A Seeking Safety Mobile App for Recovery from PTSD and Substance Use Disorder: Results of a Randomized Controlled Trial

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ABSTRACT

Background: Posttraumatic stress disorder (PTSD) and substance use disorder (SUD) co-occur frequently and have deleterious impact. Seeking Safety (SS) – an evidence-based, present-focused, coping skills model – lends itself to mobile app delivery.

Objectives: A novel SS mobile app is compared to a control app that lacks the interactivity, social engagement, and feature-richness of the SS app. We hypothesized that the SS app would outperform the control on primary outcome variables (substance use, trauma symptoms) and at least two secondary variables.

Methods: Outpatients with current PTSD and SUD (n = 116) were randomized to the apps; assessed were pre, post (12 weeks), and 3-month follow-up in this online study.

Results: The SS app outperformed the control on the primary outcomes, but not on secondary outcomes. Also both conditions evidenced significant change over time from pre to post, with gains sustained at follow-up. External medication and supports during the trial did not differ by condition.

Conclusion: This first RCT on a SS mobile app had positive results for reduction in substance use and trauma symptoms compared to a control app. This is noteworthy as mental health mobile apps, in general, evidence few positive outcomes. Our substance use finding is also notable as psychosocial interventions in PTSD/SUD populations find it harder to achieve reduction in SUD than trauma symptoms. Our control app may have represented too strong a comparison and weakened our ability to find results on secondary outcomes by condition.

Keywords: PTSD; substance use disorder; mobile apps; RCT; trauma; Seeking Safety

Background

The desire to escape pain via substance use is common across history and many cultures (Abbott & Chase, 2008). Thus, posttraumatic stress disorder (PTSD) and substance use disorder (SUD) frequently co-occur. Among people seeking SUD treatment, 40% have current PTSD; and of those developing lifetime PTSD, 58% also develop SUD (Simpson et al., 2021). Patients with PTSD and SUD have increased vulnerability compared to those with either alone, including more rapid relapse, more inpatient hospitalization, increased HIV risk, and worse treatment outcomes (Blakey et al., 2022; Najavits et al., 2017). Many experience marginalization and stigma as well.

Seeking Safety (SS), a psychosocial model for PTSD and/or SUD, was developed to help clients work on both disorders at the same time, known as integrated treatment for co-occurring disorders (Najavits, 2002). It is the earliest evidence-based model designed for PTSD/SUD, and the most widely adopted and studied (Najavits et al., 2020). It is a present-focused individual or group cognitive-behavioral approach that teaches coping skills for both disorders, such as Asking for Help, Honesty, Creating Meaning, Healing from Anger, and Coping with Triggers. Moreover, it is highly public health oriented: it can be conducted by anyone regardless of credentials or training, is low cost, and has been used at all levels of care and types of settings. It is available in 14 languages and has shown high satisfaction across genders and among ethnically and socioeconomically diverse clients (Litt et al., 2019; Najavits & Hien, 2013). It has also shown positive outcomes when delivered by peers (Crisanti et al., 2019); and is one of the most cost-effective SUD models (Washington State Institute for Public Policy, 2022). The evidence-base on SS includes pilots, randomized controlled trials (RCTs), and multisite trials (Litt et al., 2019; Najavits & Hien, 2013) and, based on meta-analyses, shows positive results (Lenz et al., 2016; Sherman et al., 2023).

The development of a mobile app for SS is a natural outgrowth than can expand the model’s reach, especially as most
people with PTSD and/or SUD do not engage in professional care (Substance Abuse and Mental Health Services Administration, 2021; Wang et al., 2005); and even those who do often need ancillary supports. A pilot project to create an initial version of the app was completed several years ago with positive results, leading to a recent project to refine the app and conduct an RCT on it. Both the pilot and RCT engaged peers to deliver SS in the context of the app. Peers offer numerous advantages (Crisantini et al., 2019) and are an especially important resource in the current mental health context of too few providers and increasingly high levels of mental health needs.

This article describes the SS app and summarizes the RCT results. We hypothesized that the SS app would outperform the control on the primary outcomes (substance use, trauma symptoms), and on at least two secondary outcomes. These hypotheses were based on the idea that the SS app would be more engaging and thus more likely to directly impact substance use and trauma symptoms.

Materials and methods

Procedure and interventions

This study was approved by the Solutions IRB and all consenting procedures followed ethical guidelines. Participants were randomized to either the SS app or the Control app. Randomization was created on www.sealedenvelope.com and carried out by a research assistant, independent of the investigator. Participants had 12 weeks to use their app, as this number of SS topics has shown positive outcomes in prior studies. Each app is described below.

