

BRIEF REPORT

A Randomized Controlled Trial of a Smartphone App for Posttraumatic Stress Disorder Symptoms

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Objective: Posttraumatic stress disorder (PTSD) is highly prevalent in the population, but relatively few affected individuals receive treatment for it. Smartphone applications (apps) could help address this unmet need by offering sound psychoeducational information and evidence-based cognitive behavioral coping tools. We conducted a randomized controlled trial to assess the efficacy of a free, publicly available smartphone app (PTSD Coach) for self-management of PTSD symptoms. **Method:** One hundred 20 participants who were an average of 39 years old, mostly women (69.2%) and White (66.7%), recruited primarily through online advertisements, were randomized to either a PTSD Coach ($n = 62$) or a waitlist condition ($n = 58$) for 3 months. Web-administered self-report measures of PTSD, PTSD symptom coping self-efficacy, depression, and psychosocial functioning were conducted at baseline, posttreatment, and 3 months following treatment. **Results:** Following the intent-to-treat principle, repeated-measures analyses of variance (ANOVAs) revealed that at posttreatment, PTSD Coach participants had significantly greater improvements in PTSD symptoms ($p = .035$), depression symptoms ($p = .005$), and psychosocial functioning ($p = .007$) than did waitlist participants; however, at posttreatment, there were no significant mean differences in outcomes between conditions. A greater proportion of PTSD Coach participants achieved clinically significant PTSD symptom improvement ($p = .018$) than waitlist participants. **Conclusion:** PTSD Coach use resulted in significantly greater improvements in PTSD symptoms and other outcomes relative to a waitlist condition. Given the ubiquity of smartphones, PTSD Coach may provide a wide-reaching, convenient public health intervention for individuals with PTSD symptoms who are not receiving care.

What is the public health significance of this article?

There is a tremendous unmet need for care among trauma survivors with posttraumatic stress symptoms. This randomized controlled trial suggests that a self-management mobile app may be an efficacious intervention that can reduce PTSD and depression symptom severity and improve psychosocial functioning to help address this unmet need in the population.

Keywords: posttraumatic stress disorder, PTSD, mobile phone intervention, mobile apps, smartphone

Supplemental materials: <http://dx.doi.org/10.1037/ccp0000163.supp>

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Posttraumatic stress disorder (PTSD) is common, with an estimated lifetime prevalence of 6.8% in the United States (Kessler et al., 2005). Many others experience significant symptoms but do not meet the diagnostic criteria, termed *partial*, *subclinical*, or *subthreshold* PTSD (Brancu et al., 2016). PTSD exacts a heavy toll in terms of compromised emotional well-being, interpersonal challenges, and productivity loss (Kessler, 2000) and thus is a significant public health problem.

Evidence-based PTSD treatments exist (Foa, Keane, Friedman, & Cohen, 2009), but their availability is limited (e.g., Shiner et al., 2013). In fact, few with PTSD receive any mental health care (Wang et al., 2005). Reasons for this include logistical concerns (e.g., cost) and beliefs about treatment seeking, such as worrying about what others might think and believing that one should handle it on one's own (Kessler, 2000; Vogt, 2011). Furthermore, younger and ethnic minority individuals are less likely to seek care (Gavrilovic, Schützwohl, Fazel, & Priebe, 2005). Lastly, in many areas, there are not enough mental health professionals to meet the need (Kazdin & Rabbitt, 2013).

Thus, alternative approaches are needed, especially population-level interventions. Smartphones are ideal for delivering such interventions, as they are carried by 68% of U.S. adults (Anderson, 2015). Ownership is higher in some populations with underserved mental health needs (e.g., young adults), and no apparent disparities exist in ownership among minority groups, including Black and Hispanic individuals (Anderson, 2015). Furthermore, ownership among those with mental health issues mirrors that of the general population, and these individuals desire to use smartphones to address mental health needs (Torous, Friedman, & Keshavan, 2014).

