

Videoconferencing psychotherapy for veterans with PTSD: Results from a randomized controlled non-inferiority trial

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Abstract

Introduction: Veterans with post-traumatic stress disorder (PTSD) face significant barriers that make it less likely for them to pursue treatment. A randomized controlled non-inferiority trial was used to determine if providing psychotherapy for PTSD via videoconference (VC) is as effective as in-person (IP) psychotherapy.

Methods: All eligible veterans ($n = 207$) received cognitive processing therapy (CPT) to treat PTSD symptoms in one of the two treatment modalities. Participant symptoms were collected at baseline, post-treatment, and six months after treatment completion. The primary outcome measure, the Clinician-Administered PTSD Scale (CAPS), was used to assess PTSD diagnosis and symptom severity. Secondary outcomes included two self-report measures of symptom severity, the Post-traumatic Stress Disorder Checklist – Specific (PCL–S) for PTSD and the Patient Health Questionnaire – 9 (PHQ–9) for depressive symptoms. A linear mixed-effects model was used to assess non-inferiority for participants who completed treatment (completers) and those who were randomized to treatment (intention-to-treat (ITT)).

Results: Both completer and ITT analyses showed that improvement in CAPS scores in the VC condition was non-inferior to that in the IP condition at six-month follow-up, but VC was inferior to IP for improvement in CAPS at post-treatment. Non-inferiority was supported by completer analyses for PCL–S and PHQ–9 in both post-treatment change and six-month follow-up change, and the ITT analysis supported the significant non-inferiority for PCL at post-treatment change.

Discussion: These findings generally suggest that CPT delivered via VC can be as effective as IP for reducing the severity of PTSD symptoms.

Keywords

Post-traumatic stress disorder, telemedicine, non-inferiority, veterans

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Introduction

Post-traumatic stress disorder (PTSD) is a condition that develops after a traumatic event such as combat, assault, or natural disaster. PTSD is a major mental

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health problem within the veteran population; high levels of combat-related PTSD (2–17%) have been found in active duty military and veterans across war eras,¹ and the provision of mental health services has been recognized by the Veterans Health Administration (VHA) as a major healthcare priority. However, one in three VHA patients live in a rural community, and these veterans have worse physical and mental health status and reduced access to care as compared to patients from metropolitan areas.^{2–4} Further, veteran patients with PTSD often experience additional barriers that prevent them from accessing care at large urban Veterans Affairs (VA) facilities, wherever they live. For example, combat veterans with PTSD may avoid traveling on roads and under overpasses due to fear and anxiety associated with their trauma, and survivors of military sexual trauma may feel uncomfortable around other veterans who remind them of their perpetrators.⁵ Studies have also found perceived stigma, transportation concerns, and time constraints to be barriers to care for veterans.^{5–7} Rather than obtain services in busy locations, such as those found at the main VHA hospitals, veterans may, therefore, prefer smaller community-based clinics as their place of care, which may also reduce travel time and costs. However, many communities do not have such local clinics, or the services they offer are limited.

Telemedicine offers a solution to many of these problems, and can be used to extend state-of-the-art PTSD care to veterans in their home communities. By providing care within or closer to the veteran's home, telemedicine may improve patient participation in treatment by reducing barriers to receiving care (e.g. accessibility obstacles, distance, trauma-related fears). Clinical telemedicine includes videoconference (VC) applications that link specialists to clients at a remote site (e.g. a VA community-based outpatient clinic) or within their homes. The goal of telemedicine is to enable healthcare providers and clients to communicate effectively, facilitate health services over large distances, and reduce barriers to care. Although VC is important as a tool for extending access to care for rural veterans, it is also helpful for non-rural veterans who have barriers to care. For example, many veterans do not seek treatment because of concerns about stigma, travel time and cost, childcare, and the VA serving as a trauma reminder for veterans. Moreover, many veterans who live in urban areas have mobility issues, and treatment may be facilitated by providing care through VC to nearby clinics or homes.

Existing studies have examined the use of both office-based and home-based VC to deliver PTSD interventions. A few studies have examined the use of office-based VC to deliver cognitive processing therapy (CPT) to veterans and civilians. Maieritsch et al.⁸

found a trend of non-inferiority (NI) of CPT delivered by VC in improving both clinician-rated and self-reported PTSD severity compared to in person (IP) at post-treatment, but it was assessed in predominantly male Iraq/Afghanistan-era veterans only, which limits generalizability to women veterans and veterans from other war eras. Morland et al.⁹ examined the delivery of group CPT via VC and IP among a sample of male veterans and found that clinician-rated PTSD symptom improvements in the VC condition were non-inferior to the IP condition at post-treatment and through six-month follow-up. Similarly, clinician-rated PTSD symptom severity following individual CPT delivered through VC was non-inferior to IP at post-treatment, three-month follow-up, and six-month follow-up, in a sample of women civilians and veterans.¹⁰ Overall, these findings indicate that individual and group CPT can effectively reduce clinician-rated and self-reported PTSD symptoms when provided via VC. However, these studies have a few limitations that could be addressed. None of these studies examined if changes in depression symptoms are non-inferior via VC compared to IP; this is an important research question because depression symptoms are highly comorbid with PTSD.¹¹ Each of the existing studies had fairly homogenous samples, so a larger NI randomized controlled trial including male and female veterans who have experienced different trauma types and represent various war eras would be useful to increase generalizability of the findings to the larger veteran population. Additional long-term follow-up data would also increase support for VC.

