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Title

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Authors

Possemato, Kyle
Johnson, Emily
Barrie, Kimberly
et al.

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Kyle Possemato, PhD[1] ⬤, Emily Johnson, PhD[1], Kimberly Barrie, MPH, MSW[1], Sharfun Ghaus, MBBS[2], Delilah Noronha, PsyD[2], Michael Wade, MS[1], Mark A. Greenbaum, MS, MA[2,3], Craig Rosen, PhD[2,4], Marylene Cloitre, PhD[2,4], Jason Owen, PhD[2], Shaili Jain, MD[2,4], Gregory Beehler, PhD[1], Annabel Prins, PhD[2], Karen Seal, MD[5,6], and Eric Kuhn, PhD[2,4]

[1]VA Center for Integrated Healthcare, Syracuse VA Medical Center, Syracuse, NY, USA; [2]National Center for PTSD, Palo Alto, CA, USA; [3]Mental Illness Research Education and Clinical Center, VA Palo Alto Health Care System, Palo Alto, CA, USA; [4]Stanford University School of Medicine, Stanford, CA, USA; [5]San Francisco VA Health Care System, San Francisco, USA; [6]University of California San Francisco, San Francisco, CA, USA

ABSTRACT

BACKGROUND: Posttraumatic stress disorder (PTSD) is common in primary care patients; however, evidence-based treatments are typically only available in specialty mental healthcare settings and often not accessed.

OBJECTIVE: To test the effectiveness of a brief primary care-based treatment, Clinician-Supported PTSD Coach (CS PTSD Coach) was compared with Primary Care Mental Health Integration-Treatment as Usual (PCMHI-TAU) in (1) reducing PTSD severity, (2) engaging veterans in specialty mental health care, and (3) patient satisfaction with care.

DESIGN: Multi-site randomized pragmatic clinical trial.

PARTICIPANTS: A total of 234 veterans with PTSD symptoms who were not currently accessing PTSD treatment.

INTERVENTION: CS PTSD Coach was designed to be implemented in Veterans Affairs PCMHI and combines mental health clinician support with the "PTSD Coach" mobile app. Four 30-min sessions encourage daily use of symptom management strategies.

MAIN MEASURES: PTSD severity was measured by clinician-rated interviews pre- and post-treatment (8 weeks). Self-report measures assessed PTSD, depression, and quality of life at pretreatment, posttreatment, and 16- and 24-week follow-ups, and patient satisfaction at post-treatment. Mental healthcare utilization was extracted from medical records.

KEY RESULTS: Clinician-rated PTSD severity did not differ by condition at post-treatment. CS PTSD Coach participants improved more on patient-reported PTSD severity at post-treatment than TAU participants ($D=.28$, $p=.021$). Coach participants who continued to have problematic PTSD symptoms at post-treatment were not more likely to engage in 2 sessions of specialty mental health treatment than TAU participants. Coach participants engaged in 74% more sessions in the intervention and reported higher treatment satisfaction than TAU participants ($p<.001$).

CONCLUSIONS: A structured 4-session intervention designed to align with patient preferences for care resulted in more patient-reported PTSD symptom relief, greater utilization of mental health treatment, and overall treatment satisfaction than TAU, but not more clinician-rated PTSD symptom relief or engagement in specialty mental health.

INTRODUCTION

Posttraumatic stress disorder (PTSD) is common (20–30%) among primary care patients who have frequent exposure to trauma (e.g., veterans, low income, urban patients) and is associated with considerable disability, including higher rates of physical health concerns, comorbid mental health disorders, and impaired functioning.[1] Evidence-based psychotherapies for PTSD are often available in mental health clinics, but primary care patients commonly do not access them due to patient and system level barriers.[2–4] Mental health providers within Veterans Affairs (VA) primary care, called Primary Care Mental Health Integrated (PCMHI) clinicians, increase engagement in mental health services[5] but lack evidence-based interventions for PTSD that are feasible to deliver in PCMHI. Therefore, brief psychotherapies that can be delivered in PCMHI are needed to increase prompt access to evidence-based PTSD care.

Incorporating mobile health (mHealth) smartphone applications (apps) in care can make treatment more accessible. Most individuals use apps and are interested in including them in their healthcare.[6] Similarly, PCMHI clinicians report commonly recommending apps to patients.[7] While many mHealth apps incorporate evidence-based symptom-management strategies, users often do not use them enough on their own and need guidance to engage with apps sufficiently to benefit.[8] Combining clinician support with mHealth has many advantages: clinicians can help patients learn when and how to use app-based strategies while providing human connection so patients feel cared for and understood.[9]

Clinician-Supported PTSD Coach (CS PTSD Coach) was designed as a brief intervention for primary care patients with problematic PTSD symptoms who are not receiving PTSD care and are unlikely to use an mHealth app on their own. It combines the widely downloaded PTSD Coach app,[10] which has demonstrated efficacy,[11] with four 20–30-min psychotherapy sessions delivered by a PCMHI clinician. CS PTSD Coach was designed with input from VA primary care and PCMHI providers to fit existing PCMHI practices, meet the needs of patients, and help veterans overcome common barriers to accessing PTSD care.[12] A pilot study of CS PTSD Coach found it increased engagement in care and led to large reductions in PTSD severity.[13]

A multi-site randomized, pragmatic clinical trial comparing CS PTSD Coach (Coach) to PCMHI Treatment as Usual (TAU) in VA primary care patients with PTSD was conducted. We hypothesized that Coach would be superior to TAU in (1) reducing clinician-rated PTSD severity, (2) engaging patients who continued to be symptomatic at post-treatment (PCL ≥ 33) in specialty mental health care, and (3) improving patient satisfaction with care. We also report on patient-rated PTSD severity, depression severity, and quality of life, rates of treatment engagement during the intervention period, and changes in engagement from before to during the study.

