Using PTSD Coach in primary care with and without clinician support: a pilot randomized controlled trial☆,☆☆

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ABSTRACT

Objective: This study aims to evaluate the feasibility and potential effectiveness of two approaches to using the PTSD Coach mobile application in primary care: Self-Managed PTSD Coach and Clinician-Supported PTSD Coach. This study also aims to gather preliminary data to investigate if clinician support improves the benefits of using PTSD Coach on posttraumatic stress disorder (PTSD) severity and specialty mental healthcare utilization.
Method: Twenty primary care veterans with PTSD symptoms were randomized to either Self-Managed PTSD Coach consisting of one 10-min session providing instructions for application use or Clinician-Supported PTSD Coach consisting of four 20-min sessions focused on setting symptom reduction goals and helping veterans fully engage with application content.
Results: Research procedures and intervention conditions appear feasible as indicated by high rates of assessment and intervention retention and high clinician fidelity and satisfaction. Both treatments resulted in reductions in PTSD symptoms, with 7 Clinician-Supported PTSD Coach and 3 Self-Managed PTSD Coach participants reporting clinically significant improvements. Clinician-Supported PTSD Coach resulted in more specialty PTSD care use postintervention and possibly greater reductions in PTSD symptoms.
Conclusions: Both PTSD Coach interventions are feasible and potentially helpful. The addition of clinician support appears to increase the effectiveness of self-management alone. A larger-scale randomized controlled trial is warranted to confirm these encouraging preliminary findings.

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1. Introduction

Posttraumatic stress disorder (PTSD) is highly prevalent in Veterans Affairs (VA) primary care patients, with an estimated 12% prevalence rate [1,2]. PTSD is associated with significant functional impairment, compromised health, early mortality and substantial economic costs [3–6]. While effective psychotherapies for PTSD are available in specialty mental healthcare settings, patients do not routinely receive them due to limited time, fear of being stigmatized or reluctance to disclose emotional problems [7,8]. Although embedded mental health clinicians are increasingly available in primary care clinics to provide brief problem-focused interventions and facilitate the transition to specialty mental healthcare when warranted, no evidence-based brief

psychotherapies for PTSD that can feasibly be delivered in primary care exist [9]. Consequently, a significant gap exists between need for and access to effective primary care-based PTSD treatment. Innovative technology can help address this gap by increasing access to and engagement in treatment for primary care patients. Smartphones are especially promising as they are now being carried by almost two thirds of U.S. adults with no apparent disparities in use across racial/ethnic and socioeconomic groups [10].

The PTSD Coach mobile application (app) is one such innovative technology that can be used by primary care patients with PTSD. It is an evidence-informed, self-management app that offers psychoeducation on PTSD symptoms and treatment, symptom monitoring, coping skills and links to social support and professional resources [11]. PTSD Coach was developed jointly by the VA and the Department of Defense and has been well received by Veterans with PTSD, with preliminary research suggesting that its use may be associated with improvement in PTSD symptoms [12,13].

Other technology-based self-management programs have also been found to effectively reduce PTSD symptoms (e.g., see Ref. [14]). Thus, having such self-management options available may suit the needs of some primary care patients with PTSD (e.g., those who cannot routinely

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attend appointments or those who are motivated and desire working on their symptoms outside of formal care). Unfortunately, interventions that rely on patient self-management alone, particularly when delivered using technology, are typically underutilized [15]. Technology-based self-help interventions that include clinician support increase treatment utilization and effectiveness [16,17]. Therefore, we have developed a treatment package that combines self-help mobile technology with clinician support: Clinician-Supported PTSD Coach (CS PTSD Coach) [18]. CS PTSD Coach was designed to meet the unique demands of the primary care setting in that it utilizes a stepped-care model providing brief, less intensive treatment to patients and then facilitating transfer to more intensive and specialized treatments for the subset of patients who need stepped-up care.

This study conducted a pilot randomized controlled trial (RCT) evaluating the feasibility of delivering two approaches to using PTSD Coach in primary care: Self-Managed PTSD Coach (SM PTSD Coach) and CS PTSD Coach. There were three aims of the present study. First, we sought to assess the feasibility of research procedures and intervention conditions to inform a future larger-scale RCT. Second, we sought to gather preliminary data on whether a self-management mobile app alone is sufficient to improve outcomes and uptake of mental health referrals. Based on previous studies [12,13], we hypothesized that SM PTSD Coach would lead to improvements in trauma symptoms over time. Finally, we sought to gather preliminary data on whether adding clinician support could intensify these effects. We hypothesized that CS PTSD Coach would lead to greater reductions in PTSD severity and increase mental healthcare utilization compared to SM PTSD Coach.

