

Research Article

TELEMEDICINE VERSUS IN-PERSON DELIVERY OF COGNITIVE PROCESSING THERAPY FOR WOMEN WITH POSTTRAUMATIC STRESS DISORDER: A RANDOMIZED NONINFERIORITY TRIAL

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Background: *This study examined the effectiveness of telemedicine to provide psychotherapy to women with posttraumatic stress disorder (PTSD) who might be unable to access treatment. Objectives were to compare clinical and process outcomes of PTSD treatment delivered via videoteleconferencing (VTC) and in-person (NP) in an ethnically diverse sample of veteran and civilian women with PTSD. Methods:* *A randomized controlled trial of Cognitive Processing Therapy, an evidence-based intervention for PTSD, was conducted through a non-inferiority design to compare delivery modalities on difference in posttreatment PTSD symptoms. Women with PTSD, including 21 veterans and 105 civilians, were assigned to receive psychotherapy delivered via VTC or NP. Primary treatment outcomes were changes in PTSD symptoms in the completer sample. Results:* *Improvements in PTSD symptoms in the VTC condition (n = 63) were noninferior to outcomes in the NP condition (n = 63). Clinical outcomes obtained when both conditions were pooled together (N = 126) demonstrated that PTSD symptoms declined substantially posttreatment (mean = -20.5, 95% CI -29.6 to -11.4) and gains were maintained at 3- (mean = -20.8, 95% CI -30.1 to -11.5) and 6-month followup (mean = -22.0, 95% CI -33.1 to -10.9. Veterans demonstrated smaller symptom reductions posttreatment (mean = -9.4, 95% CI -22.5 to 3.7) than civilian women (mean = -22.7, 95% CI -29.9 to -15.5. Conclusions:* *Providing psychotherapy to women with PTSD via VTC produced outcomes comparable to NP treatment. VTC can increase access to*

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INTRODUCTION

Posttraumatic stress disorder (PTSD) is a costly and debilitating disorder that is associated with an elevated risk for a host of problems. Lifetime PTSD prevalence is estimated to be 8.6% among women and 4.2% in the United States population.^[1] PTSD prevalence is estimated at 10–20% of veterans of the wars in Iraq and Afghanistan.^[2] Women in the military have high prevalence rates of PTSD^[3] and are more likely than male veterans to experience unique stressors while serving in the military, including military sexual trauma, which increases their risk for PTSD.^[4]

Decades of rigorous research have led to the development of evidence-based treatments (EBTs) for PTSD.^[5] Yet access to effective PTSD treatment is often limited by lack of awareness, stigma, and logistical challenges.^[6] These barriers are compounded for residents of rural areas, where access to EBTs for PTSD is typically quite limited,^[7,8] in part due to having inadequate numbers of treatment providers in the area.^[9] Even if people can access treatment, only a minority of psychotherapists offer EBTs for PTSD.^[10]

Technological innovations, such as telemedicine or videoteleconferencing (VTC), can help address many of the clinical and logistical impediments to providing specialized services to residents of rural communities and other underserved populations. The delivery of services via VTC involves the use of equipment so that a mental health provider in one location can conduct treatment sessions with patients at a different site. VTC offers a number of advantages over traditional treatment approaches, including decreases in transportation costs, travel time, and missed work^[11] and enhanced access to treatment for individuals with serious injuries or scheduling difficulties due to work, school, or childcare responsibilities. Studies of psychotherapy delivered via VTC across various patient populations have provided evidence for the efficacy, feasibility, and acceptability of this delivery modality.^[12] Furthermore, research has provided evidence for the effectiveness of VTC when conducting exposure-based PTSD care.^[13] Research conducted with veterans has shown high degrees of patient and clinician satisfaction.^[14] However, questions remain about the feasibility of using VTC to deliver trauma-focused interventions because patients with PTSD are often reluctant to engage in such therapies due to avoidance. Thus, the next step in assessing the feasibility and safety of VTC as a viable modality is a rigorous evaluation of whether trauma-focused treatments delivered by VTC produce

outcomes that are comparable to those of in-person delivery.

