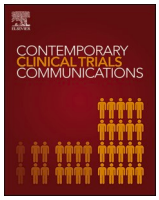
Contemporary Clinical Trials Communications 35 (2023) 101193

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

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



Feasibility and acceptability of continuous identity cognitive therapy as a recovery-oriented suicide treatment for Veterans: A study protocol

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ARTICLE INFO

Keywords:
Suicide
Veterans
Treatment development
Pilot treatment
Personal recovery
Identity
Future self-continuity
Post-acute suicidal episode

ABSTRACT

Background: Suicide is a leading cause of death among Veterans, with rates significantly higher than the general population. To address this issue, it is crucial to develop and implement more effective treatments for Veterans with suicidal thoughts and/or behaviors, particularly those in the post-acute suicidal episode (PASE) stage. The present study aims to establish the feasibility and acceptability of a novel, recovery-oriented treatment called Continuous Identity Cognitive Therapy (CI-CT) for PASE Veterans.

Methods: This 3-year open-label pilot study will include three one-arm trials and a pilot randomized controlled trial (RCT). A total of 57 Veterans with a history of an acute suicidal episode within the previous year will be recruited. Primary outcome measures will include changes in personal recovery, suicidal thoughts, and behaviors. Secondary outcomes will include changes in self-identity, life satisfaction, and hopefulness. Feasibility and acceptability will be assessed through attendance and retention rates, drop-out rates, and client satisfaction.

Conclusion: This study aims to develop and evaluate the feasibility and acceptability of a novel recovery-oriented intervention for Veterans experiencing PASE. If the intervention is found to be feasible and acceptable, a manualized version will be finalized and a large-scale multi-site RCT will be designed to assess its clinical efficacy on a broader Veteran population. The results of this trial will aid in the development of effective treatment and provide valuable insights into the preliminary feasibility, acceptability, and effectiveness of this approach in reducing suicidal thoughts and behaviors and promoting recovery and rehabilitation in this population.

1. Introduction

Suicide is ranked 12th as a means of death in the United States [1], with 17 Veterans dying daily by suicide [2]. Veteran suicide rates are disproportionately high; age and sex-adjusted suicide rates of Veterans are 57.3% higher than that of non-Veteran adults [2]. Further, despite a recent increased focus on suicide prevention, research suggests a heightened risk of suicide compared with the general population evident across Veterans of multiple eras (e.g., Vietnam and Korean wars [3]). More effective mental health care for Veterans with suicidal thoughts and/or behaviors is crucial given their increasing and disproportionate suicide rates.

While several psychotherapeutic treatments exist for acute suicidality [4], there are few recovery-oriented treatments designed to help Veterans following an acute suicidal episode (post-acute suicidal episode; PASE), particularly after acute risk declines but ongoing mental

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https://doi.org/10.1016/j.conctc.2023.101193
Received 23 March 2023; Received in revised form 29 June 2023; Accepted 15 July 2023
Available online 17 July 2023

health needs and long-term suicidal symptoms are present, that cater to their unique needs (e.g., military to civilian transition). Research has shown that hopelessness, decreased future goals, and loss of meaning promote the development and escalation of suicidal thoughts and behaviors [5–7]. Despite this, most treatment for suicide risk targets the prevention of suicidal cognitions and methods to decrease suicidal risk [8]. While this is critical due to the urgent nature of suicide risk, this results in Veterans no longer at acute risk but who may still be at some level of risk to be left in the lurch, with no sufficient methods to move toward recovery and rehabilitation.

The shift toward recovery and rehabilitation in mental health care, called "recovery-oriented care," extends beyond symptom remission and prevention to promote meaningful living in the presence of mental health symptoms [9]. Several frameworks have been developed to quantify recovery, including the well-known CHIME model [10], which defines five core processes of recovery: Connectedness, Hope and optimism, Identity, Meaning and purpose, and Empowerment. Individuals in recovery-oriented therapy displayed an increase in these processes [11]. Recently, the COURAGE model, a PASE specific personal recovery theoretical model, was developed to inform PASE recovery [12]. This model comprises seven processes: Choosing life, Optimizing identity, Understanding oneself, Rediscovering meaning, Acceptance, Growing connectedness, and Empowerment. However, despite being integrated into mental health care reform [13], the recovery movement has yet to be fully integrated into Veteran suicide treatments.

Facets of identity are particularly important to address in recovery-oriented treatment in Veteran populations. The concept of "warring identities" [14] describes the identity crises faced by Veterans in the post-war reintegration, where struggle in the transition from military to civilian life, termed the "civilian-military cultural gap" [15] disrupts identity. Similarly, Military Transition Theory [16] stresses the importance of identity malleability for successful post-war reintegration. Veterans' loss of identity which accompanies exiting the military may lead to deficits in continuous identity and the ability to feel connected to the future self, which is implicated in suicide development [17–19]. These challenges may contribute to the high rate of Veteran suicide in their military to civilian transition, which is double the overall Veteran suicide rate [20]. Helping suicidal Veterans develop a sense of identity may therefore be critical in their recovery [17,18].

