

Original Investigation

Telemedicine-Based Collaborative Care for Posttraumatic Stress Disorder

A Randomized Clinical Trial

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IMPORTANCE Posttraumatic stress disorder (PTSD) is prevalent, persistent, and disabling. Although psychotherapy and pharmacotherapy have proven efficacious in randomized clinical trials, geographic barriers impede rural veterans from engaging in these evidence-based treatments.

OBJECTIVE To test a telemedicine-based collaborative care model designed to improve engagement in evidence-based treatment of PTSD.

DESIGN, SETTING, AND PARTICIPANTS The Telemedicine Outreach for PTSD (TOP) study used a pragmatic randomized effectiveness trial design with intention-to-treat analyses. Outpatients were recruited from 11 Department of Veterans Affairs (VA) community-based outpatient clinics serving predominantly rural veterans. Inclusion required meeting diagnostic criteria for current PTSD according to the Clinician-Administered PTSD Scale. Exclusion criteria included receiving PTSD treatment at a VA medical center or a current diagnosis of schizophrenia, bipolar disorder, or substance dependence. Two hundred sixty-five veterans were enrolled from November 23, 2009, through September 28, 2011, randomized to usual care (UC) or the TOP intervention, and followed up for 12 months.

INTERVENTIONS Off-site PTSD care teams located at VA medical centers supported on-site community-based outpatient clinic providers. Off-site PTSD care teams included telephone nurse care managers, telephone pharmacists, telepsychologists, and telepsychiatrists. Nurses conducted care management activities. Pharmacists reviewed medication histories. Psychologists delivered cognitive processing therapy via interactive video. Psychiatrists supervised the team and conducted interactive video psychiatric consultations.

MAIN OUTCOMES AND MEASURES The primary outcome was PTSD severity as measured by the Posttraumatic Diagnostic Scale. Process-of-care outcomes included medication prescribing and regimen adherence and initiation of and adherence to cognitive processing therapy.

RESULTS During the 12-month follow-up period, 73 of the 133 patients randomized to TOP (54.9%) received cognitive processing therapy compared with 16 of 132 randomized to UC (12.1%) (odds ratio, 18.08 [95% CI, 7.96-41.06]; $P < .001$). Patients in the TOP arm had significantly larger decreases in Posttraumatic Diagnostic Scale scores (from 35.0 to 29.1) compared with those in the UC arm (from 33.5 to 32.1) at 6 months ($\beta = -3.81$; $P = .002$). Patients in the TOP arm also had significantly larger decreases in Posttraumatic Diagnostic Scale scores (from 35.0 to 30.1) compared with those in the UC arm (from 33.5 to 31.7) at 12 months ($\beta = -2.49$; $P = .04$). There were no significant group differences in the number of PTSD medications prescribed and adherence to medication regimens were not significant. Attendance at 8 or more sessions of cognitive processing therapy significantly predicted improvement in Posttraumatic Diagnostic Scale scores ($\beta = -3.86$ [95% CI, -7.19 to -0.54]; $P = .02$) and fully mediated the intervention effect at 12 months.

CONCLUSIONS AND RELEVANCE Telemedicine-based collaborative care can successfully engage rural veterans in evidence-based psychotherapy to improve PTSD outcomes.

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Posttraumatic stress disorder (PTSD) develops in some individuals exposed to traumatic events, such as rape, natural disasters, or combat.¹ Posttraumatic stress disorder can be disabling and treatment resistant and is prevalent in vulnerable populations.² Individuals with PTSD are more likely to engage in unhealthy activities, such as tobacco use, drug use, and alcohol misuse, and to have high rates of mortality.³⁻⁵ Posttraumatic stress disorder also has a negative effect on marriages,⁶ educational attainment,⁷ and occupational functioning.^{4,8-10} The prevalence of current PTSD is 3.5% in the general population¹¹ and is elevated in populations with high rates of exposure to traumatic events, such as combat veterans.¹²

More than half a million veterans enrolled in the Veterans Health Administration (VHA) health care system (502 546 veterans, or 9.2% of the VHA population) were diagnosed with PTSD in 2012, including 119 482 veterans (23.8% who served in Operation Enduring Freedom, Operation Iraqi Freedom, and/or Operation New Dawn (Rani Hoff, PhD, MPH; e-mail; December 31, 2013). Although psychotherapy and pharmacotherapy treatments for PTSD have proven to be efficacious in randomized clinical trials and have been disseminated widely by the VHA,^{13,14} stigma and geographic barriers often prevent rural veterans from engaging in these evidence-based treatments.¹⁵⁻¹⁷ A large portion (37.7%) of VHA enrollees diagnosed with PTSD live in rural areas,¹⁷ and two-thirds live closer to one of the 825 VHA community-based outpatient clinics (CBOCs) than to a large Department of Veterans Affairs Medical Center (VAMC).¹⁸ Although hiring on-site psychiatrists or psychologists with PTSD expertise is not typically feasible at many CBOCs, PTSD treatment needs to be improved in this geographically accessible setting. However, the quality of PTSD care is lower in general medical settings than in specialty mental health settings.¹⁹

