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Development of a mobile mindfulness smartphone app for post-traumatic stress disorder and alcohol use problems for veterans: Beta test results and study protocol for a pilot randomized controlled trial

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Abstract

Background.—Post-traumatic stress disorder (PTSD) and alcohol use disorder (AUD) are highly prevalent, and co-occurring among post-9/11 veterans. Mobile health (mHealth) applications, specifically those focused on mindfulness-based techniques, may be an effective avenue to intervene with veterans who cannot or will not seek care at traditional in-person settings. Thus, to address areas of improvement in mHealth for veterans, we developed Mind Guide and prepared it for testing in a pilot randomized controlled trial (RCT) with veterans.

Methods.—We have completed phase 1 (treatment development) and Phase 2 (beta test) of our mobile mHealth app, Mind Guide. In this paper we describe the methods for Phase 1 as well as results for our beta test (n = 16; inclusion criteria included screen for PTSD, AUD, a post-9/11 veteran, and not currently receiving treatment) for Mind Guide as well as outline procedures for our pilot RCT of Mind Guide (Phase 3). The PTSD Checklist, self-reported alcohol use, the

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Perceived Stress Scale, Penn Alcohol Craving Scale, and the Emotion Regulation Questionnaire were used.

Results.—Results of our beta test of Mind Guide show promising past 30 day effects on PTSD ($d = -1.12$), frequency of alcohol use ($d = -0.54$), and alcohol problems ($d = -0.44$), and related mechanisms of craving ($d = -0.53$), perceived stress ($d = -0.88$), and emotion regulation ($d = -1.22$).

Conclusion: Our initial beta-test of Mind Guide shows promise for reducing PTSD and alcohol related problems among veterans. Recruitment is ongoing for our pilot RCT in which 200 veterans will be recruited and followed up for 3 months.

Introduction

American veterans who have served in the post-9/11 era, are at increased risk of an alcohol use disorder (AUD), with 10% of post 9/11 veterans seeking care from the Veterans Affairs Healthcare System (VA) meeting criteria for AUD. Estimates of AUD in community samples of veterans range from 12% to 40%, representing upwards of 1 million veterans.^{1–5} Veterans who meet AUD criteria are at risk of developing other substance use disorders and problems transitioning to civilian life.^{6–8} Many of these veterans also struggle with symptoms of posttraumatic stress disorder (PTSD), and co-occurrence of AUD and PTSD is common among post 9/11 veterans in both community and VA samples, with co-occurrence rates ranging from 16% to 69%.^{9–12}

The VA and U.S. Department of Defense practice guidelines recommend empirically supported pharmacologic (e.g., paroxetine, sertraline) and psychotherapeutic treatments for AUD and PTSD¹³ have been shown to reduce hallmark features of PTSD and alcohol use.¹³ About 87% of post-9/11 veterans are eligible to receive quality substance use and mental health care at the VA or have private insurance.^{14–17} Yet, despite their heightened risk of AUD and PTSD, post-9/11 veterans underuse treatment services available to them. For example, an estimated 50% of post-9/11 veterans with behavioral health needs do not seek services.^{5, 18, 19} Barriers to treatment for veterans with AUD and PTSD include logistical barriers (e.g., high costs), institutional and cultural barriers (e.g., belief treatment would not be kept confidential), and beliefs and preferences for treatment (e.g., they can handle it on their own).^{5, 20–24} Unfortunately, post-9/11 veterans have particularly low rates of AUD treatment engagement, with only 3% of those meeting criteria for alcohol misuse receiving treatment services.^{25, 26} In addition, veterans with PTSD can be challenging for providers to engage in care, especially those reporting avoidance symptoms of PTSD,²⁷ which can include using alcohol to cope with PTSD symptoms.^{28, 29}

Mobile Mindfulness-based Interventions for Veterans

Today, most adults in the US own a smartphone (~85%),³⁰ making mobile health (mHealth) apps a promising avenue for disseminating evidence-based interventions. Understanding the utility and promise of mHealth interventions are sorely needed, especially among underserved populations such as veterans who need care, but cannot or will not seek care at traditional locations. Veterans with AUD and co-occurring PTSD, who are particularly difficult to engage in traditional in-person treatments, may benefit from

mHealth approaches. One mHealth intervention that has preliminary established efficacy is Mindfulness Coach app developed by the National Center for PTSD.³¹