Continuous Identity Cognitive Therapy (CI-CT) [17]; is a new manualized suicide intervention focused on improving Veterans' sense of the life story, personal future, and positive identity, with parallels to recovery-oriented care. Its premise is the difficulty that suicidal individuals have in perceiving and experiencing continuity with their future selves (future self-continuity; FSC) and having meaningful and achievable personal goals. It offers a concrete systematic approach to building a better present-to-future-self-narrative. This includes techniques designed to enhance PASE individual's conceptualization of their future self and to build a stronger sense of continuous identity, FSC, personal identity, and meaning. Preliminary findings have indicated that CI-CT may help with suicidality in the Veteran population by fostering continuous identity, FSC, and a meaningful life story [17].

Through its recovery-oriented approach and emphasis on unique aspects of identity (e.g., the future self), CI-CT is distinct from currently

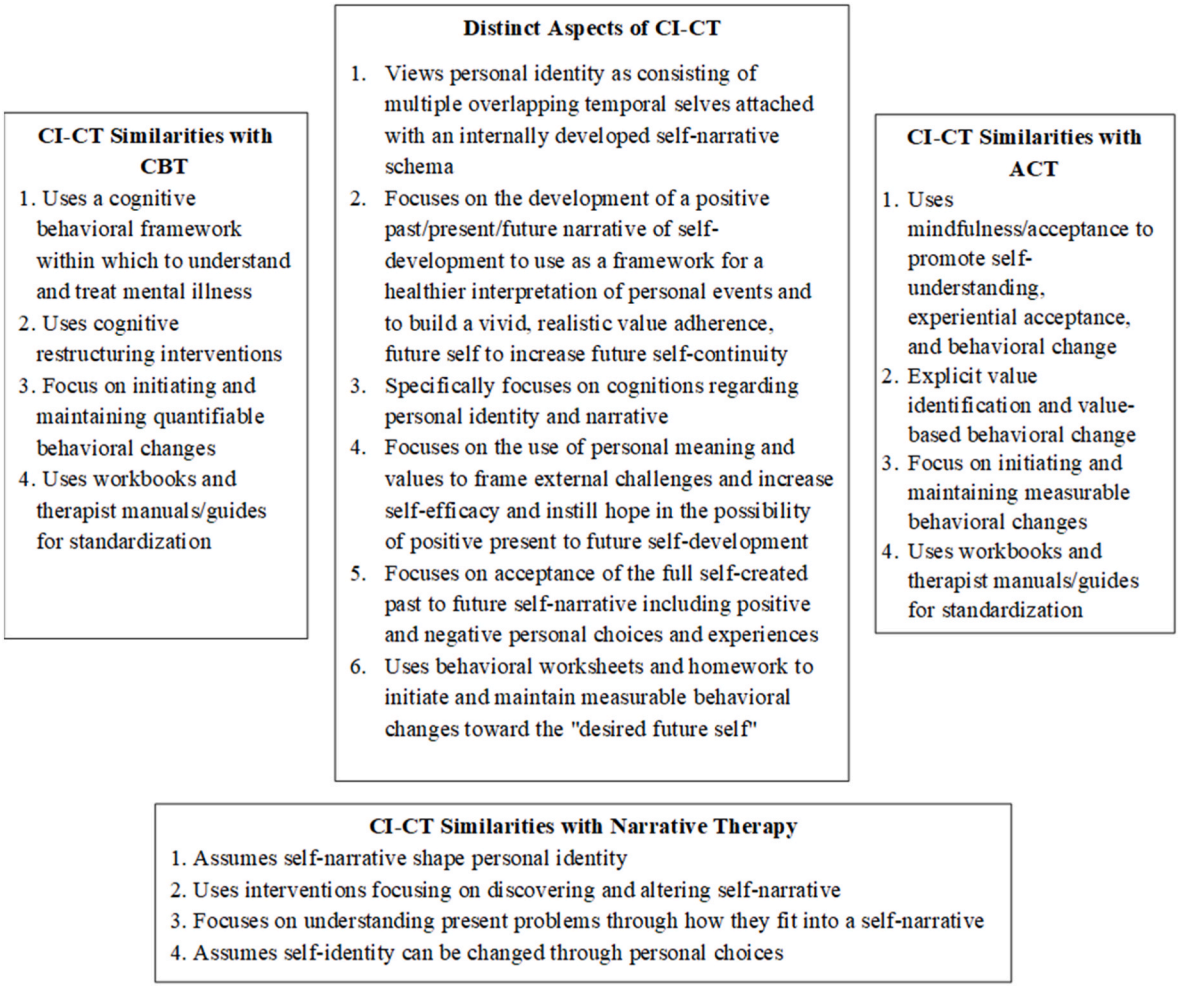

Fig. 1. Similarities and distinct aspects of CI-CT with other psychotherapies.

Table 1
CI-CT session descriptions with brief module objectives.[a,b]