One efficacious treatment for PTSD is cognitive processing therapy (CPT).^[15–17] CPT is a trauma-focused cognitive therapy that can be delivered in either an individual or group-based format. The CPT protocol includes a psychoeducation component, a series of skill-building exercises designed to teach participants about cognitive theory, practice in identifying the connection between thoughts and emotions, and rehearsal of strategies to restructure thoughts. Problematic beliefs and cognitions (stuck points) are identified and challenged through Socratic dialogue with particular attention paid to how traumatic experiences led to issues of assimilation (e.g., self-blame) and overaccommodation. Over the course of CPT treatment, patients learn to challenge their self-statements and assumptions in order to modify their maladaptive beliefs and discuss issues of safety, trust, control, esteem, and intimacy as they relate to self and others.

CPT has been found to be effective in treating PTSD in studies conducted across a variety of patient populations,^[18] including veterans with military-related PTSD,^[19,20] sexual abuse survivors,^[21] and rape victims.^[22,23] A recent trial demonstrated that VTC delivery of group CPT to male veterans produced outcomes that were comparable to outcomes of in-person group CPT.^[24] In this study, participants sat together in a group regardless of whether the therapist was present or off-site. In a group format, interaction and cohesion among group members could potentially compensate for any reduction in alliance with a remote therapist.^[25] It is unclear whether VTC delivery would be similarly effective for people treated individually. Furthermore, studies have pointed out the importance of therapist effects when conducting CPT.^[26]

The current study compares the effectiveness of VTC versus in-person (NP) individual delivery of a manualized EBT for PTSD (CPT) in a sample of civilian and veteran women to determine whether reductions of PTSD symptoms in the VTC-delivered psychotherapy were comparable to effects of NP delivery. Further, we hypothesized that key process indicators would not be significantly different between the VTC and NP conditions.

MATERIALS AND METHODS

DESIGN

A noninferiority-designed randomized clinical trial (RCT) was conducted with women veterans, reserves, and guard, and civilian women

with PTSD at the National Center for PTSD in the Department of Veterans Affairs (VA) in Honolulu, Hawaii. The VA Pacific Island Health Care System's Institutional Review Board approved the protocol.

RECRUITMENT AND ELIGIBILITY CRITERIA

Veteran and civilian women with PTSD were recruited through VA clinical sites, Vet Centers, community providers, community outreach events, and radio, newspaper, and internet advertisements. Study inclusion criteria were diagnosis of current PTSD established by the Clinician-Administered PTSD Scale (CAPS)^[27] and a stable psychotropic medication regimen for a minimum of 45 days prior to study entry for those taking such medications. Exclusion criteria were significant cognitive impairment or history of organic mental disorder, active psychotic symptoms/disorder, active homicidal or suicidal ideation, current substance dependence, and unwillingness to refrain from substance abuse during treatment. Participants provided written informed consent prior to study enrollment.

PROCEDURES

Individual CPT was delivered via VTC or NP to participants once or twice a week for a total of 12, 90-minute sessions. Therapist adherence to the treatment protocol and competence of CPT administration, rated using a standardized rating system specific to the CPT individual protocol, were found to be very high. Participants were assessed at baseline, midtreatment, approximately 2 weeks posttreatment, and 3 and 6 months posttreatment. A PTSD diagnosis was determined per the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth edition (DSM-IV)^[28] criteria. Sociodemographic and health information were assessed via a structured clinical interview. The Structured Clinical Interview for the DSM-IV^[29] was used to determine exclusionary diagnoses and comorbidities.

OUTCOMES

The primary clinical outcome was PTSD severity ratings, which were assessed with the CAPS at baseline and all follow-up assessments. Frequency and intensity ratings for each of the 17 DSM-IV PTSD criteria were summed to create symptom severity scores on the CAPS. For determining PTSD diagnoses, a symptom needed to meet a minimum frequency of occurring once per month with at least a moderate intensity.^[30] All assessments were conducted in-person by a master's or doctoral level assessor not involved with delivering the treatment.

Process variables included measures of treatment expectancies, therapeutic alliance, patient satisfaction, treatment retention, and engagement. Participants' beliefs about treatment credibility and expected outcomes were assessed at Session 2 using the 4-item Treatment Expectancy Questionnaire (TEQ).^[31] Therapeutic alliance was assessed using both the client and therapist versions of the 12-item Working Alliance Inventory (WAI) short form^[32] at Sessions 2, 6, and 12. Two measures of satisfaction with services were used post-treatment. Participants completed the 16-item Charleston Psychiatric Outpatient Satisfaction Scale-VA version (CPOSS-VA)^[33] to evaluate satisfaction with services. Participants in the VTC group also completed the 11-item Telemedicine Satisfaction and Acceptance Scale (TSAS)^[34] to assess their experiences and comfort using a digital communication medium to receive treatment. Treatment retention was assessed via the number of sessions attended and whether the participant completed the minimum dose of treatment (10 sessions). Treatment engagement was operationalized as homework completion or the number of sessions for which between-session practice forms were completed; quality of work was not assessed.

