Contemporary Clinical Trials 30 (2009) 513–522

Contents lists available at ScienceDirect

Contemporary Clinical Trials

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

Issues in the design of a randomized noninferiority clinical trial of telemental health psychotherapy for rural combat veterans with PTSD

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ARTICLE INFO

Article history:
Received 21 March 2009
Accepted 18 June 2009

Keywords:
Posttraumatic stress disorder (PTSD)
Rural
Military veterans
Telemedicine
Noninferiority trial

ABSTRACT

This methodological article provides a description of the design, methods, and rationale of the first prospective, noninferiority designed randomized clinical trial evaluating the clinical and cost implications of delivering an evidence-based cognitive-behavioral group intervention specifically treating posttraumatic stress disorder (PTSD) with a trauma-focused intervention via video teleconferencing (VTC). PTSD is a prevalent mental health problem found among returning Operation Iraqi Freedom/Operation Enduring Freedom (OIF/OEF) military populations. These returning military personnel often live in rural areas and therefore have limited access to care and specialized psychological treatments. In the field of mental health, telemental health (TMH) technology has introduced a potential solution to the persistent problem of access to care in remote areas. This study is enrolling approximately 126 returning veterans with current combat-related PTSD who are receiving services through the Veteran Administration (VA) mental health care clinics on 4 Hawaiian Islands. Cognitive Processing Therapy (CPT), an empirically supported manualized treatment for PTSD, is being delivered across 9 cohorts. Participants are assigned to either the experimental VTC condition or the in-person control condition. Assessments measuring clinical, process, and cost outcomes are being conducted at baseline, mid-treatment, post-treatment, and 3 and 6 months post-treatment. The study employs a noninferiority design to determine if the group treatment delivered via VTC is *as good as* the traditional in-person modality. In addition, a cost analysis will be performed in order to compare the cost of the 2 modalities. Novel aspects of this trial and specific challenges are discussed.

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1. Introduction

Posttraumatic Stress Disorder (PTSD) is a serious mental health problem facing military populations across the nation. Estimate rates of PTSD in military populations vary greatly but have been shown to be as high as 70% in some combat theater veteran samples [1]. An estimated 19% of returning Operation Iraqi Freedom (OIF) veterans reported a mental health problem with approximately half of these screening positive for PTSD [2]. Since the Vietnam War, cognitive-behavioral treatments (CBT) have been established as effective in the treatment of PTSD [3,4]. The Veteran's Affairs (VA) has recently mandated that all veterans, active duty Reserves and National Guardsmen with PTSD be provided access to either of the 2 evidence-based CBT therapies for PTSD, exposure therapy [5] or Cognitive Processing Therapy (CPT) [6]. CPT is a manualized therapy that

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1551-7144/$ – see front matter © 2009 Published by Elsevier Inc.
doi:10.1016/j.cct.2009.06.006

has demonstrated efficaciousness for both sexual assault victims and veteran populations in VA treatment settings [7,8] and has been recommended in the Veteran's Health Administration's Clinical Practice Guidelines for PTSD.

Military populations living in rural areas may experience disparities in health status and access to care [9,10], which have been shown to be a critical barrier to specialty care for many veteran populations [11,12]. CPT and exposure therapy both require specialized training to deliver; however VA clinics in rural areas are often under-staffed and lack providers who are trained, skilled and comfortable in delivering these treatments. Recent findings suggest that this problem will intensify with over 40% of returning OIF/OEF troops coming from the rural communities [13].

Telehealth is the use of electronic communications and information technology to provide and support health care when distance separates the provider from the patient [14]. Telehealth that is specific to mental health, often referred to as telemental health (TMH), typically includes the provision of psychological services, cognitive testing and general psychiatry. A potential solution to the persistent problem of access to care in remote areas is the use of TMH technologies, such as video teleconferencing (VTC), to deliver care [15–17]. Several studies have demonstrated the general feasibility and reliability of TMH for both civilians [16,18] and veterans [19]. However, most TMH applications have involved remote assessment, consultation [20], or psychoeducation [21,22]; few have examined the provision of psychotherapy or rigorously evaluated whether psychotherapy via VTC produces outcomes that are comparable (noninferior) to those from face-to-face care [19,21,23].

Our prior randomized VTC studies with veterans diagnosed with PTSD have used interventions that focused on social skill training and anger management [23,24] rather than trauma-focused interventions. One of these studies was a small pilot study that was not powered for a noninferiority design [23]. Thus, to date no large, carefully controlled study has examined the use of VTC to conduct an evidence-based PTSD-focused group psychotherapy with a trauma-focused intervention using a rigorous noninferiority design. We have recently launched just such a trial. The aim of this paper is to describe the design, methods, and operational aspects of this novel endeavor that is underway. This paper does not focus on results, but rather we specifically focus on the methodological and procedural issues involved with launching such a study. We delineate the rationale, specific research aims, research design, and analytic approach of an ongoing 4-year randomized clinical trial comparing the effectiveness of a group CPT delivered via VTC to in-person service delivery with a sample of rural combat veterans with PTSD. We focus on four novel features of this trial: 1) methodological issues in testing remote VTC delivery of group psychotherapy; 2) use of a noninferiority design; 3) cost analysis; and 4) selecting a trauma-focused PTSD psychotherapy that is efficacious and likely to be safe and well tolerated.