To capitalize on this potential, the U.S. Department of Veterans Affairs and Department of Defense built the PTSD Coach app (Hoffman et al., 2011; Kuhn et al., 2014). PTSD Coach provides high-quality psychoeducation, PTSD symptom assessment using the PTSD Checklist—Civilian (PCL-C; Weathers, Litz, Herman, Huska, & Keane, 1993), evidence-informed self-management tools (e.g., relaxation exercises, stress inoculation training, and grounding), and convenient access to supportive others and professional resources. It is not intended to replace professional care, if needed, but is instead designed to improve health literacy, provide strategies for coping with PTSD symptoms, and provide strategies for managing acute distress. It is available for free in both the iOS (Apple) and Android app marketplaces.

Evidence is accumulating regarding the benefits of using smartphones to address mental health issues (Donker et al., 2013), but the extant research suffers from methodological shortcomings, including small samples, lack of control conditions and follow-up data, and little research focusing on PTSD. In preparation for the trial, we conducted a pilot randomized controlled trial (RCT) of PTSD Coach, demonstrating its feasibility and acceptability (Miner et al., 2016). Its efficacy was inconclusive, as the study had a small sample ($N = 49$) and a 1-month treatment period, resulting in a small estimated treatment effect (i.e., Cohen's $d = 0.25$). Therefore, for the current study, we hypothesized that participants randomized to 3 months using PTSD Coach would achieve significantly greater improvements in PTSD symptom severity (primary outcome) and PTSD symptom coping self-efficacy (SE), depression severity, and psychosocial functioning (secondary outcomes) than those assigned to a waitlist condition. In addition, we

hypothesized that treatment effects would be maintained at 3-month follow-up.

Method

Participants

One hundred twenty adults met eligibility criteria, consented, and were randomized. Eligibility criteria included being 18 years old or older, being fluent in English, owning a mobile device capable of using PTSD Coach, having been exposed to a traumatic event more than 1 month ago, scoring 35 or greater on the PCL-C (Weathers et al., 1993), and not currently being in PTSD treatment.

Procedure

Study procedures were approved by Stanford University's Institutional Review Board. Enrollment began in February 2014, and data collection ended in May 2015. Recruitment occurred through advertisements about a study of an app for trauma survivors with PTSD symptoms using flyers ($n = 16$), media coverage ($n = 10$), social media ($n = 22$), and Craigslist ($n = 72$). Screening for eligibility occurred via an online questionnaire ($n = 189$) or phone ($n = 131$). Eligible individuals were e-mailed an online survey link (using Qualtrics) to a site where they provided informed consent and then completed the baseline assessment. Thereafter, they were randomized to conditions by the study coordinator using adaptive randomization, with the probability of condition assignment changing based on the assignment of participants already in the trial using www.randomizer.com. Three and 6 months later, they were e-mailed links to the posttreatment and follow-up assessments, respectively. They received \$75 in major retail store gift cards for completing the three assessments. Figure 1 presents a flowchart of participants through the study.

Measures

Primary outcome measure. PTSD symptoms were assessed with the PCL-C (Weathers et al., 1993), a 17-item self-report measure of *DSM-IV* PTSD symptoms (American Psychiatric Association, 1994) with strong psychometric properties (Wilkins, Lang, & Norman, 2011). Items are rated on how much the symptom bothered the respondent in the past month on a scale ranging from 1 (*not at all*) to 5 (*extremely*), with the sum score ranging from 17 to 85 providing a symptom severity rating.

Secondary outcome measures. PTSD symptom coping SE was assessed with a nine-item self-report measure developed for the study following Bandura's (2006) guidelines. Items assess confidence in managing PTSD symptoms and reaching out for support on a scale from 0 (*cannot do at all*) to 100 (*highly certain can do*). The average score provides an overall measure of SE. Cronbach's alpha at baseline was .87. Depression was assessed with the Patient Health Questionnaire Depression Scale (PHQ-8; Kroenke et al., 2009), an eight-item self-report measure of depression with evidence showing its ability to measure depression symptom severity and potential diagnosis. Items are rated on how much the symptom bothered the respondent in the past 2 weeks on a scale ranging from 0 (*not at all*) to 3 (*nearly every day*). Total scores can range from 0 to 24. Cronbach's alpha at baseline was