2. Materials and methods

2.1. Participants

VA primary care patients who screened positive for PTSD on the Primary Care — PTSD screen [19] during routine clinical care were referred to the study by primary care staff. Following referral, study staff conducted a brief phone screen and invited interested individuals to return for an in-person assessment to obtain informed consent and determine eligibility. In order to meet inclusion criteria, individuals had to be enrolled in VA primary care and have significant PTSD symptoms resulting from a military-related trauma as indicated by a PTSD Checklist-Specific (PCL) score of 40 or greater [20,21]. Participants were excluded if they intended to begin PTSD treatment in specialty care before completing study participation, had a gross cognitive impairment or had any of the following in the past 2 months: suicidal attempt or intent, mental health counseling for PTSD outside of VA primary care or a new or change in dosage of any psychotropic medication. This study was approved by the VA medical center institutional review board.

2.2. Procedure

Following written informed consent, participants completed the baseline assessment and eligible participants were then randomized equally to either the SM PTSD Coach or CS PTSD Coach. Randomization was stratified by PCL score (i.e., 40–50, >50) in an attempt to equate the groups on PTSD severity. Participants were offered a study-owned iPod Touch (model A1367, iOS 6) to use for the duration of the study with basic information on how to use it. They could also choose to use a personally owned app-compatible mobile device. Participants completed posttreatment measures at 8 weeks and follow-up measures at 12 and 16 weeks postbaseline and received US$120 for completing all assessments.

2.3. Measures

2.3.1. Feasibility metrics

The number of study referrals received, number of eligible participants enrolled per month and rate of completed follow-up assessments were measured to assess the feasibility of the research procedures. Measures of intervention fidelity included number of sessions attended and number of participants who completed their assigned intervention condition. Clinician fidelity and satisfaction with SM PTSD Coach and CS PTSD Coach were measured with forms created for this study. Clinicians endorsed what items were covered in each session and rated clinician satisfaction, clinician ease of delivery and veteran engagement within each session on a scale from 1 "low" to 5 "high". To assess the feasibility of participant use of PTSD Coach, a nonpublic, research version of PTSD Coach with the capability to capture and store app usage metadata, including times and duration of each episode of use, was used in this study. Objective app use data indicated that the CS PTSD Coach participants had more days of app use compared to SM PTSD Coach participants. However, some participants had technical difficulties with the research version of the app, and they started to use the publically available version instead, which has identical content but did not allow app usage to be collected. Therefore, we know that our objective data only provide a partial picture of app usage so they are not presented in detail and they should be interpreted cautiously.

Metrics of app use were also recorded for CS PTSD Coach participants during sessions 2, 3 and 4 by their clinicians. Clinicians inquired about the number of PCL assessments completed, which Manage categories and Learn topics were used, and if the Support function was accessed. Clinicians viewed the participants app to help gather this information, including using the "Track History" function in Assess and what Manage categories had been saved in "Favorites". Therefore, these data are a blend of participant report and objectively derived information.

2.3.2. PCL-S

This 17-item self-report measure of PTSD symptom severity asks respondents to rate how much they have been bothered by each DSM-IV PTSD symptom in the past month [20]. The PCL-S has good psychometric properties. A cutoff score of 40 was used based on evidence that 36–44 is the optimal range for screening in VA primary care [21]. It was anticipated that this cutpoint would allow participants with troubling PTSD symptoms that may not meet full PTSD diagnostic criteria (i.e., subthreshold PTSD) to participate.

2.3.3. Patient Health Questionnaire-9 (PHQ-9)

This 9-item self-report measure assesses depressive symptoms and has strong psychometric properties [22].

2.3.4. World Health Organization Quality of Life (WHO-QOL) — BREF

This 26-item self-report measure of quality of life (QOL), life satisfaction and personal well-being assesses the broad domains of physical health, psychological health, social relationships and environmental factors (e.g., finances, safety) [23]. This measure has strong psychometric properties. The psychological and social scales were assessed as outcomes measures.