METHOD

This study was approved by local VA and university Institutional Review Boards and preregistered at ClinicalTrials.gov (NCT02685358).

Participants

Veterans enrolled in primary care within VA healthcare systems in New York and California were included in the study. To be eligible, patients needed to report a traumatic event and score ≥ 33 on the PTSD Checklist-5 (PCL-5). Patients were excluded if they demonstrated conditions that might prevent them from engaging in study interventions: (1) gross cognitive impairment, (2) mania or psychosis, (3) suicidal intent, or (4) homelessness. Patients were also excluded if they (5) were receiving psychotherapy or changed the dose of a psychotropic medication for PTSD in the last 2 months, or (6) preferred to be directly referred to PTSD specialty care.

Recruitment

Patients screening ≥ 2 on their annual PC-PTSD-5 screen were referred by their primary care team. Research staff sent a letter to referred patients introducing the study and then called to assess their interest in participation. Enrollment took place from February 2017 to September 2020. Interested patients were scheduled for a baseline research appointment within their primary care clinic before March 2020. Following this date, all study procedures were virtual due to the COVID-19 pandemic.

Assessment and Randomization

Research staff obtained informed consent and administered self-report measures via REDCap[14,15] to assess eligibility criteria. Eligible participants were randomized to Coach or TAU (1:1). Next, participants completed the Clinician Administered PTSD Scale–5 (CAPS-5) interview by phone with an independent assessor blind to condition. Post-treatment (8 weeks) and follow-up assessments (16 and 24 weeks) were conducted following baseline. All assessment timepoints included the self-report battery and the 8-week assessment also included the CAPS-5 administered by phone and the Client Satisfaction Questionnaire. Participants were paid up to $150 for completing assessments.

Measures

Primary outcomes included the *Clinician Administered PTSD Scale-5 (CAPS-5)*: a 30-item structured interview assessing traumatic events and severity of DSM-5 PTSD symptoms.[16] The CAPS-5 is reliable and valid.[17] The *PTSD Checklist-5 (PCL-5)* was administered with the extended traumatic event assessment. The PCL-5 is a 20-item self-report measure assessing how much respondents have been bothered by DSM-5 PTSD symptoms in the past month.[18] The PCL-5 has good psychometric properties with a total score of ≥ 33 indicating a probable PTSD diagnosis and a drop of 15 indicating reliable change.[19–21] *VA Administrative Data* were extracted to assess utilization of mental health. The primary outcome of engagement was at least two specialty mental health visits in the follow-up period (weeks 9–24) for participants who continued to have problematic PTSD symptoms (i.e., PCL ≥ 33) at post-treatment. Other indicators included all mental health treatment visits (i.e., PCMHI-TAU, CS PTSD Coach, specialty care) attended during the intervention period (weeks 0–8) and a comparison of the rate of all mental health treatment engagement before the study (up to 10 years prior) through the 24-week study period. The *Client Satisfaction Questionnaire (CSQ)* is a widely used 8-item self-report measure assessing patient satisfaction with care. Individual items rated as "good" or "excellent" were considered endorsed by participants.[22]

Self-report measures with strong psychometric properties assessed broader aspects of patient well-being. The *Patient Health Questionnaire (PHQ-9)* assessed depressive symptoms[23] and the *WHOQOL-BREF* assessed quality of life with the psychological and social subscales[24] at each time point. The *Alcohol Use Disorders Identification Test (AUDIT)*[25] and the *Drug Assessment Screening Test (DAST)*[26] assessed baseline substance use.

Study Conditions

Clinician-Supported PTSD Coach (Coach) is a manualized intervention consisting of four 20–30-min sessions delivered over 8 weeks. It focuses on instructions for app use, setting symptom reduction goals, and assigning PTSD Coach activities (i.e., symptom monitoring, management strategies, psychoeducational readings) for completion between sessions. CS PTSD Coach was designed to match patient preferences for a flexible intervention that can be delivered in-person or by phone (and during the COVID-19 pandemic a video session option was added), and respects veterans' desire for self-reliance. Table 1 lists the main components of each session. It uses VA's stepped-care model: veterans continuing to have problematic PTSD symptoms after 4 sessions are offered facilitated referrals to specialty mental health services. Detailed descriptions of CS PTSD Coach are included in prior publications.[12,13]

CS PTSD Coach was delivered by psychologists and masters-level clinicians, most of whom also offered regular PCMHI services. Clinician training included a 1-h didactic followed by completing three recorded sessions with a standardized patient, which were reviewed for fidelity. During treatment delivery, clinicians participated in weekly group consultation. Clinicians completed fidelity checklists of essential protocol components following each session. An independent fidelity assessment was conducted using audio-recorded sessions for 96 sessions (24% of sessions) randomly selected from each of the four sessions.