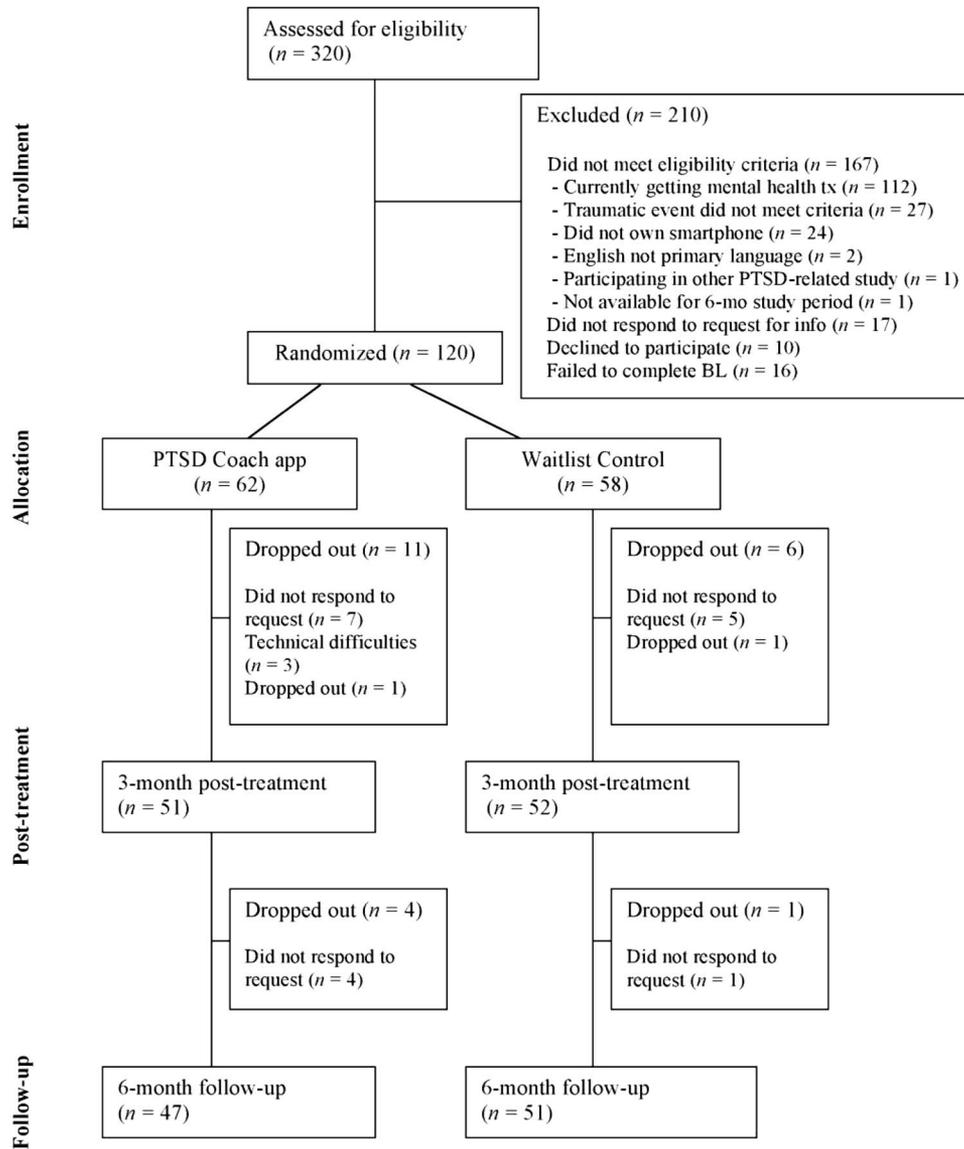


Figure 1. Flowchart of participants through the trial. Tx = treatment; BL = baseline.

.87. Psychosocial functioning was measured using the Brief Inventory of Psychosocial Functioning (B-IPF; Erb et al., 2015), a seven-item self-report measure. Items are rated on how much trouble the respondent had in the past month in relationships or other important areas of functioning (e.g., work, training, or education) on a scale ranging from 0 (*not at all*) to 6 (*very much*). An average of applicable items provides an index of psychosocial functioning. Cronbach's alpha at baseline was .82.