Mindfulness-based interventions offer a systematic set of practices that supply veterans with improved self-regulation techniques and stress reduction skills to target both PTSD symptoms and alcohol use and consequences. In recent reviews, mindfulness-based interventions have shown promising effects for reducing PTSD symptomology and preventing substance use relapse.^{32–34} Mindfulness-based interventions that incorporate aspects of relapse prevention (e.g., Mindfulness-Based Relapse Prevention, or MBRP) have also shown promise in reducing substance use behaviors and triggers (e.g., cravings).^{32, 35, 36} However, to date, there is very little research on mindfulness-based interventions in mHealth formats. Given veterans interest in these approaches, an mHealth mindfulness-based interventions could be helpful in increasing access to care for veterans with AUD and PTSD. Although promising, Mindfulness Coach has not been formally tested with veterans and currently focuses only on PTSD content. The only study assessing Mindfulness Coach is a small wait-list control study (which has not been published) among VA attending veterans.³¹ This study did note reductions in PTSD symptoms, but alcohol use was not assessed. Therefore, adding substance-specific aspects of MBRP to Mindfulness Coach could help veterans simultaneously address symptoms of AUD and PTSD. Thus, we developed a modified Mindfulness Coach mobile-app intervention with veterans screening positive for AUD and PTSD but not currently seeking any treatment. “Mind Guide” is an extension of the Mindfulness Coach in that it incorporates evidence-based MBRP content into the app to address co-occurring AUD and PTSD symptoms.

Mechanisms of Behavior Change in Mindfulness-based Interventions

Conceptual models of mindfulness-based interventions (see Figure 1) suggest that mindfulness training reduces subjective urges (e.g., cravings) and negative feeling states that arise from a stimulus (e.g., trigger, PTSD symptoms) by increasing emotion regulation, decreasing impulsivity, and decreasing stress.^{37, 38} Studies have found improvements in emotion regulation, impulsivity, and stress following an mindfulness-based intervention,^{39–43} and recent theoretical work explains that mindfulness-based interventions work through reductions in subjective urges (e.g., substance use craving) and negative feeling states.^{44, 45} Results from the few mindfulness-based intervention studies with veterans have found that assignment to an MBI (compared to treatment as usual) resulted in lower stress levels⁴⁶ and improved PTSD symptoms.⁴⁷ Recent work on in-person MBRP and related mindfulness-based interventions has found changes in perceived stress,⁴⁸ self-regulation,^{39–41} and craving^{49–51} to be key mechanisms in reducing substance use outcomes.

In sum, effective mobile tools to treat AUD and PTSD are lacking⁵² and mHealth apps are needed to address the ongoing problem of underuse of AUD and PTSD treatment services among veterans. Thus, to address areas of improvement in mHealth for veterans, we developed Mind Guide and prepared it for testing in a pilot randomized controlled trial (RCT) with veterans to (1) examine main effects of the intervention on AUD and PTSD outcomes and (2) examine key mechanisms of intervention effects. To achieve this, we

detail our three-phase approach which includes intervention development (phase 1), beta test (phase 2), and pilot RCT (phase 3).

Methods

Design Overview

We provide an overview of the study protocol which includes three phases: 1) intervention development phase; 2) beta testing phase; and 3) pilot RCT phase.

Phase 1 Methods: Mind Guide Development

Mindfulness Coach, available for both iOS and Android platforms, is a free, anonymous, evidence-informed mobile application designed by the VA's National Center for PTSD. The app provides a gradual, self-guided, training program designed to walk veterans through the process of understanding and adopting mindfulness practice. The app contains the following core, evidence-informed functionalities: (a) psychoeducational topics related to mindfulness (e.g., "What is Mindfulness?" "How to Anchor Your Attention," "Being Aware of Your Inner Critic," and "When Your Mind Makes it Difficult to Practice Mindfulness"); (b) audio-guided mindfulness exercises included with the app and a growing catalog of additional exercises available for free download; (c) self-assessment of mindfulness mastery using the Five Facet Mindfulness Questionnaire;⁵³ (d) a journal to track mindfulness practice sessions; (e) goal setting and tracking; (f) personal, customizable reminders; and (g) immediate access to support and crisis resources.

The Mind Guide app we developed builds upon Mindfulness Coach by incorporating several aspects of Mindfulness Based Relapse Prevention (MBRP)³⁶ regarding information about the triangle of awareness to understand connections among thoughts, sensations, and emotions, and specific meditations of sober breathing space and urge surfing to deal with cravings. Content was developed with the assistance of the MBRP developers and vetted with several expert researchers in the field of veteran mental health. Through six months of bi-weekly meetings the content of MBRP was reviewed and aspects that seemed relevant to the app were selected and then condensed significantly to be appropriate for app presentation. Suggestions were elicited regarding how to best condense MBRP material for the app, as well as which content was able to be woven into the original Mindfulness Coach app seamlessly. Content included, among others, the SOBER space (Stop, Observe, Breathe, Expand awareness, Respond mindfully), urge surfing (i.e., riding the wave of an alcohol use craving until it crests and subsides, successfully noticing and manage common triggers for PTSD or alcohol use) and the Loving Kindness meditation (having kindness towards self and others, understanding self-worth and acceptance). Content balanced didactic content and also repeated exposure to these terms and exercises that are central to MBRP (see Table 1). All edits were reviewed and approved by the entire study team. Once all content was added by the programmers, all research investigators tested the app and provided comments and feedback prior to a beta test launch.