Session 1	*The Importance of Understanding Your Story*
	● Review of positive and negative experiences that form sections of one's life story
	● Acknowledging the present as one part of a complicated life story
	● Identifying a role model to examine how facing difficulties can be part of a role model's story
	● Identifying challenging actions you have taken for your future benefit and current actions that can benefit your future self
Session 2	*Learning About My Recovery Journey*
	● What is recovery- and the complications and lack of perfection along the way?
	● Acknowledging that everyone is in recovery
	● Recovery involves finding one's path to a meaningful life and rediscovering purpose
	● Discovering what are the essential ingredients for personal recovery
	● The COURAGE model and how it relates to personal recovery
Session 3	*Value Identification*
	● Defining and understanding the importance of values and a "valued life story"
	● Using a values identification worksheet to select the four most important values
	● Using a group values worksheet to share and discuss group members' top values
	● Thinking about one's life story in terms of the choice to live by their values and vice versa
Session 4	*My Future*
	● Selecting different present-to-future stories impacts the meaning of the full life story
	● Reflecting on their past-to-present life story and exploring possible present-to-future pathways based on making choices aligned or against identified values
	● Selecting actions in the present that are in line with their preferred present-to-future life story
Session 5	*My Story*
	● Understanding how your changing self can create meaning in your life and how past and future selves can guide current choices
	● Creating a list of positive traits you want to have in the future ("desired future self") and visualizing this self through tasks
	● Visualizing cross-temporal self-continuity through a facilitator-led meditation
	● Writing letters to your past and future selves from the perspective of your various selves
Session 6	*Understanding My Story*
	● Understanding how a life story is created and how this "internal life story" differs from an "external life story"
	● Selecting traits describing you as a child, young adult, present person, and future person to identify patterns over time
	● Understanding how formative events throughout life shaped your self and how to achieve your desired self
Session 7	*The Present Chapter Of My Life Story*
	● Using your "valued life story" as a framework to understand how your current life difficulties fit within the life story you want to create
	● Using metaphors including "an ant on the Mona Lisa, the "Puzzle house," and posttraumatic growth to help reframe current difficulties in the context of a life story
	● Engaging in temporal perspective-taking writing exercises, for example, writing a letter to your future self about your current situation
Session 8	*Mindfulness Training*
	● Learning about mindfulness and understanding why the awareness of sensory perceptions and reactions is important in avoiding automatic behavioral reactions that interfering with developing into your desired future self
	● Learning how to use mindfulness to make choices in line with your values toward our valued life story
	● Practicing mindfulness through writing, five-senses mindful-ness, and a mindfulness meditation
	● Understanding the importance of practicing mindfulness daily; providing information on resources available
Session 9	*Changing My Life Story*
	● Using a series of written exercises and discussion points to understand a current life difficulty through the lens of your desired life story; specific behaviors that are for or against your desired life story; potential barriers and how your desired future self would overcome them
	● Visualizing your future self overcoming an issue with which you are struggling
	● An activity to practice using your values to navigate current challenges
Session 10	*Intersecting Life Stories*
	● Exploring the topic of "Sonder"-The realization that everyone around us has their own internal story.
	● Each person's life story is different yet connected with others, and recognizing this interaction broadens our perspective and helps us incorporate the role of others in our life stories.
	● Learning about the intersection of personal and others' life stories, how to interpret others' life stories, and the influence it has on our life stories
	● Who we choose to surround ourselves with shapes and brings meaning to our life
Session 11	*Building Connections*
	● Learning how we can improve ourselves through our relationships
	● Focus on what works in relationships, what makes you feel comfortable discussing and receiving support - consider ways to deepen and add meaning to interactions with others.
	● Using discussions, meditations, and group exercises to learn how to improve ourselves within a relationship
Session 12	*Overcoming Setbacks and Moving Forward*
	● No life story is straightforward. Creating a valued life story requires learning from obstacles and setbacks.
	● How to use setbacks as tools for success and look out for an approaching setback
	● Review of main points from all sessions
	● Using a visualization exercise to learn about creating setback plans
	Conclusion and Reflecting Back
	● It's important always to remember that we do not control the outside world, but in the long run, controlling our own actions is far more important in our lives.
	● Review and takeaways from the therapy

Note. COURAGE = choosing life, optimizing identity, understanding oneself, rediscovering meaning, acceptance, growing connectedness, and empowerment [12].
[a] Each bullet point represents a reading, writing task, and/or group discussion about the topic.
[b] Each module represents one weekly session (12 sessions total).

available suicide treatments including Cognitive Behavioral Therapy for Suicide Prevention (CBT-SP) [21], Collaborative Assessment and Management of Suicidality (CAMS) [22], and Dialectical Behavioral Therapy (DBT) [23]. Perhaps due to their focus on acute aspects of suicide risk, the treatments have limited focus on rebuilding positive identity, self-continuity, and the future self. For instance, CBT-SP was developed as a risk reduction and relapse prevention approach and primarily emphasizes safety plan development, skill building, psychoeducation, family intervention, and relapse prevention [21], which differs from CI-CT's unique recovery orientation. Similarly, Dr. Marsha Linehan, the creator of DBT, initially created four stages of DBT treatment, where stages three and four (focused on obtaining happiness, self-respect, and freedom) are more aligned with personal recovery. However, most research and current manualized treatment focus on stage 1, which is focused on basic capabilities by reducing life-threatening behavior and increasing behavioral skills [24]. In this line, DBT in the context of suicidality is used for risk management and reduction [25,26]. Unlike most suicide treatments, CI-CT is not focused on risk or suicidal symptoms but rather on enhancing PASE individuals' sense of themselves, their life story, and their future.

To develop an intervention to therapeutically improve aspects of identity through a recovery orientation, CI-CT was made through the integration and adaptation of components of Cognitive Behavioral Therapy (CBT) and Acceptance and Commitment Therapy (ACT). CI-CT also incorporates psychological findings not typically targeted by CBT, ACT, and suicide-specific therapies relating to the changing self, deficits in identity, and self-continuity [17,27,28]. By using techniques to encourage a perception of self-continuity, self-narrative, and building meaning in life, CI-CT also incorporates techniques from Existential Psychology and Narrative Therapy. The therapy adapts these techniques to create a unique theoretical framework that includes practical conceptualizations that have shown promise for Veterans [17,18,28]. For CI-CT's similarities with other psychotherapies and distinct aspects, see Fig. 1.