STATISTICAL ANALYSES

We tested the noninferiority hypothesis that PTSD symptom treatment outcomes in VTC are noninferior to those in NP. This statistical method requires specifying a noninferiority margin, which was the maximum amount by which VTC can be "worse than" than NP without having a clinically meaningful difference in outcomes between conditions. This was determined a priori to be 10 points on the CAPS.^[35] Noninferiority testing procedures involve construction of a 95% confidence interval (CI) on the difference in CAPS scores between the two treatment conditions (VTC minus NP) with a negative value indicating greater reduction in PTSD symptoms in VTC compared to NP. The noninferiority hypothesis is supported if the upper limit of the 95% CI for the difference between treatment conditions is less than the preset noninferiority margin. Using Optimal Design software program, the required sample size to obtain power = 0.90 was estimated to be 55 women per condition with $\alpha = 0.20^1$ and $\beta = 0.10$.

Primary analyses were done on an intent-to-treat (ITT) basis. Missing values were multiply imputed using the Markov Chain Monte Carlo method via SAS procedure MI^[36] with 20 data sets. We used a mixed effects modeling (MEM) approach (SAS PROC MIXED)^[36] to estimate differences in CAPS scores between conditions at posttreatment and 3- and 6-month followups. All analyses adjusted for change from baseline to each postbaseline assessment point for military service status (e.g., veteran vs. civilian) and cluster effects of patients within therapists. Between and within intervention group effects from MEM analyses were combined across multiple imputations using PROC MIANALYZE.^[36] Effect sizes (ES) were calculated using Cohen's *d* statistic and represented standardized mean differences between treatment conditions or change from baseline within groups. Analyses were repeated for the completer sample using the same approach. Analyses of process variables were conducted using the same MEM approach, but we tested for significant differences between treatment modalities while controlling for nesting of participants within therapists and military service status as covariates at individual time points. The trial is registered with clinicaltrials.gov, Identifier NCT02362477.

¹In traditional clinical trials, it is typically hypothesized that one treatment is superior to another treatment. In this traditional situation, a Type I error (false positive) is more serious than a Type II error (false negative) because in a Type I error the conclusion is drawn to adopt the novel treatment when it offers no benefit over the standard treatment and may even be less effective. Therefore, in traditional analyses the value for α (probability of a Type I error) is set at .05. The value for β (probability of a Type II error) is allowed to be higher than α and is usually set to .20. Power is equal to $1 - \beta$ and hence, is generally set to .08. The proposed study, however, is not traditional because it is hypothesized that the two treatment modalities under examination (VTC vs. NP) are equivalent. If a Type I error should occur, it would imply that we found the NP mode to be significantly better than the VTC mode, when in fact there was no difference or vice versa. The consequence of this error is that the novel VTC mode of treatment would not be recommended over the standard treatment when it should be recommended. If a Type II error should occur, it would imply that we found no difference between the groups, when the NP mode was in fact superior or vice versa. The consequence of this error is that we would recommend the novel treatment when it is less effective. Note that the consequence of a Type I error in this study is the same as the consequence of a Type II error in traditional studies (i.e., the novel treatment is not recommended when it should be recommended). The consequence of a Type II error in this study is the same as the consequence of a Type I error in traditional studies. For these reasons, we need to adjust our α and β values. Instead of setting α to .05, as in traditional studies, we will set it to .20. Instead of setting β to .20, we will set it to .10 with resultant Power set to .90.