Phase 2 Participants and Methods: Beta test and continued development of Mind Guide

The beta test portion of the study was a combination of qualitative focus groups and a brief feasibility and satisfaction survey of veterans with PTSD and AUD. We completed this beta test portion of the project with 16 veterans recruited from social media. To do this we used targeted ads on popular social media sites including Facebook, Instagram, Twitter, and veteran specific sites such as RallyPoint and Reddit discussion boards for veterans. Eligibility criteria were (a) veterans aged 18 or older who had separated or discharged from military service from the Air Force, Army, Marine Corps, or Navy; (b) not currently affiliated with active duty service or in the reserves or guard units; (c) served during or after 9/11/01; (d) no current treatment for alcohol or drug use or PTSD at the VA or other health care provider or clinic; (e) AUDIT-C score of 3 (for women) or 4 (for men) or higher, which represents probable AUD screen in civilian and military samples^{54, 55} and is the VA's criterion for warranting referral to a substance use treatment clinic; and (f) a score of at least 1 on the Primary Care Screen for PTSD,⁵⁶ representing a probable PTSD diagnosis for this veteran population. Potential participants were given a screening survey to determine eligibility. If potential participants screened in, our project manager called each potential participant to double check consistency on screener (e.g., asked similar or same questions to ensure responses matched) and explained the study in more detail. If the potential participant was interested and passed the second round of screening the project manager consented participants. Demographics for the participants in the beta test are described in Table 3.

Following consent, participants were asked to download the application onto their phone, use it each day for 2 weeks, and explore the content of all modules. Prior to beginning use of the app, participants completed a 15-minute online baseline survey. Two weeks later, participants completed a 15-minute post-beta test survey that assessed PTSD symptoms, alcohol use and consequences, self-regulation, stress, and craving. Participants were also invited at this time to a follow-up interview to discuss acceptability, feasibility, and satisfaction with the Mind Guide app. These semi-structured interviews were designed to assess participants' satisfaction with the app and feasibility/acceptability of the app in preparation for the larger pilot trial. Participants were asked how they used the app and each of its modules, typical times and places/situation they used the app, barriers to app use (e.g., limited time, difficulty using, not getting much from the app), how helpful information in each module was, how often they engaged in mindfulness practice, and if so, how helpful it was, and open-ended items about what they liked best/least. All participants consented to have their app usage data monitored to assess usability data (e.g., time spent within the app). Each participant received a \$20 Amazon gift card for completing each of the baseline and post-beta test surveys. They received a \$30 Amazon gift card for interview participation (\$70 total).

Interview Data Collection.—One interviewer from our research team conducted the semi-structured interviews, following procedures by Morgan,⁵⁷ and with each interview lasting 30 to 60 minutes. Discussions followed a funnel interview structure, starting with broader researcher-driven issues and narrowing to more participant-driven specific illustrations. Although predetermined probes were used to guide the discussion, the interviewer was trained to elicit all relevant opinions related to experiences with similar

interventions, stress, PTSD symptomology, and resources and constraints relating to the dissemination and implementation of Mind Guide. Probes were focused on what barriers or difficulties participants had with the app, with attention paid to suggestions for app improvement (e.g., what would help make this app more accessible to other veterans”).

To ensure credibility of results and enhance the validity and reliability of data collected, interviews were recorded and coded by two members of the research team. Themes for the interviews were discussed among the two coders and reviewed with the broader research team. Lists of codes developed by each investigator were matched and integrated into a single codebook.

Survey Data Collection.—The baseline and post-beta test survey data was collected via the online platform Qualtrics.

Measures

Post-traumatic stress disorder.

The PTSD Checklist^{58, 59} is a 20-item self-report measure that assesses the 20 DSM-5 symptoms of PTSD. Sum scores on the PTSD Checklist were used to examine pre-post PTSD symptom severity scores, as well for each of the four subscales. A score of 33 or more is indicative of probable PTSD and this score was used to describe the sample.

Alcohol use disorder.