The collaborative care model is designed to promote initiation and adherence to evidence-based treatments and self-care strategies. Collaborative care is effective at improving depression, anxiety, and alcohol disorders in primary care settings²⁰⁻²² and bipolar disorder in specialty mental health settings.^{23,24} Collaborative care is well suited to PTSD³; however, few randomized clinical trials have been conducted to examine its effectiveness. One trial conducted among 120 civilians admitted to a large urban level I trauma center found that, compared with usual care (UC), patients randomized to collaborative care had a lower prevalence of PTSD at follow-up.^{25,26} However, PTSD interventions demonstrated to be effective in civilian populations are not always effective in veteran populations.²⁷ A trial conducted among 195 primary care patients at 4 large urban VAMCs²⁸ found no differences in PTSD outcomes between veterans randomized to collaborative care and UC. Another trial conducted among 355 veterans discharged from residential PTSD treatment²⁹ also failed to show a clinical benefit of collaborative care. In addition to the differences between civilian and veteran populations in these trials, an important distinction between the interventions tested is that only the one tested by Zatzick et al^{25,26} specifically facilitated the delivery of evidence-based psychotherapy in addition to optimizing pharmacotherapy. This

difference is salient because although 2 antidepressant medications (paroxetine hydrochloride and sertraline hydrochloride) have been approved by the US Food and Drug Administration to treat PTSD, only 4 of 7 antidepressant trials relevant to veterans demonstrated a statistically significant improvement in PTSD symptoms.¹² Moreover, the largest antidepressant (sertraline) trial conducted in a sample consisting entirely of veterans did not demonstrate efficacy.³⁰ In contrast, cognitive processing therapy (CPT), a protocol-driven psychotherapy that combines exposure and cognitive restructuring, has been shown to reduce PTSD symptoms significantly for combat veterans with chronic PTSD.³¹

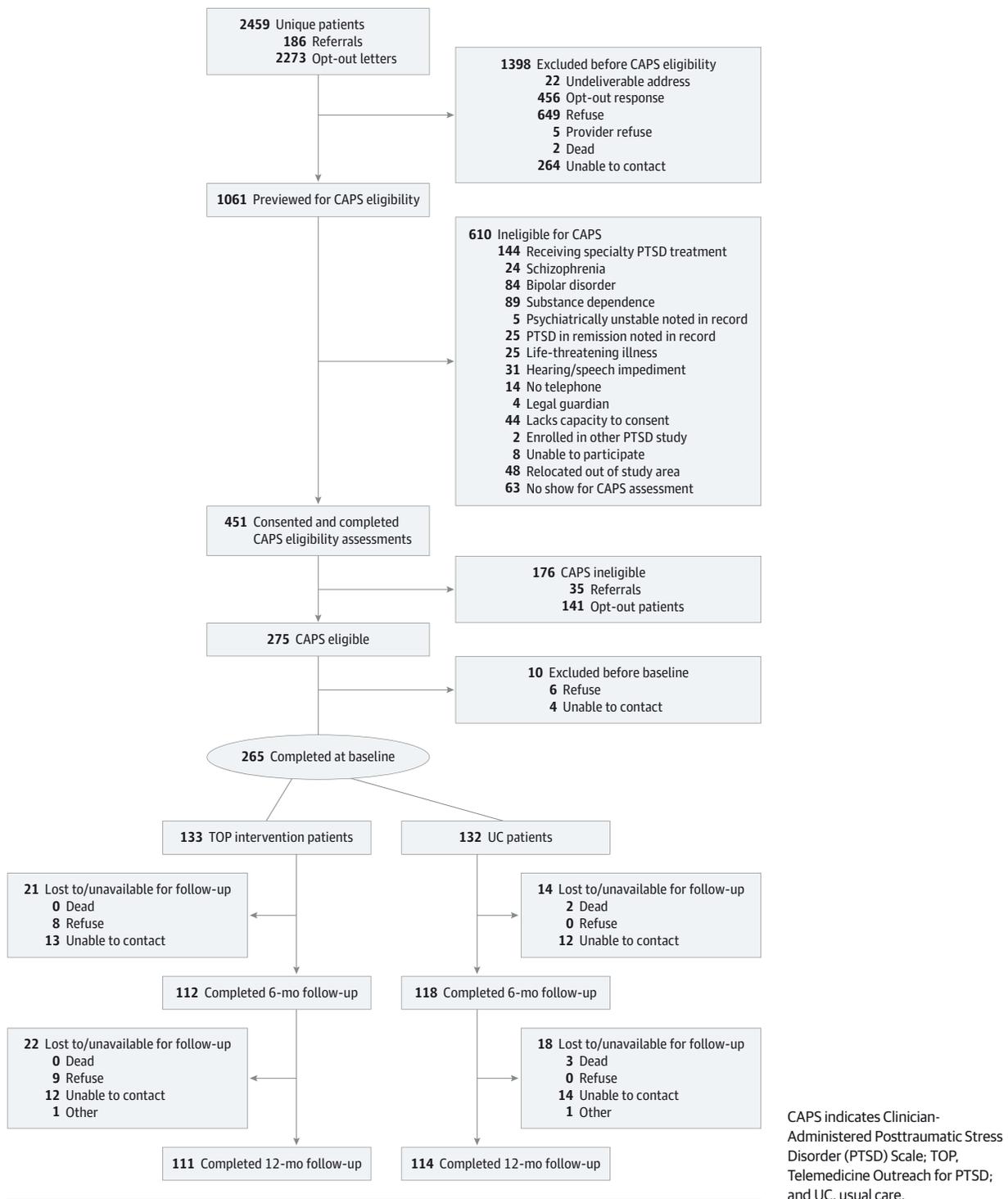
The objective of this pragmatic effectiveness trial was to test a collaborative care model designed to improve access to and engagement in evidence-based psychotherapy and pharmacotherapy for rural veterans. To improve PTSD outcomes for veterans treated in CBOCs without on-site psychiatrists or psychologists, we developed the Telemedicine Outreach for PTSD (TOP) intervention. An off-site PTSD care team used telemedicine technology (eg, telephone, interactive video, and shared electronic medical records) to support the PTSD treatment delivered by CBOC providers. Interactive video improves access and generates outcomes equivalent to those of face-to-face mental health treatment encounters. One large trial³² randomized veterans with depression to face-to-face or interactive video encounters with a psychiatrist and found no differences in clinical outcomes. Other studies among veterans^{33,34} have demonstrated the safety and acceptability of psychotherapy for PTSD delivered via interactive video, and 2 randomized clinical trials^{35,36} have demonstrated equivalency of PTSD psychotherapy delivered to veterans via interactive video compared with face-to-face psychotherapy.