SS app features

This app takes the content of SS, repackages it, and enhances it for a mobile environment, emphasizing the following.

1. **Community of support.** Participants can share content with their SS app group and/or the entire app community; message others; attend a weekly SS live session via Zoom on the app; connect with a coping coach; share their progress with trusted people outside the app; and engage with app special interest groups.

2. **Rolling content.** Each week a new SS topic launches and the app content changes with it, to keep participants engaged and learning the SS material. The 12 topics in the RCT were Safety; PTSD: Taking Back Your Power; Healthy Relationships; Grounding; Detaching From Emotional Pain; When Substances Control You; Honesty; Setting Boundaries In Relationships; Compassion; Asking For Help; Creating Meaning; Taking Good Care of Yourself; and Red and Green Flags.

3. **Safety-oriented features.** In keeping with the SS focus on safety above all, participants can track their level of safety; explore interactive audio and visual exercises on safety; and get reminders of their weekly SS “commitment” (homework). If any other person’s post is concerning they can flag it for moderation.

4. **Repeated actions.** A benefit of an app is the ability to encourage rehearsal of new skills. The app provides daily and weekly options to keep participants moving forward and creating routines to stay on track.

SS app development

The app was designed in a multi-stage process that included several rounds of iterative feedback from adults who screened positive for current PTSD and SUD. We had a phase 1 pilot that began with focus interviews with 12 adults to identify optimal app features, then developed an initial prototype of the app and evaluated it a feasibility study with 19 adults. In the current project, phase 2, we conducted another round of front end feedback focus interviews with 18 adults, and also obtained a final round of feedback from 18 study participants before finalizing the app. We also obtained developmental feedback from counselors and consultants who were familiar with the SS model.

In terms of technology, the app was originally coded in Unity, which was recommended by our developers. However, after launching the SS app for the RCT there were compatibility problems with some Android phones, especially lower-end models. We thus had the app rebuilt in React Native. It is available on Google Play and the iOS App Store.

Control app

This app offered content from the SS book (the same 12 SS topics as for the SS app) but as flat text rather than the technology-enhanced version of the SS app. The control thus provided content from SS but without the interactivity, social engagement, and feature-richness of the SS app, so as to evaluate whether the SS app provided benefit over and above the content per se. It was built on a “do it yourself” online mobile app platform.

Participants

Participants were recruited via electronic methods (professional listservs, social media). Inclusion criteria were: ages 18–65; outpatient; met criteria for current SUD and current PTSD (the latter full or subthreshold, with the latter defined per Mota et al. (2016); and had a smartphone, either Android or iOS. Exclusion criteria were: current uncontrolled psychotic or bipolar disorder; current suicidality (presence of imminent intent and/or plan); living in a controlled environment restricting substance use (e.g., jail, sober house and residential treatment) or legally required to report substance use (e.g., to probation officer) as these would impact substance use and/or reporting of such. We kept our criteria minimal to obtain a typical SUD/PTSD sample.

Our target sample was 72 (36 per condition) based on power analysis. We calculated effect sizes from three measures in our Phase 1 feasibility study: 0.85 for the CAGE-AID
(Brown & Rounds, 1994), 0.78 for the Coping Self-Efficacy Scale (Chesney et al., 2006), and 0.44 for the Trauma Symptom Checklist-40 (Briere, 1996). Calculated power assumed $d=0.60$ (a medium effect size and approximately the mid-range of our Phase 1 study effect sizes); a one-tailed test (as no study of SS has ever found a negative outcome); 0.05 alpha; 0.80 power; and 1:1 allocation.

Per the CONSORT chart (Figure 1), we met and indeed exceeded our target of 72 analyzable cases. For the intent-to-treat analysis we had $n=116$ (58 per study arm). This analysis was all randomized participants, regardless of assessment completion, using multiple imputation for the 31 participants lost to follow-up (i.e., who did not complete the 12-week end-of-active-phase assessment). We also conducted an assessment-completion analysis (all randomized participants who completed both baseline and the 12-week assessment), which had $n=85$ (38 in the SS app condition, 47 in the control). We conducted both analyses as both met, and in fact exceeded, the target sample based on our power analysis. Note that we recruited more participants than originally planned due to the initial incompatibility of the SS app with some users’ phones, described above.

There were an additional 14 participants not included in either analysis due to data integrity issues, typically filling out so little of a scale that a score could not be calculated. Per our IRB specifications, participants could leave blank any items they did not want to answer.