Other measures. The baseline survey included items about gender, age, race and ethnicity, education, and income. It also included the Life Events Checklist (Weathers, Keane, & Davidson, 2001) to assess direct exposure (i.e., *happened to me* and *witnessed*) to 17 types of traumatic events. During screening, potential participants described a traumatic event that caused them the most current distress, which was used as the index trauma for the

PCL-C. At posttreatment, participants were asked if they received any professional treatment for PTSD. The iOS research version of PTSD Coach enabled objective monitoring of app use. All user behavior in the app (e.g., pages visited) was logged. Average days used per week (with any app activity qualifying as a day of use) served as the measure of objective app use. Technical problems prevented capture of usage data for the Android version. Self-reported usage data were collected using the following question: *On average, how many days per week did you use the app?* Response options ranged from 0 to 7 days.

Conditions

PTSD Coach condition participants were instructed to download the app and use it however they would like in an attempt to mimic

real-world use. Users of iOS devices ($n = 33$) downloaded the research version from a password-protected website and were informed that their app use would be monitored. Android device users were asked to identify an alternative iOS device ($n = 3$), were lent an iPod touch (Model A1367, iOS 4.3; $n = 2$), or were asked to download the app from the Google Play Store ($n = 24$). PTSD Coach is a skills-based, nontrauma-focused intervention that includes four major sections: Learn, Self Assessment, Manage Symptoms, and Find Support. In the Learn section, information on trauma, PTSD, and treatment options is provided. In the Manage Symptoms section, users can practice cognitive behavioral therapy (CBT)-based tools for PTSD-related symptoms (e.g., progressive muscle relaxation, stress inoculation training for managing trauma triggers). In the Self Assessment section, users can complete assessments, schedule future assessments, and view past assessments of their PTSD symptoms using the PCL-C (Weathers et al., 1993). Finally, the Find Support section allows users to connect with their own personal contacts and crisis and emergency services (e.g., the National Suicide Prevention Lifeline, 911). The app allows personalization by offering users the ability to incorporate their own music, photos, and contacts into tools within the app. (For a more thorough description of PTSD Coach, please see the supplemental material.)

Waitlist participants received no intervention during the treatment period. After the posttreatment assessment, they were told that the app being studied was PTSD Coach, that the app was available in the App Store and Google Play Store, and that they were now free to download and use it if they would like.

Data Analyses

Using SPSS 21, repeated-measures analyses of variance (ANOVAs) were conducted to assess the Condition \times Time (baseline to posttreatment) interaction effects covarying report of PTSD treatment. Following the intent-to-treat principle, data from all randomized participants were analyzed, and multiple imputation was used to replace missing values, with 10 imputed data sets being generated. Averages of descriptive and inferential statistics computed across these data sets are presented. Cohen's d s were calculated by dividing the between-group mean difference from baseline to posttreatment by the baseline-pooled standard deviation. Clinical significance was set as a decrease of 10 or more points on the PCL-C (Monson et al., 2008), and a chi-square test assessed the difference between conditions in the proportions meeting this threshold. A power analysis using G*Power 3 software (Faul, Erdfelder, Lang, & Buchner, 2007) indicated that to achieve 80% power to detect an effect size in the magnitude (i.e., $d = 0.25$ – 0.33) of that evidenced in our pilot study (Miner et al., 2016) with an alpha of .05 and a correlation between repeated measures of .5, 60 participants per condition would be needed. We hypothesized that extending the intervention period from 1 to 3 months would increase the treatment effect, resulting in even greater power.

Results

Table 1 provides sample characteristics. No significant between-group differences were found on any of the outcomes at baseline (see Table 2) except the B-IPF, $t(118) = 2.60$, $p = .009$. There