In addition to examining the use of VC to deliver CPT, studies have evaluated the use of VC for prolonged exposure therapy (PE) and other evidence-based psychotherapies. One recent randomized trial¹² studied the NI of PE delivered via home-based telehealth compared to IP care in reducing self-reported PTSD severity and depression. The researchers found that home-based VC was non-inferior to IP for PTSD severity at each time point (post-treatment, three-month follow-up, and six-month follow-up), although it was inferior for depression at post-treatment and the three-month follow-up. This study suggests that PE can be effectively delivered through home-based VC modalities. In addition to the aforementioned studies,¹³ Gros et al. conducted a review of both randomized and non-randomized PTSD studies comparing VC and IP care in delivering evidence-based psychotherapies. Several studies have found that telemedicine can be effective,^{14–17} but these studies were either based on small sample size^{14,16,17} or did not assess gold-standard measures of PTSD severity such as the Clinician-Administered PTSD Scale (CAPS) and the self-reported Post-traumatic Stress Disorder

Checklist – Specific (PCL–S).¹⁵ Many of the extant studies are also limited by other methodological shortcomings, such as limited generalizability due to homogeneous samples, designs that only examined superiority of an intervention rather than equivalence or NI, and a lack of follow-up analyses.¹⁸

The existing literature provides promise for the use of VC to deliver evidence-based psychotherapies, such as CPT and PE. The current study aims to expand upon the existing literature by improving upon the aforementioned limitations while comparing CPT delivered via VC to IP care in a large sample of male and female veterans with mixed trauma types from various war eras. CPT is recommended as a treatment for PTSD in the *VA/DOD Clinical Practice Guideline for the Management of Post-traumatic Stress Disorder and Acute Stress Disorder* (US Department of Veterans Affairs and Department of Defense, 2017); this guideline specifically recommends that additional studies examine the utility of telemedicine for the delivery of PTSD treatments. The primary aim of this study was to conduct a systematic NI randomized clinical trial of CPT administered via VC versus IP for veterans with PTSD. PTSD severity was assessed using clinician-rated PTSD severity, self-reported PTSD severity, and self-reported depression, and compared for NI between conditions. The present study is the largest conducted to date that compares the efficacy of CPT administered to a diverse group of veterans via VC versus IP.

Methods

The study was conducted at the VA San Diego Healthcare System (VASDHS) and was approved by the VA Institutional Review Board.

Participants

Eligible participants included veterans from VASDHS primary care and mental health clinics who were recruited via clinician referral or self-referral (from flyers in waiting rooms). Inclusion criteria were adult (age ≥ 18) male and female patients who were competent to provide informed consent, had a primary diagnosis of PTSD, and were fluent in English. Exclusion criteria included: a) unmanaged dementia, psychosis, or manic episodes in the past year; (b) substance abuse or alcohol dependence in the past year; (c) concurrent psychotherapies targeting PTSD or depression; (d) severe cardiovascular or respiratory disease that would make it difficult to ensure regular attendance at psychotherapy sessions; (e) severe impairments in speech, vision, or hearing; and (f) history of a head trauma resulting in loss of consciousness longer than

20 minutes. Informed written consent was obtained from all enrolled participants.

Measures

CAPS was the primary clinician-rated outcome measure for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) PTSD.¹⁹ The scale is appropriate for combat veterans based on its high internal consistency (alphas of 0.87 and 0.88 for the PTSD symptom clusters and 0.95 for PTSD symptoms overall) and high validity with this population when compared to a computer-assisted version of the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised (DSM-III-R) Structured Clinical Interview for DSM Axis I Disorder (SCID-I).²⁰ The CAPS can be administered in 45–60 minutes, and it yields PTSD diagnostic status as well as a total severity score. The F1/I2 method of scoring was used in the current study.²¹ The scale also assesses social and occupational functioning, dissociation, and the validity of the items. The CAPS was administered at pre- and post-treatment and follow-up by master's or doctoral-level independent clinical evaluators who were trained to a gold-standard criterion with an experienced assessor and supervised throughout the study. Evaluators were blinded to the study hypotheses and to conditions assigned, and participants were instructed to refrain from discussing treatment modality with the evaluators. Each participant was assigned to the same independent evaluator throughout their participation in the study, to facilitate consistent ratings and maximize comfort for participants.

The PCL–S is a brief and widely used self-report instrument to measure the severity of DSM-IV-TR PTSD symptoms related to a specific (worst) traumatic event.²² It consists of 17 items scored on a one-point (not at all) to five-point (extremely) scale. Initial psychometric data include test–retest reliability (0.96) and validity, as indicated by a kappa of 0.64 for a diagnosis of PTSD from the SCID-I. Alpha coefficients for internal consistency reliability have ranged from 0.89 to 0.92.

The Patient Health Questionnaire – 9 (PHQ–9) is a brief depression measure, which scores each of the nine DSM-IV criteria as '0' (not at all) to '3' (nearly every day). It has strong psychometric properties that provide both dimensional (i.e. total score) and diagnostic status (depression or not) for depressive symptoms. The PHQ–9 is a reliable and valid measure of depression severity. There was good agreement between the diagnosis assigned by mental health professionals and PHQ–9 diagnosis (a PHQ–9 score ≥ 10 with 0.88 for sensitivity and specificity).²³

The PCL–S and PHQ–9 were administered at each therapy session, as well as baseline, post-treatment, and

six-month follow-up. The demographic questionnaire and diagnostic co-morbidity interview were completed only at baseline.

Covariates. Participant sociodemographic variables (age, sex, race, income, educational level, war era) were recorded. Clinical characteristics, including onset of PTSD symptom (acute versus chronic), duration of PTSD symptoms, prior treatment for PTSD, any prior experience with telemedicine, current use of psychotropic medications, and status of PTSD compensation and service connection were recorded. Therapy attendance and homework completion were also assessed.