**Assessment**

Assessments were conducted at screening, baseline, 12 weeks (end of active phase), and 3-month follow-up.

The initial online screen included the CAGE-AID (Brown & Rounds, 1994) to screen for past-year SUD and the PTSD Screen for DSM-5 (Prins et al., 2016). Those passing the screen were invited to do an assessment to verify inclusionary/exclusionary diagnoses using the Structured Clinical Interview for DSM-5 (SCID; First et al., 2016), which was administered by research assistants trained and supervised by the PI. If the SCID confirmed that inclusion/exclusion criteria were met, the participant then completed the

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**Figure 1.** CONSORT flow diagram.
baseline assessment battery (see next paragraph for list of measures).

Primary outcomes were the Brief Addiction Monitor substance use subscale (Cacciola et al., 2013) and the Trauma Symptom Checklist-40 total score (Briere, 1996). Secondary outcomes were the Brief Addiction Monitor risk subscale; and total scores on the BASIS-24 (Eisen, 2004) (functioning), the PTSD Checklist for DSM-5 (PTSD Checklist for DSM-5 (PCL-5), 2013), the Coping Self-Efficacy Scale (Chesney et al., 2006), the Self-Compassion Scale (Neff, 2003), and Centers for Disease Control Healthy Days (Moriarty et al., 2005). App satisfaction was rated on the Mobile App Rating Scale (Stoyanov et al., 2016); and SS satisfaction on the Seeking Safety End of Treatment Questionnaire (Najavits, 2002). App feedback was also obtained on a free-form written measure and, for SS app participants, an optional end-of-study one-hour Zoom feedback interview. The Treatment Services Review (McElhan et al., 1992) quantified concurrent treatments/supports participants used.

All measures were collected on randomized participants regardless of app usage or SS session attendance, i.e., full intent-to-treat design. So too, participants were paid for assessments but not for using their app nor attending SS sessions. Payment occurred at just one timepoint (follow-up) for $90 via amazon.com e-gift card. SS app participants could also receive $25 for the optional one-hour feedback interview. Data collection occurred online for self-report measures; and via phone or Zoom for interview-based measures by research staff with study condition masked.

Peer leaders

As part of the RCT, SS app participants had the option to attend a weekly 1 h SS group during their 12 weeks with the app. These Zoom sessions had up to nine participants per group, delivered by one of two SS peer leaders. The goal of the peer-led sessions was to offer adjunctive support, to encourage use of the SS app, and to reinforce the week’s SS app topic. “Peer” was defined as without formal professional training in mental health or addiction, but with at least one year of recovery from both trauma symptoms and SUD. They were certified in conducting SS prior to the RCT, which involved audio-recorded work samples of sessions, rated by a certified SS trainer on the Seeking Safety Adherence Scale (Weathers, 2013), a fidelity measure.

Data analysis

Sociodemographic and satisfaction data were analyzed with descriptive statistics and frequencies; and for comparing study conditions on these variables, independent samples t-tests or chi squares, depending on data type. We used multiple imputation procedures in SPSS version 29 (SPSS Inc., Chicago, IL) to address missing data so as to include the full intent-to-treat sample; we used the pooled result of 25 imputations. For outcomes, we conducted two-way mixed ANOVAs (all measures were continuous). All variables at all timepoints passed Levene’s test for homogeneity of variance (>0.05). We also evaluated Mauchley’s test of sphericity and for any variable that did not pass, report Greenhouse-Geisser estimates. To minimize Type 1 error we analyzed summary scores rather than subscales (except for the BAM, which does not have a summary score). To further minimize Type 1 error we used Bonferroni correction for simple main effects analyses. We conducted the latter for all outcome variables because our main question was change from pre to post rather than across all three timepoints (participants could use their app only from pre to post). Conducting simple main effects for all variables is consistent with numerous statisticians (e.g., Bernhardson, 1975; Hsu, J, 1996; Maxwell & Delaney, 2004) and also with the exploratory nature of this first study on the SS app. We report the omnibus F test as well even though it does not focus on our main question (pre/post change). Effect sizes (partial eta squared) are interpreted as small 0.01, medium 0.06, and large 0.14.

Results

Sample descriptive data

Our sample was predominantly female (n = 83, 71.6%) with 29 (25%) male, 1 (0.86%) nonbinary, and 3 (2.6%) missing gender information. The sample was 57.8% White and 39.7 nonwhite and 2.6% missing. Nonwhite participants were 28.4% (n = 33) Black, 5.2% (n = 6), Asian, 4.3% (n = 5) more than one race, and 1.7% (n = 2) Native Hawaiian or other Pacific Islander. By ethnicity, 10.3% (n = 12) were Hispanic. The mean age was 33.31 (SD = 11.36). There were no differences between study conditions at baseline on gender, race, ethnicity, or age.