Table 1
Baseline Characteristics by Group

Characteristics	PTSD Coach ($n = 62$)		Waitlist ($n = 58$)	
	n/M	%/SD	n/M	%/SD
Female	46	74.2	37	63.8
Age	39.43	15.16	39.12	14.08
Ethnicity				
White	41	66.1	39	67.2
African American or Black	9	14.5	10	17.2
Asian	7	11.3	2	3.4
Hispanic	13	21.0	7	12.1
American Indian or Alaskan Native	2	3.2	2	3.4
Asian Indian	0	.0	0	.0
Pacific Islander	2	3.2	0	.0
Other	0	.0	2	3.4
Education				
Less than high school	2	3.2	0	.0
High school graduate	6	9.7	6	10.3
Some college	28	45.2	25	43.1
College graduate	13	21.0	14	24.1
Some graduate school	6	9.7	3	5.2
Graduate degree	7	11.3	10	17.2
Income				
<\$25,000	28	45.2	25	43.1
\$25,000–\$49,000	12	19.4	15	25.9
\$50,000–\$74,999	12	19.4	8	13.8
\$75,000–\$99,999	4	6.5	8	13.8
\$100,000–\$124,999	4	6.5	0	.0
\$125,000–\$149,999	0	.0	0	.0
\$150,000+	2	3.2	2	3.4
Index trauma				
Physical assault	31	50.0	25	43.1
Sexual assault	10	16.1	7	12.1
Serious accident	16	25.8	9	15.5
Life-threatening illness or injury	1	1.6	6	10.3
Disaster exposure	0	.0	3	5.2
Combat exposure	2	3.2	2	3.4
Other event	2	3.2	6	10.3
Time since index trauma (years)	9.88	11.59	9.77	10.22
Lifetime trauma exposure ^a				
Physical assault	55	88.7	49	84.5
Sexual assault	48	77.4	39	67.2
Serious accident	50	80.6	45	77.6
Life-threatening illness or injury	36	58.1	36	62.1
Disaster exposure	48	77.4	41	70.7
Combat exposure	5	8.1	3	5.2
Other event	59	95.2	52	89.7
Number of traumatic event types	8.95	3.39	8.10	3.60
Probable PTSD diagnosis ^b	57	91.9	54	93.1

Note. PTSD = posttraumatic stress disorder.

^a The 17 Life Events Checklist trauma types were summarized into seven categories to simplify presentation. ^b Probable PTSD diagnosis is based on the PTSD Checklist—Civilian at baseline using DSM-IV symptom criteria, with a symptom being positive if endorsed at moderately or greater.

was no significant difference, $\chi^2(1, N = 120) = 1.348$, $p = .246$, in proportion of dropouts at posttreatment between the PTSD Coach (17.7%, $n = 11$) and waitlist (10.3%, $n = 6$) conditions.

Table 2 presents the means of the outcomes across time points. For all outcomes except PTSD symptom coping SE, there was a significant Condition \times Time interaction (see Figure 2) while covarying receipt of PTSD treatment ($n = 4$ in each condition). For the PCL-C, the PTSD Coach condition had a greater reduction

Table 2
Between-Condition Comparisons of Primary and Secondary Outcomes Using Imputed Data

Measure	Condition	Time			Condition × Time interaction (Cohen's <i>d</i>)
		Baseline <i>M</i> (<i>SD</i>)	Posttreatment <i>M</i> (<i>SD</i>)	Follow-up <i>M</i> (<i>SD</i>)	
Primary outcome					
PCL–C	PTSD Coach (<i>n</i> = 62)	63.19 (11.78)	51.93 (14.04)	49.15 (13.94)	.41*
	Waitlist (<i>n</i> = 58)	60.59 (10.24)	53.90 (13.78)		
Secondary outcomes					
PTSD coping SE	PTSD Coach (<i>n</i> = 62)	49.63 (19.28)	56.09 (18.35)	58.12 (21.06)	.25
	Waitlist (<i>n</i> = 58)	50.77 (19.10)	52.36 (19.16)		
PHQ–8	PTSD Coach (<i>n</i> = 62)	15.06 (6.36)	11.03 (5.29)	9.57 (5.08)	.45**
	Waitlist (<i>n</i> = 58)	13.62 (5.55)	12.31 (5.88)		
B–IPF	PTSD Coach (<i>n</i> = 62)	3.85 (1.55)	2.86 (1.47)	2.78 (1.66)	.51**
	Waitlist (<i>n</i> = 58)	3.15 (1.40)	2.91 (1.49)		

Note. PCL–C = PTSD Checklist—Civilian; PTSD coping SE = posttraumatic stress disorder symptom coping self-efficacy; PHQ–8 = Patient Health Questionnaire Depression Scale; B–IPF = Brief Inventory of Psychosocial Functioning.

p* < .05. *p* < .01.

than did the waitlist condition, $F(1, 117) = 4.55, p = .035$, and means did not differ at posttreatment, $t(118) = 0.73, p = .466$. With missing cases considered not to have changed, a higher proportion, $\chi^2(1, N = 120) = 5.64, p = .018$, of PTSD Coach participants (46.8%, $n = 29$) than waitlist participants (25.9%, $n = 15$) had clinically significant improvement. Treatment effects appeared to be maintained based on nonsignificant within-group change from posttreatment to follow-up, $t(61) = 1.61, p = .113$.