Procedures

CPT was conducted in 12 weekly 60-minute sessions, according to the manual used in the VA CPT²⁴. Based on a social cognitive theory of PTSD and trauma, CPT focuses on the content of trauma-related thoughts, whether these thoughts are consistent or inconsistent with patient's prior schema about the world, and the effect these thoughts have on emotions and behaviors.²⁴ In this study, we used the primary version of the treatment (previously called CPT-C, or cognitive-only version), which focuses on the cognitive therapy components and does not include the written account of the trauma.²⁴ This version does not include exposure to a written account of the traumatic event, and it was used because there is evidence of lower attrition and faster symptom improvement compared to CPT with the written account (CPT-A).²⁵ Per protocol, participants were educated about PTSD symptoms, cognitive theory, and treatment goals; wrote about how traumatic experiences have influenced thoughts and beliefs about themselves, others, and the world; identified problematic thoughts ('stuck points') related to the traumatic event; learned how these thoughts influence emotions; and learned to challenge distorted thoughts and identify more balanced alternative thoughts.

Eighteen therapists, including licensed psychologists, social workers, and family therapists, participated in conducting CPT at the two clinics (La Jolla VA and Mission Valley VA) in San Diego. Each therapist had completed the standardized training and consultation in CPT to be identified as a VA CPT provider, and received weekly consultation throughout the study. Study therapists conducted both the VC and IP therapy sessions, with the exception of four therapists who had seen only one or two participants. On average, each therapist provided therapy to 11.5 participants (standard deviation (SD) 9.6, range 1–27). Each therapist provided therapy for approximately equal numbers of participants in each study arm. Study coordinators

were always present for VC meetings to assist with the VC equipment and technology used for therapy.

We enrolled 207 eligible participants in the study; 104 were randomized to IP and 103 to VC (Figure 1). The randomization was stratified by study therapists such that each therapist provided therapy for a similar number of IP and VC participants. The study coordinator escorted participants randomized to the VC group to a clinic room located in a VA community-based outpatient clinic in San Diego County (the Mission Valley VA Community-Based Outpatient Clinic). The study coordinator oriented the participant to the VC equipment, initiated the VC call, and connected with the study therapist located at the San Diego VA hospital (in La Jolla, CA). The two study sites were only 13 miles apart, to enable participants and providers to feasibly commute to each site depending on randomization. The study was designed to demonstrate the relative effectiveness of the two conditions, rather than the direct benefits of reducing distance to treatment.

Each participant was provided with the study coordinator's contact information and was encouraged to contact him or her, as needed, for technical support or crisis management. Once the VC connection between the participant and therapist was established, the study coordinator exited the clinic room. Participants randomized to the IP condition met with therapists IP at the VA hospital.

Data analysis

Descriptive statistics were used to summarize baseline demographics and outcomes. Wilcoxon rank-sum test and Fisher's exact test were used to compare the difference in demographics and outcomes between VC and IP groups. Any variables that were significantly different between two intervention groups were included as potential covariates in the multivariable analysis.

We examined the symptom severity outcomes, including CAPS (primary outcome), PCL, and PHQ-9 scores (secondary outcomes) using a linear mixed-effects (LME) model to assess the difference in the change of scores between VC and IP care groups. An interaction term for time by group was included in the LME model. Since participants were clustered within therapists and visits were clustered within participants, we considered the random effects of both therapists and participants. If the therapist effect was not significant, only the random effect of participants was included in the model. Since the post-treatment assessment time varied, time was treated as a continuous variable in the model. We performed the analysis with and without adjustment of baseline characteristics. Backward variable elimination was used to select the main effects in the final

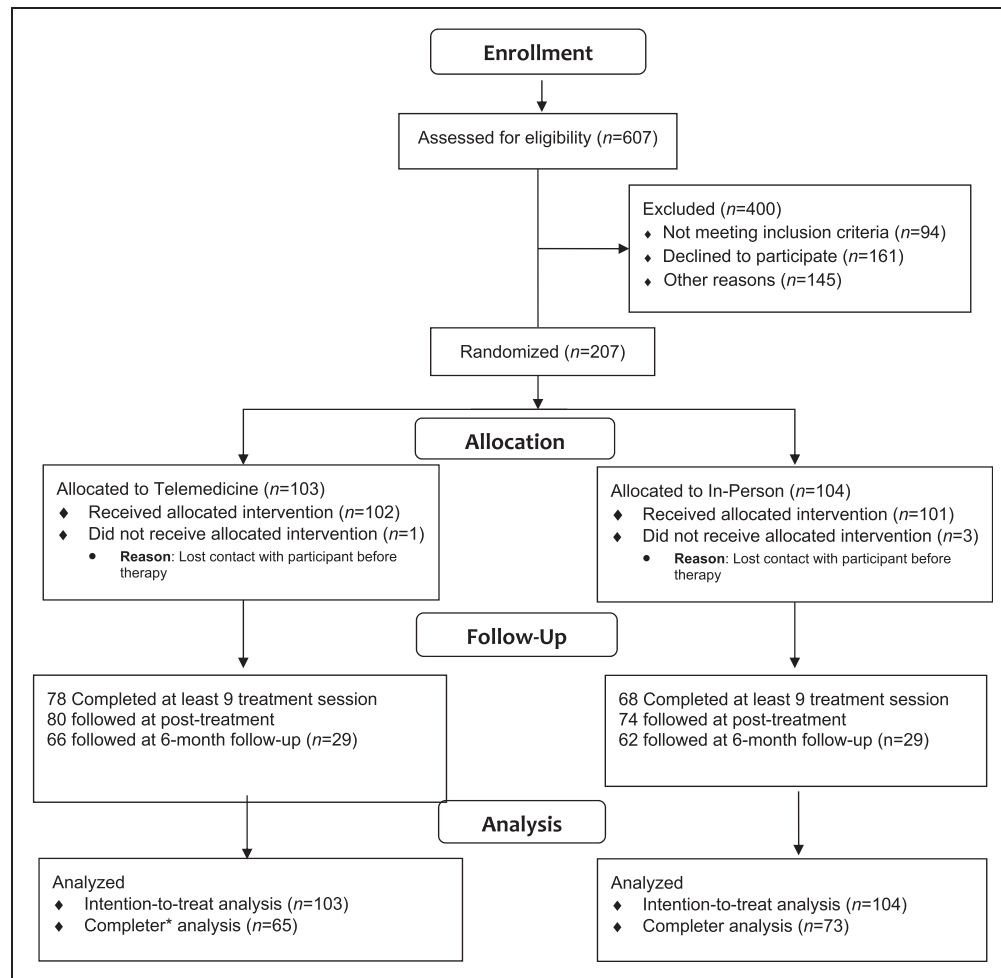


Figure 1. CONSORT Veterans Outreach for PTSD Services flow diagram.