CI-CT was originally developed as an identity-based group therapy for suicide reduction in Veterans in a day hospital setting [17], and in a small pilot (N = 17) was found to have high levels of feasibility, acceptability, and lead to increased hopefulness about the future and decreased suicidal thoughts and behaviors [17]. To date, CI-CT has not been used for the PASE Veteran population. In addition, this original version of CI-CT had limitations based on feedback from group participants and an incomplete alignment with the recovery processes [17]. CI-CT has since been updated and adapted to align with the COURAGE processes [12].

This multi-part study aims to develop and pilot a CI-CT group-based intervention tailored to the unique characteristics of PASE Veterans that have been acutely suicidal in the past year but are longer at high risk. The primary aim of this multi-part study is to first optimize CI-CT's effectiveness for a PASE population and then assess its feasibility and acceptability. This includes nine components: 1) constructing a continuous identity narrative, 2) mindfulness training, 3) life values identification, 4) developing a self-growth perspective, 5) identifying possible future selves - timelines, 6) connecting with the desired future self, 7) continuous identity as context for current problems, 8) enhancing the life story through relationships, and 9) moving toward the future self. These are addressed in 12 sessions. For brief session descriptions, see Table 1.

This protocol consists of three one-arm trials (N = 4–6/trial) and a pilot randomized control trial (RCT) (N = 30). The purpose of the three one-arm trials is to develop the CI-CT intervention and materials and evaluate the preliminary feasibility and acceptability of the intervention. Before and after each trial, Veteran feedback and feasibility and acceptability data will be collected and used to update the intervention with guidance from scientific and Veteran consumer advisory boards. Findings will be used to adapt treatment materials and develop a randomized control trial (RCT) pilot protocol. The goal of the pilot RCT is to establish whether the key components necessary for conducting the proposed main RCT, including the processes for assessing eligibility, conducting baseline assessments, randomization procedures, treatment fidelity, and follow-up assessments, all function well together (see Ref. [29] for the distinction between one-arm trials and pilot RCTs). The results of the pilot RCT will inform the development and administration of a large-scale RCT.

2. Materials and methods

2.1. Study design

This 3-year open-label pilot study aims to establish the feasibility and acceptability of CI-CT with Veterans who have a history of suicide risk. This study will employ three one-arm trials and a subsequent pilot RCT with an experimental and control group. The study will be conducted through telehealth means due to Covid-19. The primary focus will be on assessing the feasibility and acceptability of the therapy and the RCT study protocol. A pretest-posttest design will be used to gather preliminary evidence of CI-CT's ability to increase hopefulness, levels of FSC, and social connectedness, and reduce suicide risk among Veteran participants.

2.2. Participants and recruitment

Veterans will be recruited to participate in the CI-CT one-arm trials and pilot RCT administered through telehealth from the James J. Peters Department of Veteran Affairs Medical Center (JJPVAMC). All participants will be pre-screened for basic information (e.g., access to a device with internet and webcam). All participants will provide informed consent before enrolling and beginning the first session. Clinical characteristics will be collected using The Columbia Suicide History Form [30] to assess lifetime suicide attempt(s) and the Mini-International Neuropsychiatric Interview (MINI) [31] to assess mental health diagnosis through semi-structured interviews. The Beck Scale for Suicide

Table 2
Inclusion and exclusion criteria for the CI-CT one-arm trials and pilot RCT.

Inclusion criteria
1. Minimum of 18 years of age
2. Current participant in mental health services at the JJPVAMC
3. Veteran of the United States Military
4. Residence in the New York City region
5. Access to a reliable computer, tablet, or smartphone with internet connection and a webcam
6. Sufficient clinical stability and readiness for group therapy as deemed by a mental health treatment provider
7. Sufficient medical stability as deemed by a medical provider
Exclusion criteria
1. Active alcohol or opiate dependence requiring medically supervised withdrawal
2. Imminent risk (clinician-determined) of suicidal (i.e., suicide attempt) or homicidal behavior
3. Acute suicidal episode within the past week (determined by the C-SSRS inclusion criteria items)
4. Current acute suicidal thoughts and/or behaviors (determined by a BSI score 2 SDs above the mean and SBQ-R score > 3 on item four).
5. Inability to perform CI-CT treatment tasks based on their performance on a sample reading and writing task from the CI-CT manual (given during screening)
6. Non-English speaking
7. Lack of capacity to consent
8. Unable or unwilling to provide at least one contact for emergency purposes,
9. Unable to attend outpatient group treatment program
10. Participation in another intervention RCT
11. Insufficient interpersonal functioning to function appropriately within the group assessed through consultation with the referrer and the Veterans' mental health provider and a chart review searching for disruptive behavior in group therapy

Note. CI-CT = Continuous Identity Cognitive Therapy; JJPVAMC = James J. Peters Veteran Affairs Medical Center; RCT = Randomized Control Trial; BSI = Beck Scale for Suicide Ideation; SD = standard deviation; SBQ-R = Suicidal Behaviors Questionnaire- Revised.