2. Design and method

2.1. Study design

This project is a prospective, randomized designed study evaluating the effectiveness of a psychotherapy intervention, CPT, delivered via 2 different modalities (see Fig. 1). The design and methodology of this study allow for a rigorous comparison of the VTC and in-person modalities and a sophisticated analysis of equivalency (noninferiority) between the clinical outcome domains. A noninferiority design is being utilized in order to rigorously assess the equivalency of the 2 treatment modalities. The noninferiority design is often used in trials in which the primary objective is to show that a novel intervention is as effective as the standard intervention. The use of these designs is becoming increasingly relevant to mental health research; however the design is often not well understood. Noninferiority designs are a one-sided test used to determine if a novel intervention is no worse than a standard intervention. Issues related to the comparability between the novel interventions and better established ones are of great importance to improving health service delivery across a wide range of settings and contexts. In the current study a noninferiority analysis will be conducted to determine if the clinical outcomes (i.e., symptoms severity) of participants in the VTC condition are *as good as* those in the in-person condition. The standard testing for significant differences will be conducted to determine if the process outcomes (i.e., perception of treatment, satisfaction, group therapy alliance, treatment compliance, and attrition and treatment credibility) are better in the in-person condition and costs are lower in the VTC condition. In addition, a cost-minimization analysis will be performed to compare each modality and secondary analyses will examine the potential influence that personal and environmental characteristics (e.g., ethnicity, education, military branch, war era, distance from clinic, utilization of VA services) and other factors may have on outcomes.

Eligible participants are assigned to either the experimental VTC condition or the in-person control condition through the use of a block randomization scheme in order to achieve an assignment balance on the variable of war era. After the treatment condition randomization, participants are asked to attend an individual 2-hour orientation session with the treatment clinician, either in-person or by VTC technology, depending on the condition assignment. Consistent with the

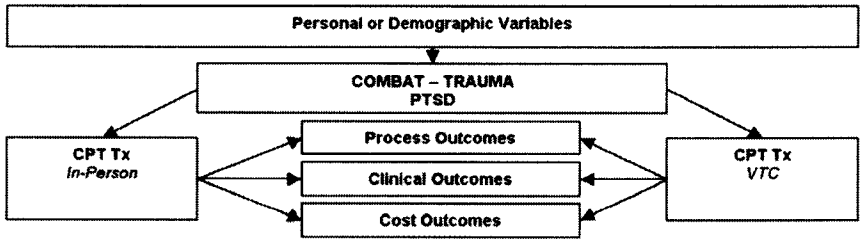

Fig. 1. Conceptual model.

IRB requirements, an observer is in the room for the orientation session conducted over the VTC modality. This orientation session has been suggested by several CPT experts, as a way to facilitate a basic understanding of the materials and concepts that are being used throughout the groups and in order to gain the greatest treatment benefit. This orientation session is particularly important for the population of interest, as there is a wide range of cognitive abilities within each group and variability in each participant's ability to grasp the concepts within the context of the group format. These sessions are scheduled between the participants' last pre-treatment assessment and the first group session. Additionally, some veterans who have had little to no previous psychoeducation or mental health treatment benefit from learning basic coping skills and receiving more education about PTSD during this individual session.

2.2. Setting

The geographic dispersion of the Hawaiian Islands is particularly well suited for this project, as it affords the realistic opportunity to examine the difficulties that may be associated with providing mental health care from a distance. In Hawaii, delivering specialty mental health care to rural patients often requires the expense of flying either the provider or the patient to a different island, therefore limiting the number of patients who can be served. Specific clinical sites have been selected based on the demonstrated clinical need for PTSD treatment services (i.e., existing veterans with PTSD and high numbers of returning OIF/OEF reservists, guardsmen and veterans) and the availability of a group room with VTC equipment, appropriate VTC connection, and a back-up on-site clinician. Ultimately, this project will yield findings that are highly generalizable to other VA and Department of Defense (DOD) locations that are highly rural and where access to care is a challenge.

