5 = almost always). Higher scores represent greater difficulties in emotion regulation. The DERS has been shown to have high internal consistency [58].

Significant Others Response to Trauma Scale [SORTS; [59]. The SORTS is a 14-item measure of spousal accommodation. It will be completed by the spouse of the individual with PTSD and be used as a mechanism

measure in the study. Items on the SORTS consist of two components: frequency of behavior within the past month (0 = never, 4 = daily or almost every day) and distress (0 = not at all, 4 = extremely). Items are summed to create a frequency subscale score, a distress subscale score, and a total score, with higher scores indicating greater spousal accommodation. The measure has been shown to have high internal consistency and test-retest reliability and strong construct validity [59].

4.5. Qualitative interview

In the qualitative part of this study, a sub-sample of 20 couples will undergo a semi-structured qualitative interview twice – once before therapy and one after therapy. The interview will consist of pre-defined open-ended questions. The pre-treatment interview will assess the ways trauma affects the relationship, as well as expectations from therapy. Sample questions will be: How has trauma affected your relationship? Has it changed since the traumatic event?; What are your expectations from the intervention you are about to receive here? What are your thoughts on the intervention being conducted via Zoom?. The post-treatment interview will assess the impact and efficacy of the intervention on the couple's relationship and psychological distress, as well as changes that occurred in couples' mutual understanding of PTSD and how they contend with PTSD and react considering these effects. A specific focus will be put on behavioral change. Sample questions will be: In your opinion, what were the main components that worked in treatment?; How do you experience your relationship now, after treatment? What were the low points or less successful aspects of treatment?

This process will give participants a chance to describe their experiences over the course of therapy in their own words. Each couple will be interviewed together, with both partners attending, in order to shed light on their dyadic experience.

4.6. Therapeutic intervention

Couples will attend 15 weekly, 75-min sessions via videoconferencing (i.e., Zoom). The therapeutic protocol has been modified to accommodate the cultural change to the Israeli culture and has been in use for a few years at the Bar-Ilan University clinic for couple intervention following posttraumatic distress. Remote therapy will enable more couples to take part in this therapy regardless of where they live in Israel, while adhering to COVID-19 regulations.

Sessions are organized into three phases of treatment: (1) psychoeducation about PTSD, its impact on relationship functioning, and strategies to promote both physical and emotional safety in the relationship (e.g., conflict management skills), sessions 1–2; (2) behavioral interventions to enhance relationship functioning, such as communication skills training, as well as to address PTSD-related avoidance through approach behavior tasks, sessions 3–7; and (3) dyadic cognitive interventions designed to contextualize trauma memories and address trauma-relevant cognitions held by both partners that fuel PTSD and/or relationship distress, sessions 8–15. Each session includes psychoeducation, learning and practicing of skills, and out-of-session assignments, which are designed to assist the couple in reinforcing skills learned in the sessions.

The intervention will be delivered by social workers/psychologists trained in the CBCT protocol. All therapists will receive ongoing group supervision throughout the study period, by an experienced clinician with many years of experience in CBCT treatment and training. In the event of clinical challenges, a consultation with Dr. Monson will be held. Therapy sessions will be recorded for supervision and fidelity assessment.

4.7. Treatment fidelity

Two independent trained members of the research team will conduct fidelity assessment. These members will rate a random sample of 15% of

the treatment sessions for protocol adherence and therapist competence in delivering the specific elements of that session [60]. Both members will evaluate sessions from the beginning, middle, and end of treatment to sample different stages of treatment. Independently of each other, they will rank how true the actual sessions are to the written protocol.

4.8. Statistical analytic plan

The full statistical analytic plan is elaborated in Table 1. In a preliminary test using the G* power program while taking into account a medium effect as a minimum threshold, alpha of 0.05, multivariate repeated measures design with two research groups (treatment and waiting list), the analysis produced the required $n = 86$. If we consider a dropout percentage of 20% between the beginning of the treatment and the end, we will need to sample at least 103 participants and we intend to do an oversampling of $n = 120$ participants for a safety margin.