In terms of substance use, at baseline the Brief Addiction Monitor for the past 30 d indicated that the majority of the sample had used alcohol (n = 94) and/or illegal drugs (n = 78). Among those who reported alcohol use, the mean number of days was 16.95 (SD = 9.41). Among those who reported illegal drug use, the mean number of days was 19.03 (SD = 10.01). Breakdown by drug type was marijuana (n = 45; M = 16.26, SD = 11.53); opiates (n = 32, M = 16.01, SD = 10.92); sedatives/tranquilizers (n = 28, M = 13.54, SD = 9.35); cocaine or crack (n = 19, M = 15.33, SD = 10.85); other stimulants (e.g., methamphetamine) (n = 28, M = 20.20; SD = 10.22); inhalants (n = 4, M = 4.53, SD = 0.98); other drug (n = 18, M = 17.42; SD = 13.33). The latter was typically misuse of an over-the-counter or prescribed drug (e.g., benadryl, trazadone, and suboxone); or a hallucinogen (e.g., LSD, mushrooms, ecstasy).

Outcomes

Intent-to-treat analysis

Table 1 provides all intent-to-treat outcome analyses. Results indicate a consistent pattern of the SS app condition outperforming the control.

The primary outcome Brief Addiction Monitor substance use subscale showed the SS app condition significantly
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<th>Table 1. Primary and secondary outcomes.</th>
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Significant results are in bold font.
outperforming the control on the time x condition omnibus F test. Simple main effects by condition were significant in favor of the SS app at post (12 weeks), which, as noted earlier, was our primary focus; also there was a trend at follow-up.

The other primary outcome, the Trauma Symptom Checklist-40 total score was also significant in favor of the SS app on the time x condition omnibus F test. Simple main effects by condition showed SS app participants significantly more symptomatic than the control at baseline, but improved to the same level as the control by post, which indicates greater improvement.

On the secondary outcome Brief Addiction Monitor risk subscale the omnibus time x condition F test was significant in favor of the SS app. Simple main effects by condition were significant in favor of the SS app at both post (12 weeks) and follow-up. All other secondary outcomes showed no difference between conditions.

Effect sizes for condition simple main effects were between small and medium.

Another key pattern was that both conditions significantly improved over time (time simple main effects) on most variables from pre to post and also from pre to follow-up. This pattern occurred on seven of the eight outcome variables. We also found that on all variables gains were sustained from post to follow-up (i.e., no significant decrease from post to follow-up). One measure, Coping Self-Efficacy, actually showed significant increased gains, for the SS app condition only, from post to follow-up. The Brief Addiction Monitor risk subscale showed a trend for increased gains for the control only, from post to follow-up.

**Assessment-completion analysis**

The results for this analysis were consistently the same as for the intent-to-treat analysis above. The only difference that would change interpretation of the results was on the Brief Addiction Monitor substance use scale, where the simple main effects by condition showed post effect size (np) at 0.069 and follow-up at 0.052.

**External treatments**

On the Treatment Services Review SS app and control participants did not differ in amount of medication nor external supports during the study (e.g., counseling, self-help); and these also did not change over time. These findings reinforce that observed outcome results are likely related to the apps.

**Peer session attendance**

There was extremely low attendance of the weekly peer sessions, despite reminders and encouragement to attend. Across 64 sessions held during the project, a mean of 1.75 patients attended per session (SD = 1.59; range 0–6).

**Satisfaction**

On the Seeking Safety End of Treatment Questionnaire, which was completed only by SS app participants, means were strong: on a scale of −3 to +3 (least to most satisfied), means were 1.93 for helpfulness of SS, 1.90 for specific SS aspects, and 1.60 for SS topics.

The Mobile App Rating Scale was completed by both conditions; the total score (scaled 1–5, least to most positive) was moderately strong in both conditions, but not different between them ($M = 3.24, SD = 0.31$ for the SS app; $M = 3.20, SD = 0.30$ for the control).

Participants also provided free-response feedback. Positive examples for the SS app are: "I love the app. I think it can save lives" and "Seeking Safety is what it says it is...it is an app where one can seek safety when they feel unsafe. The peer support, the help with grounding and rating and just letting your feelings out...it helps!" Negative comments on the SS app focused primarily on technology (slow load, phone incompatibility) and esthetics, which we improved on the final version.