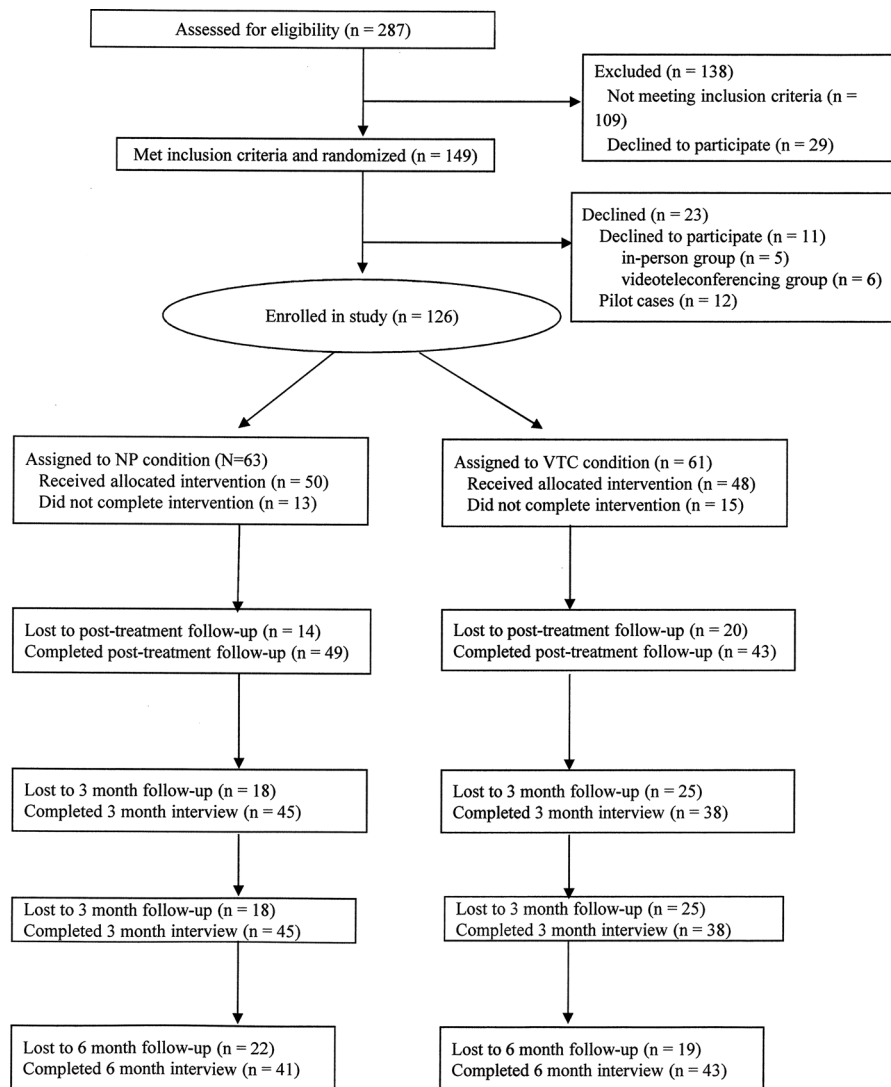


Figure 1. Trial profile. CONSORT, consolidated standards of reporting trials; NP, in-person; VTC, videoteleconferencing.

RESULTS

A total of 287 civilian ($n = 214$) and veteran, reserve, and guard personnel ($n = 73$) women were referred to and assessed for eligibility (see Fig. 1). The ITT sample was comprised of 126 women, including 21 veterans and 105 civilians, who were randomized and attended the first treatment session. Of the participants in the ITT sample (NP = 63, VTC = 63), 98 participants (NP = 50, VTC = 48) attended at least 10 of the 12 treatment sessions and were therefore included in the completer sample. Table 1 describes participant demographic characteristics and psychiatric comorbidity by treatment modality. No significant differences were found between groups on any background variables, including veteran status.

Means, 95% CIs, and results of analyses of CAPS scores at each time point for the NP and VTC

conditions are shown in Table 2. Pooling both conditions, mean change scores (95% CIs) between pretreatment and posttreatment, 3-month and 6-month followups were -20.5 ($-29.6, -11.4$), -20.8 ($-30.1, -11.5$), and -22.0 ($-33.1, -10.9$), respectively, for the ITT sample. Figure 2 depicts mean differences between treatment conditions with 95% CIs for changes in CAPS scores over time. The noninferiority hypothesis was supported in that clinical outcomes in the VTC condition were not significantly lower than those in the NP condition. Results using the completer sample (not shown) demonstrated a similar pattern of results.