2.3. Participants

Approximately 126 eligible OIF/OEF Reservists, National Guard and veterans are being recruited by VA and DOD mental health care clinicians, OIF/OEF Coordinators and Vet Center personnel. This study is open to all male Reservists, National Guard and veterans with PTSD who are located on 1 of the 4 participating Hawaiian Islands. Consistent with the "effectiveness designs," we are incorporating nonselective inclusion criteria in order to be clinically realistic [25] and generalizable to the PTSD military population. Inclusion and exclusion criteria are designed to allow a broadly representative sample. Participants are eligible if they meet the diagnostic criteria for current combat-related PTSD, as determined by the Clinician Administered PSTD Scale (CAPS-1) [26,27]. Since PTSD is typically accompanied by high rates of comorbid psychiatric disorders, patients with comorbid depressive disorders and anxiety disorders are included so that the intervention results may be applied to a representative sample of the population. In addition, veterans with substance abuse and personality disorders are also not excluded, because these conditions are frequently concurrent with PTSD in military populations [28]. In all cases included, PTSD is considered the primary disorder. Previous research endeavors employing these criteria have reported that approximately 70–85% of referred participants met the inclusion criteria and were then randomized into the corresponding study [29–31]. Consistent with the previous research, thus far, of the 18 veterans we have assessed for our Cognitive Processing Therapy with cognitive therapy only (CPT-C) pilot cohort, 13 (72%) met the study criteria and were enrolled in the active treatment phase. Of these 13 enrolled participants, 11 (85%) completed the 12-session CPT-C group therapy yielding a 15% attrition rate.

The exclusion criteria selected are consistent with the large PTSD randomized clinical trials (RCTs) such as CSP420 [30,31] and PTSD Telepsychiatry research [21]. Similarly, these criteria are consistent with the research using the CPT protocol with combat veterans with PTSD in VA settings [8,32]. Participants with any of the following criteria are excluded: 1) active psychotic symptoms/disorder as determined by the SCID for DSM-IV; 2) active homicidal or suicidal ideation as determined by the structured clinical interview; 3) any significant cognitive impairment or history of Organic Mental Disorder as determined by the structured clinical interview; 4) active (current) substance dependence as determined by the SCID (lifetime substance dependence or substance abuse not excluded); and 5) unwillingness to refrain from substance abuse during treatment. Female veterans are excluded from the current study due to their small numbers at the participating clinics and the resulting inability to establish a therapeutic gender mix within groups.

While participating in the project, research participants are allowed to continue health care or services they may already be receiving, including medication management. Participants taking psychoactive medications are required to have a stable regimen for at least 2 months prior to study entry. Medication changes are allowed during the study if clinically justified. In such cases, the changes are documented for secondary data analyses.

2.4. Recruitment and retention

Nine group of cohorts are being conducted across 4 clinical sites. A minimum of 14 participants are being recruited for each cohort, with 7 being randomized into each condition (VTC vs. in-person control). Recruitment can be a challenge in most RCTs. In order to avoid difficulties with recruitment, we include the following steps: 1) selecting clinical sites where there is a great need for PTSD services as determined in the previous pilot projects and expressed by clinicians and the OIF/OEF coordinator; 2) working closely with the designated local project liaison at each clinical site including on-site visits and weekly communication; 3) allowing 2 months of active recruitment at each site prior to the start of each group cohort; recruitment will be facilitated by the use of information flyers distributed at each site and referrals by designated clinical staff; 4) providing $10.00 per session financial compensation (gift cards) for participants' travel to and from the clinic twice a week and to the individual orientation session ($20.00 a week—average estimated commute time is 60 min, with a range from 20–190 min each way), providing $50 compensation (gift cards) for each participant's Phase I assessment, $50 (gift cards) compensation for Phase II assessment, and $50 compensation (gift cards) for follow-

up assessments; 5) flexible scheduling of the CPT groups to allow both employed and unemployed participant involvement; and 6) contacting participants every week during the active treatment phase to confirm attendance at groups.

Based on the clinical and research experiences in providing PTSD groups on the neighbor Hawaiian Islands, we anticipate 10–15% attrition [21,24]. Ethnicity did not create difficulties for recruitment or participation in the previous studies investigating the provision of PTSD group services on the neighbor Hawaiian islands (Kona, Hilo, and Maui) [21,22]. Further, participation in the previous groups has been well represented by the Asian-Pacific Island population for both the TMH and in-person group conditions. This is consistent with our initial pilot cohort for this study. For our first pilot group we enrolled 13 participants, of which all participants were of Asian-Pacific Island ethnicity. Of the 13 enrolled in the treatment, 11 (85%) participants completed the 12-session CPT-C group and 2 veterans did not complete the treatment. Successful prior research studies using highly structured CBT interventions with the Asian-Pacific Island PTSD population in Hawaii have demonstrated approaches to ensure effectiveness with this population [21,33]. However, we are assessing participant ethnicity in order to account for any imbalance between the 2 groups.