The AUDIT^{54, 55, 60} is a brief 10-item alcohol screen that identifies individuals who had probable AUD in the past year. A score of 8 or more represents the highest specificity for capturing an AUD diagnosis and is used by the VA to screen for referral to AUD treatment.⁶¹ The AUDIT was used to describe the sample at baseline.

Frequency of alcohol use and related problems.

Alcohol use was measured with a single item for frequency, assessing past 30 day drinking days. Number of alcohol consequences experienced in the past month was assessed with the Short Inventory of Problems (SIP-2L), modified from the Drinker Inventory of Consequences (DrInC)⁶² specifically to assess past 30 days alcohol problems. A sum score was used. Alcohol outcomes were assessed at baseline and post-beta test to examine change over time.

Proposed mechanisms of behavior change.

In preparation for the larger pilot trial, we included measures of the proposed mechanisms of behavioral change: perceived stress, emotion regulation, and craving. In the beta test, these were used to evaluate changes from baseline to post-beta test two weeks later.

Perceived stress.

The 10-item Perceived Stress Scale^{63, 64} was used to assess how participants subjectively viewed stress in their lives in the past month. The scale has been used with many clinical populations and has shown acceptable internal consistency reliability ($\alpha = .78$).

Emotion regulation.

The 10-item Emotion Regulation Questionnaire⁶⁵ (ERQ) assesses habitual use of cognitive reappraisal (i.e., thinking differently about a situation in an attempt to modify emotional reaction) and expressive suppression of situations (reduce outward expression of emotion).

Craving.

The Penn Alcohol Craving Scale⁶⁶ is an established measure of alcohol craving with demonstrated validity and reliability. An adapted version included in MBRP studies has demonstrated excellent internal consistency.³⁵

Phase 2 Results

Interview results.—Table 2 provides a detailed summary of interview results. In terms of intervention content and delivery, most participants noted they had a positive experience, especially those who were first-time users of mindfulness as a vehicle for behavior change. One participant even stated: “*Why drink when you can meditate?*” For others, Mind Guide aided them in understanding core aspects of mindfulness, such as the idea that negative (and positive) feelings are temporary:

“In terms of drinking, it’s just part of the overall wellness plan, I think it helps build momentum where it’s, okay, I’m doing good things for myself. Let me kind of keep that going . . . , I think if I’m dealing with something that’s stressful or frustrating, just the simple reminder to breathe and thinking about how these feelings are temporary. That’s helpful for me to know that, even if I’m feeling poorly, like it’s not gonna last forever.”

In terms of dealing with symptoms of PTSD, participants noted several areas in which Mind Guide aided them, especially in moments when anxiety or flashbacks would occur. On several occasions, participants mentioned the usefulness of the app tracking capabilities, which tracks progress on mindfulness cues and triggers. Participants noted that the modules aided them with letting go of [negative] thoughts, recognizing negative self-talk, and improving on their self-compassion. For example, one participant discussed how using Mind Guide aided in their ability to cope with heightened anxiety:

“I get anxiety and heart palpitations . . . Sometimes I just kind of power through them, but this time I was able to just enjoy the outside, show my kid the trees, and simply be aware of everything. It just made everything feel better, sort of like powering through the anxiety attack in a much healthier way than sometimes I’ve done.”

However, not all participants felt as though mindfulness aided them with symptoms of PTSD or alcohol use. In some cases, participants noted that during the guided meditations, it was difficult to sit with thoughts [especially if these thoughts were negative] and, on occasion made them feel uncomfortable and was a catalyst for more negative self-talk. We should note that this is a common experience for individuals when engaging in mindfulness interventions – mostly because mindfulness provides participants an opportunity to sit with their thoughts, emotions, and feelings (e.g., increasing present awareness). This runs

contrary to most interventions that either provide participants with coping activities or restructuring their thought processes (e.g., cognitive behavioral therapy).

Requested changes that were possible to make (within the project budget) included a clearer tracking system and the ability to export their progress outside of Mind Guide, more reminder (push) notifications (or at least more customization for notification preferences), better instruction on the guided portions of each module, and to replace some of the longer guided meditations (those that are 10 minutes +) with shorter versions. Participants made several recommendations that, while our budget would not allow, will be useful in the next iteration of testing Mind Guide. For example, participants requested having several testimony videos from other former veterans that use mindfulness as a tool for coping with psychological distress. Participants also asked to have various tracking systems, for example, including tracking of PTSD symptoms, triggers, and alcohol use.