Methods

Setting, Recruitment, Eligibility, and Consent

The TOP intervention was tested using a multisite pragmatic randomized effectiveness trial that followed PTSD study design guidelines developed for the VHA and the National Institute of Mental Health.³⁷ A detailed description of recruitment and evaluation of participants, the study intervention, and data analysis is found in the eAppendix in the Supplement. The study was approved by the institutional review boards of the VAMCs in Little Rock, Arkansas, Shreveport, Louisiana, and Loma Linda, California. Patients were recruited from 11 affiliated CBOCs for 22 months (November 23, 2009, through September 28, 2011). Patients whose designated PTSD provider practiced at the CBOC were recruited by provider-encouraged self-referral and by sending opt-out letters to patients with a PTSD diagnosis in their electronic health record. Of the 186 patients referred to the study, 43 (23.1%) refused to participate after being contacted. Of the 2273 patients sent opt-out letters, 456 (20.1%) opted out before being contacted and 606 who were contacted (26.7%) refused to participate (Figure 1). Written informed consent was obtained via interactive video. Exclusion criteria consisted of receiving specialty PTSD treatment at a VAMC; a diagnosis of schizophre-

Figure 1. CONSORT Diagram Depicting Combined Referral and Opt-Out Recruitment Methods



nia, bipolar disorder, substance dependence, or hearing impairment; having no telephone; having a life-threatening illness; and lacking capacity to consent. The inclusion criterion consisted of meeting diagnostic criteria for current PTSD, and 275 patients of the 451 who consented and completed eligibility assessments (61.0%) were eligible according to the Clinician-Administered PTSD Scale (CAPS) SXCAL (Structured Clinical In-

terview for DSM symptom calibrated) scoring rule,³⁸ which has 88% efficiency. A total of 265 eligible patients completed the baseline interview and were randomized to TOP or to UC. Randomization was conducted in blocks of 10 and stratified by VAMC and period of wartime service during Operation Enduring Freedom, Operation Iraqi Freedom, and/or Operation New Dawn as recommended by the Institute of Medicine.¹²

Intervention and Usual Care

Table 1 lists the clinical services that were available to UC and TOP patients. During the 12-month study period, patients in both arms were eligible to receive any services offered at the distant VAMC and the local CBOC. The UC patients were not referred to any particular treatment by the research team. The TOP intervention was designed to support the on-site CBOC provider designated to manage the patient’s PTSD. The CBOC providers included on-site primary care physicians, on-site psychiatric advanced practice nurses, on-site master’s degree-level social workers, and off-site telepsychiatrists. Three off-site PTSD care teams were located at the VAMCs and included a telephone nurse care manager (registered nurse), a telephone clinical pharmacist (doctor of pharmacy), a telepsychologist (doctor of philosophy), and a telepsychiatrist (doctor of medicine). The on-site CBOC providers prescribed psychotropic medications and provided counseling. The off-site telephone nurse care managers conducted care management activities supported by a web-based decision support system (<https://www.netdss.net/>).³⁹ Care manager activities included (1) PTSD symptom monitoring (using the civilian version of the Posttraumatic Stress Disorder Checklist)⁴⁰; (2) education and activation; (3) barrier assessment and resolution; (4) scheduling and monitoring self-management goals; (5) monitoring and promotion of adherence to medication regimens; (6) monitoring and management of adverse effects; and (7) monitoring and promotion of counseling adherence. Follow-up calls were scheduled every 2 weeks. The off-site telephone clinical pharmacists were responsible for reviewing the patient’s history of psychotropic medication use (via electronic health record and/or telephone). Using guidelines developed by the International Psychopharmacology Algorithm Project for the treatment of PTSD (<http://www.ipap.org>), the TOP psychiatrist and pharmacist recommended specific medications and dosages to CBOC providers. The off-site telepsychologists delivered 12 sessions of individual CPT (veteran/military version) to interested patients. In addition to monitoring PTSD symptoms for the telepsychologist, the nurse care manager encouraged CPT initiation, attendance, and homework adherence. The off-site telepsychiatrist educated CBOC providers, supervised the TOP care team, and conducted interactive video psychiatric consultations as necessary.