Ideation (BSI) [32] and Suicidal Behaviors Questionnaire-Revised (SBQ-R) [33] will be used to screen for acute suicidal thoughts and/or behaviors, and the Columbia Suicide Severity Rating Scale (C-SSRS) [34] will screen for suicide attempt or creation of a suicide plan with intent or preparatory behavior within the past year. Eligible participants (see section 2.3 for eligibility criteria) will be asked to complete a variety of baseline measures. All consent and baseline measures will be collected via telephone. If there is no response following the pre-screen, the Veteran will be called on three occasions before discontinuation.

To have a final sample size of approximately 15 in the one-arm trials of CI-CT, considering the possibility of attrition, 19 subjects will be recruited (estimating 20% attrition). Participants will be divided into three groups with four to six participants each. Using the same ratio, to have a final sample size of 30 in the pilot RCT, 38 participants will be recruited, 19 for the experimental group and 19 for the active control group. This is a sufficient sample size for pilot RCTs [35]. There will be three cohorts with 10 participants in each. The 20% estimated attrition rate is based on the initial CI-CT pilot data. A total of 57 participants will be recruited.

2.3. Inclusion and exclusion criteria

Inclusion and exclusion criteria are the same for the three one-arm trials and pilot RCT but may be adjusted for the pilot RCT based on lessons learned from the one-arm trials. Inclusion criteria consist of elevated suicide risk with either a past suicide attempt or the creation of a suicide plan with intent or preparatory behavior within the past year. This will be assessed using the C-SSRS items of "Active Suicidal Ideation with Some Intent to Act, without Specific Plan" (item 4) and "Active Suicidal Ideation with Specific Plan and Intent" (item 5) in the "Suicidal Ideation" subscale, and the "Actual Attempt" and "Preparatory Acts or Behavior" questions in the "Suicidal Behavior" subscale. These items will be modified to assess for past-year where applicable. Of note, there is no requirement for a specific mental health diagnosis. For full inclusion and exclusion criteria, see Table 2.

2.4. Outcome measures

In line with CI-CT's recovery-oriented and suicide-focused emphases, personal recovery and suicidal ideation are the primary outcomes of interest. Constructs related to quality of life; life satisfaction; hopelessness; disability; FSC;suicide-related constructs; and recovery are secondary outcomes. Four assessment time points are used to track Veterans through the end of the one-year PASE period: (TP-1) baseline, (TP-2) post-intervention, (TP-3) follow-up at three months post-intervention, and (TP-4) six months post-intervention.

2.4.1. Primary outcome measures

Recovery Assessment Scale (RAS) [36]. The RAS evaluates the recovery process among people in recovery from mental illness. The original RAS had 41 items, which was refined to 24 through subsequent factor analysis [36]. Items are rated on a 5-point Likert scale, with higher total scores indicating increased recovery. To allow for the RAS's use in this population (who may not have a mental illness) for convergent validity, we will edit the item's language using the same method as [37]. For example, the statement "Coping with my mental illness" will be changed to "Coping with my suicidality." The RAS has been described as the most acceptable and valid measure of personal recovery available [38].

Columbia Suicide Severity Rating Scale (C-SSRS)[34]. The C-SSRS distinguishes between suicidal ideation and behavior, measuring four constructs. The first subscale (severity scale) is a 5-point ordinal scale, ranging from 1 (wish to be dead) to 5 (suicidal intent with a plan). The second subscale, (intensity scale) is composed of five items (i.e., frequency, duration, controllability, deterrents, reasons for ideation), rated on an ordinal scale. The third subscale (behavior scale) is a 5-point scale assessing interrupted, aborted, and actual suicide attempts; preparatory behavior for a suicide attempt; and non-suicidal self-injurious behavior. The fourth subscale (lethality subscale) rates actual and potential lethality of attempts and is rated on a 6-point ordinal scale, and if actual lethality is zero, potential lethality of attempts is rated on a 3-point ordinal scale.

2.4.2. Secondary outcome measures

World Health Organization Quality of Life-BREF (WHOQOL-BREF) [39]. The WHOQOL-BREF is a 26-item instrument assessing four domains of quality of life (QOL): physical health, psychological health, social relationships, and environment. Items are rated on a 5-point Likert scale. Scores are calculated by multiplying the mean domain score (range 4–20) by four, with higher scores indicating higher QOL. The WHOQOL-BREF has high internal consistency across general, mental, and physical health domains [39].

Satisfaction With Life Scale (SWLS) [40]. The SWLS, a measure of global cognitive judgments of life satisfaction will be used to measure life satisfaction. Individuals provide a self-report response to five items on a 7-point Likert scale. Items are summed for a total score that can range from 5 to 35, with increasing scores indicating increased satisfaction with life. The SWLS has demonstrated good reliability and validity [41].

Beck Hopelessness Scale (BHS) [42]. The BHS, a 20-item dichotomous (true/false) self-report measure, will be used to assess hopelessness. Total scores are created by reverse-coding appropriate items and summing the item scores, with higher scores indicating greater hopelessness (range 0–20). The BHS has demonstrated adequate reliability and concurrent validity predictive capacity for suicidality across psychiatric samples [42–44].

Future Self Continuity Questionnaire (FSCQ) [45]**.** The FSCQ will be used to assess individuals' temporal sense of personal identity from the present to the future in three areas: vividness, similarity, and positivity. There are 10 items with a 6-point response metric. The total FSCQ score is averaged from all items and subscale scores from the mean of associated items. Higher scores indicate increased FSC. Both the total FSCQ and the FSCQ components have high levels of reliability and validity [45].