Phase 2 Beta Test Results.—Table 3 provides participant demographics as well as simple paired samples *t*-test results for our primary outcomes and proposed mediators for the pilot study. In terms of the paired samples *t*-tests, we showed significant reductions in our two primary alcohol outcomes: frequency of alcohol use ($d = -0.54$) and alcohol problems ($d = -0.44$). We also observed a significant decrease in PTSD symptoms ($d = -1.12$). Though not part of our primary hypotheses, we also provide PTSD subscale analyses in Table 3, noting reductions in each of the four subscales: re-experiencing ($d = -0.74$), avoidance ($d = -0.91$), negative alterations in mood ($d = -1.04$), and hyperarousal ($d = -1.09$). For our proposed mediators, we noted significant reductions in one aspect of emotion regulation; expressive suppression ($d = -1.22$), but no significant effect on cognitive reappraisal. We noted significant reductions in craving ($d = -0.53$) and perceived stress ($d = -0.88$).

Phase 3 Participants and Methods: Pilot RCT of Mind Guide

Following completion of the beta test, we completed suggested feasible modifications to the Mind Guide. We will now move to Phase 3, which is the implementation of a pilot RCT. Here, we have a target recruitment of 200 non-treatment seeking veterans to be randomly assigned to the Mind Guide app ($n = 100$) or a stress management control condition mobile website ($n = 100$).

All recruitment efforts and eligibility criteria will remain identical to the beta test. All participants will complete a baseline survey, two surveys during the treatment phase (4 weeks into treatment phase and 8 weeks into treatment phase), and follow-up surveys at 12 weeks and 16 weeks post treatment. See Figure 2 for recruitment and follow-up flow diagram. Surveys will be 20 minutes each with a \$20 gift card for completing each of the surveys.

Measures.—All survey measures described for the beta test will be used in the Phase 3 pilot RCT. Primary outcomes were prespecified as alcohol use (frequency of days used), alcohol-related consequences, and PTSD symptoms. These will be assessed at all time points for the past 30 days. Prespecified mediators are perceived stress, emotion regulation,

and craving. An additional measure will be used to assess for mindfulness practice at each of the five timepoints.

Dispositional mindfulness.—The Five Facet Mindfulness Questionnaire⁵³ will be used to assess five mindfulness skills (observing, describing, acting with awareness, nonjudging of inner experience, and nonreactivity to inner experience). The FFMQ has demonstrated validity ranging from 0.80 to 0.95 across studies.

Phase 3 analytic plan.—To assess differences in primary outcomes (PTSD and alcohol use) and mechanisms (emotion regulation, perceived stress, impulsivity, and craving), a taxonomy of bilinear spline latent growth models will be estimated⁶⁷ in Mplus version 8.⁶⁸ Bilinear spline models are useful when there are reasons to separate time into discrete phases, which can aid in explaining observed rates of change within each phase. Each discrete phase is usually a simple growth model, and the segments that connect the growth models are called *knot* or *transition* points. Bilinear spline models will assess the effects of treatment assignment during the treatment phase (8 weeks; slope 1) and post-treatment phase (8 weeks; slope 2). To assess between-group differences in the intercept and growth factors across both phases, we will regress each on a dummy variable representing the experimental (Mind Guide = 1) and control (CTL = 0) groups. In addition to assessing the treatment effect on changes over time in our outcomes and mechanisms, we will fit model constraints to assess between-group differences (e.g., simple slopes) in the outcomes at substantively meaningful points in time: halfway through treatment period, at treatment end, and then 4- and 8-weeks after treatment completion (12 and 16 months post-baseline). To understand practical significance, we will calculate standardized mean differences (Cohen's *d*) at all four points, which will provide descriptive indicators of effect size.⁶⁹ Variance estimates to scale *d* will be estimated using total variance of the outcome over time.⁷⁰

Exploratory secondary outcome.—It is possible that use of the Mind Guide app will encourage use of more formal treatment for PTSD or alcohol use. We will also descriptively report the proportion of participants in each condition that (a) report receipt of any type of behavioral health treatment during both the treatment phase and the post-intervention phase and (b) report intention to pursue any behavioral health treatment.

Power analysis: Primary outcomes.—Monte Carlo simulations (Mplus) using variance, covariance, and effect size ($d_{\text{range}} = 0.36\text{--}1.10$) estimates from our prior work and similar mindfulness studies^{32, 33} suggest a sample size of 200 is adequately powered to detect medium and large effects using bilinear spline models ($\beta = 0.75\text{--}0.82$). Effect sizes obtained in this pilot study will help to inform the sampling plan for a planned larger trial of Mind Guide.

Mechanisms.—We will assess the effects of our proposed mechanisms (e.g., emotion regulation, impulsivity, cravings, and stress) by utilizing bootstrapped indirect-effect SEMs (see Figure 1). Specifically, to assess if changes in perceived stress, emotion regulation, and cravings mediate the association between intervention assignment and our outcomes of interest (PTSD and alcohol use outcomes), three regressions will be estimated: intervention assignment predicting end of treatment change in mediators (path

a), intervention assignment predicting alcohol use outcome at 12 and 16 week follow ups (path c), and changes in mediators predicting changes in substance use outcomes (path b). Mediation will be tested by assessing the indirect effect (e.g., path a \times path b).