2.5. Assessment

Participants are assessed at baseline, mid-treatment, immediately post-treatment, and at 3 and 6 months post-treatment. Assessment information is obtained in 2 phases. The timetable of assessments is shown in Table 1. The comprehensive intake evaluations are being conducted over 2 sessions to maximize the accuracy of the assessment and to minimize the burden of completing the questionnaire battery and 2 clinical interviews. The aim of the first meeting is to introduce the study, assess the participant's interest, availability and initial eligibility for participation, and obtain informed consent. At intake participants are administered a general, structured clinical interview that is designed to obtain information regarding demographic variables and personal data including: age, gender, education level, ethnicity, marital status, employment status, service connection status, era of service, military branch, legal history, current and past mental and medical treatment, and approximate length of commute (miles) to the clinic. A 4-item brief self-report instrument, the CAGE Questionnaire [34], is administered to screen for alcohol dependence.

Participants interested in and eligible for a second assessment are interviewed by a master's or doctoral level psychologist using the CAPS. Diagnosis of other AXIS I disorders are also assessed using the Structured Clinical Interview for DSM-IV (SCID) [35]. Only participants who are confirmed by the CAPS interview to have a current diagnosis of PTSD are eligible for inclusion in the study. Self-report measures were selected due to their wide use in the clinical evaluation of combat-related PTSD. These measures are empirically sound and have demonstrated sensitivity to clinically meaningful changes in the PTSD symptoms following the CBT treatment. The clinical measures include the PTSD Checklist-Military Version (PCL-M) [36], Beck Depression Inventory-II (BDI-II) [37], Quality of Life Inventory (QOLI) [38], Medical Outcome Short Form (12) Survey (SF-12) [39], Trait and State subscales of the State-Trait Anger Expression Inventory (STAXI) [40], Trauma-Related Guilt Inventory (TRGI) [41], Posttraumatic Cognitions Inventory (PTCI) [42], Posttraumatic Symptom Scale-Inventory (PSS-I) [43], Social Adjustment Inventory (SAI) [44]. Process outcome measures include the Charleston Psychiatric Outpatient Satisfaction Scale (CPOSS-VA) [45], Group Therapy Alliance Scale (GTAS) [46], Group Climate Questionnaire (GCQ) [47], Borkovec and Nau Treatment Credibility Scale [48], and Service Delivery Perceptions Questionnaire [23]. Additionally, treatment adherence, session attendance, study attrition, and technological difficulties are systematically tracked weekly and assessed using a standardized tracking form developed for our previous TMH projects.

Table 1
Schedule of assessment procedures.

Assessment measure	Baseline phase I	Baseline phase II	Wkly	Mid-tx	Post treatment		
					1 week	3-month	6-month
CAGE	X						
Clinical interview	X						
PCL-M	X		X				
PSS-I		X			X	X	X
SCID		X					
CAPS		X			X	X	X
BDI-II		X	X		X	X	X
QOLI		X			X	X	X
SF-12	X			X	X	X	X
STAXI (subscale)	X				X	X	X
TRGI	X			X	X	X	X
PTCI	X			X	X	X	X
CPOS S-VA			X	X	X		
GTAS				X	X		
GCQ				X		X	
Treatment credibility[a]							
SDPQ					X		
SAT	X				X		X

[a] Denotes administration at session 2, in addition to assessment administrations.

2.6. Treatment delivery

The present study elected to test Cognitive Processing Therapy with cognitive therapy only (CPT-C), a dismantled variant of CPT, in a group format since this format is potentially a more feasible and efficient way to deliver care and maximize the number of patients who can be served within a large healthcare organization such as the VA. The research with conducting CPT in the group format has shown an effect size that ranges from medium [49] to large [8], depending on the population. We chose to use CPT-C, which excludes the written exposure, instead of the traditional CPT because CPT-C has been found to be just as effective as the CPT but with fewer drop-outs [50]. This is perhaps due to the intense nature of the written accounts. Following completion of the Phase II assessment, the consented participants are randomly assigned into either the VTC or the control group condition located at their corresponding clinical site.

The decision to deliver CPT-C using a group format has 2 implications for the study design. First, it requires us to assess whether interpersonal group processes were similar in the VTC and face-to-face conditions. It also requires use of a clustered design in the analyses (see Statistical methods).

CPT-C is a manualized, 12 session, CBT for PTSD that has a primary focus on targeting cognitive symptoms of PTSD [6]. Each group session is 90 min in length. The treatment procedure includes a psychoeducation component, as well as a series of skill building exercises designed to teach participants about cognitive and information processing theory and to practice strategies to restructure thoughts and support continued recovery [51]. Problematic beliefs and cognitions ("stuck points") are explored through Socratic questioning used to identify specific problems of assimilation and self-blame. The following exercises are discussed and examples are worked through during the CPT-C sessions: 1) the A–B–C worksheet, used to identify stuck points and their link to negative emotional states; 2) the Challenging Questions Worksheet, which challenges single beliefs related to trauma; and 3) the Patterns of Problematic Thinking Worksheet. Participants are encouraged to practice the techniques learned during the sessions on a daily basis between the sessions. Finally, the participants discuss issues of safety, trust, control, esteem, and intimacy as they relate to self and the others. Treatment gains are consolidated in the final sessions.