In this RCT, we will employ an intention-to-treat (ITT) approach, meaning that we will analyze the data of all individuals who were randomized. Thus, we will attempt to reach and assess all participants at the post-treatment/WL assessments, even if they discontinued treatment. In the statistical analyses, whenever relevant gender, mental health disorders (other than depression or anxiety) will be controlled for. In other analyses gender will be examined as a moderating factor.

4.9. Ethics

This study will be carried out in accordance with The Declaration of Helsinki. The study will be funded by the Israel Science Foundation (ISF), grant number 2326/20 and is registered with the National Institute of Health (NIH) (ID: NCT05045859). The participants will all sign

Table 1
Statistical analytic plan.

Psychological variables analysis (self-report questionnaire)	Physiological variables analysis	Qualitative interviews analysis
<p>1. Multivariate analysis of variance (MANOVA) with repeated measures, with Time as the within-subject factor, Group (WL/CBCT) as the between-subject factor, and outcomes such as PTSD and relationship satisfaction as the dependent variables (controlling for background variables). *We will calculate Cohen's d effect size and rely on norms for low (~0.2), medium (~0.5), and high (~0.8) effects.</p> <p>2. Hierarchical linear modeling to analyze dyadic data with a two-level model: The Level 1 model combines the longitudinal model for individuals with the cross-sectional model for matched pairs [65]. The traumatized individual and partner's growth curves are modeled simultaneously, and there is a separate intercept and slope for each partner. At Level 2, the WL is contrasted with the CBCT, using dummy coding.</p> <p>4. Mediation hypothesis of mechanisms (i.e., accommodation, emotion regulation, and physiological synchrony) will be explored via Hayes' PROCESS hierarchical regression modules [66].</p>	<p>1. The HRV and EDA time-series for each partner will be inputted to Matlab, and a time-domain time-series analysis of Cross Correlation Function (CCF) with a temporal lag of about 3 s (data point lag = -6 to +6) will be computed to find the maximum dyadic correlations of HRV and GSR data between the couple. Results of the CCF analyses will be used to assess the maximal degree of synchronicity between each dyad's time-series and to represent phasic versus anti-phasic correlations [63,64].</p>	<p>1. Content analysis [61,62], categorizing interviews into main themes and sub-themes related to (a) perceptions of the effects of PTSD on the relationship (b) the treatment's strengths and weaknesses and therapeutic experience, as well as changes in the way couples cope before and after therapy.</p>

an informed consent form and a confidentiality waiver. By signing these forms, the participants will be allowing for the recording of the therapy sessions for purposes of training and fidelity assessment. In the event of high psychological distress, immediate suicidal risk, psychosis, or significant relationship violence, an experienced staff member will talk to the couples to better understand the distress, refer them to an appropriate mental health provider, and ask to speak with the referring therapist if there is one, or the family doctor for updating.

5. Discussion

The proposed study will be the first to use mixed methods to assess the efficacy of CBCT for PTSD, as well as its underlying change mechanisms. Knowing more about how the treatment works has the potential to improve its effectiveness and guide therapists on how to improve their skills. The unique characteristics of the proposed study could make a valuable theoretical and clinical contribution, as it could provide the most comprehensive and integrative evaluation of CBCT to date. The proposed study will be the first RCT about CBCT to take place in Israel, allowing for a cross-cultural validation of the CBCT protocol [67].

The proposed study will be the first to use videoconferencing to deliver the full treatment protocol, thus providing much needed knowledge about the efficacy and applicability of CBCT via video conferencing. The potential advantages of video conferencing include easier access to psychological treatment, regardless of where patients live, their level of mobility, or avoidance of leaving home, a common phenomenon among individuals with PTSD. On the other hand, the disadvantages include the partial visibility of the body and the physical distance from the therapist.

Trauma impacts and changes not only our mental state but also our physiological state. Although research exists on the physiological changes following individual PTSD therapy [68–71], no studies exist on the physiological changes in couple therapy for PTSD. The aim of the proposed study is to be the first to achieve a better understanding of the physiological processes that individuals with PTSD and their spouses undergo during and after CBCT. This examination will take place at both the individual partner level and at the dyadic level (e.g., physiological synchrony).