Exploratory moderators of treatment effects will assess for whom and under what conditions the Mind Guide app works. To assess moderation, we will use a treatment (Mind Guide vs. control) by moderator (e.g., sex [men versus women], race/ethnicity [white versus non-white] and recency of discharge [within the past 5 years versus over 5 years ago]) interaction to predict our outcomes of interest. As an exploratory analysis, we will assess app engagement as a potential moderator. Any significant moderation will be plotted and simple slopes used to determine which condition is driving the moderation effect.

Power analysis: Mechanisms and moderator data.—We estimated a series of Monte Carlo simulations using small, medium, and large effect sizes as well as attrition up to 25%. Power tables with combinations of small, medium, large, and small–medium effects were used⁷¹ to determine sample sizes needed to test mediated effects. Using bias-corrected bootstrapped models, we will be powered (0.80) with N ranging from 60–115 to detect a mediated effect with path estimates that are combinations of small–medium (0.26), medium (0.39), and large (0.59).

We expect to be underpowered to detect moderation effects. Despite efforts to recruit a sample that is composed of 20% women and 40% racial/ethnic minorities, which is almost twice the proportion of women and racial/ethnic minority veterans in the population, we may be underpowered in this pilot study to detect significant treatment effects for men and women, and for white versus non-White veterans, comparatively (e.g., moderation). We are similarly underpowered to detect significant differences in treatment engagement and do not anticipate that the app will lead to substantial treatment pursuit in either condition during the brief follow-up.

Discussion

In this paper, we described the development and beta testing of a MBRP mobile app, Mind Guide. Using a pre-post single arm design, we found that veterans who used the mobile app significantly improved on all three primary outcomes over the two-week beta test period. Specifically, we observed medium to large effects for reductions in frequency of alcohol use, alcohol-related problems, and PTSD symptoms from baseline to the two-week follow-up. The largest effect was for PTSD symptoms, which reduced from a mean above the clinical cutoff for PTSD to a score below the cutoff; a clinically meaningful change⁷² even after just two weeks of app use. Though we did not include a control condition in the beta test, these findings are quite promising, and bode well for the planned pilot test of Mind Guide that will compare the app to a control condition.

In the beta test, we also noted significant, medium-to-large effects in three of the four assessed proposed mechanisms of change: perceived stress, craving for alcohol, and the expressive suppression component of emotion regulation. This again bodes well for the planned pilot trial, as we saw effects for one of the planned pathways to test mediation in the

larger trial (i.e., does the intervention have an effect on the mediator). In the Phase 3 trial, we will again test this pathway, as well as the pathways specified to determine if changes in these mechanisms lead to changes in the primary outcomes. This will provide us with important information about why we may see Mind Guide effects. We will also explore moderators of gender, race/ethnicity, and recency of discharge to determine who Mind Guide works best for, and explore whether those receiving Mind Guide are more likely than control to pursue additional treatment options during or after app use.

The promising beta test results and the planned pilot test analyses can pave the way for greater implementation of Mind Guide. Should we find hypothesized effects, we will use these findings to prepare for a larger efficacy trial and widespread dissemination of Mind Guide. Mindfulness Coach, the app that Mind Guide builds upon, is a popular app supported by the VA's National Center for PTSD. Having a version of the app that specifically addresses both PTSD and AUD will allow for more veterans to access and see success from using the mindfulness app, as it addresses both common problems concurrently. Veterans in our beta test found the Mind Guide app accessible, easy-to-use, and helpful, and with their suggested improvements implemented, we anticipate that Mind Guide will become a helpful tool for many veterans. Although the promise of this intervention as a stand-alone treatment for PTSD symptoms and alcohol use outcomes is apparent, in a larger trial with a longer follow-up period beyond 16 weeks, we can evaluate secondary outcomes such as whether participants assigned to the intervention group are more likely to seek in-person behavioral health treatment at the VA and elsewhere. This would indicate the app's potential to engage individuals who otherwise are resistant to seek care. We can also evaluate the app's promise to address other secondary outcomes often co-occurring with PTSD and AUD, such as relationship difficulties, other substance use, and poor physical health. However, these mobile based intervention studies are not without challenges, especially in terms of user engagement. The majority of studies report very high engagement at the beginning of each study, which trails off to less than 50% engagement at the end of the study period. We expect a similar trajectory with our sample and will employ strategies from prior work as well as our own to increase engagement.