All intervention components were implemented using telemedicine technology. Care manager and pharmacist activities were conducted by telephone (to the patient’s home). Psychotherapy and psychiatric consultations were delivered via interactive video (to the CBOC). All feedback and treatment recommendations were given to CBOC providers via the electronic health record with requests for additional signatures when clinical action was needed.

Evaluation

During baseline and follow-up telephone interviews, blinded research assistants collected information about case mix and outcomes. At baseline, the following case-mix factors were collected: age, sex, race/ethnicity, education, living in a rural

Table 1. Clinical Services Available to Patients Randomized to UC and TOP Intervention

Service	UC Group	TOP Group
UC Services		
Available at distant VAMC		
Psychotropic medications for PTSD prescribed by psychiatrist ^a	X	X
Evidence-based psychotherapy for PTSD delivered by psychologist or social worker ^a		
CPT (individual and group)	X	X
Prolonged exposure therapy (individual)	X	X
Acceptance and commitment therapy (individual and group)	X	X
Eye movement desensitization and reprocessing (individual)	X	X
Seeking safety (individual and group)	X	X
Supportive PTSD-focused therapy delivered by psychologist or social worker (individual and group) ^a	X	X
Supportive therapy delivered by psychologist or social worker (individual and group)	X	X
Emergency services (24-h crisis)	X	X
Available at local CBOC		
Psychotropic medications for PTSD		
Prescribed by primary care physician	X	X
Prescribed by psychiatric advanced-practice nurse	X	X
Prescribed by telepsychiatrist	X	X
Supportive PTSD-focused therapy delivered by social worker (individual and group)	X	X
Supportive therapy delivered by social worker (individual and group)	X	X
CPT (group) ^b	X	X
TOP Services		
Delivered to patient at home		
Telephone nurse care manager		
PTSD symptom monitoring (using PCL-C)	NA	X
Education and activation	NA	X
Barrier assessment and resolution	NA	X
Scheduling and monitoring self-management goals	NA	X
Medication regimen adherence monitoring and promotion	NA	X
Adverse effect monitoring and management	NA	X
Counseling adherence monitoring and promotion	NA	X
Telephone pharmacist		
Medication management	NA	X
Delivered to patient at CBOC		
Telepsychologist		
CPT (individual) via interactive video	NA	X
Telepsychiatrist		
Psychiatric consultation via interactive video	NA	X
Treatment recommendations to CBOC prescriber	NA	X

Abbreviations: CBOC, community-based outpatient clinic; CPT, cognitive processing therapy; NA, not available; PCL-C, civilian version of the Posttraumatic Stress Disorder Checklist; PTSD, posttraumatic stress disorder; TOP, Telemedicine Outreach for PTSD; UC, usual care; VAMC, Department of Veterans Affairs Medical Center; X, available.

^a Receiving face-to-face PTSD treatment at a VAMC during the 6 months before baseline was an exclusion criterion, but these services were available to participants during the study period.

^b Group CPT was available at only 3 CBOCs, and capacity was limited. Patients were not recruited while they were currently receiving CPT at a CBOC.

area, travel distance, income, marital status, social support, period of wartime service, combat vs civilian trauma, disability claim status, acceptability of pharmacotherapy and psychotherapy, treatment history, presence of psychiatric comorbidities, and number of co-occurring physical health problems. Disability claim status was categorized as (1) approved, subject to reassessment; (2) approved, total, and permanent; (3) pending; (4) denied; or (5) never applied. The Mini-International Neuropsychiatric Interview was used to measure comorbid depression, panic, and generalized anxiety disorders.⁴¹ The Alcohol Use Disorders Identification Test was used to measure alcohol misuse.⁴² Follow-up telephone interviews were completed for 86.8% of the study participants at 6 months and 84.9% at 12 months. At baseline and follow-up, information was collected about the primary outcome, PTSD severity, as measured by the Posttraumatic Diagnostic Scale (PDS),⁴³ and secondary outcomes, including depression severity as measured by the Hopkins Symptom Checklist⁴⁴ and health-related quality of life as measured by the Mental Component Summary (MCS) and Physical Component Summary (PCS) scores of the 12-Item Short Form Health Survey for Veterans.⁴⁵ Pharmacotherapy process-of-care measures included being prescribed any medication for PTSD, number of prescribed PTSD medications (to assess switching and augmenting), and prescription of prazosin hydrochloride (for nightmares). To assess adherence to the medication regimen, medications prescribed for PTSD were identified in the electronic health record before conducting the follow-up interview, and participants were asked about their use of each prescribed medication by name. Patients were classified as being adherent to each medication regimen if they reported taking it at least 80% of days in the last month. Patients were then classified as being adherent to their PTSD medication regimen overall if they reported being adherent to at least 80% of their medication regimens. Receipt of CPT and psychiatric care (consultation or medication management) was determined by review of the medical records. Participants who attended at least 8 CPT sessions were classified as having an adequate dose of CPT.⁴⁶ Therapist fidelity to CPT was assessed via medical record review by dichotomously classifying each session as per protocol (ie, session 1, impact statement; sessions 2-7, stuck points; session 8, safety; session 9, trust; session 10, power/control; session 11, esteem and impact statement; and session 12, intimacy and impact statement). Overall CPT fidelity was defined as the percentage of sessions delivered per protocol.