*completer: participants who finished baseline and post-treatment visits as well as nine treatment sessions.

multivariable model, and the variable with the largest p -value was removed from the model first until all variables had p -values < 0.10 . The likelihood ratio test was used for model comparison.

Two-sided 95% confidence intervals (CIs) were calculated for the difference in the outcome (change score from baseline to follow-up visit) between the VC and IP group. We compared the lower bound with the NI margin. Since there is no better basis for pre-specified NI margin, our a priori NI margin ranged from 0.1 SD to 1.0 SD, and 0.5 SD was used for the interpretation of results. The common SD of the outcome was estimated from original data. We compared the upper bound of the difference (VC change score minus IP change score) with the NI margin. If the upper bound was less than the NI margin, we would conclude that VC is non-inferior to IP. We also conducted the test for NI of VC by comparing the changes in outcomes from baseline to post-treatment and from baseline to six-month follow-up with IP groups, using the modified

t -statistic.²⁶ The modified t -statistic is calculated by subtracting the NI margin from the estimate of inferiority and dividing the difference by the standard error. The p -value < 0.025 indicates a significant NI.²⁷

In NI trials, an intention-to-treat (ITT) analysis alone may increase the risk of falsely claiming NI (type I error). Therefore, we conducted primary analyses using the data from ‘completers’ (i.e. participants who had completed at least nine treatment sessions¹⁵ and who had provided full assessment data at both baseline and post-treatment visit) and conducted a secondary analysis using the ITT principle as recommended for NI trials.^{27,28}

Results

Baseline characteristics

The baseline characteristics for study participants are presented in Table 1. The mean age was younger in the

Table 1. Patient characteristics.

		Total (n = 207)		In person (n = 104)		Videoconferencing (n = 103)		p-value ^a
		n	%	n	%	n	%	
Demographics								
Age (years)	Mean (SD)	48.4	14.1	45.6	13.5	51.4	14.1	0.004
Education (years)	Mean (SD)	14.3	2.87	14.3	2.77	14.3	2.98	0.631
Gender	Male	154	77.4	76	74.5	78	80.4	0.397
	Female	45	22.6	26	25.5	19	19.6	
Race/ethnicity	Hispanic	40	20.6	24	24.2	16	16.8	0.483
	Caucasian	107	55.2	50	50.5	57	60	
	Black	30	15.5	15	15.2	15	15.8	
	Others	17	8.8	10	10.1	7	7.4	
Ever married	No	34	17.1	20	19.6	14	14.4	0.353
	Yes	165	82.9	82	80.4	83	85.6	
Employment	Full-time	44	22.6	22	21.8	22	23.4	0.662
	Part-time	31	15.9	14	13.9	17	18.1	
	Others	120	61.5	65	64.4	55	58.5	
Income (USD)	<30,000	97	50	44	43.1	53	57.6	0.119
	30,000–75,000	65	33.5	40	39.2	25	27.2	
	>75,000	32	16.5	18	17.6	14	15.2	
WWII	No	122	61.3	73	71.6	49	50.5	0.004
	Yes	77	38.7	29	28.4	48	49.5	
War of freedom ^b	No	148	74.4	70	68.6	78	80.4	0.074
	Yes	51	25.6	32	31.4	19	19.6	
One or more wars	No	30	15.1	18	17.6	12	12.4	0.171
	Yes	122	61.3	56	54.9	66	68	
Clinical characteristics								
Medication: antidepressant	No	106	53.3	51	50	55	56.7	0.394
	Yes	93	46.7	51	50	42	43.3	
Medication: anxiolytics	No	177	88.9	89	87.3	88	90.7	0.502
	Yes	22	11.1	13	12.7	56	9.3	
Number of medications	0	81	40.7	43	42.2	38	39.2	0.703
	1	62	31.2	29	28.4	33	34	
	>1	56	28.1	30	29.4	26	26.8	
Receiving PTSD compensation	No	130	65.7	57	56.4	73	75.3	0.007
	Yes	68	34.4	44	43.6	24	24.7	
PTSD Service connection (%)	Mean (SD)	15.8	29.2	21.2	31.8	10.2	25.1	0.003
	Median (IQR)	0	0-30	0	0-37.5	0	0-0	
Past PTSD treatment	No	26	13.1	10	9.8	16	16.5	0.207
	Yes	173	86.9	92	90.2	81	83.5	
No. of past treatment sessions	Mean (SD)	3.55	1.58	3.62	1.57	3.48	1.60	0.617
Duration of disturbance (months)	Mean (SD)	250	188	221	185	279	189	0.028
Onset of symptom	Acute	1	0.5	0	0	1	1	0.498
	Chronic	206	99.5	104	100	102	99	
Type of trauma	Accident	16	7.7	8	7.7	8	7.8	0.765
	Physical assault	21	10.1	10	9.6	11	10.7	
	Sexual assault	38	18.4	20	19.2	18	17.5	
	Combat	81	39.1	42	40.4	39	37.9	
	Unexpected death	19	9.2	6	5.8	13	12.6	
	Child abuse	13	6.3	7	6.7	6	5.8	
	Others	19	9.2	11	10.6	8	7.8	
TBI	No	94	45.9	49	47.6	45	44.1	0.675
	Yes	111	54.1	54	52.4	57	55.9	
Alcohol abuse	No	205	99	102	98.1	103	100	0.498
	Yes	2	1	2	1.9	0	0	

(continued)

Table 1. Continued.