Conclusion

In sum, this proposed pilot RCT aims to create a viable and easily-disseminated integrative mobile intervention that aims to improve behavioral health symptoms for at-risk veterans in need of services. The unique strengths of this proposal are its focus on a population in need of services, focus on prevalent co-occurring AUD and PTSD, innovative delivery of a promising evidence-based intervention, and potential for large-scale implementation. The next steps for our research team is to assess Mind Guide in a fully powered RCT. This process will include further tweaking and content change based on our initial feedback from veterans and implementation of advanced algorithms that can aid in determining when and how often individuals may need intervention reminders. We will also work with other researchers testing out mobile apps to learn best practices for engaging veterans in a full course of program completion, such as through the use of peers to help increase engagement.⁷³

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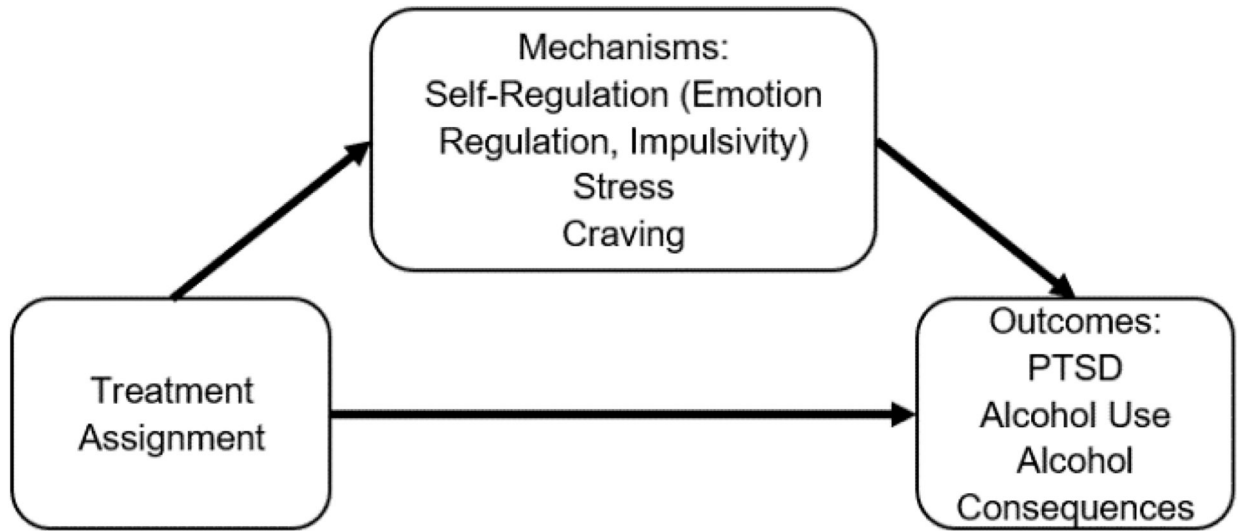


Figure 1.
Proposed Mechanisms of Behavior Change

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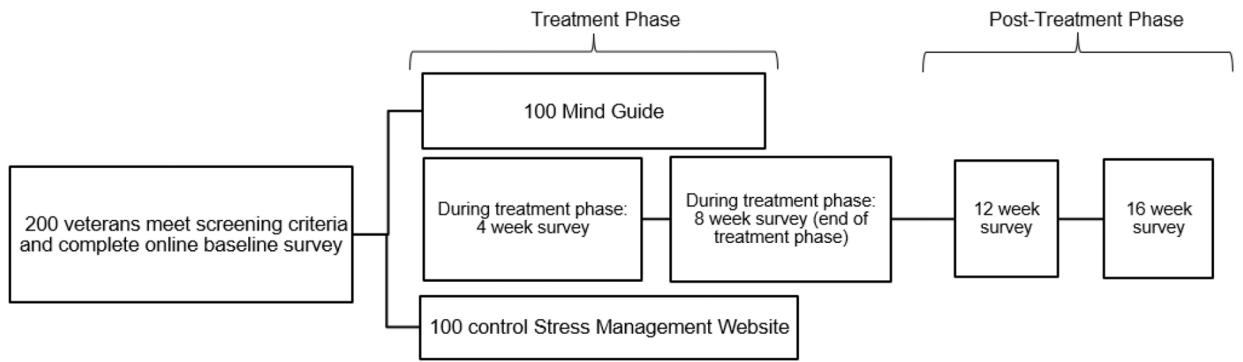


Figure 2.
Proposed Phase 3 (Pilot RCT) Study Flow

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Table 1.