2.3.5. Healthcare utilization

Electronic medical record reviews assessed mental healthcare utilization in terms of referrals made, clinics attended and number of sessions received in the 16-week posttreatment.

2.4. Interventions

Participants received their first intervention session immediately following the baseline assessment. PC-MHI clinicians, including a licensed psychologist, a licensed social worker and a predoctoral psychology intern, delivered both treatment conditions. The first author provided training and supervision to the clinicians. Following each session, clinicians used a fidelity checklist to endorse what treatment components they delivered and rated their ease of delivery and satisfaction with the session content. Participants in the SM PTSD Coach condition received one 10-min session that was guided by a handout detailing

basic information about the app, including its primary features, with images showing where to find each feature. They were not asked to use the app in any particular way or on any particular schedule.

Participants in the CS PTSD Coach condition received four 20-min sessions over 8 weeks focused on instructions for app use, setting PTSD symptom reduction goals and assigning specific PTSD Coach activities for completion between sessions. Session 1 was in-person and sessions 2–4 were in-person or by phone, based on patient preference (24% of all sessions were conducted by phone in this trial). Each session followed a CBT structure (i.e., setting an agenda, checking symptoms, reviewing homework, introducing new material and assigning homework) with content being presented from each of the four core modules of PTSD Coach (i.e., Learn, Self Assessment, Manage Symptoms and Find Support). In a given session, the clinician and participant might listen to a Learn topic, practice a Manage Symptoms tool, review the results of the Self Assessment (i.e., the PCL) and check-in about any support the participant elicited since the previous session. Homework was generated based on the participant's current interests, needs and symptoms and consisted of completing the self-assessment weekly, reviewing one to two Learn topics and using specific Manage tools for their most troubling symptoms daily. A treatment manual provided guidance on session structure.

All participants were offered referrals to additional mental health services post-PTSD Coach treatment. This occurred in the fourth treatment session for CS PTSD Coach participants and at the 8-week assessment for SM PTSD Coach participants. If participants reported significant PTSD symptoms (PCL≥50), they received a recommendation to go to the PTSD specialty clinic. Participants with less serve symptoms were given other treatment recommendations, including continuing to receive primary care-based mental health services. Participant preference ultimately determined what referrals were made.

2.5. Data analyses

Descriptive and summary statistics were used to assess feasibility. Effectiveness analyses applied intention to treat (ITT) principles and used an Estimation Maximization algorithm to impute missing data for participants who did not complete posttreatment assessments. We calculated within group and group by time effects for (1) PTSD severity, (2) depression severity, (3) psychological QOL and (4) social QOL. Cohen's d effect sizes were calculated by subtracting the posttreatment mean from the baseline mean then dividing by the standard deviation of that condition's baseline mean. Group by time effect sizes were calculated using the following equation: [(CS PTSD Coach baseline mean−posttreatment mean)−(SM PTSD Coach baseline mean−posttreatment mean)]/standard deviation of the pooled change scores. This pilot study was not powered to detect significant statistical differences; however, 2×2 (group×time) repeated-measures ANOVA tests were performed to explore potential differences between treatment conditions. Effect sizes (φ) were also calculated for the comparisons between SM PTSD Coach and CS PTSD Coach participants on percentage who (1) experienced a clinically significant change in PTSD symptoms, (2) accepted mental health referrals, (3) attended any mental health services posttreatment and (4) attended PTSD-focused mental health services posttreatment. Pearson's chi-squared significance tests were performed for these comparisons.