Table 3 displays results for effects of treatment modality on process outcomes, adjusting for therapist and military service status. Treatment retention and engagement did not differ between modalities. There was not a significant difference between the NP ($n = 5$) and VTC

TABLE 1. Participant demographic characteristics and comorbid psychiatric diagnoses

Characteristic	Total sample (N = 126) ^a		In-Person group (n = 63)		VTC group (n = 63)		p ^b
	Mean	SD	Mean	SD	Mean	SD	
Age (years)	46.4	11.9	46.0	12.1	46.9	11.8	.66
PTSD symptoms							
CAPS	67.1	16.0	67.1	16.8	67.2	15.3	.38
PCL	57.6	11.9	58.7	11.6	56.5	11.6	.84
		N	%	n	%	n	%
Self-reported primary ethnicity							.27
Asian		18	14.3	11	17.5	7	11.1
Caucasian		60	47.6	33	52.4	27	42.9
Pacific Islander		15	11.9	5	7.3	10	15.9
Other ^c		33	26.2	14	22.2	19	30.2
Married		29	23.0	16	25.4	13	20.6
War era							.53
OIF/OEF		14	66.7 ^e	9	42.9	5	23.8
		N	%	n	%	n	%
Other war era ^f		12	57.1 ^e	5	45.5	7	70.0
Comorbid psychiatric diagnoses							
Current		56	46.7	25	41.0	31	52.5
Major depressive disorder		35	29.2	17	27.9	18	30.5
Anxiety disorder		33	26.8	13	21.3	20	32.3
Substance use disorder		4	3.2	2	3.2	2	3.2
Lifetime		116	92.1	59	93.7	57	90.5
Major depressive disorder		91	76.5	48	80.0	43	72.9
Anxiety disorder		41	33.6	18	29.5	23	37.7
Substance use disorder		67	53.2	31	49.2	36	57.1

CAPS, Clinician-Administered PTSD Scale; OIF/OEF, Operation Iraqi Freedom/Operation Enduring Freedom; PTSD, posttraumatic stress disorder; VTC, videoteleconferencing.

^aThe total intent-to-treat sample (N = 126) was used.

^bDifferences between conditions for demographic and other baseline characteristics (P-values) were assessed using chi-square (χ²) tests of independence for categorical or ordinal variables and Student t-tests for interval variables.

^c“Other” category included Hispanic, Black, and Native American.

^dSince some veterans served during the OIF/OEF war era and another war era, to maintain independence of observation in order to perform the χ² test, we compared veterans who served in OIF/OEF war era only compared to those in who in all other war, which included five veterans who had also served in the OIF/OEF war era.

^ePercentages add to greater than 100% because some veterans served in multiple war eras.

^fOther war eras included Vietnam, Desert Storm/Desert Shield, and post-Vietnam to Desert Storm/Desert Shield.

(n = 6) conditions on the number of participants who dropped out between randomization and attending Session 1, χ²(1) = 0.1, P = .75. Treatment compliance was high, with participants attending an average of 10 of 12 sessions. The proportion of participants who were “completers” (attended 10 or more sessions) did not differ between NP (79.4%) and VTC (76.2%). Participants completed an average of 79.5% between-session practice assignments in the NP condition and 76.5% of assignments in the VTC condition.

At Session 2, women in the NP condition reported statistically significantly higher therapeutic alliance compared to women in the VTC condition, with a 0.3 difference between groups on a 7-point scale, representing a small standardized effect size (ES = 0.07). No differences were found in therapeutic alliance ratings between participants at Sessions 6 (ES = -0.01) or 12 (ES = 0.01) or

therapists at any time point (ES = -0.01, -0.03, -0.01 at Sessions 2, 6, and 12, respectively). Therapeutic alliance scores at all time points and for both raters averaged approximately 6 out of 7 points. There were no differences between modalities on treatment expectations (ES = -0.03), with both groups indicating moderate levels of confidence in the treatment services.

At posttreatment, women reported high levels of satisfaction with services. Women in the NP condition rated all 14 of the CPOSS items as “very good” or “excellent,” whereas the VTC group rated 12 of 14 items as “very good” or “excellent.” However, there was a statistically significant difference (t(345.9) = -2.24, P = .03) between treatment modalities with NP women reporting scores 4.3 points higher (out of 79) compared to VTC women (ES = -0.24). Participants in the VTC condition had slightly, but statistically significantly,

TABLE 2. PTSD symptom scores and effect size estimates of between group differences