		Total (n = 207)		In person (n = 104)		Videoconferencing (n = 103)		p-value ^a
		n	%	n	%	n	%	
Other substance abuse (Excluding alcohol)	No	203	98.5	103	99	100	98	0.620
	Yes	3	1.5	1	1	2	2	
Percentage of completed homework (n = 86)	Mean (SD)	0.45	0.3	0.47	0.29	0.43	0.3	0.612
Number of attended sessions	Mean (SD)	9.3	4.3	9.7	4.0	8.9	4.5	0.153

SD: standard deviation; IQR: interquartile range; TBI: traumatic brain injury; PTSD: post-traumatic stress disorder.

^ap-values were based on Wilcoxon' rank-sum test or Fisher's exact test.

^bWar of freedom includes Operation Enduring Freedom and Operation Iraqi Freedom.

IP group ($p = 0.004$), and a higher proportion of participants received PTSD compensation in the IP group ($p = 0.007$), but the proportion of participants involved in World War II (WWII) was higher in VC ($p = 0.004$). The following characteristics were not significantly different between IP and VC group. Participants were mostly male, ethnically diverse, and not employed full or part-time; the majority had been married at least once. Most had previously received some PTSD treatment. The most common type of trauma was combat (39.1%), followed by sexual assault (18.4%). During the treatment period in this study, participants attended an average of 9.3 treatment sessions (median 12, SD 4.3, interquartile range 6–12) out of a total 12 sessions. Note that 14 patients did not start the treatment after randomization, so the absolute range was 0–12 sessions.

Outcomes

Overall, among those who finished baseline visit, 25.6% dropped out at the post-treatment visit; this is consistent with the rates reported in other clinical trials with PTSD participants.²⁹ There was no statistically significant difference ($p = 0.429$) in dropout rates between the IP condition (28.2%) and the VC condition (23.1%). The descriptive statistics for CAPS, PCL, and PHQ-9 scores by visit are provided in Table 2 for both ITT participants and completers, and the longitudinal change of these scores by visit is provided in Figures 2–4.

CAPS. For completers, both groups had comparable PTSD severity at baseline ($p = 0.498$; Table 2). Since the results from the LME without adjustment for baseline covariates was similar to the adjusted LME, we included only adjusted analysis results in Tables 3 and 4. For completers, the VC group showed significantly smaller improvement in CAPS scores from

baseline to post-treatment ($p = 0.004$), but showed similar symptom improvements ($p = 0.784$) from baseline to six-month follow-up. VC did not show NI in improvement at post-treatment ($p = 0.430$; difference = 0.58 per week; 95% CI = 0.19, 0.96; NI margin = 0.61; Table 4), but it showed NI in improvement at six-month follow-up ($p = 0.011$; difference = 0.03 per week; 95% CI = -0.17, 0.22; NI margin = 0.26). The ITT analyses showed the same pattern of results.

PCL-5. Both groups had comparable PCL scores ($p = 0.950$; Table 2) at baseline for completers. With adjustment for baseline characteristics, the VC group did not show a significant difference in PCL improvement either at post-treatment ($p = 0.475$) or at six-month follow-up ($p = 0.427$). The NI test showed that VC is non-inferior to the IP group ($p < 0.001$; difference = -0.10 per week; 95% CI = -0.37, 0.17; NI margin = 0.40) for both post-treatment and six-month follow-up improvement ($p < 0.001$; difference = -0.05 per week; 95% CI = -0.17, 0.07; NI margin = 0.16). In ITT analysis, the NI was still significant for post-treatment change; however, we did not find the NI for six-month follow-up ($p = 0.070$; difference = 0.06 per week; 95% CI = -0.07, 0.20; NI margin = 0.17) when the NI margin is 0.5 SD. The NI was found when the NI margin for change rate (per week) was 0.7 SD, which is equal to 0.23.

PHQ-9. Both groups had comparable PHQ-9 scores ($p = 0.356$) at baseline for completers. With adjustment for baseline characteristics, there was no significant difference in PHQ-9 score improvement from baseline to post-treatment ($p = 0.861$) or from baseline to six-month follow-up ($p = 0.854$) between the VC and IP group. The VC group was found to be non-inferior to the IP group for improving PHQ-9 at post-treatment ($p = 0.002$; difference = 0.01 per week; 95% CI = -0.09, 0.11; NI margin = 0.16) as well as at six-

Table 2. Descriptive statistics for CAPS, PCL, and PHQ-9.

		n	Total		In person		Videoconferencing	
			Mean	SD	Mean	SD	Mean	SD
ITT								
CAPS	Baseline	207	71.9	17.8	72.5	18.4	71.3	17.4
	Post	154	57.6	27.1	53.4	26.2	62.1	27.5
	Month 6	125	57.0	27.6	57.3	26.9	56.6	28.5
PHQ-9	Baseline	178	16.0	6.1	16.4	5.8	15.6	6.5
	Post	122	12.8	6.9	12.7	6.7	12.9	7.2
	Month 6	103	12.9	6.9	13.3	6.9	12.5	6.8
PCL	Baseline	179	58.9	13.1	58.5	12.6	59.1	13.7
	Post	122	50.3	16.5	49.3	16.7	51.3	16.3
	Month 6	103	49.9	16.9	51.5	16.7	48.3	17.0
Completers								
CAPS	Baseline	138	71.5	17.8	72.5	18.8	70.4	16.7
	Post	138	56.5	27.3	52.2	26.9	61.3	27.0
	Month 6	118	56.7	27.9	57.3	27.0	56.1	29.0
PHQ-9	Baseline	106	15.9	6.5	16.5	6.2	15.3	6.7
	Post	106	12.8	6.8	13.0	6.8	12.6	6.8
	Month 6	75	12.7	6.5	13.9	6.4	11.5	6.5
PCL	Baseline	107	59.4	12.9	59.4	12.7	59.4	13.3
	Post	107	50.9	16.4	50.5	16.6	51.3	16.3
	Month 6	76	50.8	16.1	54.0	15.5	47.5	16.3

ITT: Intention-to-treat; SD: standard deviation; CAPS: Clinician-Administered Post-traumatic Stress Disorder (PTSD) Scale; PHQ-9: Patient Health Questionnaire – 9; PCL: PTSD Checklist.