Comparison Condition: PCMHI Treatment as Usual (TAU). An electronic consult or a warm handoff to PCMHI services was given to participants randomized to PCMHI-TAU. In VA, PCMHI consisted of licensed mental health providers (mostly psychologists and clinical social workers) embedded within primary care teams to provide brief assessment and intervention services. Sessions are 20–30 min with a typical episode of care being four sessions

or less.[27] Patients needing additional care after PCMHI are referred to specialty mental health services.[28] Past research on PCMHI-TAU for PTSD indicates that treatment is not standardized but typically includes psychoeducation, relaxation skills, and/or a facilitated referral to PTSD specialty care.[29]

Data Analysis

PTSD Severity, Depression Severity, and Quality of Life. Using SAS 9.4, mixed-effect models compared outcomes between and within conditions across the four timepoints. Condition, time, a cross-level interaction term (Condition × Time), and site were included as fixed effects, whereas intercept and slope terms were added as random effects. Fixed effects of site, condition, and time were dichotomous and discrete nominal variables with no imposed trajectory on the time and outcome association. Random effects were added to models to accommodate correlation among timepoints while allowing for subject-specific deviations from the mean. Pre-planned contrasts used fixed effects to estimate means and assess change from baseline to each timepoint. All hypothesis tests were two-sided using an alpha of 0.05.

Access and Engagement. The occurrence and number of mental health care visits were analyzed using generalized mixed binominal and Poisson models, respectively. Effects entered into the model were similar to those above except that measurement occasion consisted of three levels (historic, intervention, follow-up) and an unstructured variance/covariance matrix was used to accommodate the correlation among occasions. An odds ratio (OR) and 95% confidence interval (CI) were used to described results of binomial models, whereas means and incidence rate ratios (IRR) and associated CIs for count data were used for Poisson models.

Table 1 CS PTSD Coach Treatment Overview and Fidelity Elements

	Session 1	Session 2	Session 3	Session 4
Format	In-person	In-person/phone		In-person/phone
Content	1.Overview of treatment 2. Instructions for app use 3.Discuss Learn modules 4.Complete PCL in app 5.Target problem domain 6.Try 1–2 Manage strategies	1.Review homework 2.Discuss change on PCL graph 3.Discuss Manage strategies used 4.Target new symptom domain to manage 5.Problem solve any adherence issues		1.Review homework 2. Discuss Learn, Assessment and Manage tools used since last session 3.Recommend treatment based on PCL score 4.Make treatment or self-management plan
Homework	1.Complete PCL weekly 2.Read at least 2 Learn topics 3.Use Manage strategies daily	1.Complete PCL weekly 2.Read at least 2 Learn topics 3.Use Manage strategies daily		1.Follow-through on tx plan 2.Continue to use app as desired

PCL, PTSD Checklist-5

Treatment Satisfaction. *T*-test and chi-square tests compared satisfaction by condition.

RESULTS

Participants and Participant Flow

Participants ($N = 234$) had a mean age of 50.91 (SD = 15.43) years and 90% ($n = 211$) were men. Approximately 18% identified as Black, 6% as Asian, and 5% as Native American. Table 2 provides additional details of the sample. Most participants ($n = 209$, 89%) had received VA mental health treatment over the past 10 years including 29% ($n = 68$) who received psychotherapy for PTSD. Outcome measures at baseline are in Table 3. Assessment

retention was 91% at posttreatment, 81% at 16 weeks, and 79% at 24 weeks (Fig. 1).

CS PTSD Coach Engagement and Fidelity

Coach engagement was high with 81% of participants completing all sessions. Fifty-four percent of sessions were completed in-person, 38% by phone and 8% via video. Clinician's self-rated 95% of their sessions as having perfect fidelity. Independent ratings of 96 sessions indicated 81% had perfect fidelity, resulting in an 82% agreement between self-rated and independently rated fidelity. Most imperfect sessions were only missing one essential element. Independent raters assessed participants as having good to excellent session engagement including tracking session content,

Table 2 Sociodemographic and Selected Clinical Characteristics at Baseline

Characteristics	Entire sample $N = 234$	CS-PTSD Coach $n = 115$	PCMHI TAU $n = 119$
	n (%)/ Mean (SD)	*n* (%)/ Mean (SD)	*n* (%)/ Mean (SD)
Age	50.92 (15.43)	50.04 (15.39)	51.75 (15.47)
Education (years)	15.48 (2.58)	15.40 (2.30)	15.56 (2.84)
Gender			
Male	211 (90.2%)	101 (87.83%)	110 (92.44%)
Income	$58,608 ($36,190)	$60,782 ($36,847)	$56,608 ($34,396)
Ethnicity[a]			
Caucasian	177 (75.6%)	89 (77.4%)	88 (74.0%)
African American	41 (17.5%)	16 (13.9%)	25 (21.0%)
Asian/Pacific American	13 (5.6%)	7 (6.1%)	6 (5.0%)
Native American	12 (5.1%)	4 (3.5%)	8 (6.7%)
Other	2 (0.9%)	1 (0.9%)	1 (0.8%)
Hispanic	23 (9.8%)	9 (7.8%)	14 (11.8%)
Marital status			
Married/partnered	135 (57.7%)	66 (57.4%)	69 (58.0%)
Non-married/partnered	96 (41.0%)	47 (40.9%)	49 (41.2%)
Employment			
Yes	117 (50.0%)	61 (53.0%)	56 (47.9%)
No	114 (48.7%)	53 (46.1%)	61 (51.3%)
Military branch			
Navy	37 (15.8%)	20 (17.4%)	17 (14.3%)
Marine	49 (20.9%)	23 (20.0%)	26 (21.9%)
Air Force	24 (10.3%)	13 (11.3%)	11 (9.2%)
Army	137 (58.6%)	69 (60.0%)	68 (57.1%)
Coast Guard	1 (0.4%)	0 (0.0%)	1 (0.8%)
Deployments			
OEF	69 (29.3%)	34 (29.6%)	35 (29.4%)
OIF	62 (26.5%)	28 (24.4%)	34 (28.6%)
Gulf War I	26 (11.1%)	12 (10.4%)	14 (11.8%)
Vietnam	59 (25.2%)	27 (23.5%)	32 (26.9%)
Other wars	54 (23.1%)	27 (23.5%)	27 (22.7%)
Mental health Tx history[b]			
Any treatment	209 (89.3%)	101 (87.8%)	108 (90.8%)
Any psychotherapy	201 (85.9%)	95 (82.6%)	106 (89.1%)
No. of psychotherapy sessions	28.37 (50.35)	22.20 (44.85)	34.28 (54.65)
PTSD psychotherapy	68 (29.1%)	26 (22.6%)	42 (35.3%)
Any medication	157 (67.1%)	73 (63.5%)	84 (70.6%)
PTSD diagnosis via CAPS-5	69 (29.49%)	32 (27.83%)	37 (31.09%)
Hazardous substance use			
AUDIT ≥ 8	59 (25.21%)	29 (25.2%)	30 (25.2%)
DAST ≥ 3	26 (11.11%)	17 (14.8%)	9 (7.6%)