For PTSD symptom coping SE, the Condition × Time interaction was not significant, $F(1, 117) = 2.99, p = .086$, and means did not differ at posttreatment, $t(118) = -0.94, p = .350$. For the PHQ–8, the PTSD Coach condition showed more improvement than the waitlist condition, $F(1, 117) = 8.34, p = .005$, and means did not differ at posttreatment, $t(118) = 1.21, p = .227$. For the B–IPF, the PTSD Coach condition had greater improvement than the waitlist condition, $F(1, 117) = 7.63, p = .007$, and conditions did not differ at posttreatment, $t(118) = 0.22, p = .828$. Treatment effects appeared to be maintained based on the within-group change from baseline to follow-up for these latter two measures, PHQ–8: $t(61) = 6.54, p < .001$; B–IPF: $t(61) = 4.10, p < .001$.

PTSD Coach Use

In the PTSD Coach condition, 26 treatment completers used the iOS research version of the app, logging an average of 1.29 days of use per week ($SD = 0.77$), which was significantly correlated, $r = .51, p < .01$, with their self-reported average days used per week ($M = 1.96, SD = 1.46$). Across all 51 PTSD Coach condition completers, the self-reported average days used per week was 2.27 ($SD = 1.76$). Correlations between self-reported use and changes in outcomes were all not significant ($p > .05$).

Discussion

This is the first study to our knowledge that has rigorously evaluated the efficacy of a mobile app for PTSD symptoms. The results support our main hypothesis, showing that 3 months of PTSD Coach use resulted in greater reductions in PTSD symptom severity compared to no intervention and that more PTSD Coach participants achieved clinically significant improvement compared to waitlist par-

ticipants. Improvements shown in the PTSD Coach condition appeared to be maintained at follow-up, although the design precluded testing of between-group effects at that time point. The results also confirm our other hypothesis regarding broader benefits of PTSD Coach for depression symptoms and psychosocial functioning. However, across all outcomes, there were no significant differences in means between conditions evidenced at posttreatment.

Although effects are modest and clearly much smaller than have been found for evidence-based psychotherapies (Foa, Keane, Friedman, & Cohen, 2009), this publicly available free app has vast potential to reach the sizable population of individuals with PTSD symptoms who are not receiving mental health care. The impact of public health interventions has been characterized as the product of their efficacy and reach (Abrams et al., 1996), so the overall impact of PTSD Coach could be quite large, especially if public health campaigns were launched to raise awareness in the population about PTSD and the app.

These initial findings on the efficacy of PTSD Coach contribute to the scant but developing literature supporting the potential of smartphone interventions to help address mental health symptoms. A recent meta-analysis (Lindhiem, Bennett, Rosen, & Silk, 2015) found that smartphone apps demonstrated the most powerful effects relative to other mobile interventions for behavioral health issues, although the superiority of effects was not statistically significant. For PTSD in particular, we were unable to find any RCTs that evaluated a smartphone app other than our own pilot studies of PTSD Coach (Miner et al., 2016; Possemato et al., 2016).

The mechanisms through which PTSD Coach may operate on outcomes are not clear. There was no significant relationship between app use and improvements in outcomes. PTSD Coach was informed by social–cognitive theory, which posits that enhancing skills and social support increases one's confidence to meet challenges, such as managing PTSD symptoms. However, app users did not show greater improvements in PTSD symptom coping SE. Further research is needed to assess if such theoretical targets are actually mediating outcomes.