Lubben Social Network Scale-Revised (LSNS-R) [46]**.** The LSNS-R, a 12-item measure that assesses social support received by family, friends, and mutual supports, will be used to assess social networks. Scores for each question range from zero to five, with increased scores indicating greater social integration. The total score is summed from all item scores (range 0–60), with higher scores indicating a greater level of social support and low risk for isolation. The LSNS-R has high internal consistency and has been used in clinical and non-clinical populations [46].

Interpersonal Needs Questionnaire (INQ) [47]**.** The INQ, a 15-item assessment of thwarted belongingness (9 items; scores range from 9 to 63) and perceived burdensomeness (6 items; scores range from 6 to 42), will be used to assess a sense of belonging and burden. Individuals provide self-report responses on a 7-point metric ranging from 1 (Not at all true for me) to 7 (Very true for me). Appropriate items are reverse-coded, and the total score is calculated from the summed item scores, with higher scores indicating greater levels of each. The INQ has demonstrated strong psychometric properties [47].

World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) [48]**.** The WHODAS 2.0 will be used to assess disability. The WHODAS 2.0 is a 36-item questionnaire that assesses six domains of functioning across physical and mental health disorders in clinical and non-clinical populations: cognition, mobility, self-care, getting along, life activities, and participation. Items are scored on a 5-point Likert scale ranging from 1 (None) to 5 (Extreme or cannot do) and are summed to create total and domain scores.

2.5. Protocol and procedure

After participants in all conditions consent and complete the baseline measures, they will begin the intervention within two weeks. All follow-up data will be collected one month after treatment completion. In the event of attrition, follow-up data will be collected one month from the date of leaving the program. Participants will be compensated up to $225 for assessment completion (TP-1 = $45, TP-2 = $55, TP-3 = $60, TP-4 = $65), but not for intervention attendance, to minimize the potential impact of compensation on treatment engagement.

2.5.1. CI-CT intervention

The CI-CT intervention will be used in the one-arm trials and pilot RCT. CI-CT is a manualized treatment in which participants meet weekly and employs the use of a participant workbook and a facilitator manual. CI-CT's treatment aim is to help Veterans develop a better present-to-future life story as a framework for increasing hopefulness, a sense of life meaning, empowerment, and an ability to attain future self-goals. Groups will be run by two facilitators at all times from within the JJPVAMC including a licensed psychologist and/or doctoral-level psychology fellow, and/or bachelor's level psychology technician supervised by a licensed clinician. All facilitators will be guided on how to manage problems that arise within the group; from participants veering discussions off-topic; and to how to respond to an inflammatory comment made by an individual and suicidal sharing within the group, among many other guidelines. Facilitators will be guided to use supportive language to lead the group and promote group discussion.

2.5.2. One-arm trials

CI-CT individual groups will consist of 4–6 participants (for a total sample of approximately 15) and will meet through telehealth means for 90-minute weekly meetings over a 12-week course. The meetings will be run by two facilitators: The Principal Investigator (PI), accompanied by the study coordinator for assistance. Before the first session, each participant will be sent the CI-CT workbook containing all CI-CT therapy content and individual work to be completed between sessions. At the initial meeting, the facilitator will introduce themselves to the participants and review group rules (e.g., respect for their peers and facilitator), the purpose of the treatment, the treatment format, and general guidelines on how the group will be conducted. Participants will be provided a session link for access to the group therapy, the date and time for the weekly CI-CT session, and contact info for the therapy facilitators. All measures will be collected at four-time points (see 2.4). Facilitator and participant qualitative data will be collected following each session.

2.5.3. Pilot RCT

Following revisions of treatment materials from the three one-arm trials, treatment materials will be used to run a pilot RCT to assess whether the key components necessary for conducting the proposed main RCT function well together. The consumer and scientific advisory boards will receive the updated version of the CI-CT materials from the one-arm trials and will be consulted to determine whether the final version is ready for the pilot RCT. Any final suggestions will be implemented, and the updated version will be sent out again. Following agreement by the consumer and scientific advisory boards that the treatment is ready for piloting, participant recruitment (see section 2.2 for details) will begin.

2.5.4. Pilot RCT control group

Following enrollment and baseline assessment, participants will be randomized to one of two treatment conditions (1:1 allocation): CI-CT or active control (AC), using PROC PLAN in SAS by an independent research staff member from another project who will place treatment assignments in separate envelopes according to the randomization sequence. Individual subjects will be randomized using a computer-generated permuted blocked randomization, with condition order permuted within blocks of varying size. Randomization will be stratified by suicidal behavior history (none vs. $\geq$ past suicide attempt) because multiple suicide attempt history is associated with a risk of subsequent suicidal behavior. The interventionists will not be blind to the condition, but the research assistant who completes the assessments conducted after randomization will be blind. The subject characterization process will be the same as the three one-arm trials with any revisions based on difficulties encountered during running the trial groups.