Statistical Analysis

For bivariate statistical analyses, we used unpaired 2-tailed *t* tests and Pearson χ^2 tests. For multivariate statistical analyses, we used commercially available software (PROC GLIMMIX; SAS, version 9.3; SAS Institute, Inc) which uses the method of maximum likelihood to estimate beta coefficients and SEs (used to calculate 95% CIs). Regressions included group randomization status as the explanatory variable and all available covariates that were significant at the level of $\alpha \leq 0.1$ in bivariate analyses. All regressions specified the VAMC as a random effect to adjust for the potential clustering of patients

within facilities or PTSD care teams. For continuously specified dependent variables (eg, change scores), we used a normal distribution and identify link. For dichotomously specified dependent variables (eg, medication regimen adherence), we used a binomial distribution and logit link and exponentiated the beta coefficients to obtain odds ratios (ORs). For dependent variables with count distributions (eg, number of prescribed medications), we used a negative binomial distribution and log link and exponentiated the beta coefficients to obtain risk ratios. Missing data were not imputed. With a baseline sample of 265, a follow-up rate of 86.8%, and an intraclass correlation coefficient of 0.01 at the VAMC level, we had 81% power to detect a group difference of 4 points (SD, 8) for the change in the PDS score in an intention-to-treat analysis.

Results

Descriptive Statistics

Table 2 summarizes the baseline characteristics of the sample ($n = 265$), which consisted primarily of rural, unemployed, middle-aged men with a military service-connected disability for PTSD. Symptoms of PTSD were severe, with mean Clinician-Administered PTSD Scale scores of 75.0. Half of the sample reported that their worst trauma was combat related. Mental health comorbidity was highly prevalent, with 78.9% meeting current diagnostic criteria for major depressive disorder; 44.2%, for panic disorder; and 67.2%, for generalized anxiety disorder. The MCS and PCS scores were about 1.5 SDs below the national mean. Most participants reported that they had previously taken a psychotropic medication and/or received counseling for a mental health problem, and 78.1% reported receiving treatment specifically for PTSD. None of the outcome measures or case-mix factors differed significantly between the TOP and UC groups.

Care Management

Care managers completed 133 baseline telephone encounters (100.0%) and 1785 of 2729 scheduled follow-up encounters (65.4%). The mean number of care manager encounters per patient was 14.4. During 1785 follow-up encounters, care managers monitored PTSD symptoms during 1735 encounters (97.2%), assessed adherence to medication regimens during 1758 (98.5%), assessed adverse effects during 1575 (88.2%), assessed counseling adherence during 1753 (98.2%), and monitored self-management goals during 1505 (84.3%).

Medications

Process-of-care and clinical outcomes are reported in **Table 3**. When we controlled for case mix, the TOP group was more likely than the UC group to be prescribed any PTSD medications during the first 6 months (OR, 2.98 [95% CI, 1.03-8.68]; $P = .045$), but not the second 6 months (OR, 2.32 [95% CI, 0.82-6.61]; $P = .11$). In particular, the TOP group was more likely to be prescribed prazosin during the first 6 months (OR, 2.43 [95% CI, 1.14-5.20]; $P = .02$) and second 6 months (OR, 3.58 [95% CI, 1.71-7.48]; $P < .001$). Group differences in the number of prescribed PTSD

Table 2. Sociodemographic and Clinical Characteristics of the Sample

Characteristic	Patient Group ^a			P Value
	All (N = 265)	TOP (n = 133)	UC (n = 132)	
Age, mean (SD), y	52.2 (13.8)	51.9 (14.0)	52.5 (13.6)	.73
Male sex	89.8	88.7	90.9	.56
Race				
White	63.8	57.9	69.7	.15
African American	19.6	23.3	15.9	
Hispanic	7.6	9.0	6.1	
Other	9.0	9.8	8.3	
Annual household income <\$20 000	25.3	26.3	24.2	.70
Married	69.8	68.4	71.2	.62
High school graduate	94.0	93.2	94.7	.62
Employed	25.7	28.6	22.7	.28
Distance to closest VAMC, mean (SD), km	92.8 (40.8)	91.0 (40.8)	94.6 (41.0)	.49
Living in urbanized area	20.8	22.6	18.9	.47
Social support score, mean (SD) ^b	3.5 (1.0)	3.5 (1.1)	3.5 (0.9)	.72
Period of wartime service				.52
OEF/OIF/OND	29.1	30.8	27.3	.36
Other	70.9	69.2	72.7	
Combat trauma	49.3	46.6	52.3	
PTSD service connection				
Never applied	15.8	14.4	17.2	.39
Applied, denied	9.6	9.9	9.4	
Applied, pending	23.1	26.5	19.5	
Approved	50.8	47.7	53.9	
Psychotropic medications acceptable				
Definitely	44.9	43.6	46.2	.85
Probably	34.3	36.8	31.8	
Probably not	9.1	8.3	9.9	
Definitely not	11.1	11.3	12.1	
Individual psychotherapy acceptable				
Definitely	63.7	63.9	63.6	.82
Probably	27.9	26.3	29.5	
Probably not	7.6	9.0	6.2	
Definitely not	0.8	0.8	0.8	
Prior PTSD-specific treatment	78.1	74.4	81.8	.15
Prior use of any psychotropic medication	89.8	91.0	88.6	.53
Prior use of any psychotherapy	90.9	88.0	93.9	.09

(continued)

medications were not significant during the first 6 months (risk ratio, 1.18 [95% CI, 0.98-1.43]; $P = .08$) or the second 6 months (risk ratio, 1.19 [95% CI, 0.99-1.44]; $P = .06$). Group differences in medication adherence were not significant during the first 6 months (OR, 0.86 [95% CI, 0.46-1.62]; $P = .64$) or the second 6 months (OR, 0.91 [95% CI, 0.47-1.78]; $P = .79$).