Finally, in the proposed study we will also employ qualitative interviews. Examining couples' subjective experiences will allow us to gain a deeper understand of their psychological experience and of the therapeutic process they underwent. Examining subjective experiences, in the couples' own words, will also help enrich the knowledge gathered via the psychological and physiological measures and may help shed light on some of the results.

5.1. Potential pitfalls and limitations

Despite the major strengths of the proposed study, it also involves several challenges and limitations. First, this study will use self-report questionnaires, which may be prone to memory and reporting biases [72]. For this reason, we will be employing diverse methods of assessment, which will allow us to obtain a more reliable and complete assessment. Second, using video conferencing has two notable limitations to be considered. The first is a lack of control over patients' environment during therapy, and the second is the difficulty of forming a strong therapeutic alliance [73]. To address these limitations, the therapists in the study will set firm boundaries to emphasize that sessions conducted via video conferencing warrant the same consideration from both therapist and patient as those conducted face-to-face. In addition, the therapists in the study will undergo specific training emphasizing ways to create a solid therapeutic alliance in remote therapy.

Third, the couples in this study will receive Empatica E4 wristbands, to be worn during therapy sessions at home; they may, therefore, encounter technical difficulties along the way. In order to handle this potential problem, a research assistant will contact each couple on a

weekly basis, check if they encountered any difficulties operating the wristbands, and provide technical support in solving the difficulties, if needed.

A final limitation has to do with the nature of the control group. The control group is a wait-list group, and they will not be receiving any other intervention or care while waiting for therapy. As such, a comparison cannot be made between CBCT and other trauma-focused treatments [74]. Such a comparison would be a natural next step in future studies.

Finally, some clinical challenges may arise during the intervention, such as changes in Israel's security situation, potentially triggering symptomatic deterioration in patients' condition. Deterioration in marital relations may also occur, making it difficult for couples to continue treatment. In the face of these or similar situations, the therapist will consult with the clinical supervisor of this study, and/or bring problematic cases to discussion with the clinical team. The safety of patients will be of top priority in this study, and we will leave much room for consultation.

In conclusion, the proposed study includes a comprehensive and challenging design. Nonetheless, it has the potential to shed light on the complex dynamics of couple therapy for PTSD, expanding the body of knowledge regarding PTSD in general and CBCT in particular. We believe the study will increase our ability to offer effective and attainable treatments for individuals with PTSD and their partners.

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.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.cct.2023.107280>.