[a]Participants who endorsed multiple ethnicities were counted for each ethnicity they endorsed

[b]Includes up to 10 years medical history

Table 3 Means, Standard Errors, and Results of Mixed-Effects Models

Outcome	Condition	0 weeks* M (SE)	8 weeks M (SE)	Change 0–8 weeks p, Cohen's D	16 weeks M (SE)	24 weeks† M (SE)
CAPS-5‡	Coach	28.52 (0.97)	24.69 (1.00)	p = 1.0, D = .01	–	–
	TAU	30.01 (.95)	26.19 (0.96)		–	–
PCL-5§	Coach	46.30 (1.05)	36.46 (1.20)	p = .021, D = .28	35.42 (1.43)	34.61 (1.69)
	TAU	47.18 (1.03)	40.68 (1.15)		38.99 (1.35)	38.05 (1.58)
PHQ-9‖	Coach	12.51 (.48)	11.03 (.50)	p = .118, D = .01	10.79 (.55)	10.22 (.61)
	TAU	13.63 (.47)	12.12 (.48)		11.80 (.52)	11.39 (.57)
WHO-Psych¶	Coach	17.82 (.35)	18.16 (.37)	p = .352, D = .10	18.04 (.39)	18.29 (.42)
	TAU	17.51 (.34)	17.50 (.35)		17.65 (.37)	17.47 (.40)
WHO-Social#	Coach	8.88 (.24)	9.31 (.24)	p = .276, D = .15	9.23 (.26)	9.01 (.27)
	TAU	8.56 (.23)	8.71 (.23)		8.58 (.24)	8.40 (.25)

*Conditions did not significantly differ at baseline on any measures

†There is no significant condition by time changes at 16 and 24 weeks for any outcomes

‡CAP-5 within-group change was statistically significant for both conditions

§PCL-5 within-group change was statistically significant for both conditions at each time point

‖PHQ-9 within-group change was statistically significant for both conditions at each time point

¶WHO-Psych within-group change was not statistically significant in either condition at any time point

#WHO-Social within-group change for Coach condition from 0 to 8 weeks was statistically significant ($p = .024$); no other WHO-QOL within-group changes were significant

using the app appropriately, sharing appropriate experiences, and/ or asking relevant questions. Some to all of homework was completed in 96% of reviewed sessions. Coach participants were also able to receive the typical services offered in primary care during the intervention period. Fifty-one (44.7%) received some type of mental healthcare in primary care with psychiatric medication ($n = 43$, 37.4%) being the most common.

Services Received in Treatment as Usual

Most TAU participants ($n = 102$, 86%) received mental health treatment within the 8-week intervention period (Fig. 1). PCMHI treatment was the most common ($n = 86$, 72.3%) followed by psychiatric medication ($n = 48$, 40.3%) and psychotherapy in specialty mental healthcare ($n = 47$, 39.5%). TAU participants attended an average of 2.23 visits (SD = 1.91) during the intervention period.

PTSD Severity, Depression Severity, and Quality of Life

Contrary to hypotheses, clinician-rated PTSD symptoms did not significantly differ by condition at posttreatment (Table 3), both conditions experienced significant improvement. However, Coach participants had significantly larger PCL-5 decreases at posttreatment with improvement maintained at follow-up assessments (Table 3). Coach participants were also more likely to drop below 33 (Coach 41% v. TAU 26%, $x^2 = 5.45$, $p = 0.020$) and have a 15-point decrease (i.e., reliable change) on the PCL-5 (Coach 34% v. TAU

18%, $x^2 = 7.25$, $p = 0.007$) at posttreatment. There were no significant condition by time treatment effects for depression (both conditions showed significant improvement) or for quality of life scales (Table 3).

Engagement in Care

Contrary to our hypothesis, among participants ($n = 142$) who continued to have problematic PTSD symptoms (i.e., PCL ≥ 33) at posttreatment, subsequent engagement in at least two specialty mental healthcare visits did not differ significantly between Coach and TAU participants (36% vs. 24%, respectively, $x^2 = 2.22$, $p = 0.136$). Yet during the intervention period, Coach participants engaged in 74% more sessions compared to TAU participants (mean (SE) = 3.87(0.15) for Coach vs. 2.22(0.17) for TAU, $p < 0.001$). Also, compared to the previous 10 years, Coach participants were 3.91 times more likely to have accessed mental healthcare in the intervention period while TAU participants were 7% less likely to access care ($p = 0.016$).