CPT and Psychiatry

During the 12-month study period, 54.9% of patients randomized to TOP received some CPT compared with 12.1% random-

Table 2. Sociodemographic and Clinical Characteristics of the Sample (continued)

Characteristic	Patient Group ^a			P Value
	All (N = 265)	TOP (n = 133)	UC (n = 132)	
PTSD provider				
Primary care physician	16.6	12.8	20.5	.38
Psychiatric advanced practice nurse	32.8	36.8	28.8	
Social worker	33.2	30.8	35.6	
Telepsychiatrist	6.4	7.5	5.3	
Other	11.0	12.0	9.9	
PTSD severity				
CAPS, mean (SD) score	75.0 (12.7)	75.9 (13.3)	74.0 (12.0)	.22
PDS, mean (SD) score	34.2 (8.1)	35.0 (8.0)	33.5 (8.2)	.12
Depression severity, SCL-20, mean (SD) score	2.1 (0.6)	2.2 (0.6)	2.1 (0.7)	.47
PCS, mean (SD) score	35.0 (12.8)	34.9 (12.0)	35.2 (13.6)	.86
MCS, mean (SD) score	32.8 (10.3)	31.9 (10.2)	31.8 (10.4)	.14
No. of chronic physical illnesses, mean (SD)	4.3 (2.3)	4.2 (2.4)	4.4 (2.3)	.38
Current major depressive disorder	78.9	80.5	77.3	.53
Current panic disorder	44.2	47.4	40.9	.29
Current generalized anxiety disorder	67.2	66.2	68.2	.73
AUDIT treatment recommendation (zone)				
Alcohol education (1)	77.7	79.8	75.6	.82
Simple advice (2)	11.9	10.1	13.7	
Brief counseling and continued monitoring (3)	3.9	3.9	3.8	
Referral to specialist (4)	6.5	6.2	6.9	

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; CAPS, Clinician-Administered PTSD Scale; MCS, Mental Component Summary of the 12-Item Short Form Health Survey for Veterans; OEF/OIF/OND, Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn; PCS, Physical Component Summary of the 12-Item Short Form Health Survey for Veterans; PDS, Posttraumatic Diagnostic Scale; PTSD, posttraumatic stress disorder; SCL-20, Hopkins Symptom Checklist; TOP, Telemedicine Outreach for PTSD; UC, usual care; VAMC, Department of Veterans Affairs Medical Center.

^a Unless otherwise indicated, data are expressed as percentage of patients.

^b From the Medical Outcomes Study Social Support Scale, with 5 indicating the most and 1 the least social support.

ized to UC ($\chi^2 = 58.87$; $P < .001$). Likewise, 27.1% of the TOP group attended at least 8 CPT sessions compared with 5.3% of the UC group ($\chi^2 = 23.09$; $P < .001$). When we controlled for case mix, we found significant group differences in receipt of any CPT (OR, 18.08 [95% CI, 7.96-41.06]; $P < .001$) and in attending at least 8 CPT sessions (OR, 7.86 [95% CI, 3.15-19.61]; $P < .001$). Overall, the TOP group attended significantly more CPT sessions than the UC group (mean number, 4.2 vs 0.8; risk ratio, 9.51 [95% CI, 4.58-19.77]; $P < .001$), and among those TOP patients attending any CPT sessions, the mean number of sessions attended was 7.6 and the median was 7.0. Among TOP patients attending any CPT sessions, 505 of the 514 sessions (98.2%) were conducted via interactive video, and the mean fidelity score to the CPT protocol was 79.8%. During the 12-month period, 33.1% of TOP participants had an encounter with a psychiatrist compared with 40.9% of UC participants ($\chi^2 = 1.74$; $P = .19$). This difference was

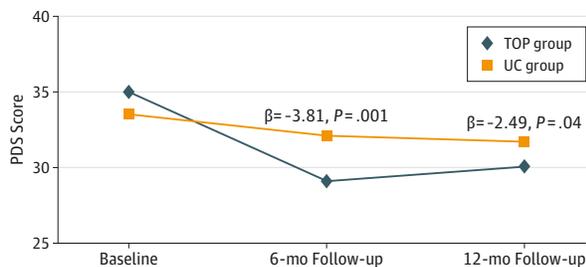
Table 3. Bivariate and Multivariate Results for Process-of-Care and Clinical Outcomes