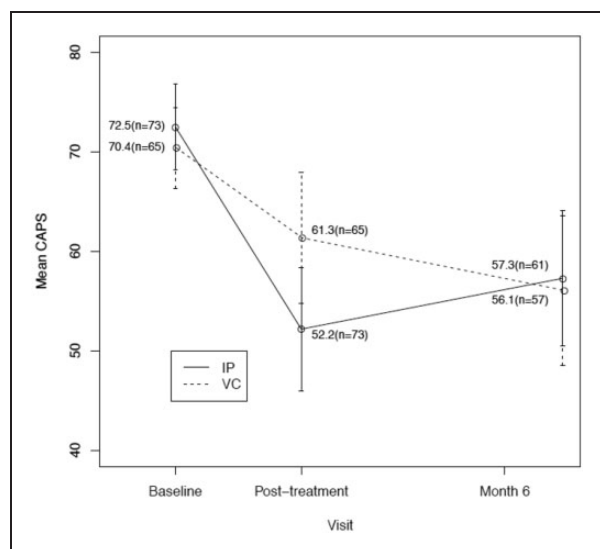


Figure 2. Mean CAPS score by visit for completers. Error bars indicate 95% confidence intervals (mean \pm 1.96 \times standard error) for mean CAPS score. Mean CAPS score and sample size were given at each visit.

IP = in person; VC = videoconferencing; CAPS = Clinician-Administered Posttraumatic Stress Disorder (PTSD) Scale.

month follow-up ($p = 0.004$; difference = 0.005 per week; 95% CI = -0.04, 0.05; NI margin = 0.07). However, in ITT analysis, the NI was not found for the NI margin of 0.5 SD. NI was found when the NI

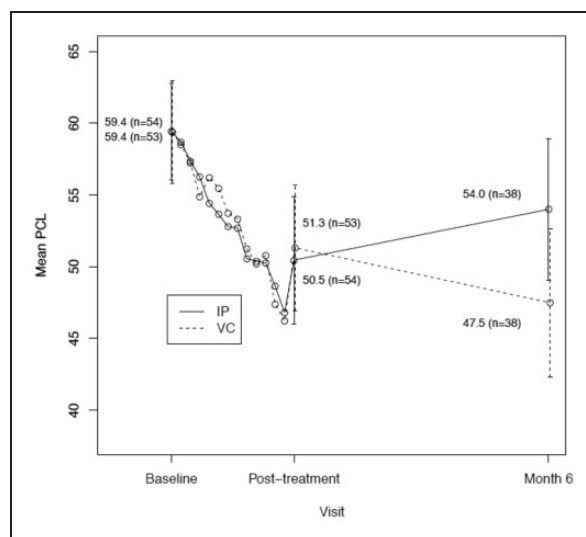


Figure 3. Mean PCL score by visit for completers. Error bars indicate 95% confidence intervals (mean \pm 1.96 \times standard error) for mean PCL total score. Mean PCL total score and sample size were given at each visit.

IP = in person; VC = videoconferencing; PCL = Post-traumatic Stress Disorder (PTSD) Check List.

margin for the change rate of PHQ-9 was greater than 0.6 SD (0.18) for baseline to post-treatment, and when the NI margin was 0.8 SD (0.11) for baseline to six-month follow-up.

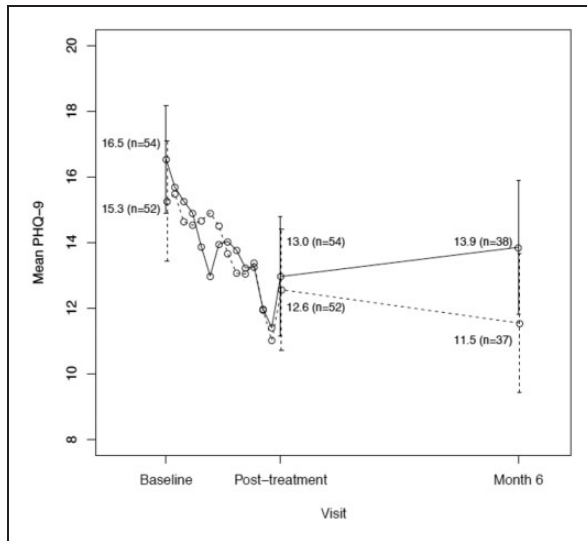


Figure 4. Mean PHQ-9 score by visit for completers. Error bars indicate 95% confidence intervals (mean \pm 1.96 \times standard error) for mean PHQ-9 total score. Mean PHQ-9 total score and sample size were given at each visit. IP = in person; VC = videoconferencing; PHQ-9 = Patient Health Questionnaire - 9.

Discussion

Videoconferencing is becoming an increasingly popular modality for the delivery of evidence-based PTSD treatments and has the ability to reduce barriers to care for veterans. The current study examined if changes in self-reported PTSD severity, clinician-rated PTSD severity, and self-reported depression severity following CPT are non-inferior when delivered through VC compared to IP. This randomized controlled trial demonstrated that CPT delivered via VC could improve PTSD and depression severity comparable to an IP modality. The study showed that VC was non-inferior to IP psychotherapy as measured by self-reported PTSD and depression symptoms at both post-treatment and six-month follow-up by completer analysis. This is consistent with previous studies^{8,12} that assessed PCL improvements and found equivalence for home-based VC and a trend for equivalence for office-based VC compared to IP in improving PCL scores. There was no significant difference in dropout rates between the IP and VC conditions.