References

- [1] D. Bestha, L. Soliman, K. Blankenship, J. Rachal, The walking wounded: emerging treatments for PTSD, *Curr. Psychiat. Rep.* 20 (2018) 1–8.
- [2] S. Woodhouse, R. Brown, S. Ayers, A social model of posttraumatic stress disorder: interpersonal trauma, attachment, group identification, disclosure, social acknowledgement, and negative cognitions, *J. Theoret. Soc. Psychol.* 2 (2) (2018) 35–48.
- [3] F. Edition, Diagnostic and statistical manual of mental disorders, *Am. Psychiatric. Assoc.* 21 (21) (2013) 591–643.
- [4] R.A. Bryant, M.L. O'donnell, M. Creamer, A.C. McFarlane, C.R. Clark, D. Silove, The psychiatric sequelae of traumatic injury, *Am. J. Psychiatr.* 167 (3) (2010) 312–320.
- [5] J.E. Lambert, R. Engh, A. Hasbun, J. Holzer, Impact of posttraumatic stress disorder on the relationship quality and psychological distress of intimate partners: a meta-analytic review, *J. Fam. Psychol.* 26 (5) (2012) 729.
- [6] C.T. Taft, L.E. Watkins, J. Stafford, A.E. Street, C.M. Monson, Posttraumatic stress disorder and intimate relationship problems: a meta-analysis, *J. Consult. Clin. Psychol.* 79 (1) (2011) 22.
- [7] M.W. Miller, E.J. Wolf, A.F. Reardon, K.M. Harrington, K. Ryabchenko, D. Castillo, R.E. Heyman, PTSD and conflict behavior between veterans and their intimate partners, *J. Anxiety Disord.* 27 (2) (2013) 240–251.
- [8] D.S. Riggs, C.A. Byrne, F.W. Weathers, B.T. Litz, The quality of the intimate relationships of male Vietnam veterans: problems associated with posttraumatic stress disorder, *J. Traumat. Stress: Off. Pub. Int. Soc. Traum. Stress Stud.* 11 (1) (1998) 87–101.
- [9] A.D. LaMotte, C.T. Taft, A.F. Reardon, M.W. Miller, Agreement between veteran and partner reports of intimate partner aggression, *Psychol. Assess.* 26 (4) (2014) 1369.
- [10] C.A. Lunney, P.P. Schnurr, Domains of quality of life and symptoms in male veterans treated for posttraumatic stress disorder, *J. Traumat. Stress: Off. Pub. Int. Soc. Traum. Stress Stud.* 20 (6) (2007) 955–964.
- [11] C.M. Monson, S.J. Fredman, A. Macdonald, N.D. Pukay-Martin, P.A. Resick, P. P. Schnurr, Effect of cognitive-behavioral couple therapy for PTSD: A randomized controlled trial, *Jama* 308 (7) (2012) 700–709.
- [12] S.M. Glynn, S. Eth, E.T. Randolph, D.W. Foy, M. Urbaitis, L. Boxer, J. Crothers, A test of behavioral family therapy to augment exposure for combat-related posttraumatic stress disorder, *J. Consult. Clin. Psychol.* 67 (2) (1999) 243.
- [13] C.M. Monson, A. Macdonald, S.J. Fredman, J.A. Schumm, C. Taft, Empirically supported couple and family therapies for PTSD, in: M.J. Friedman, P.P. Schnurr, T.M. Keane (Eds.), *Handbook of PTSD: Science and Practice*, The Guilford Press, 2021, pp. 377–399.
- [14] C.M. Monson, S.J. Fredman, *Cognitive-Behavioral Conjoint Therapy for PTSD: Harnessing the Healing Power of Relationships*, Guilford Press, 2012.
- [15] R.E. Liebman, K.M. Whitfield, I. Sijercic, N. Ennis, C.M. Monson, Harnessing the healing power of relationships in trauma recovery: A systematic review of cognitive-behavioral conjoint therapy for PTSD, *Curr. Treat. Opt. Psychiat.* 7 (3) (2020) 203–220.
- [16] N.D. Pukay-Martin, A. Macdonald, S.J. Fredman, C.M. Monson, Couple Therapy for PTSD, 2016.
- [17] J.A. Schumm, S.J. Fredman, C.M. Monson, K.M. Chard, Cognitive-behavioral conjoint therapy for PTSD: initial findings for operations enduring and Iraqi freedom male combat veterans and their partners, *Am. J. Fam. Ther.* 41 (4) (2013) 277–287.
- [18] P. Shnaider, N.D. Pukay-Martin, S.J. Fredman, A. Macdonald, C.M. Monson, Effects of cognitive-behavioral conjoint therapy for PTSD on partners' psychological functioning, *J. Trauma. Stress.* 27 (2) (2014) 129–136.
- [19] A.C. Wagner, L. Torbit, T. Jenzer, M.S. Landy, N.D. Pukay-Martin, A. Macdonald, C.M. Monson, The role of posttraumatic growth in a randomized controlled trial of cognitive-behavioral conjoint therapy for PTSD, *J. Trauma. Stress.* 29 (4) (2016) 379–383.