Outcome	Unadjusted Differences		Bivariate Analysis		Multivariate Analysis	
	TOP	UC	Statistic	P Value	Statistic (95% CI)	P Value
Process of Care						
Prescribed any PTSD medications, %						
First 6 mo	92.86	85.59	$\chi^2 = 3.13$.08	OR = 2.98 (1.03 to 8.68)	.045
Second 6 mo	91.89	85.96	$\chi^2 = 2.00$.16	OR = 2.32 (0.82 to 6.61)	.11
Prescribed prazosin hydrochloride, %						
First 6 mo	26.79	15.25	$\chi^2 = 4.63$.03	OR = 2.43 (1.14 to 5.20)	.02
Second 6 mo	31.53	11.40	$\chi^2 = 13.58$.01	OR = 3.58 (1.71 to 7.48)	<.001
No. of VA-prescribed PTSD medications, mean (SD)						
First 6 mo	2.6 (1.43)	2.2 (1.40)	$t = 2.16$.03	RR = 1.18 (0.98 to 1.43)	.08
Second 6 mo	2.4 (1.36)	2.1 (1.36)	$t = 1.75$.08	RR = 1.19 (0.99 to 1.44)	.06
Adherence to VA-prescribed PTSD medication regimen $\geq 80\%$, %						
First 6 mo	59.41	67.01	$\chi^2 = 1.23$.27	OR = 0.86 (0.46 to 1.62)	.65
Second 6 mo	57.43	67.37	$\chi^2 = 2.06$.15	OR = 0.91 (0.47 to 1.78)	.79
Any psychiatry encounters at 12 mo, %	33.1	40.9	$\chi^2 = 1.74$.19	OR = 0.69 (0.35 to 1.35)	.28
Any CPT sessions at 12 mo, %	54.9	12.1	$\chi^2 = 58.87$	<.001	OR = 18.08 (7.96 to 41.06)	<.001
≥ 8 CPT sessions at 12 mo, %	27.1	5.3	$\chi^2 = 23.09$	<.001	OR = 7.86 (3.15 to 19.61)	<.001
No. of CPT sessions at 12 mo, mean (SD)	4.2 (5.4)	0.8 (2.6)	Wilcoxon	<.001	RR = 9.51 (4.58 to 19.77)	<.001
Clinical						
Change in PDS score, mean (SD) ^a						
6-mo follow-up	-5.31 (10.91)	-1.07 (7.73)	$t = 3.42$	<.001	$\beta = -3.81$ (-6.19 to -1.43)	.002
12-mo follow-up	-4.17 (9.82)	-1.32 (8.79)	$t = 2.30$.02	$\beta = -2.49$ (-4.90 to -0.08)	.04
Change in SCL-20 score, mean (SD) ^b						
6-mo follow-up	-0.43 (0.62)	-0.16 (0.56)	$t = 3.41$.01	$\beta = -0.25$ (-0.40 to -0.10)	.001
12-mo follow-up	-0.43 (0.72)	-0.23 (0.62)	$t = 2.14$.03	$\beta = -0.23$ (-0.40 to -0.05)	.01
Change in PCS score, mean (SD) ^c						
6-mo follow-up	0.77 (7.50)	-1.45 (9.47)	$t = 1.93$.055	$\beta = 2.67$ (0.45 to 4.91)	.02
12-mo follow-up	-1.02 (8.30)	-1.56 (8.30)	$t = 0.48$.63	$\beta = 0.97$ (-1.09 to 3.03)	.35
Change in MCS score, mean (SD) ^d						
6-mo follow-up	2.24 (10.20)	2.79 (10.84)	$t = -0.39$.70	$\beta = -0.12$ (-2.88 to 2.63)	.93
12-mo follow-up	2.72 (11.92)	4.05 (10.07)	$t = -0.89$.37	$\beta = -1.36$ (-4.24 to 1.52)	.36

Abbreviations: CPT, cognitive processing therapy; MCS, Mental Component Summary of the 12-Item Short Form Health Survey for Veterans; OR, odds ratio; PCS, Physical Component Summary of the 12-Item Short Form Health Survey for Veterans; PDS, Posttraumatic Diagnostic Scale; PTSD, posttraumatic stress disorder; RR, risk ratio; SCL-20, Hopkins Symptom Checklist; TOP, Telemedicine Outreach for PTSD; UC, usual care; VA, Department of Veterans Affairs.

^a Measures PTSD symptom severity.
^b Measures depression symptom severity.
^c Measures physical health functioning.
^d Measures mental health functioning.

Figure 2. Case-Mix-Adjusted Posttraumatic Stress Disorder (PTSD) Severity Change Scores



We measured PTSD severity using the Posttraumatic Diagnostic Scale (PDS). TOP indicates Telemedicine Outreach for PTSD; UC, usual care.

not significant when we controlled for case mix (OR, 0.69 [95% CI, 0.35-1.35]; $P = .28$). Of the 274 psychiatric encounters, 192 (70.1%) were conducted via interactive video.

Clinical Outcomes

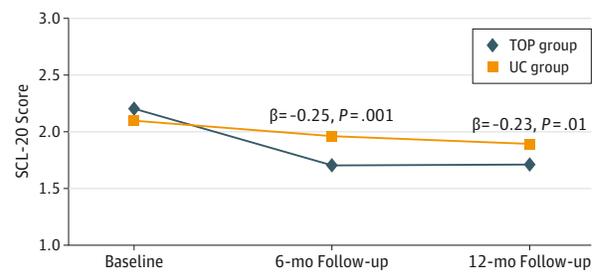
At the 6-month follow-up, patients randomized to TOP experienced a mean 5.31 decrease in PDS PTSD symptom severity compared with a 1.07 decrease for patients randomized to UC (unpaired, 2-tailed $t = 3.42$; $P < .001$; Cohen $d = 0.45$). At the 12-month follow-up, patients randomized to TOP experienced a mean 4.17 decrease in PDS PTSD symptom severity compared with a mean 1.32 decrease for patients randomized to UC ($t = 2.30$; $P = .02$; Cohen $d = 0.31$). When we controlled for case mix, group differences in PDS change scores were significant at the 6-month ($\beta = -3.81$ [95% CI, -6.19 to -1.43]; $P = .002$) and 12-