In contrast to the PCL findings, the CAPS showed significantly less reduction in the VC group compared

Table 3. Multivariable linear mixed-effects model for association between intervention and change of CAPS, PCL, and PHQ9.

		Baseline to post			Baseline to six months		
		Coefficient	SE	p-value	Coefficient	SE	p-value
Completers							
CAPS ^a	Group ^g	-0.67	3.13	0.830	1.27	3.56	0.722
	Time	-0.98	0.13	<0.001	-0.31	0.07	<0.001
	Group by time	0.58	0.20	0.004	0.03	0.099	0.784
PHQ-9 ^b	Group	-0.31	2.89	0.793	-1.23	0.79	0.279
	Time	-0.17	1.18	<0.001	-0.07	1.13	<0.001
	Group by time	0.01	0.05	0.861	0.005	0.02	0.854
PCL ^c	Group	1.05	2.51	0.677	-1.22	2.81	0.666
	Time	-0.50	0.10	<0.001	-0.19	0.04	<0.001
	Group by time	-0.10	0.14	0.475	-0.05	0.06	0.427
ITT							
CAPS ^d	Group	0.64	2.58	0.805	3.14	1.16	0.249
	Time	-0.92	0.13	<0.001	-0.34	0.07	<0.001
	Group by time	0.51	0.19	0.008	0.07	0.10	0.469
PHQ-9 ^e	Group	-0.17	0.78	0.828	-0.10	0.78	0.899
	Time	-0.22	0.03	<0.001	-0.11	0.02	<0.001
	Group by time	0.06	0.05	0.236	0.05	0.03	0.080
PCL ^f	Group	1.10	1.82	0.548	1.28	1.92	0.505
	Time	-0.63	0.08	<0.001	-0.32	0.05	<0.001
	Group by time	0.10	0.12	0.426	0.06	0.07	0.367

ITT: Intention-to-treat; SE: standard error; CAPS: Clinician-Administered Post-traumatic Stress Disorder (PTSD) Scale; PHQ-9: Patient Health Questionnaire - 9; PCL: PTSD Checklist.

^aBaseline to post-treatment and baseline to six-month analyses were adjusted for WWII.

^bBaseline to post-treatment analysis was adjusted for war of freedom and no adjustment for baseline to six-month analysis.

^cNo adjustment for baseline to post-treatment and baseline to six-month analyses.

^dBaseline to post-treatment and baseline to six-month analyses were adjusted for WWII and time since symptom.

^eBaseline to post-treatment and baseline to six-month analyses were adjusted for war of freedom.

^fBaseline to post treatment and baseline to 6-month analyses were adjusted for WWII and age

^gGroup: VC is coded as 1 and IP is coded as 0 (reference group).

Table 4. Results of non-inferiority test for CAPS, PCL, and PHQ-9 with videoconferencing versus in-person consultation.

Variable	Visit	Difference in change ^a (per week)	95% CI	p-value	NI margin ^b (0.5 SD)
Completers					
CAPS	Post	0.58	(0.19, 0.96)	0.430	0.61
	M6	0.03	(-0.17, 0.22)	0.011 ^c	0.26
PCL	Post	-0.10	(-0.37, 0.17)	<0.001 ^c	0.40
	M6	-0.05	(-0.17, 0.07)	<0.001 ^c	0.16
PHQ-9	Post	0.01	(-0.09, 0.11)	0.002 ^c	0.16
	M6	0.005	(-0.04, 0.05)	0.004 ^c	0.07
ITT					
CAPS	Post	0.51	(0.14, 0.88)	0.245	0.64
	M6	0.07	(-0.12, 0.26)	0.025 ^c	0.26
PCL	Post	0.10	(-0.14, 0.33)	0.007 ^c	0.40
	M6	0.06	(-0.07, 0.20)	0.070	0.17
PHQ-9	Post	0.06	(-0.04, 0.15)	0.028	0.15
	M6	0.05	(-0.01, 0.10)	0.220	0.07

ITT: intention-to-treat; CI: confidence interval; M6: month six; NI: non-inferiority; CAPS: Clinician-Administered Post-traumatic Stress Disorder (PTSD) Scale; PHQ-9: Patient Health Questionnaire - 9; PCL: PTSD Checklist.

^aDifference in change is equal to VC change minus IP change rate.

^bNon-inferiority margins were obtained by multiplying 0.5 to the pooled standard deviation of raw change scores (baseline minus six-month follow-up).

^cNon-inferiority supported. Non-inferiority determined by the upper bound of the 95% CI smaller than the non-inferiority margin or p-value for the modified t-test < 0.025.

to the IP group at post-treatment, and NI was not observed in either completer or ITT analyses. However, at the six-month follow-up, NI was observed between the treatment modalities, consistent with previous studies.^{9,10} Specifically, the differences between VC and IP became insignificant at six-month follow-up, as the CAPS scores continued to drop in the VC group but increased in the IP group. This may reflect slightly different PTSD severity in dropouts between the two groups, where we found that patients dropping out from the VC group had a trend of higher CAPS at post-intervention (although the dropout rates were not statistically significant between two modalities). Alternatively, it may indicate that something about the mode of treatment affects longer-term maintenance of gains. It is possible that the remote nature of video teleconferencing fosters a generalization of skills learned in psychotherapy due to more independence (i.e. no IP contacts with the therapist), but this would require additional research focused on that issue. The differences may be also due to differences in power to detect NI, as fewer data were collected for the CAPS (i.e. at baseline, post-treatment, and six-month follow-up) than for the PCL and PHQ-9 (i.e. at every treatment and assessment session), and our completer requirement was for full data at the major time points and attendance at a minimum of nine treatment sessions. Nonetheless, these findings provide support that changes in clinician-rated PTSD symptoms in the VC condition at six-month follow-up are comparable

to the IP condition. Overall, our findings suggest that telehealth to deliver CPT could be an effective alternative to IP care, which would be beneficial for rural veterans and urban veterans with other barriers to care.