2.5.5. Pilot RCT active comparator: general health education active control group

The control condition will receive General Health Education (GHE), a structured manualized group health education intervention previously developed by MIRECC investigators as a control condition for group psychotherapy RCTs. A Postdoctoral fellow and research assistant from within the JJPVAMC will administer GHE. It has 12 1.5-hour weekly group sessions focusing on health and wellness topics. GHE was chosen for the AC because it aligns in many respects with CI-CT (e.g., length of sessions, similar expectations) while diverging in specific topics and skills targeted allowing for control of common factors without confounding. GHE recruitment, screening, subject characterization, and training procedures will match the CI-CT one-arm trials. If a participant brings up suicidality in GHE, the facilitator will monitor this and ensure they receive proper care.

2.5.6. Feasibility and Acceptability

To examine feasibility, ease of implementation, recruitment, attendance, and retention rates will be tracked. Collected data on each of these areas will be compared to our predetermined criteria. Ease of implementation will be tracked by recording the number of hours that CI-CT facilitators from within the JJPVA spend in preparation, delivery of the intervention, and supervision. For more details on determining feasibility please see section 2.6. While we will target a 60 hour/12-session cycle, we anticipate beginning cycles to take longer while the intervention is being learned. Recruitment will be tracked by measuring rates of successful referral to CI-CT and by monitoring the total number of sessions and which specific sessions each Veteran attends.

Acceptability will be assessed using attendance, satisfaction, and participant feedback. Participants and CI-CT facilitators will complete a brief survey after each session and upon completion of the intervention. The Client Satisfaction Questionnaire (CSQ-8) [49] will be used to measure client satisfaction with the treatment. The CSQ-8 contains eight items with a 4-point response metric. Sample items include, "Did you get the kind of service you wanted?" and "To what extent has our program met your needs?" An overall score is calculated by summing the score for each scale item, with higher values indicating higher satisfaction. The CSQ-8 has strong internal consistency and construct validity [49]. The CSQ-8 has been widely used in mental health studies, containing items about quality and helpfulness [49]. Homework adherence will be regularly monitored by noting the number of participants who completed the homework at the beginning of the following session.

2.5.7. Facilitators and treatment fidelity

Overall, the CI-CT training process will be the same for the one-arm trials and the pilot RCT. To ensure standard of care from the facilitator and fidelity to the CI-CT manual (in the pilot RCT), group facilitators will receive one full day of CI-CT training with the PI. This involves conducting an in-depth review of the group workbook and facilitator manual, engaging in discussions about the underlying philosophy and therapeutic modality that will be utilized throughout the therapy, equipping facilitators with the necessary tools to handle the challenges that have arisen and are likely to arise during the therapy, and engaging in role plays to enable them to practice their skills. Facilitators will also receive weekly supervision with the PI and audio-taping and review of sessions. While the overall training process will be the same for the one-

arm trials and the pilot RCT, the one-arm trials will only be using a preliminary version of the therapy workbook and manual.

Treatment fidelity will be assessed in the pilot RCT. An adherence scale will be developed during the three one-arm trials and piloted to assess treatment fidelity during the pilot RCT to evaluate key aspects of its structure, contents, treatment principles, and overall clinical competence (e.g., building rapport). The three elements of the adherence scale will cover adherence to (1) general CI-CT requirements, (2) session-specific requirements and (3) general group psychotherapy requirements. Items will be scored on a 5-point Likert scale ranging from 1 (Undesirable) to 5 (Very desireable). Facilitators will need to maintain an average score of 4 for each session to demonstrate their adherence to the updated CI-CT manual. If ratings fall below this standard, supervision will be increased, and adherence will be monitored until the required level is reached.

In the pilot RCT, for both CI-CT and GHE, a structured supervision format that includes the audio recording of all sessions, weekly supervision conducted by the PI, and an objective assessment of fidelity will be utilized. The interventionist adherence rating scale that was developed will be used for CI-CT, and the previously developed adherence rating scale being used for GHE. 20% of CI-CT and GHE session recordings will be assessed by one of the study researchers for fidelity and competence. The interventionist will not know which sessions are to be selected as they will be chosen at random. After the pilot RCT's completion, overall fidelity percentages will be calculated to assess overall fidelity. Interventionist fidelity will be demonstrated if at least 85% of interventionist behaviors in the CI-CT and GHE sessions have been rated acceptable to excellent.

2.6. Data analytic plan

2.6.1. Three one-arm trials

Data from the three one-arm trials will be entered into a Statistical Package for the Social Sciences (SPSS) database at the JJPVA. The data system includes double data entry, range checks, and exclusion of identifiers that can be traced to individuals. The computers are only accessible to authorized study personnel. The preliminary analyses will include computing descriptive statistics and inspecting features and patterns of data to determine whether data transformations are needed. Feasibility data will be assessed for 1) ease of implementation, 2) recruitment, and 3) attendance/retention. Based on rates in previous studies, the predetermined criteria for retention will be "adequate" if 70% of participants attend at least 9 of the 12 sessions, and "inadequate" otherwise. A similar strategy will be used for recruitment rates, with "adequate" feasibility if at least 65% of Veterans approached for participation in the study agree. Feasibility and acceptability levels will be set at 75% satisfaction from participants' qualitative feedback. A feasible follow-up response level is 70%. These benchmarks are consistent with VA study protocol standards [50] and data derived from the small CI-CT pilot [17]. Due to the small sample size (N = 15), null hypothesis testing is not feasible and assessment data will be examined using descriptive statistics rather than inferential statistics. Due to lack of precision of estimates caused by using pilot trial sample sizes (which have extremely wide confidence intervals), we will not compute effect sizes. The satisfaction questionnaires will be reviewed and summarized. Following the three one-arm trials, feasibility and acceptance data will be reviewed and a written summary will be sent to the scientific and consumer advisory boards to determine changes needed to the CI-CT treatment materials or design. Any suggested changes will be implemented before moving to the pilot RCT.