Both the experimental (VTC) and the control conditions (in-person) receive the same CPT-C protocol, delivered in accordance with the detailed CPT-C manual. An organized CPT-C participant workbook complements the treatment sessions. All cohorts are taking place sequentially with approximately 6 weeks, depending on referrals, between each cohort. The sessions take place twice a week over a 6 week period. The CPT-C intervention is being delivered simultaneously (within the same week) and at the same time of day to the 2 groups (VTC vs. control) in each cohort. Each cohort uses the same room at the corresponding clinic site and the same therapist and co-therapist for both conditions.

2.6.1. VTC modality

Approximately 15 min prior to the group meeting, the on-site research coordinator facilitates the VTC connection with the therapists located on the island of Oahu. A VA Information Resource Management Service staff member on Oahu is on-call during the scheduled group in case of any technical difficulties with the VTC equipment that require troubleshooting. The conference rooms at each of the corresponding clinical sites are outfitted with the Tandberg 880 Model Health Care System (HCS III) videoteleconferencing systems. The VA VISN 21 supports 2 kinds of VTC standards, H.320 and H.323. The video quality of the Tandberg system is excellent, with a Tandberg to Tandberg connection supporting up to 4CIF (Common Intermediate Format), a better image than the CIF, the international standard. This equipment is available and has been tested for reliability of connection between the proposed sites. A technician is available during each scheduled VTC group session, twice a week for each 6 week telemental health group, to aid in any required technical troubleshooting.

Participants in the VTC group arrive at the corresponding clinic and are led into the group room by the on-site research observer. Upon entering the group room, the VTC equipment is on and the therapists are visible to the group members on the VTC screen. Each group will be led by a doctoral level therapist and co-therapist. Participants sit in a semi-circle around the table facing the VTC monitor. The therapists have a marking board available to use during the group; this marking board is positioned to the right of the therapists and visible on the screen to the participants.

The on-site designated research observer is a project member (rotated between the project clinical supervisor and the project manager) and has been trained in both the CPT-C protocol and the VTC technology. As a team member, this observer has completed all the required research training, including the human subject's protection training. The observer sits in the room for the duration of the group session and does not participate in the group session unless there are technological or clinical difficulties.

2.6.2. In-person modality

The in-person modality follows the same protocol as the VTC modality; however, the therapists are in the room.

2.6.3. Therapist selection, training and supervision

The intervention is delivered by doctoral level clinicians. The clinicians delivering the intervention are not blind to the treatment assignment, which can introduce potential bias into the study. Although the unblinded nature of this study design is unavoidable, in order to adjust for potential biases that may be introduced, quality control procedures have been incorporated into the study design to ensure integrity and standard administration of the CPT intervention across both conditions. Careful emphasis is placed on the training and supervision of the clinicians administering this protocol. A 4-day formal, in-depth training to criterion in CPT was provided by Patricia Resick, Ph.D., the clinical psychologist who developed CPT and has conducted several research trials using CPT. The project clinical coordinator and supervisors have clinical experience in conducting CPT, but participated in this training and worked with Dr. Resick on the important aspects of implementing CPT as a research protocol.

The therapists receive supervision throughout their participation in the study. Initially, supervision occurred after each group session for the first group cohort. All CPT sessions are audiotaped for supervision purposes and for the monitoring of

overall competence and adherence to the protocol. Additionally, the audiotapes of select therapy sessions are mailed to Dr. Kathleen Chard via Fed-Ex with secure signature tracking. Dr. Chard is a designated CPT expert within the VA whose primary role is to disseminate CPT training across the VA sites. She has experience with off-site audio consultation from other VA and non-VA sites engaged in the CPT treatments.

The assessments are performed by masters or doctoral level clinicians who are not involved in the delivery of the intervention and are blind to the treatment assignment at the onset of the individual's participation in the study. The assessment clinicians are required to have a minimum of 2 years experience in diagnostic interviewing and a minimum of 1 year of clinical experience with the veteran population. Assessment clinicians have received formal training in the administration of the CAPS and the SCID by our assessment supervisor. The assessment supervisor provides weekly supervision for the assessment clinicians.

2.6.4. Fidelity monitoring

In order to ensure that the CPT treatment is administered in accordance with the manual for both groups, 20% of the sessions are randomly selected (predetermined), and audiotapes are rated for content by raters who are blind to group assignment and session. These audiotapes are transcribed by the research assistant. The tapes are rated independently by 2 raters to allow for the computation of inter-rater reliability. Therapist adherence is measured using an adapted version of a therapist adherence measure previously used with CPT [6]. This rating is completed on an ongoing basis during the project, and results are incorporated into feedback. Additionally, all assessments are audiotaped and 25% checked for reliability by a doctoral level psychologist and by the assessment supervisor.