The current study had several strengths, including adequate power, a control condition, random assignment, a follow-up assessment, and relatively low attrition (i.e., 14%). Despite these, several limitations

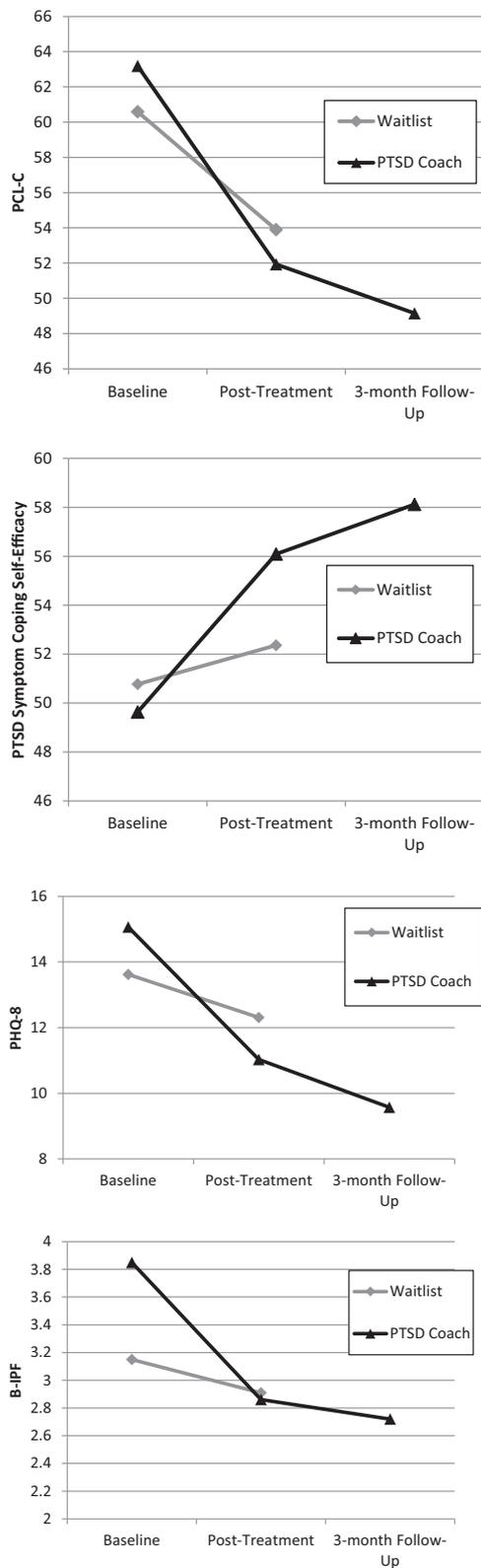


Figure 2. Changes in outcomes. PCL-C = PTSD Checklist—Civilian; PHQ-8 = Patient Health Questionnaire Depression Scale; B-IPF = Brief Inventory of Psychosocial Functioning.

require consideration. First, there was an exclusive reliance on self-report measures, with a couple lacking strong psychometric evidence. Relatedly, a clinical interview was not used to assess PTSD. Second, objective app usage data were not available for all PTSD Coach participants. Although the correlation between the objective and self-reported data was fairly large, there was considerable discrepancy between these data sources. Third, use of a waitlist control did not provide the most stringent comparison (e.g., to control for possible digital placebo effects; Torous & Firth, 2016). Lastly, sample characteristics may limit to whom the findings would apply. Most notably, our sample was composed primarily of individuals who were women, White, and fairly well educated, with a majority reporting an index trauma of interpersonal violence. In addition, most participants were recruited online, possibly skewing our sample to be composed of those who are comfortable using technology. Thus, it is uncertain if the findings would replicate among other populations of trauma survivors (e.g., male combat veterans).

In conclusion, our findings suggest that PTSD Coach holds promise to help address the tremendous unmet need of trauma survivors with PTSD symptoms who are not receiving mental health care. Although PTSD Coach effects would be considered small to medium, the app could be a helpful first step toward recovery for some trauma survivors. PTSD Coach was primarily designed to increase ability to cope with trauma-related distress and not intended to treat PTSD symptoms or replace professional care, but early work suggests that it could have modest positive effects on PTSD and related symptoms. However, it is also clear that the benefits may not be robust enough to serve as the only care step for many with PTSD. Therefore, further development of PTSD Coach is needed to possibly enhance its potency. In addition, future research is required to determine if using PTSD Coach as self-management promotes (or possibly hinders) subsequent treatment seeking. Regardless, given the limited availability of existing treatment options and significant barriers to care at this time, PTSD Coach could help fill a gap that to date has not been adequately addressed.

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Received January 21, 2016

Revision received September 28, 2016

Accepted October 5, 2016 ■