Time point	Condition	Intent to treat		Completer	
		Mean ^a (95% CI)	Raw difference ES difference ^b	Mean ^a (95% CI)	Raw difference ES difference ^b
Baseline	In-person	67.3 (62.5, 72.1)	n/a	66.7 (61.4, 72.1)	n/a
	VTC	67.6 (62.7, 72.5)	0.28 0.006	67.2 (61.4, 72.1)	0.4 0.004
Posttreatment	In-person	53.6 (43.9, 63.3)	n/a	48.6 (41.1, 56.1)	n/a
	VTC	50.5 (39.9, 61.0)	-3.2 -0.06	44.0 (35.3, 52.8)	-4.5 -0.05
3-month followup	In-person	54.5 (44.7, 64.4)	n/a	49.4 (41.1, 57.6)	n/a
	VTC	50.9 (40.1, 61.7)	-3.6 -0.11	45.4 (35.8, 55.1)	-4.0 -0.08
6-month followup	In-person	52.3 (39.6, 65.0)	n/a	52.3 (39.6, 65.0)	n/a
	VTC	46.5 (35.3, 57.7)	-5.8 -0.17	46.5 (35.3, 57.7)	-5.8 -0.17

95% CI, 95% confidence intervals around least squares mean; ES, effect size as estimated by Cohen's *d*; PTSD, posttraumatic stress disorder; SD, standard deviation; VTC, videoteleconferencing.

^aPTSD symptom scores measured using the Clinician-Administered PTSD scale.

^bEffect size differences for VTC versus in-person condition; positive values indicate directionally greater symptom reduction in the in-person condition than in the VTC condition and negative value indicate directionally greater symptom reduction in the VTC condition.

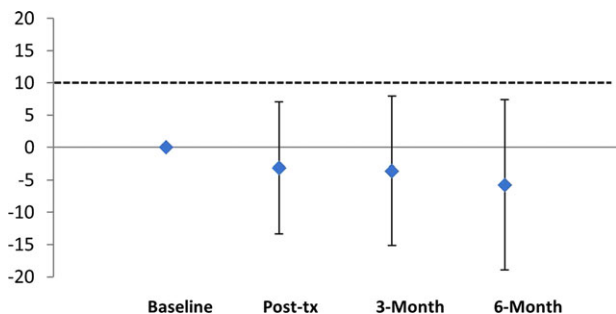


Figure 2. Noninferiority margins and 95% CIs for differences in CAPS scores between treatment conditions. The total ITT sample ($N = 126$) was used for all analyses. Per protocol analyses (not shown) yielded similar results. All CIs are two-sided (95%). The dotted line shows the minimum clinically meaningful difference (10 points on the CAPS). A decrease of 10 points on the CAPS represents an approximate effect size of $d = 0.5$, as research with veterans has demonstrated a $SD = 20$ in this population.^[20] The vertical axis represents differences in CAPS change scores between conditions with negative values indicating greater improvement in PTSD symptoms over time in the VTC group compared to the NP group. CAPS, Clinician-Administered PTSD Scale; ITT, intent to treat; CI, confidence intervals; PTSD, posttraumatic stress disorder; VTC, videoteleconferencing; NP, in-person.

lower ratings than NP participants for “respect shown for your opinions about treatment” and “information provided about what services you will receive here.” Interestingly, even though VTC and NP participants were treated in the same clinic space, VTC participants

gave statistically significantly lower ratings on atmospheric factors (“appearance of the office,” “appearance of the waiting area,” and “helpfulness of secretary”) than NP participants. On the TSAS, VTC participants reported very high levels of satisfaction with services received via VTC, with a scale mean score of 51.8 of 54 ($SD = 2.80$). All item scores averaged 4.5 or higher (4 = “very good,” 5 = “excellent”). Finally, 95.6% of participants reported they would “definitely recommend this service to a friend or family member” while the remaining participants reported they would “probably recommend” these services.

Given that PTSD psychotherapy outcomes are often weaker in studies conducted with combat veterans than in those with civilians,^[37] we conducted a post hoc comparison of civilians’ and veterans’ responses to CPT. We collapsed across NP and VTC modalities for this analysis. At intake, civilian’s CAPS scores were an average of 3.4 points lower ($ES = -0.03$, $P = .41$) than those of veterans. However, civilians’ posttreatment mean CAPS scores were 14.3 ($ES = -0.14$, $P = 0.05$), 16.7 ($ES = -0.25$, $P = 0.03$), and 10.7 ($ES = -0.22$, $P = 0.27$) points lower than veterans’ scores at posttreatment, 3-month followup, and 6-month followup, respectively. Veteran and civilian women did not differ in the number of types of lifetime traumatic events [$t(114) = -0.12$, mean = 6.2 of 12, $P = .91$]. In addition, Criterion A events used for the CAPS interviews were coded for the presence of several characteristics (i.e., sexual assault, physical assault, happening to oneself vs. others, age at trauma), which were used in a binary regression to predict veteran status. While the overall model was significant [$\chi^2(9) = 21.6$, $P = .01$], none of the predictors