- [20] S. Fogiel-Bijaoui, Families in Israel, in: C.L. Shehan (Ed.), *The Wiley Blackwell Encyclopedia of Family Studies*, Wiley-Blackwell, New York, 2016, pp. 1222–1226.
- [21] Y. Lavee, R. Katz, The family in Israel: between tradition and modernity, *Marriage Fam. Rev.* 35 (1–2) (2003) 193–217.
- [22] L.A. Morland, K.C. Knopp, C.E. Khalifian, A. Macdonald, K.M. Grubbs, M. A. Mackintosh, C.M. Monson, A randomized trial of brief couple therapy for PTSD and relationship satisfaction, *J. Consult. Clin. Psychol.* 90 (5) (2022) 392.
- [23] J. Bomyea, A.J. Lang, Emerging interventions for PTSD: future directions for clinical care and research, *Neuropharmacology* 62 (2) (2012) 607–616.
- [24] J. Iribarren, P. Prolo, N. Neagos, F. Chiappelli, Post-traumatic stress disorder: evidence-based research for the third millennium, *Evid. Based Complement. Alternat. Med.* 2 (4) (2005) 503–512.
- [25] T. Varker, R.M. Brand, J. Ward, S. Terhaag, A. Phelps, Efficacy of synchronous telepsychology interventions for people with anxiety, depression, posttraumatic stress disorder, and adjustment disorder: A rapid evidence assessment, *Psychol. Serv.* 16 (4) (2019) 621.
- [26] I.T. Fonkoue, P.J. Marvar, S. Norrholm, Y. Li, M.L. Kankam, T.N. Jones, J. Park, Symptom severity impacts sympathetic dysregulation and inflammation in post-traumatic stress disorder (PTSD), *Brain Behav. Immun.* 83 (2020) 260–269.
- [27] N. Pole, The psychophysiology of posttraumatic stress disorder: a meta-analysis, *Psychol. Bull.* 133 (5) (2007) 725.
- [28] W.M. Troxel, A. DeSantis, A. Germain, D.J. Buysse, K.A. Matthews, Marital conflict and nocturnal blood pressure dipping in military couples, *Health Psychol.* 36 (1) (2017) 31.
- [29] T.W. Smith, C. Deits-Lebehn, C.M. Caska-Wallace, K.D. Renshaw, B.N. Uchino, Resting high frequency heart rate variability and PTSD symptomatology in veterans: effects of respiration, role in elevated heart rate, and extension to spouses, *Biol. Psychol.* 154 (2020), 107928.
- [30] T. Sexton, K.C. Gordon, A. Gurman, J. Lebow, A. Holtzworth-Munroe, S. Johnson, Guidelines for classifying evidence-based treatments in couple and family therapy, *Fam. Process* 50 (3) (2011) 377–392.
- [31] B. Rodgers, R. Elliott, Qualitative methods in psychotherapy outcome research, in: O. Gelo, A. Pritz, B. Rieken (Eds.), *Psychotherapy Research: Foundations, Process, and Outcome*, Springer-Verlag, Vienna, 2015, pp. 559–578.
- [32] A. Owoso, D.M. Ndeti, A.W. Mbwanyo, V.N. Mutiso, L.I. Khasakhala, D. Mamah, Validation of a modified version of the PRIME screen for psychosis-risk symptoms in a non-clinical Kenyan youth sample, *Compr. Psychiatry* 55 (2) (2014) 380–387.
- [33] World Health Organization (Ed.), AUDIT: the Alcohol Use Disorders Identification Test : guidelines for use in primary health care / Thomas F. Babor ... et al., 2nd ed, World Health Organization, 2001.
- [34] H.A. Skinner, The Drug Abuse Screening Test Addictive Behaviors 7, 1982, pp. 363–371.
- [35] S.J. Adamson, F.J. Kay-Lambkin, A.L. Baker, T.J. Lewin, L. Thornton, B.J. Kelly, J. D. Sellman, An improved brief measure of cannabis misuse: the Cannabis use disorders identification test-revised (CUDIT-R), *Drug Alcohol Depend.* 110 (1–2) (2010) 137–143.
- [36] E.S. Paykel, J.K. Myers, J.J. Lindenthal, J. Tanner, Suicidal feelings in the general population: A prevalence study, *Br. J. Psychiatry* 124 (1974) 460–469.
- [37] D.D. Blake, F.W. Weathers, L.M. Nagy, D.G. Kaloupek, F.D. Gusman, D.S. Charney, T.M. Keane, The development of a clinician-administered PTSD scale, *J. Trauma. Stress.* 8 (1) (1995) 75–90.
- [38] L.E. Watkins, R.C. Maldonado, D. DiLillo, The cyber aggression in relationships scale: A new multidimensional measure of technology-based intimate partner aggression, *Assessment* 25 (5) (2018) 608–626.
- [39] M.A. Straus, S.L. Hamby, S. Boney-McCoy, D.B. Sugarman, The revised conflict tactics scales (CTS2) development and preliminary psychometric data, *J. Fam. Issues* 17 (3) (1996) 283–316.