3. Results

Twenty eligible veterans were randomized to the study conditions. Participants were predominantly male ($n=19$, 95%), with an average age of 42 years ($SD=12$). Sixty-five percent ($n=13$) were White and 45% ($n=9$) were employed. Most participants ($n=18$, 90%) had served in Iraq and/or Afghanistan. Fig. 1 provides details on study referrals, enrollment, treatment allocation and follow-up rates. Given that our target population was veterans with PTSD who were not currently seeking any mental health treatment, we knew that many referred veterans would
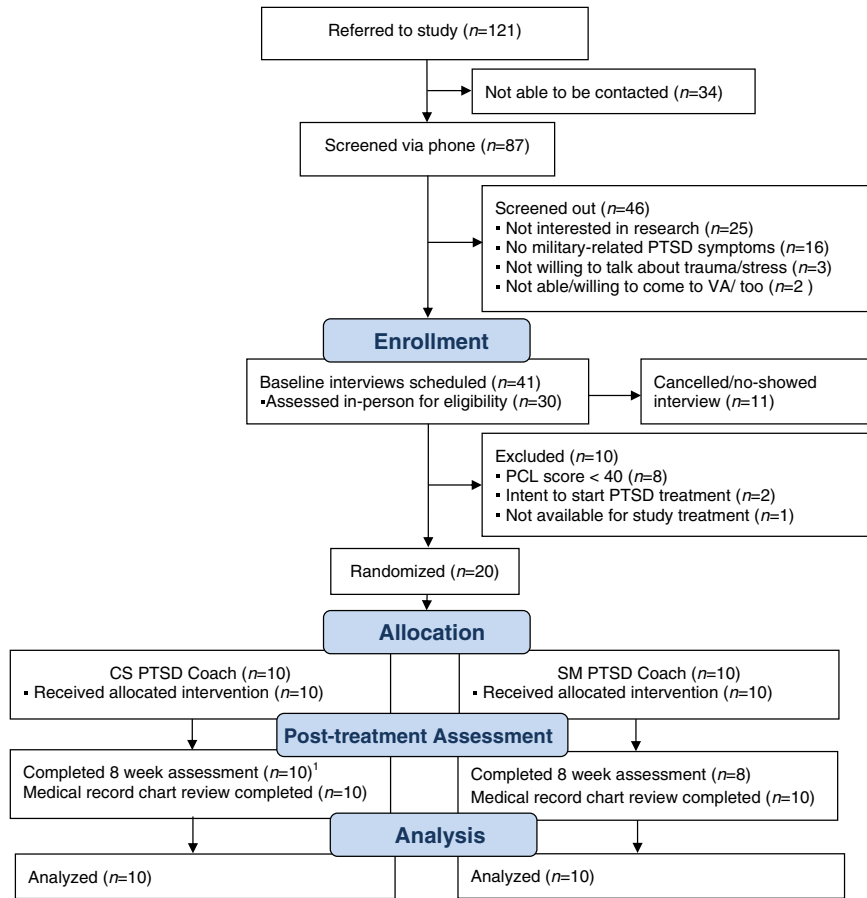
not be interested in participating in a mental health treatment study. Therefore, recruitment efforts casted a wide net to account for low interest among potential recruits. Participants were recruited over 4 months, averaging 5 enrolled and eligible participants per month. All participants completed every treatment sessions (i.e., 1 session of SM PTSD Coach or 4 sessions of CM PTSD Coach). Retention in study assessments was also high with 80% ($n=8$) of participants in the SM PTSD Coach condition and 100% ($n=10$) in the CS PTSD condition completing posttreatment assessments. The fidelity checklists completed by clinicians support delivery of high-fidelity treatment: more than 99% of required elements were endorsed across conditions. Clinicians reported high satisfaction (average: 4.5/5) and ease of delivery (average: 4.6/5) and good veteran engagement (average: 4.0/5) across sessions and conditions. App usage among CS PTSD Coach participants was high over the 8 weeks of active study treatment. On average, participants completed 5.1 ($SD=1.9$, range=1–8) PCL assessments and 11.7 ($SD=6.2$, range=4–22) Learn topics, and they utilized 5.3 ($SD=2.7$, range= 3–8) Manage categories. Multiple Manage strategies were used within each category with "Worried/Anxious", "Angry", and "Avoiding Triggers" being the most commonly used categories. Participants were asked to use at least one Manage strategy daily. One participant used strategies daily for all 8 weeks, 5 had daily use for 4 weeks, 3 had daily use for 2 weeks and 1 reported no daily use. Five participants used the Find Support materials sometime during the study.