TABLE 3. Descriptive statistics and mixed model results for process outcomes

Measure	In-Person Mean (95% CI)	VTC Mean (95% CI)	α	d	t (df)	P
WAI Total Scale Score						
Client: Session 2	6.1 (5.88, 6.36)	5.8 (5.56, 6.04)	.90	-.071	-2.28 (4105.1)	.02
Client: Session 6	6.1 (5.75, 6.44)	6.1 (5.70, 6.44)	.86	-.013	-0.19 (825.0)	.85
Client: Session 12	5.7 (4.95, 6.47)	5.6 (4.80, 6.47)	.71	.005	-0.25 (9205.8)	.80
Therapist: Session 2	5.7 (5.49, 5.80)	5.6 (5.46, 5.77)	.90	-.013	-0.36 (3140.3)	.72
Therapist: Session 6	5.9 (5.56, 6.15)	5.8 (5.46, 6.11)	.93	-.034	-0.52 (914.3)	.61
Therapist: Session 12	5.5 (4.82, 6.07)	5.4 (4.72, 6.07)	.93	-.005	-0.20 (7520.6)	.84
CPOSS-VA	70.8 (65.4, 74.7)	66.5 (61.0, 72.0)	.90	-.241	-2.24 (345.9)	.03
TEQ ^a	29.8 (27.5, 32.1)	28.6 (26.3, 30.9)				.37
Percentage of sessions attended ^b	85.7% (28.8%)	82.1% (31.2%)	n/a	.090	0.67 (124)	.51
Treatment completion ^{b,c}	79.4%	76.2%	n/a	n/a	0.18 (1)	.67
Homework ^b	79.5% (32.6%)	76.5% (34.6%)	n/a	.120	0.52 (124)	.61

d , Cohen's d ; NP, in-person therapy group ($n = 64$); VTC, videoteleconferencing therapy group ($n = 61$); α , Chronbach's alpha.

^aTreatment expectancy/credibility was assessed at Session 2.

^bSince there was no missing data for the following variables, results are based on analyses of raw data.

^cSince treatment completion was a binomial variable, the descriptive statistics is the percentage of participants completing at least 10 sessions. Analyses conducted using a chi-square test.

CPOSS-VA, Charleston Psychiatric Outpatient Satisfaction Scale-VA; TEQ, treatment expectancy questionnaire; WAI, working alliance inventory.

were significant. Review of the classification table indicated that none of the veterans were correctly classified based on these characteristics. Civilians reported higher treatment expectancies and stronger working alliance at Session 2 than veterans. These effects were small ($ES = 0.07$ – 0.10) but statistically significant ($P < .05$). Analyses of pre–post CAPS change scores indicated that civilians demonstrated significant reductions at all time points; posttreatment mean = -22.7 ($-29.9, -15.5$), 3-month followup mean = -23.6 ($-30.4, -16.8$), and 6-month followup mean = -23.8 ($-30.9, -16.8$). However, for veterans there was no significant reductions in CAPS at any time point; posttreatment mean = -9.4 ($-22.5, 3.7$), 3-month followup mean = -6.9 ($-19.9, 6.1$), and 6-month followup mean = -13.0 ($-31.2, 5.1$).

DISCUSSION

Results of this RCT demonstrate that a manualized EBT for women trauma survivors with PTSD (CPT) provided via telemedicine is feasible and produces clinical and process outcomes that are comparable to NP delivery. Participants in both the VTC and NP groups demonstrated considerable reductions in PTSD symptoms after completing CPT, though most still reported moderate levels of PTSD symptomatology at followup. Process outcomes also confirm the acceptabil-

ity and safety of telemedicine for women with PTSD. Treatment drop out (16.1%) was consistent with the 18–35% rates reported in other RCTs with PTSD patients.^[38] The telemedicine technology (Tandberg 880 Model Health Care System) evidenced very few disruptions and no sessions were cancelled due to technological difficulties.