2.7. Statistical methods

The intent-to-treat (ITT) sample will comprise all participants who have at least one post-baseline randomization measurement. The active treatment phase completer sample will comprise participants who complete 80% of the 6-week active treatment phase (10 sessions) and for whom all required measurements have been collected. To handle missing data, multiple imputation procedures will be employed for the ITT analyses set prior to the calculation of the correlations and other analyses. SAS procedures MI (Multiple Imputation using the Markov chain Monte Carlo method) and MIANALYZE will be used for the imputation in the ITT analysis. Analyses will be carried out separately for the ITT sample and for the completer sample. The results of the analyses using study completers (completer analyses) will be compared with the results using the full set of all randomized participants (ITT analyses) to assess sensitivity of the study conclusions to study drop-outs. To investigate the potential limits on generalizability, we will compare clinical and demographic characteristics of the participants who were considered premature exits with those who were completers. Our design involved 3 sets of statistical challenges: 1) establishing adequate power and noninferiority; 2) multilevel analyses for an intervention delivered in groups; and 3) economic analyses.

2.7.1. Noninferiority design and power

This study uses a noninferiority design as it is the most rigorous methodology for testing if a novel intervention that provides increased access to care, is easier to use and/or is less costly, is *as good as* the standard intervention. In this case, we test whether CPT-C via VTC is no more than a pre-specified value less effective than the standard intervention, face-to-face CPT-C. A noninferiority design differs from the standard designs in several significant ways [52]. In the traditional clinical trials, it is typically hypothesized that one treatment under investigation is superior to another comparison treatment. Our study, however, hypothesizes that the 2 treatment modalities under examination (VTC vs. in-person) are roughly equivalent. Specifically, we test the probability that the actual difference between the 2 treatments is smaller than some predetermined threshold delta (Δ) for a minimum clinically meaningful difference on the primary outcome measure. Other secondary outcomes are conducted using traditional hypothesis testing.

Study designs for the traditional superiority trials balance limiting Type I error (chance of a false positive result) with reducing Type II error (chance of a false negative). In a noninferiority design, the roles and relative importance of Type I and Type II error change. Type I error is the chance of erroneously concluding noninferiority when evidence is lacking that the novel treatment truly is noninferior to the standard treatment and a Type II error is the probability of erroneously failing to reject the null hypothesis of inferiority when the novel treatment is truly inferior to the standard by the pre-specified amount (Δ). In a noninferiority trial, the recommended Type I error value is 0.025.

In setting the delta, or margin of noninferiority, we must first decide how big a difference would be large enough to be clinically meaningful. Based on the expert consultation, we defined the minimum clinically meaningful difference value (Δ) for our primary outcome measure, the CAPS, as a difference of 10 points. This is consistent with the minimum effect that was considered clinically meaningful in a landmark trial of PTSD group therapy [30] and a program evaluation study of Group Based Exposure Therapy [53]. This translates into a ½ SD, as the CAPS has been found to have a SD of about 20 in combat PTSD patient samples [27,54]. The few published noninferiority trials of mental health outcomes have used a similar minimum clinically meaningful difference [55,56].

2.7.2. Multilevel modeling

A multilevel (also called hierarchical or random effects) modeling procedure will be used for the analyses [57–59] due to the fact that the intervention is delivered to groups of patients. This method will include both individuals and sessions (group cohorts) as units of analysis, with participants (Level 1) nested within sessions (Level 2). Including the baseline values for the outcome measure as a covariate in the model will ensure the comparability across treatments and sessions at baseline. Specialized multilevel modeling software, Hierarchical Linear and Nonlinear Modeling (HLM 5) [60], will be employed for these analyses. The primary outcome measure will be a significant change in the PTSD symptoms on the CAPS. Secondary analyses will include the same approach as the procedure used above to evaluate noninferiority using the difference in change from baseline

mean scores for the continuous clinical measures (PCL-M, BDI, QOLI) for the VTC and in-person conditions. The magnitude of the difference in the means (effect sizes), as estimated by the confidence intervals, will provide useful clinical information and will allow a clinical judgment relative to the noninferiority of the 2 modes of delivery.

In a multilevel design such as this one, power is influenced not only by the number of participants, the effect size, and the α-level, but also by the number of clusters (i.e., the number of cohorts) and the effect size variability (measured as the effect size variance across cohorts). High values of the effect size variability would result in a reduced power, but because care will be taken to ensure that all sessions will undergo the same procedures, there is no reason to expect high effect size variability. Power for detecting the treatment effect was determined through the software application Optimal Design [61]. There will be nine clusters each with 14 participants. The SD for the CAPS is 20. The change of SD from baseline would be around 20–30. Based on the SD of 30 for CAPS changes and sample size of 63 for each group, with similar patterns of loss to follow-up (55 participants in post-treatment, 40 in 3 month and 6 month follow-up for each group) and moderate effect size of 0.2, the power to detect the noninferiority will be 0.94, 0.91 and 0.90 for these follow-ups. Assuming that the 3 tests are independent, the power to detect noninferiority in all 3 will be about 0.77 ($=0.94\times0.91\times0.90$); however, these tests are not independent. Therefore the actual power to detect noninferiority for CAPS changes at all 3 follow-ups should be around 0.8 or higher.