Treatment Satisfaction

Coach participants reported higher treatment satisfaction on the CSQ-8 (M(SD): Coach = 27.10 (3.73), PCMHI-TAU = 24.60 (4.82), $t(199) = 4.06$, $p < 0.001$). To illustrate some of the differences reported between conditions, Coach participants were more likely to report treatment helped them "deal more effectively with their problems" and that they "got the amount of treatment they wanted" than TAU participants (94% vs. 73% ($x^2 = 11.52$, $p ≤ 0.001$), 91% vs.73% ($x^2 = 11.09$, $p = 0.001$), respectively).

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│ Based on VHA administrative data and provider referrals patients      │
│ eligible to be sent a recruitment letter (n = 2519)                   │
└─────────────────────────────────────────────────────────────────────┘
                               ↓
┌─────────────────────────────────────────────────────────────────────┐
│ Patients contacted by phone (n = 1598)                                │
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│ Scheduled baseline assessment (n = 380)                               │
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        │ Excluded (n = 146)                                    │
        │  • PCL-5 < 33 (n = 131)                               │
        │  • Baseline not completed (n =7)                      │
        │  • Psychotherapy or change of dose of a               │
        │    medication for PTSD outside of for PTSD (n = 4)    │
        │  • Cognitive concerns (n = 1)                         │
        │  • Suicidal Intent (n = 1)                            │
        │  • Severe substance use (n = 1)                       │
        │  • Psychosis (n = 1)                                  │
        └──────────────────────────────────────────────────────┘
                               ↓
        ┌──────────────────────────────────────────────────────┐
        │ Eligible and randomized (n = 234)                     │
        └──────────────────────────────────────────────────────┘
              ↙                              ↘
┌──────────────────────────────┐   ┌──────────────────────────────┐
│ Randomized to PCMHI TAU      │   │ Randomized to CS PTSD Coach   │
│ (n = 119)                    │   │ (n = 115)                     │
└──────────────────────────────┘   └──────────────────────────────┘
              ↓                              ↓
┌──────────────────────────────┐   ┌──────────────────────────────┐
│ Engagement in PCMHI-TAU and  │   │ Engagement in CS PTSD Coach   │
│ referrals (n =102)           │   │ Sessions (n = 109)            │
│  • PCMHI (n = 86)            │   │  • ≥1 session (n = 108)       │
│  • Psychiatric Medication    │   │  • ≥2 sessions (n = 100)      │
│    (n = 48)                   │   │  • ≥3 sessions (n = 96)       │
│  • Psychotherapy in Specialty │   │  • =4 sessions (n = 93)       │
│    Care (n = 47)              │   │                               │
│  • PTSD Clinic (n = 5)        │   │                               │
│  • Substance Use Clinic (n=1) │   │                               │
└──────────────────────────────┘   └──────────────────────────────┘
              ↓                              ↓
┌──────────────────────────────┐   ┌──────────────────────────────┐
│ 8 weeks Completed (n = 112)  │   │ 8 weeks Completed (n = 100)   │
│   Withdrew from study (n = 3)│   │   Withdrew from study (n = 7) │
│   Unable to locate (n = 4)   │   │   Unable to locate (n = 8)    │
└──────────────────────────────┘   └──────────────────────────────┘
              ↓                              ↓
┌──────────────────────────────┐   ┌──────────────────────────────┐
│ 16 weeks Completed (n = 102) │   │ 16 weeks Completed (n = 87)   │
│   Withdrew from study (n = 1)│   │   Withdrew from study (n = 1) │
│   Unable to locate (n = 13)  │   │   Unable to locate (n = 20)   │
└──────────────────────────────┘   └──────────────────────────────┘
              ↓                              ↓
┌──────────────────────────────┐   ┌──────────────────────────────┐
│ 24 weeks Completed (n = 100) │   │ 24 weeks Completed (n = 84)   │
│   Withdrew from study (n = 0)│   │   Withdrew from study (n = 0) │
│   Unable to locate (n = 15)  │   │   Unable to locate (n = 23)   │
└──────────────────────────────┘   └──────────────────────────────┘
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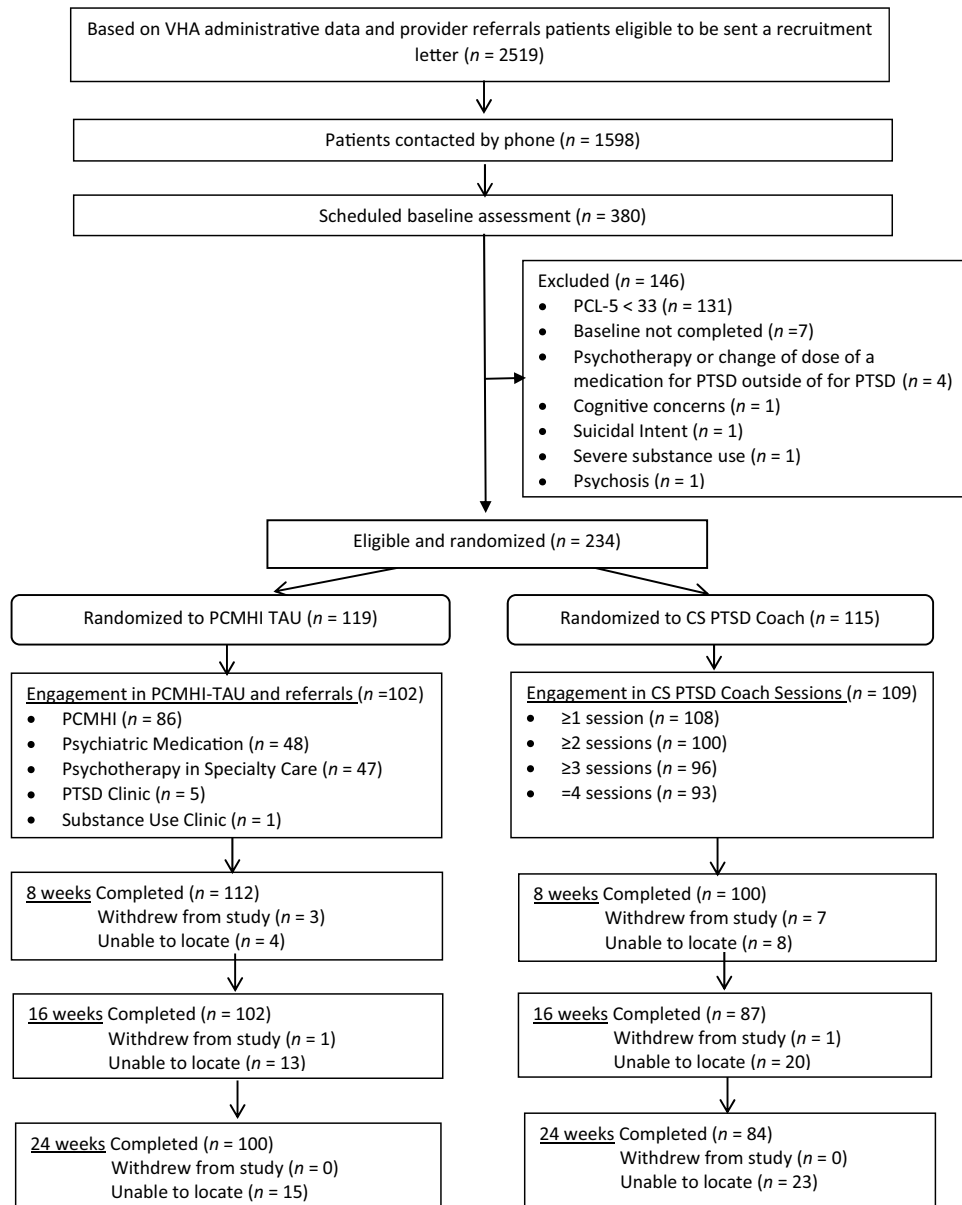
Figure 1 Recruitment and retention flow diagram.