month ($\beta = -2.49$ [95% CI, -4.90 to -0.08]; $P = .04$) follow-ups (Figure 2). In a post hoc mediation analysis, attendance at 8 CPT sessions or more significantly predicted improvement in PTSD symptom severity ($\beta = -3.86$ [95% CI, -7.19 to -0.54]; $P = .02$) and fully mediated the intervention effect at the 12-month follow-up. When we controlled for case mix, the TOP group had significantly greater reductions in depression severity (measured by the Hopkins Symptom Checklist) compared with the UC group at the 6-month ($\beta = -0.25$ [95% CI, -0.40 to -0.10]; $P = .001$) and 12-month ($\beta = -0.23$ [95% CI, -0.40 to -0.05]; $P = .01$) follow-ups (Figure 3). Compared with the UC group, the TOP group had significantly greater increases in PCS scores at the 6-month ($\beta = 2.67$ [95% CI, 0.45 to 4.91]; $P = .02$) but not the 12-month ($\beta = 0.97$ [95% CI, -1.09 to 3.03]; $P = .35$) follow-ups. Group differences in MCS change scores were not significant at the 6-month ($\beta = -0.12$ [95% CI, -2.88 to 2.63]; $P = .93$) or the 12-month ($\beta = -1.36$ [95% CI, -4.24 to 1.52]; $P = .36$) follow-ups.

Discussion

The rural veterans in this sample had considerable illness burden reflected by high levels of PTSD severity, numerous comorbidities, and poor health-related quality of life. About half reported combat-related trauma and half had service-connected PTSD. Nearly all the veterans reported previously taking psychotropic medications and/or receiving counseling, and veterans randomized to UC experienced virtually no improvement in symptoms. Thus, the sample can be characterized as being highly treatment resistant. In addition, UC in the VA represents a high bar with annual PTSD screenings and nationwide training of therapists in CPT and prolonged exposure therapy. Moreover, VHA patients diagnosed with PTSD have a national mean of 14.3 outpatient mental health encounters per year (Rani Hoff, PhD, MPH; e-mail; December 31, 2013). Nevertheless, compared with veterans randomized to UC, those randomized to TOP experienced significantly greater improvements in PTSD and depression severity, although the effect sizes ranged from small to medium. As a benchmark, Monson et al³¹ reported an effect size twice as large for veterans who completed a course of CPT (Cohen $d = 0.69$ for the Clinician-Administered PTSD Scale change score at 1-month follow-up). The TOP intervention attempted to improve access to and engagement in evidence-based pharmacotherapy and evidence-based psychotherapy. The intervention increased prescribing of prazosin, but we found no effect on the total number of prescribed PTSD medications or adherence to medication regimens. However, the TOP intervention increased CPT engagement. Veterans randomized to TOP had 18 times higher odds of initiating CPT and 8 times higher odds of completing at least 8 sessions (minimal therapeutic dose). Long travel distances to the VAMC likely discouraged UC patients from engaging in CPT. In a post hoc mediation analysis, attending at least 8 sessions of CPT completely mediated the effect of the TOP intervention. This finding suggests that the primary mechanism of action in the intervention was improved engagement in CPT. This interpretation is consistent with the find-

Figure 3. Case-Mix-Adjusted Depression Severity Change Scores



We measured depression severity using the Hopkins Symptom Checklist (SCL-20). TOP indicates Telemedicine Outreach for Posttraumatic Stress Disorder; UC, usual care.

ing that, of the 3 previous randomized clinical trials of collaborative care for PTSD, only the intervention with an evidence-based psychotherapy component had a significant treatment effect.^{25,26,28,29} Although pharmacotherapy-focused collaborative care has been shown to be effective for depression,⁴⁷⁻⁴⁹ these results suggest that the larger effect size associated with collaborative care models that have pharmacotherapy and psychotherapy components⁵⁰ is needed to improve PTSD outcomes among veterans. Our findings suggest that collaborative care models can encourage veterans to initiate and adhere successfully to evidence-based psychotherapies for PTSD.

Our findings are limited in that, although the face-to-face Clinician-Administered PTSD Scale is the reference standard for assessment of PTSD severity, we chose to administer the briefer PDS by telephone to maximize our follow-up rate. Care managers used a third instrument (the civilian version of the Posttraumatic Stress Disorder Checklist) to monitor PTSD severity to avoid habituation to the PDS among those randomized to TOP. Another limitation is that we did not have rigorous measures of quality of care, including CPT fidelity. In addition, because we augmented self-referral recruitment methods with opt-out letters, the high refusal rates may limit the generalizability of our findings for patients with high levels of avoidance. Also, although the research assistants conducting follow-up assessments were blinded, patients and providers could not be, given the nature of the intervention. Finally, because the trial was designed to be pragmatic rather than explanatory, we could not confirm the mechanism of action for the TOP intervention.

Conclusions

This pragmatic effectiveness trial provided telemedicine-based collaborative care to rural veterans with PTSD to increase their access to and engagement in evidence-based treatments. Despite its limitations, this trial introduces a promising model for managing PTSD in a treatment-resistant population. Findings suggest that telemedicine-based collaborative care can successfully engage this population in evidence-based psychotherapy for PTSD, thereby improving clinical outcomes.

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