2.7.3. Economic analyses

The economic analysis in this study will be conducted to: 1) determine the cost of individual components of the TMH and the traditional in-person treatment modalities (including related capital expenditures and physician and staffing effort and travel); 2) veteran-related healthcare utilization (including hospitalizations, procedures, prescriptions, rehabilitation and outpatient visits); and 3) assess whether providing a group PTSD treatment intervention, CPT, via VTC for combat veterans with PTSD is as costly to the VA at 3 and 6 month follow-up as the traditional in-person treatment modality. This will allow us to estimate the combined spectrum of investment expenditures and patient-related VA costs of TMH as well as cumulative health costs over 6 months. A cost-minimization analysis will be used to compare the 2 treatment modalities at 3 and 6 months. Cost-minimization analyses are appropriate when the effectiveness of the alternative treatment modalities is assumed to be equal. Thus, for noninferiority or equivalence designs, the economic analysis simply revolves around costs. As a secondary analysis, a multivariate cost model to compare total costs to the VA of the 2 treatment modalities at months 3 and 6 will be developed. This model will permit comparison of costs between the 2 modalities that incorporates the potential influences that personal and environmental characteristics may have on costs. Finally, to gain further insight into the variation in the resource utilization and costs of each treatment modality, sensitivity analyses will be performed. Sensitivity analysis involves systematically altering our assumptions about the costs of each modality and noting the effect on the resulting cost comparisons.

3. Discussion

The current study examines the efficacy of delivering CPT in a group format through VTC in order to overcome some of the recognized barriers to widespread usage among veterans diagnosed with PTSD; especially among veterans in rural communities. The primary hypothesis is that a novel mode of service delivery, using VTC, will be as effective as the traditional mode of service delivery (in-person) for providing CPT for PTSD on clinical outcomes (symptom severity) and process outcomes (satisfaction, patients' perception of services, therapeutic group alliance, treatment adherence, attendance, attrition and treatment credibility). The secondary hypothesis is that cost estimates of individual components of resource use for VTC, including related travel expenses, capital expenditures, patient hospitalizations, procedures, length of stay, diagnostic procedures, rehabilitation and outpatient visits, will be lower in the VTC condition than in the traditional in-person condition. In addition, it is hypothesized that providing a validated CBT treatment for PTSD, CPT, via a VTC modality for combat veterans with PTSD will provide cost-savings by 6 months.

The use of VTC to deliver psychotherapy to veterans diagnosed with PTSD involves some specific challenges in four domains: 1) treatment provided in a group format is preferable because it enables more patients to be served with limited staff resources and provides peer support; 2) due to the challenges in managing adverse reactions remotely, it is important that the treatment be well tolerated and safe; 3) the effectiveness of VTC treatment should be comparable to face-to-face delivery of the same treatment; and 4) VTC treatment should be less costly than face-to-face care that entails travel costs.

3.2. Choice of intervention: Balancing efficacy with tolerability and safety

This is an effectiveness trial testing whether or not modifying and adapting an evidence-based treatment for PTSD delivered in a group format over VTC substantially reduces its effectiveness. Several factors led to our selecting a group format of CPT-C as the most suitable candidate for VTC delivery. The efficacious evidence-based treatments for PTSD, such as Prolonged Exposure and CPT, involve having patients reprocess traumatic memories and recount details of their traumatic experiences [6,29,62]. This therapeutic process is often emotionally distressing, but such distress does not have long-term negative effects if patients receive adequate support [63]. However, it may be more difficult to provide such support when treatment is provided remotely, so safety and tolerability concerns become more important. As a result, telemedicine delivery may require making some modifications to existing treatments.

The original format of CPT involves writing exercises that focus on the individual participant's cognitive appraisal of the traumatic events and the impact of those thoughts on his belief system. Writing about trauma is the most distressing element of CPT. Resick and colleagues [50] recently compared the efficacy of the standard CPT and a dismantled variant of CPT which excluded writing about the trauma (CPT-C). CPT-C does involve emotional processing as participants are encouraged to

challenge their emotions through appraisals and thoughts, but it is less emotionally evocative. Resick and colleagues found that CPT-C was as efficacious as original CPT. We therefore elected to use CPT-C for remote delivery, as it offered potentially greater tolerability with less treatment drop-out and no loss of efficacy. As an additional safeguard, this study will ensure that there is an on-site clinical observer who will be available in the event of any undue emotional escalation during the VTC treatment condition; however, this was not the case in a recent study we completed comparing the efficacy of providing an evidenced-based anger management group therapy protocol over VTC as compared to in-person for veteran with PTSD and high levels of anger. In this study, we did not observe any differences between the 2 conditions in safety or tolerability (24). Similarly, in our recently completed pilot cohort ($n = 13$) conducting CPT-C group over VTC, there were no observed differences in safety or tolerability.