**Discussion**

This first RCT on a novel SS mobile app offers some important findings. The SS app outperformed the control app on both primary outcomes (substance use and trauma symptoms), which is what the study was powered to detect and was consistent with our first study hypothesis. Effect sizes were small to medium. We also found that both conditions improved from pre to post and maintained those gains at 3-month follow-up.

Our SS app results are especially notable as the optional weekly peer-led SS group sessions for in this study arm showed extremely low attendance (a mean of 1.75 people per session). This may reflect that our sample preferred a purely solitary experience rather than traditional interactive sessions (i.e., perhaps signed up for the study because the app did not require interaction). Or it could reflect logistics issues such as busy schedules or the often chaotic life circumstances associated with PTSD and SUD. In any event, the low attendance improves the internal validity of our outcomes, i.e., results observed are likely due to the app rather than to the impact of SS group sessions.

A question arises as to whether the control app, which provided content from SS, may have been too strong a comparison and thus weakened our ability to find results by condition on secondary outcomes (thus not confirming our second study hypothesis). The control app being strong on content would also help explain why the control participants improved significantly by time (pre to post) on most measures; and why their satisfaction ratings for the control app were so high on the Mobile App Rating Scale. Lack of statistical power is also relevant in this relatively small-sample study.

A recent meta-analysis of mental health electronic interventions (web-based and/or mobile apps) has found that experimental interventions typically fell short in comparison to a control (Goldberg et al., 2022), especially when control conditions were more rigorous. Questions arise as to whether additional components could boost results, and whether
altering the intensity or timing of the interventions may help. There may also be generational differences in acceptability and impact of mental health mobile apps.

We are heartened by some of the implications of our results. Obtaining a reduction in both substance use and trauma symptoms is a strong finding. Indeed, it is known to be especially difficult to obtain a finding on substance use in trials on PTSD/SUD comorbid patients in behavioral therapy trials, whereas reduction in trauma symptoms is easier to obtain (Najavits et al., 2020). It is also encouraging that the use of peer leaders for weekly sessions was viable. This is consistent with prior literature on peer-led SS (Crisanti et al., 2019; Najavits et al., 2014), but goes further in that in our study all sessions were via telehealth (Zoom) rather than in person. The absence of adverse events, even in a complex sample such as ours with co-occurring PTSD and SUD (and few exclusionary criteria), is notable too. Finally, the study provided useful iterative feedback to improve the app in real-world conditions with typical end users.

In terms of implications for treatment, we can identify several key points. First, the SS app may be especially helpful as a stand-alone app for people who are not interested in traditional interactive treatment. As noted, we had very low attendance at the free peer-led SS sessions that were available to SS app participants (although we do not know enough, based on our data, to understand the reasons so for this). The SS app may also be a very useful adjunctive option for clients who are engaged in SS treatment as the app content and features can reinforce what they are learning in their sessions. Clients’ use of the app can alleviate therapists’ workload, such as providing the SS handouts and going over key concepts, thus allowing more time in session to explore the material in light of clients’ current issues. Second, people with PTSD and SUD are a vulnerable population. It is important to address their needs with as many resources as possible. This may include the SS app as well as referral to additional services of all kinds to promote recovery. No one resource is sufficient; instead the goal is to encourage as much supportive care as possible of all types. Third, special attention may be warranted for those who are especially marginalized. PTSD and SUD can create significant isolation and incur notable stigma and judgments by people who do not understand how these disorders develop and continue over time. People with PTSD and SUD often encounter others not understanding their experience or judging them (“Why don’t you just stop drinking?”), which can turn into self-stigma and self-judgment. A major aspect of the SS app is to empower people with PTSD and SUD to develop greater compassion for their experience and to develop a network of supports.

Nonetheless, we are aware of the study limitations and the need for future research. Hopefully future studies will have a higher sample size, especially to detect secondary outcomes; will offer a longer course of SS as longer doses of care produce stronger outcomes in SUD treatment (only 12 of the 25 SS topics were used in the current study); and will explore mechanisms of action to better understand what facets of the app are most helpful. It would also be helpful to identify what subtypes of people with PTSD and SUD are most likely to benefit from the SS app.

**Declaration of interest**

Dr. Najavits is director of Treatment Innovations, which provides training, consultation, and materials related to behavioral therapies, including the Seeking Safety model that she developed and for which she receives book royalties from Guilford Press. All other authors have no competing interests to declare.

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**References**