- [40] O. Mayo, I. Gordon, In and out of synchrony—behavioral and physiological dynamics of dyadic interpersonal coordination, *Psychophysiology* 57 (6) (2020), e13574.
- [41] L.L. Verhofstadt, A. Buysse, W. Ickes, M. Davis, I. Devoldre, Support provision in marriage: the role of emotional similarity and empathic accuracy, *Emotion* 8 (6) (2008) 792.
- [42] J.F. Thayer, S.S. Yamamoto, J.F. Brosschot, The relationship of autonomic imbalance, heart rate variability and cardiovascular disease risk factors, *Int. J. Cardiol.* 141 (2) (2010) 122–131.
- [43] R. Hinrichs, S.J. van Rooij, V. Michopoulos, K. Schultebrucks, S. Winters, J. Maples-Keller, T. Jovanovic, Increased skin conductance response in the immediate aftermath of trauma predicts PTSD risk, *Chronic Stress* 3 (2019), 2470547019844441.
- [44] N.R. Carlson, *Physiology of Behavior*, Pearson Higher Ed, 2012.
- [45] A.A. Schuurmans, P. de Looft, K.S. Nijhof, C. Rosada, R.H. Scholte, A. Popma, R. Otten, Validity of the Empatica E4 wristband to measure heart rate variability (HRV) parameters: A comparison to electrocardiography (ECG), *J. Med. Syst.* 44 (11) (2020) 1–11.
- [46] N. Milstein, I. Gordon, Validating measures of electrodermal activity and heart rate variability derived from the empatica e4 utilized in research settings that involve interactive dyadic states, *Front. Behav. Neurosci.* 148 (2020).
- [47] J.C. Hunt, S.A. Chesney, T.D. Jorgensen, N.R. Schumann, T.A. deRoos-Cassini, Exploring the gold-standard: evidence for a two-factor model of the clinician administered PTSD scale for the DSM–5, *Psychol. Trauma Theory Res. Pract. Policy* 10 (5) (2018) 551.
- [48] C.A. Blevins, F.W. Weathers, M.T. Davis, T.K. Witte, J.L. Domino, The posttraumatic stress disorder checklist for DSM-5 (PCL-5): development and initial psychometric evaluation, *J. Trauma. Stress.* 28 (6) (2015) 489–498.
- [49] J.H. Wortmann, A.H. Jordan, F.W. Weathers, P.A. Resick, K.A. Dondanville, B. Hall-Clark, B.T. Litz, Psychometric analysis of the PTSD Checklist-5 (PCL-5) among treatment-seeking military service members, *Psychol. Assess.* 28 (11) (2016) 1392.
- [50] G.B. Spanier, Measuring dyadic adjustment: new scales for assessing the quality of marriage and similar dyads, *J. Marriage Fam.* (1976) 15–28.
- [51] J.M. Graham, Y.J. Liu, J.L. Jeziorski, The dyadic adjustment scale: A reliability generalization meta-analysis, *J. Marriage Fam.* 68 (3) (2006) 701–717.
- [52] K. Kroenke, R.L. Spitzer, The PHQ-9: a new depression diagnostic and severity measure, *Psychiatr. Ann.* 32 (9) (2002) 509–515.
- [53] L. Manea, S. Gilbody, D. McMillan, A diagnostic meta-analysis of the patient health Questionnaire-9 (PHQ-9) algorithm scoring method as a screen for depression, *Gen. Hosp. Psychiatry* 37 (1) (2015) 67–75.
- [54] L.R. Derogatis, L. Kathlyn, The SCL-90-R and brief symptom inventory (BSI) in primary care, in: *Handbook of Psychological Assessment in Primary Care Settings*, Routledge, 2000, pp. 310–347.
- [55] C.D. Spielberger, *State-Trait Anger Expression Inventory Research Edition. Professional Manual*, Psychological Assessment Resources, Odessa, FL, 1988.
- [56] R.G. Tedeschi, L.G. Calhoun, The posttraumatic growth inventory: measuring the positive legacy of trauma, *J. Trauma. Stress.* 9 (3) (1996) 455–471.
- [57] E.S. Kubany, S.N. Haynes, F.R. Abueg, F.P. Manke, J.M. Brennan, C. Stahura, Development and validation of the trauma-related guilt inventory (TRGI), *Psychol. Assess.* 8 (4) (1996) 428.