We also concluded that group delivery would be the most efficient way of delivering care and would better fit in with the common VA practices. A group format of standard CPT has been tested with civilians [61] and veterans [8], but not CPT-C. We crafted a slightly new treatment variant (group CPT-C for veterans) from different elements that have been empirically-validated (group CPT tested with civilians and veterans, individual CPT tested with veterans, and dismantled individual CPT-C tested with civilians).

3.3. Relevance of noninferiority design

The primary hypothesis of this trial is that the novel mode of mental health service delivery, VTC, will be equally effective as a traditional mode of mental health service delivery (in-person) for providing a specialized mental health intervention (CPT-C) to combat veterans with PTSD. The rationale for the VTC delivery of CPT-C is not that it is superior to the in-person care, but rather that it is more feasible to deliver to rural areas. The potential benefits are not at the individual level in terms of better outcomes for patients in treatment; rather, the benefits are at a population level and therefore enable more patients to receive treatment. Enhancing access to care is only valuable if the care itself is effective. As a result, there is a need to show that VTC is reasonably comparable (even if not exactly equal) to face-to-face care. Noninferiority designs have been developed in order to meet this need and these designs are becoming increasingly relevant to mental health research. As empirically-validated treatments emerge, they will inevitably be modified to enhance attributes such as convenience, accessibility, tolerance, or cost. Noninferiority trials will be needed to test if the modified version retains most of the effectiveness of the original standard version. However, noninferiority designs pose a number of methodological challenges and are frequently misunderstood or improperly applied. This study makes use of and improves upon the rigor used in the first noninferiority trial of group therapy using VTC [24].

3.4. Cost

The issue of cost is central to discussions of the continued implementation of TMH approaches [64]. The cost analyses are important because if a new intervention or the mode of care delivery has greater clinical effectiveness at a lower cost and the measure of effectiveness is clinically compelling, the decision is clear. However, if the new intervention has only a slightly higher clinical effectiveness at a substantially higher cost, then the consideration of pros and cons of this intervention should be informed by an analysis of the value of the money expended for this new intervention compared to currently used approaches. Initial attempts to address the question of cost-effectiveness have suggested that the TMH programs can be less expensive for patients: reducing travel time, travel costs, and time off from work [65,66]. A key rationale for using VTC is that it is less costly to deliver than having a clinician travel to a remote location or flying patients to care. If there proves to be no difference in costs, VTC may have little value even if it produces outcomes that are roughly comparable to those from face-to-face care. Conversely, if the differences in costs is very large, VTC might fail the noninferiority test (i.e., it might be slightly less effective than face-to-face care), yet it still might be more cost-effective. In that case, the VTC delivery might be a "second best" yet still worthwhile treatment option when face-to-face care is not feasible.

4. Closing comments

The provision of empirically supported treatments for returning military with PTSD residing in rural locations is a significant challenge to DOD and VA clinicians treating this population. While the VA and DOD have improved their ability to detect and treat the psychiatric disorders that result from combat exposure, it is now time that they take the necessary step to ensure that evidence-based treatments are accessible to all military populations in need of services, regardless of location. In response to this long-standing access to care problem, the DOD and VA Office of Care Coordination have developed several initiatives that prioritize the role of TMH for increasing access to quality care for veterans residing in remote locations. Thus, there has been an influx of TMH programs across the nation. However, limited research has been conducted to evaluate the clinical effectiveness and cost implications of these applications.

While TMH research demonstrates the extensive needs that might be met, there are several marked limitations. The most salient limitation is the lack of prospective RCTs of VTC applications [16,67]. This study is a RCT to test the effectiveness of an evidence-based group therapy for PTSD delivered via remote VTC. Specifically, this study uses a noninferiority design to evaluate the equivalency of the effectiveness of CPT-C delivered via VTC and in-person modalities across clinical, process, and cost domains. The results of this RCT will provide an initial evaluation of an empirically-validated psychological intervention for PTSD delivered via the VTC modality. The long-term goal of this research endeavor is to aid in the development of an evidence-based TMH protocol for the treatment of PTSD in order to facilitate the extension of manual-guided, clinically proven services to remote sites through the use of VTC technology.

Acknowledgements

This work is partially supported by Grant PT074516 from the Department of Defense. This work is also supported by the Office of Research and Development, Medical Research Service, Department of Veterans Affairs. All views and opinions expressed herein are those of the authors and do not necessarily reflect those of our respective institutions or the Department of Veterans Affairs.

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