Table 1 displays means and standard deviations for PTSD, depression and QOL outcomes at baseline and posttreatment, as well as within and group by time effects size estimates and significance tests. The mean change between conditions was calculated by subtracting the mean change from one condition from the mean change from the other condition for each outcome. The between-group mean along with 95% confidence intervals around this mean are also displayed in Table 1. Participants in both treatment conditions experienced a statistically significant decline in PTSD symptoms from pretreatment to posttreatment. While PCL scores for the CS PTSD Coach condition decreased more than those of the SM PTSD Coach condition, there was not a statistically significant group by time difference. A medium group by time effect size was observed for change in PTSD symptoms; however, the effect sizes for the symptom change outcomes must be interpreted along with the confidence intervals around the observed between-group change. Seventy percent of CS PTSD Coach participants demonstrated clinically significant improvement in PCL scores (i.e., a decrease of ≥10) compared to 38% ($n=3$) of SM PTSD Coach participants (Table 2). Group by time effect sizes for changes in depression, psychological QOL and social QOL were small ($d=.09$), medium ($d=.59$) and large ($d=1.46$), respectively; however, the social QOL effects must be interpreted cautiously because baseline differences between conditions were present. Limiting analyses to those who completed the follow-up assessment ($n=18$) produced the same magnitude of effect sizes for each outcome as the ITT analyses.

Table 2 presents rates of postintervention referral acceptance and treatment utilization by treatment condition, as well as tests of whether the conditions significantly differed at posttreatment. CS PTSD Coach participants were significantly more likely to accept a referral for mental health treatment compared to SM PTSD Coach participants, equating to a large effect size ($\varphi=.66$). CS PTSD Coach participants were also more likely to attend at least one additional mental health session and at least one session focused on PTSD treatment, but only the difference in PTSD session attendance was statistically significant. Since the majority of participants sought specialty mental healthcare following the PTSD Coach intervention, 12- and 16-week follow-up assessment scores are not reported, as these are likely to be more reflective of the care they received following the research intervention.

4. Discussion

The study found support for the feasibility and potential effectiveness of using PTSD Coach in primary care with and without clinician

Referred to study (*n*=121)

Not able to be contacted (*n*=34)

Screened via phone (*n*=87)

Screened out (*n*=46)
- Not interested in research (*n*=25)
- No military-related PTSD symptoms (*n*=16)
- Not willing to talk about trauma/stress (*n*=3)
- Not able/willing to come to VA/ too (*n*=2)

Enrollment

Baseline interviews scheduled (*n*=41)
- Assessed in-person for eligibility (*n*=30)

Cancelled/no-showed interview (*n*=11)

Excluded (*n*=10)
- PCL score < 40 (*n*=8)
- Intent to start PTSD treatment (*n*=2)
- Not available for study treatment (*n*=1)

Randomized (*n*=20)

Allocation

CS PTSD Coach (*n*=10)
- Received allocated intervention (*n*=10)

SM PTSD Coach (*n*=10)
- Received allocated intervention (*n*=10)

Post-treatment Assessment

Completed 8 week assessment (*n*=10)[1]
Medical record chart review completed (*n*=10)

Completed 8 week assessment (*n*=8)
Medical record chart review completed (*n*=10)

Analysis

Analyzed (*n*=10)

Analyzed (*n*=10)

Note: [1] One participant completed only the PTSD Checklist at the 8-week follow-up. His data for the other assessments at the 8-week follow-up was imputed.

Fig. 1. Consort diagram. Note: [1]One participant completed only the PTSD checklist at the 8-week follow-up. His data for the other assessments at the 8-week follow-up was imputed.

support. Thirty-eight percent of participants who engaged in SM PTSD Coach experienced significant reductions in PTSD symptoms and 40% went on to seek additional mental health treatment. Our lack of a "treatment as usual" control group does not allow us to know if these gains represent an improvement from typical primary care services; however, it appears that the use the PTSD Coach app is associated with positive patient-level outcomes. Our data suggest that the addition of clinician support to a self-management mobile app may improve patients' outcomes and access to and utilization of mental health services. Seventy percent of participants with clinician support experienced significant reductions in PTSD symptoms and 70% went on to seek additional mental health treatment. Clinician support appeared to facilitate high engagement in the treatment process as evidenced by frequent app use and more patient interest in pursuing additional treatment. These findings are consistent with the Supportive Accountability Model that argues that clinician support increases intervention adherence through accountability to a clinician who is seen as trustworthy, helpful and experienced [24]. CS PTSD Coach may strike a good balance between the convenience and self-autonomy offered by mobile interventions and the support and guidance offered through brief primary care-based treatment.

These results offer promise for the advancement of delivering PTSD services in the context of primary care and warrant a larger-scale RCT to support the effectiveness of using PTSD Coach in this setting. CS

Table 1
Effects of SM PTSD Coach and CS PTSD Coach on PTSD, depression and QOL.