DISCUSSION

Results from this pragmatic trial indicate that CS PTSD Coach was not superior to PCMHI-TAU in our primary outcomes of reducing clinician-rated PTSD severity and engaging participants in two visits of specialty mental care following the study intervention phase. Findings suggest that PCMHI-TAU was a rigorous comparison condition that resulted in significant within-condition improvements in PTSD and depression symptoms. However, Coach was superior on other important outcomes: it resulted in more improvement in patient-reported PTSD severity at post-treatment, higher rates of engagement in mental health treatment during the intervention period, more access to new episodes of treatment, and higher treatment satisfaction. The advantage of Coach on PTSD symptom improvement over TAU was modest but may be potentially meaningful given the high PTSD prevalence and low rates of mental health treatment engagement among primary care patients.

Our results do not indicate what components of Coach were most helpful for participants. The conditions most likely share common treatment elements including PTSD psychoeducation, strategies to manage anxiety and other concerns, and referral to additional treatment. Unique elements of Coach include its structured and manualized content for 4 sessions and use of an app to complete out-of-session symptom management activities. These elements likely resulted in participants getting a larger dose of treatment in and outside of sessions than TAU participants. Because CS PTSD Coach requires minimal provider

training and providers find it easy to delivery, it can be considered as a way to more primary care–based treatment for PTSD.

The results extend findings from earlier work on CS PTSD Coach showing a similar amount of symptom reduction on the PCL (i.e., 11 points) and high treatment satisfaction.[12,13] This study adds to the evidence base for interventions that combine clinician support with mHealth interventions and helps address several gaps in this area, including research with individuals with PTSD, use of a technology that is publicly available, and rigorous methods (e.g., recruitment of a clinical population, use of diagnostic and follow-up assessments).[30] Clinical service models of how to incorporate mHealth into regular care are needed to realize its full potential.

To date, this study is the largest clinical trial of a brief psychotherapy intervention for PTSD in primary care. However, other promising brief interventions exist, including Prolonged Exposure for Primary Care (PE-PC). PE-PC focuses on fear extinction through exposure and requires more therapist training and skill to deliver. It has similar within-condition effects as CS PTSD Coach.[31] Having multiple brief treatments for PTSD will allow clinicians to choose the one that best matches their skillset and patient needs.