Using information gathered during the three one-arm trials an objective scale will be developed to assess core features of its structure, contents, and treatment principles along with general clinical competence (e.g., building rapport). This measure will be piloted during the pilot RCT to assess treatment fidelity.

2.6.2. Pilot RCT

Data management, including all feasibility criteria, for both conditions of the pilot RCT will be identical to the one-arm trials. Summary statistics of demographic, clinical, and baseline outcome scale scores will be calculated for the total sample and compared between treatment groups to check the success of the randomization and for outliers. If any covariates are out-of-balance, adjustments will be made in between-group comparisons. Following intent-to-treat principles, regardless of the level of participation, efforts will be made to assess all randomized participants at each time point, and analyses will include all available data.

The purpose of this pilot RCT is to serve as a "dress rehearsal" for the full RCT (Abbot, 2014). Given that this is intended for feasibility purposes and not effectiveness, power analysis is inappropriate for this pilot. Our selected sample size (N = 30) was determined sufficient for this task through a statistical consultation and does not allow for statistically powered (at 0.80) null hypothesis testing. Due to errors in effect size estimation in small sample studies, we will not compute effect sizes. Exploratory analyses will be used to examine changes over time using mixed models with 95% confidence intervals. This approach is used in small sample clinical trials and accounts for missing data without imputation. The analysis will consider a single predictor, group indicator, and random participant effect. The covariance matrix will be specified using restricted maximum likelihood and heterogeneous first-order autoregressive structure. Adjustments will be made for multiplicity in the primary outcome confidence intervals.

After considering the time and resources available, we believe it feasible to randomize 19 individuals per condition. We expect 20% of those randomized in each condition to be missing assessments at time point two, 27% at time point three, and 34% at time point four. The sample size will not be sufficient to detect minimal clinically important differences or medium-sized differences (Cohen's d = 0.50) with 80% power as would be expected of a larger confirmatory RCT.

3. Discussion

CI-CT, a novel manualized recovery-oriented treatment for Veterans, combines influences from ACT and CBT with a focus on a Veteran audience to employ a recovery orientation to suicidal experiences. This is a novel method of suicidal care for Veterans, as typical treatments are not typically offered or tailored to the PASE stage. This paper describes a project that aims to evaluate and establish the feasibility and acceptability of the CI-CT intervention and RCT procedures through the one-arm trials and pilot RCT, respectively. Potential benefits of CI-CT include decreased suicide risk and increased FSC, hopefulness, and social connectedness. If CI-CT is found feasible and acceptable in the three one-arm trials and pilot RCT, a manualized version of CI-CT for PASE Veterans will be finalized, and a large-scale multi-site RCT study will be designed, administered, and assessed for a wider Veteran population.

This two-stage pilot study has some limitations. The first is a diversity limitation, as all study participants will be recruited from an urban northeast VA medical center. While the JJPVA is diverse in race and ethnicity, the results may not fully generalize to Veterans in more central, western, or rural areas of the USA. Future studies should seek to extend the findings to more culturally diverse Veteran populations. Additionally, due to the gender ratio prevalence of clients seeking care in the VA [51], we expect that the majority of participants will be male. Further, the sole focus of the present series of studies is on treatment development, feasibility, and acceptability. While the sample sizes selected are within the accepted range of sample sizes considered sufficient for development and feasibility and acceptability pilot studies [35,52,53], they do not allow for conclusive testing of hypotheses. Rather, they are designed to create and test a research protocol in preparation for a large-scale RCT study sufficiently powered to draw definitive conclusions. Results from this series of studies will be used to identify adaptations to optimize CI-CT for PASE Veterans and inform the

development and administration of a large-scale RCT to determine its clinical efficacy in this population.

Trial Status: Currently, the first stage of the study has begun. The third of three one-arm trials is being administered, and data on feasibility and acceptability is being collected as outlined above.

Funding statement

This work is supported by an RR&D Career Development Award for the Veteran Affairs Research Department (RX-003571-01A1).

Contribution statement

Yosef Sokol: Conceptualization; Funding acquisition; Writing – original draft; Writing – review & editing. Sarah Andrusier: Writing – original draft; Writing – review and editing. Sofie Glatt: Writing – original draft; Writing – review and editing. Lisa Dixson: Conceptualization; Writing – review and editing. Josephine Ridley: Conceptualization; Writing – review and editing. Clayton Brown: Conceptualization; Writing – review and editing. Yulia Landa: Conceptualization; Writing – review and editing. Shirley Glynn: Conceptualization; Writing – review and editing. Marianne Goodman: Conceptualization; Writing – review and editing.

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.

Acknowledgments

The authors would like to acknowledge and thank the U.S. Department of Veterans Affairs Rehabilitation Research and Development Service and the New York/New Jersey VA Health Care Network (VISN 2) Mental Illness Research, Education and Clinical Centers (MIRECC) at the James J. Peters VA Medical Center for their support of this project. We would also like to thank the Veterans who participated in the CI-CT pilot study at the VA Northeast Ohio Healthcare System, making this research possible.

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