Measure	Condition	Baseline	Posttreatment	Preeffects/posteffects		Group×time effects		
		M (SD)	M (SD)	Effect size d	Significance test t test (df), P	Between-group change M (95% CI)	Effect size d	Significance test F(df), P
PCL (PTSD)	SM	56.0 (15.3)	49.8 (18.1)	.41	2.8 (9), P=.02	−4.8 (−9.7 to 4.1)	.54	F(1,18)=.93 P=.30
	CS	51.0 (7.7)	40.0 (10.9)	1.4	5.4 (9), P≤.01			
PHQ-9 (Depression)	SM	11.3 (9.7)	8.7 (8.3)	.27	1.7 (9), P=.12	.4 (−3.5 to 4.3)	.09	F(1,18)=.05 P=.83
	CS	11.6 (6.7)	9.4 (5.5)	.33	1.9 (9), P=.09			
WHO-QOL Psychological	SM	57.3 (23.2)	57.3 (24.6)	.00	-.03 (9), P=.98	6.4 (−4.6 to 17.3)	.59	F(1,18)= 1.5 P=.21
	CS	51.7 (12.0)	58.1 (12.0)	.28	−1.8 (9), P=.11			
WHO-QOL Social	SM	63.3 (29.2)	52.6 (25.5)	.37[a]	2.0 (9), P=.07	21.0 (7.5–34.4)	1.46	F(1,18)= 11 P≤.01
	CS	37.5 (19.7)	47.7 (16.1)	.52	−2.0 (9), P=.02			

Notes: SM, SM PTSD Coach; CS, CS PTSD Coach; d, Cohen's d.
[a] This effect represents a worsening of Social QOL.

Table 2

Effects of SM PTSD Coach and CS PTSD Coach on clinically significant change in PTSD severity and healthcare utilization.

Measure	Condition	Posttreatment		Group effect	
		n	%	Effect size φ	Significance test x^2 (df), P
Clinically significant	SM	3	37.5	.33	$x^2(1,18)=1.9$
PTSD change	CS	7	70		$P=.17$
Accepted MH referral	SM	2	25	.66	$x^2(1,18)=7.9$
	CS	9	90		$P\leq.01$
Attended any MH	SM	4	40	.30	$x^2(1,20)=1.8$
treatment	CS	7	70		$P=.18$
Attended PTSD	SM	1	10	.61	$x^2(1,20)=7.5$
treatment	CS	7	70		$P\leq.01$

Notes: SM, SM PTSD Coach; CS, CS PTSD Coach.

PTSD Coach is a manualized treatment that can be easily disseminated to PC-MHI clinicians, is feasible to deliver to primary care patients and is likely to be appealing to individuals with PTSD given the balance between patient autonomy and, if desired, clinician support. CS PTSD Coach was effective in increasing mental healthcare utilization by all indicators, with the largest effect found for PTSD-focused treatment. This may be because the symptom-focused treatment increased patients' recognition of their problems and knowledge about PTSD treatment options. While all participants were offered referrals for additional mental health treatment, those who received CS PTSD Coach also engaged in a discussion about overcoming any barriers to pursuing additional treatment with their clinician. CS PTSD Coach may serve as an introduction to mental health treatment; if this introduction is favorable, patients may be more likely to seek additional treatment. This is important, as previous research has found that veterans who are diagnosed with PTSD in primary care are less likely to attend additional mental health visits than those who are diagnosed in mental health clinics [25].

As a pilot study primarily intended to assess feasibility of using PTSD Coach in primary care, conclusions regarding the effects of the intervention are preliminary, as they are limited by the small sample, lack of clinician-administered outcome measures and objective use data of questionable validity. Our small sample size decreases confidence in our effect size estimates; thus, these must be viewed as preliminary [26]. Strengths include the use of a treatment manual, randomized assignment to condition and testing in a real-world, practical setting. In conclusion, PTSD Coach appears to be a promising intervention that can be delivered in primary care with and without clinician support. Adding clinician support appears to increase the effectiveness of the self-management mobile app in terms engagement in PTSD specialty care and possibly leads to greater reductions in PTSD symptoms compared to using the app alone. Based on these encouraging findings, planning for a full-scale RCT trial is now underway.

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