The lack of support for our primary hypotheses warrants discussion. Coach participants did not have larger deceases in clinician-rated PTSD than TAU, possibly indicating that no such benefit exists or that the impact of Coach on PTSD is too modest for the CAPS-5 to detect a between-group difference. The CAPS-5 is not only a more reliable indicator of PTSD than the PCL-5, but it also is less sensitive to change.[17] Whereas the CAPS-5 captures PTSD severity related to frequency, intensity, and impairment, the PCL-5 captures distress related to PTSD symptoms, which may be a more valued indicator within primary care where patient perception of symptoms is valued over clinical symptom profiles.

Among participants with problematic PTSD at posttreatment, engagement in two visits of specialty mental health was not more likely in the Coach than TAU. Because of the amount of symptom remission across both conditions, only 142 participants were used for this test and a post hoc power analysis indicated low power (0.34). Our fully powered tests on overall rates of treatment engagement, which indicated significant advantages of Coach over TAU, may be more valid treatment engagement results. Also, Coach was not designed to address systemic access problems in specialty care, which could have limited utilization rates in both conditions.

Results must be viewed considering study strengths and limitations. While our assessment attrition was low, Coach had a lower posttreatment assessment rate (87%) than TAU (95%). Treatment arms that require more participant effort often have greater drop-out; however, this may have biased our results in favor of treatment completers, especially for treatment satisfaction. Studies that compare novel treatment to TAU may be subject to providers being more enthusiastic about the novel treatment and this can possibly bias results and limit their generalizability. Many aspects of our sample were study strengths (e.g., ethnically diverse, recruited with few exclusion criteria from clinical settings) that increase the generalizability of the results. However, our results may not generalize to treatment-naïve individuals but instead may represent the impact of providing a brief, easy to access intervention to patients with chronic PTSD and long mental health histories.

In conclusion, VA PCMHI-TAU provides quality treatment that results in good access to care and improved PTSD and depression. CS PTSD Coach offers additional benefits over PCMHI-TAU including greater patient-reported PTSD symptom relief, higher rates of access to new episodes of care, more treatment engagement, and better patient satisfaction. Mental health clinicians in primary care can be trained to deliver CS PTSD Coach with high fidelity within a few hours. Thus, healthcare systems looking to implement a structured, brief, easy-to-learn intervention for PTSD can consider using CS PTSD Coach. Future research is needed to understand if dose (i.e., sessions, amount of app use) and what components (i.e., clinician support, PTSD Coach) of treatment relate to clinical outcomes and if patient characteristics predict who will benefit from CS PTSD Coach.

Declarations

Conflict of Interest *The authors declare that they do not have a conflict of interest.*

Disclaimer *The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the US government.*

REFERENCES

1. **Greene T, Neria Y, Gross R.** Prevalence, Detection and Correlates of PTSD in the Primary Care Setting: A Systematic Review. J Clin Psychol Med Settings. 2016;23(2):160-80. https://doi.org/10.1007/s10880-016-9449-8.

2. **Wray LO, Szymanski BR, Kearney LK, McCarthy JF.** Implementation of primary care-mental health integration services in the Veterans Health Administration: program activity and associations with engagement in specialty mental health services. J Clin Psychol Med Settings. 2012;19(1):105-16. https://doi.org/10.1007/s10880-011-9285-9.

3. **Fischer EP, McSweeney JC, Wright P, Cheney A, Curran GM, Henderson K, et al.** Overcoming Barriers to Sustained Engagement in Mental Health Care: Perspectives of Rural Veterans and Providers. J Rural Health. 2016;32(4):429-38. https://doi.org/10.1111/jrh.12203.

4. **Possemato K, Wray LO, Johnson E, Webster B, Beehler GP.** Facilitators and Barriers to Seeking Mental Health Care Among Primary Care Veterans With Posttraumatic Stress Disorder. J Trauma Stress. 2018;31(5):742-52. https://doi.org/10.1002/jts.22327.

5. **Cook JM, Zeber JE, Simiola V, Rossom R, Scherrer JF, Owen-Smith AA, et al.** Comparisons Between Patients Diagnosed with PTSD in Primary Care Versus Mental Health Care in Five Large Civilian Health Care Systems. Journal of Clinical Psychology in Medical Settings. 2021;28(2):221-8. https://doi.org/10.1007/s10880-020-09706-8.

6. **Erbes CR, Stinson R, Kuhn E, Polusny M, Urban J, Hoffman J, et al.** Access, utilization, and interest in mHealth applications among veterans receiving outpatient care for PTSD. Mil Med. 2014;179(11):1218-22. https://doi.org/10.7205/milmed-d-14-00014.

7. **Miller KE, Kuhn E, Yu J, Owen JE, Jaworski BK, Taylor K, et al.** Use and perceptions of mobile apps for patients among VA primary care mental and behavioral health providers. Prof Psychol: Res Pract. 2019;50(3):204-9. https://doi.org/10.1037/pro0000229.

8. **Amagai S, Pila S, Kaat AJ, Nowinski CJ, Gershon RC.** Challenges in Participant Engagement and Retention Using Mobile Health Apps: Literature Review. J Med Internet Res. 2022;24(4):e35120. https://doi.org/10.2196/35120.

9. **Schueller SM, Tomasino KN, Mohr DC.** Integrating Human Support Into Behavioral Intervention Technologies: The Efficiency Model of Support. Clin Psychol: Sci Pract. 2017;24(1):27-45. https://doi.org/10.1111/cpsp.12173.

10. **Kuhn E, Greene C, Hoffman J, Nguyen T, Wald L, Schmidt J, et al.** Preliminary evaluation of PTSD Coach, a smartphone app for posttraumatic stress symptoms. Mil Med. 2014;179(1):12-8. https://doi.org/10.7205/milmed-d-13-00271.