- [58] S.E. Victor, E.D. Klonsky, Validation of a brief version of the difficulties in emotion regulation scale (DERS-18) in five samples, *J. Psychopathol. Behav. Assess.* 38 (4) (2016) 582–589.
- [59] S.J. Fredman, V. Vorstenbosch, A.C. Wagner, A. Macdonald, C.M. Monson, Partner accommodation in posttraumatic stress disorder: initial testing of the significant Others' responses to trauma scale (SORTS), *J. Anxiety Disord.* 28 (4) (2014) 372–381.
- [60] S.J. Fredman, A. Macdonald, C.M. Monson, K.A. Dondanville, T.H. Blount, B. N. Hall-Clark, A.L. Peterson, Intensive, multi-couple group therapy for PTSD: A nonrandomized pilot study with military and veteran dyads, *Behav. Ther.* 51 (5) (2020) 700–714.
- [61] A.D. Wilson, A.J. Onwuegbuzie, L.S.P. Manning, Using paired depth interviews to collect qualitative data, *Qual. Rep.* 21 (9) (2016) 1549–1573.
- [62] N.L. Leech, A.J. Onwuegbuzie, Beyond constant comparison qualitative data analysis: using NVivo, *Sch. Psychol. Q.* 26 (2011) 70–84.
- [63] R.V. Palumbo, M.E. Marraccini, L.L. Weyandt, O. Wilder-Smith, H.A. McGee, S. Liu, M.S. Goodwin, Interpersonal autonomic physiology: A systematic review of the literature, *Personal. Soc. Psychol. Rev.* 21 (2) (2017) 99–141.
- [64] E.A. Butler, A.K. Randall, Emotional coregulation in close relationships, *Emot. Rev.* 5 (2) (2013) 202–210.
- [65] S.W. Raudenbush, R.T. Brennan, R.C. Barnett, A multivariate hierarchical model for studying psychological change within married couples, *J. Fam. Psychol.* 9 (2) (1995) 161.
- [66] A.F. Hayes, *Introduction to Mediation, Moderation, and Conditional Process Analysis: A Regression-Based Approach*, Guilford Publications, 2017.
- [67] K. Kumpfer, C. Magalhães, J. Xie, Cultural adaptation and implementation of family evidence-based interventions with diverse populations, *Prev. Sci.* 18 (6) (2017) 649–659.
- [68] M.G. Griffin, P.A. Resick, T.E. Galovski, Does physiologic response to loud tones change following cognitive-behavioral treatment for posttraumatic stress disorder? *J. Trauma. Stress.* 25 (1) (2012) 25–32.
- [69] D. Bach, G. Groesbeck, P. Stapleton, R. Sims, K. Blickheuser, D. Church, Clinical EFT (emotional freedom techniques) improves multiple physiological markers of health, *J. Eviden.-Based Integrat. Med.* 24 (2019), 2515690X18823691.
- [70] A.C. Katz, A.M. Norr, B. Buck, E. Fantelli, A. Edwards-Stewart, P. Koenen-Woods, F. Andrasik, Changes in physiological reactivity in response to the trauma memory during prolonged exposure and virtual reality exposure therapy for posttraumatic stress disorder, *Psychol. Trauma Theory Res. Pract. Policy* 12 (7) (2020) 756.
- [71] B.C. Wangelin, P.W. Tuerk, Taking the pulse of prolonged exposure therapy: physiological reactivity to trauma imagery as an objective measure of treatment response, *Depress. Anxiety* 32 (12) (2015) 927–934.
- [72] T.F. van de Mortel, Faking it: social desirability response Bias in self-report research, *Australian J. Adv. Nurs.* 25 (4) (2008) 40–48.
- [73] E.R. Wrape, M.M. McGinn, Clinical and ethical considerations for delivering couple and family therapy via telehealth, *J. Marital. Fam. Ther.* 45 (2) (2019) 296–308.
- [74] J.A. Cunningham, K. Kypri, J. McCambridge, Exploratory randomized controlled trial evaluating the impact of a waiting list control design, *BMC Med. Res. Methodol.* 13 (1) (2013) 1–7.