This study has several strengths. This was an important demonstration of the feasibility and effectiveness of an empirically based treatment conducted via VC. We utilized psychometrically sound measures; a manualized, empirically based treatment protocol; and a six-month follow-up period. We recruited a large, diverse sample of veterans with PTSD, including adult men and women of different ages, military eras, trauma types, and psychiatric co-morbidity, suggesting that the procedures and the results may generalize to a broad population of veterans. Further, we examined depression symptoms in addition to PTSD symptoms. Mixed-effects regression models were used to assess the longitudinal change in outcomes. This statistical approach considered the correlation between observations from the same participant and/or the same therapist by including random effects of time and therapist. It accommodated unequal time intervals and included all available data points in the ITT analysis, minimizing the effect of missing data. Since clinically meaningful NI margins have not been established for our study outcomes, we used 0.5 SD as the pre-specified margin, as used in the literature.^{30,31} The actual margins are reported in the tables to help other researchers to determine whether they are clinically meaningful. In addition, we assessed a range of NI margins (0.1–1.0 SD).

For PCL and PHQ-9, when we did not find NI of VC at the pre-specified margin, we reported the margins where NI was held. To our knowledge, this is the first study to report a range of NI margins when no established NI margins are available.

There are also limitations to the study. First, we excluded participants with dementia or recent psychosis, mania, or substance dependence, as well as those at imminent risk of harm. Therefore, we are unable to assess the impact of those factors on our study findings. Second, we conducted VC from one major VA hospital to clinics using state-of-the-art videoconferencing technology. Although veterans using the VA Healthcare System typically have access to these resources, veterans who are not seeking care at a VA and individuals who have PTSD in the community may not. It is possible that non-VA technologies may be less clear, regarding video images and audio quality, or that they may be less reliable. However, modern off-the-shelf technologies have improved significantly in recent years. Indeed, free software such as Skype and FaceTime are used widely for business and clinical applications because they have excellent quality and reliability. Third, we had a study support person available at the remote site for technological or clinical support as needed. Sites without such support staff may not be as successful with the VC mode of treatment.

Fourth, the study was designed to enable participants and providers to feasibly commute to each site, depending on randomization group. The aim of the study was to demonstrate the relative effectiveness of the two conditions, rather than the direct benefits of reducing distance to treatment. Our study was not designed to apply only to rural veterans or to test the benefits of VC generally, but rather to compare VC to IP treatment. Thus, treatment was provided at the local VA hospital and one community-based outpatient clinic, separated by only 13 miles. While we did not exclude rural veteran and we did not assess distance to travel, we expect that most of our subjects lived in the more urban sections of San Diego County. We assessed participants' satisfaction with the distance that they travelled to see the therapist at the baseline visit. On a scale of 1 to 5 (with 5 indicating very satisfied), the median satisfaction score was 4 and the interquartile range was 2.5–5. We expect that rural veterans would be even more pleased with treatment that could be provided closer to home. Individuals in rural settings are more likely to screen positive for PTSD, less likely to receive psychotherapy, have greater suicide risk, and have poorer health-related quality of life.^{32–35} Thus, it is possible that rural veterans would have demonstrated greater improvements in the VC mode due to having easier access to PTSD care via VC.

Fifth, the measures used DSM-IV-TR criteria because the study began prior to the publication of the DSM-5.³⁶ However, scores on these versions are highly associated (e.g. a kappa of 0.84 for diagnoses and a correlation of $r=0.83$ for total severity score on the CAPS).³⁷ Sixth, while evaluators were blinded to study conditions, they were not blinded to the time point of assessments. This may have influenced their ratings of improvements but not the relative ratings for each condition. Finally, our study was not designed to test the treatment, CPT, since we expected, based on many previous studies, that it would reduce PTSD symptoms for all participants. Although we do not report fidelity data, all study therapists had completed the standardized VA training and consultation to be identified as VA CPT providers. Each attended weekly supervision with a CPT national trainer throughout the study, who watched video recordings of some sessions, and no problems with adherence were reported. Nearly all study therapists conducted VC and IP therapy sessions, with the exception of four therapists who had treated only one or two participants.

VC is a format familiar to many users, and the cost of the technology has decreased while the quality of the communication has improved. The current study adds to a literature that generally suggests that PTSD psychotherapies delivered by VC can be as effective as IP care for reducing PTSD and depression severity. This could enable individuals living in rural settings and those with other barriers to care (e.g. childcare, limited physical mobility) to access empirically based treatments such as CPT. Additional research is needed to determine if differences at some follow-up assessment points are due to differences in PTSD severity in dropouts or to differences in generalization of skills between the two conditions.

There are many opportunities to conduct novel research using VC technology. Teleconferencing allows sessions between therapy offices and patients' homes, sessions in inpatient or residential settings, and sessions in different formats (e.g. couples, families, groups). Mobile platforms, such as tablets or smart phones, allow for portable connections between patients and providers. However, smaller screen sizes may reduce rapport and general communication, and a temptation to use such devices in public settings can introduce additional privacy concerns. Cost analyses will help to determine how health systems can best integrate VC with existing services, and surveys of clients' preferences for using technology could help guide decisions. Empirical data from studies of VC could potentially help match clients to optimal treatment modalities.

The VA has made a concerted effort to improve access to services for all veterans. Much of this effort has focused on the benefits of electronic technologies.

The VA has implanted MyHealtheVet to improve communication and the management of health records,³⁸ as well as a suite of resources to improve telehealth.³⁹ This has included the creation of national hub sites to serve rural community-based outpatient clinics and regional telemedicine centres to address PTSD, depression, and other mental health conditions. Some research has been done to assess the association between patients' familiarity and confidence in the telehealth and PTSD symptom change⁴⁰ as well as patients' satisfaction with the telehealth,⁴¹ but there is a need for additional research on veterans' comfort and satisfaction with these novel approaches.

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