11. **Kuhn E, Kanuri N, Hoffman JE, Garvert DW, Ruzek JI, Taylor CB.** A randomized controlled trial of a smartphone app for posttraumatic stress disorder symptoms. J Consult Clin Psychol. 2017;85(3):267-73. https://doi.org/10.1037/ccp0000163.

12. **Possemato K, Kuhn E, Johnson EM, Hoffman JE, Brooks E.** Development and refinement of a clinician intervention to facilitate primary care patient use of the PTSD Coach app. Transl Behav Med. 2017;7(1):116-26. https://doi.org/10.1007/s13142-016-0393-9.

13. **Possemato K, Kuhn E, Johnson E, Hoffman JE, Owen JE, Kanuri N, et al.** Using PTSD Coach in primary care with and without clinician support: a pilot randomized controlled trial. Gen Hosp Psychiatry. 2016;38:94-8. https://doi.org/10.1016/j.genhosppsych.2015.09.005.

14. **Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al.** The REDCap consortium: Building an international community of software platform partners. J Biomed Inform. 2019;95:103208. https://doi.org/10.1016/j.jbi.2019.103208.

15. **Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG.** Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377-81. https://doi.org/10.1016/j.jbi.2008.08.010.

16. **Weathers FW, Blake DD, Schnurr PP, Kaloupek DG, Marx BP, Keane TM.** The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). Boston, MA: National Center for PTSD; 2013.

17. **Marx BP, Lee DJ, Norman SB, Bovin MJ, Sloan DM, Weathers FW, et al.** Reliable and clinically significant change in the clinician-administered PTSD Scale for DSM-5 and PTSD Checklist for DSM-5 among male veterans. Psychol Assess. 2022;34(2):197-203. https://doi.org/10.1037/pas0001098.

18. **Weathers FW, Litz BT, Keane TM, Palmieri PA, Marx BP, Schnurr PP.** The PTSD Checklist for DSM-5 (PCL-5). Boston, MA: National Center for PTSD; 2013.

19. **Bovin MJ, Marx BP, Weathers FW, Gallagher MW, Rodriguez P, Schnurr PP, et al.** Psychometric properties of the PTSD Checklist for Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (PCL-5) in veterans. Psychol Assess. 2016;28(11):1379-91. https://doi.org/10.1037/pas0000254.

20. **Forkus SR, Raudales AM, Rafiuddin HS, Weiss NH, Messman BA, Contractor AA.** The Posttraumatic Stress Disorder (PTSD) Checklist for DSM–5: A systematic review of existing psychometric evidence. Clin Psychol-Sci Pr. 2022; Advance online publication. https://doi.org/10.1037/cps0000111.

21. **National Center for PTSD.** Using the PTSD Checklist for DSM-5 (PCL-5). Department of Veterans Affairs. https://www.ptsd.va.gov/professional/assessment/documents/using-PCL5.pdf.

22. **Attkisson CC, Greenfield TK.** The UCSF Client Satisfaction Scales: I. The Client Satisfaction Questionnaire-8. In: Maruish ME, editor. The use of psychological testing for treatment planning and outcome assessment 3ed. Mahwah, NJ: Lawrence Erlbaum Associates; 2004. p. 799–811.

23. **Kroenke K, Spitzer RL, Williams JB.** The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606-13. https://doi.org/10.1046/j.1525-1497.2001.016009606.x.

24. **Murphy B, Herrman H, Hawthorne G, Pinzone T, Evert H.** Australian WHOQoL instruments: User's manual and interpretation guide. Melbourne, Australia: Australian WHOQOL Field Study Centre 2000.

25. **Saunders JB, Aasland OG, Bebor TF, de la Fuente JR, Grant M.** Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption II. Addiction. 1993;88(6):791-804.

26. **Yudko E, Lozhkina O, Fouts A.** A comprehensive review of the psychometric properties of the Drug Abuse Screening Test. Journal of Substance Abuse Treatment 2007;32:189-98.

27. **Cornwell BL, Brockmann LM, Lasky EC, Mach J, McCarthy JF.** Primary Care-Mental Health Integration in the Veterans Affairs Health System: Program Characteristics and Performance. Psychiatr Serv. 2018;69(6):696-702. https://doi.org/10.1176/appi.ps.201700213.

28. **Funderburk JS, Shepardson RL.** Recent advances in primary care behavioral health. Current Opinion in Psychology. 2015;5:37-41. https://doi.org/10.1016/j.copsyc.2015.03.015.

29. **Possemato K, Ouimette P, Lantinga LJ, Wade M, Coolhart D, Schohn M, et al.** Treatment of Department of Veterans Affairs primary care patients with posttraumatic stress disorder. Psychol Serv. 2011;8(2):82-93. https://doi.org/10.1037/a0022704.

30. **Newman MG, Szkodny LE, Llera SJ, Przeworski A.** A review of technology-assisted self-help and minimal contact therapies for anxiety and depression: is human contact necessary for therapeutic efficacy? Clin Psychol Rev. 2011;31(1):89-103. https://doi.org/10.1016/j.cpr.2010.09.008.

31. **Cigrang JA, Rauch SA, Mintz J, Brundige AR, Mitchell JA, Najera E, et al.** Moving effective treatment for posttraumatic stress disorder to primary care: A randomized controlled trial with active duty military. Fam Syst Health. 2017;35(4):450-62. https://doi.org/10.1037/fsh0000315.