This trial, using a rigorous noninferiority design, adds to a growing research literature base confirming that manualized, EBTs for PTSD can be delivered via telemedicine with outcomes comparable to those obtained with in-person care. Moreover, our outcomes confirm that psychotherapy for PTSD can be delivered remotely with no degradation of clinical benefit. Potentially, rapport among group participants could compensate for any reduced alliance with the therapist. Two prior telemedicine noninferiority studies with PTSD patients have involved group therapy.^[17,39] In this study, working alliance, as reported by clients at Session 2, was lower in the VTC condition, but this difference disappeared as treatment progressed.

It is a notable finding that civilians showed greater improvement than veterans regardless if treatment was delivered in-person or via VTC. In fact, veterans' average change with treatment (8.5 CAPS points) is below the specified clinically meaningful cutoff (10 points). Prior meta-analyses also found less improvement in

psychotherapy studies involving male combat veterans than studies involving (often women) civilians.^[37] However, these meta-analyses were not definitive because they compared results across different therapies and often confounded trauma type, veteran status, and gender. Our findings are more persuasive because civilian and veteran participants were the same gender, had similar levels of psychopathology at intake, and received exactly the same treatment.

Several unmeasured factors might explain why civilian women responded more strongly to CPT than women veterans. Literature suggests that many women veterans with PTSD often have experienced a combination of childhood abuse, sexual assault, and/or combat traumas;^[40] however, civilian and veteran women did not differ in the range of exposure to traumatic events or characteristics of the “worst” events that were the focus of CPT. Veteran and civilian participants may have different treatment histories. Veterans, being eligible for VA services, may have received more prior mental health care than the civilians. Thus, the civilian sample may have included more women naïve to psychotherapy and the veteran sample may have included more women who had continued PTSD symptoms despite prior treatment. In this veteran sample, a range of treatment responses was shown, including clinically significant improvement, no change, and deterioration. Another potentially important factor in cognitive therapy is how military acculturation impacts beliefs about guilt and responsibility. Military training instills beliefs such as “if everyone does their job, everyone will come home,” or “you are always responsible for the personnel in your unit.” While these beliefs may enhance performance in the field, they could impede recovery from trauma if they are held too rigidly and overgeneralized.^[41] Civilians do not ascribe to this warrior ethos. Future research could compare changes in veterans’ and civilians’ trauma-related cognitions during cognitive therapy to assess how the degree of military acculturation impacts trauma survivors’ ability to modify guilt-related beliefs.

Strengths of this study include a priori noninferiority analyses and sample size calculations, use of a manualized EBT, careful monitoring of therapist fidelity, followup assessments up to 6 months, and high participant adherence and retention rates. This study was conducted with a difficult-to-treat clinical population with broad inclusion criteria. The sample included high proportions of rural residents and racial minorities (52.4%), two groups who have previously demonstrated limited access to mental health services and are often underrepresented in research.

Along with its strengths, this study has some limitations. The CAPS was administered approximately 2 weeks posttreatment, which may not accurately reflect the entire therapy progress as the CAPS assesses symptom over the previous 30 days; therefore, the CAPS administered at 2 weeks posttreatment assessed PTSD symptoms during the last 2 weeks of treatment. The time frame for this posttreatment assessment might also ex-

plain why the veterans only showed significant improvement at the 3-month followup. Local mental health facilities may not have the state-of-the-art equipment used for VTC delivery; thus, these results cannot be directly generalized to services provided by more commonly used low bandwidth VTC (i.e., Skype). Additionally, participants with acute safety concerns (homicidal or suicidal) and current substance dependence were excluded. However, there is research to suggest that both substance use and crisis management issues can be safely addressed via telemedicine.^[42]

Future research should rigorously assess the effectiveness and safety of delivering psychotherapy for PTSD to patients in their homes, as not requiring patients to travel to a clinic could further reduce barriers to access. Cost-benefit analyses can help assess the impact of investing in telemedicine technology to reach underserved populations. The differences in clinical outcomes between civilians and veterans in this study suggest that more research is needed to understand how to maximize treatment for women veterans. Finally, the consistent finding that telemedicine-delivered psychotherapy is noninferior to in-person care suggests we need to shift from effectiveness to implementation research. We now need to distribute practical information to practitioners regarding the use of telemedicine in the delivery of evidence-based treatments, determine how to best disseminate research already conducted on this mode of treatment delivery, and integrate telemedicine into existing models of care.^[43]

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