Example of Mindfulness Based Relapse Prevention Session Content

MBRP themes	Skills acquired	Meditations
Major themes of (1) using mindfulness in daily life and (2) using mindfulness to cope with triggers and craving.	<ul style="list-style-type: none"> Integrating SOBER breathing space into daily life Bring awareness to daily activities Noticing triggers and how to deal successfully with them 	<ul style="list-style-type: none"> SOBER breathing space Mindful eating Urge surfing Mountain meditation
Major themes of (1) using mindfulness in high risk situations, (2) self-care and lifestyle balance, and (3) social support and continuing practice, (4) False Refuge	<ul style="list-style-type: none"> Remaining present focused in challenging situations Working with craving and high-risk situations Understanding the importance of a social support network Benefits of continued practice Understanding craving and reactions to craving 	<ul style="list-style-type: none"> SOBER breathing space in a challenging situation Sitting meditation: thoughts Urge surfing in risky situations Loving Kindness meditation False refuge

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Table 2.

Qualitative Interview Results

Beta Test Area	Main Positives	Feedback
<i>Enrollment</i>	Liked images of veterans, USC affiliation, advertising of compensation	Don't use traumatic images (combat), obvious stock photos, reddit posts could maybe use an image to capture attention
<i>Intervention and Delivery</i>	Helpful meditation breaks A lot like existing mindfulness apps but is more helpful Exercises overall were good, detailed, with well-written scripts Helpful, calming, nice visuals, good feedback on sober space (broke up the other exercises as it was a bit different) Liked tree visuals as a "fun" incentive Helps to relax Easy to use	Could use more automated guidance within the app itself in a later version Not useful for people who need to be "sold" on mindfulness More notifications and reminders to encourage use (perhaps expand settings) Automated format to guide people through the program more easily, make it so exercises are easier to find and play More brief/engaging – repetitive More clear progress marks to indicate advancing through the program (e.g., Tracker could be more automated, including badges/awards) Some could be more interactive or allow multitasking (e.g., mindfulness while doing the dishes or going for a walk and noticing those sensations) Longer audio bits could be shorter Make the reminders more personal (e.g., "Hi X, it's time for your noon session") Highlight that mindfulness techniques can be difficult when first starting out when dealing with mental or physical issues; participants may feel more aware of these. Can be difficult to just sit down and do it – allow for more of "incorporating functional healing things into the dysfunction" Adding in personal anecdotes or audios from actual veterans to tailor it more to them could distinguish from apps like Calm or Headspace to make it seem more applicable to just veterans
<i>Using mindfulness for management of PTSD and alcohol use</i>	Appreciated learning about mindfulness and challenged pre-conceived notions about what it was, and how it can be helpful for anyone, including veterans Quick seated sessions are helpful to break up day and relax Helped as a resource to calm down and be present; stay grounded when anxious, upset, angry – "Why drink when you can meditate?" Tracking helps identify trends regarding symptoms (how often, when they start, etc.) and triggers Helps with letting go, spotting negative self-talk, self-compassion Can help everyone in daily life Being in the moment with other people "Mistreating self can lead to mistreating others" so addressing symptoms with mindfulness can help with repairing relationships or outlook on relationships	Had some pre-conceived notions about mindfulness so had bias that it would not help symptoms Some participants didn't feel it was helpful for alcohol use specifically, or felt the SOBER space meditation was not necessary Mindfulness can be triggering and uncomfortable – don't want to sit with thoughts Two weeks may not be long enough to address symptoms
<i>Measures and Assessment</i>	Some felt assessments were good – not intrusive or too long Knew this was a credible study from an institution so felt comfortable answering questions truthfully Familiar with the questions as they have seen them before (in other mental health assessments outside of the study)	Felt the surveys could be more specific (e.g., combat related questions were pretty general) – some open-ended questions Some questions felt intrusive or triggering or could be for newer veterans
<i>Outcomes</i>	Used app frequently, almost every day or every other day for most participants Many did not want the reminders Used on average 15–45 mins/day Brief seated practice was useful A useful and easy resource to tap into during the day Felt they can benefit from using the app alongside therapy or other resources	Doesn't feel that the trial was long enough to impact behavior overall More notifications to remind participants to do exercises would be helpful to enhance positive outcomes

Table 3.

Phase 2 beta test participant characteristics, test-statistics, and effect sizes.

Variable	M(SD) or n(%) Baseline	M(SD) or n(%) Follow-up	<i>t</i> -test (<i>p</i>) or χ^2 (<i>p</i>)	Cohen's <i>d</i>
Age				
Sex (male)	12 (75.0%)			
Race/Ethnicity				
Non-Hispanic White	9 (56.3%)			
Non-Hispanic Black	1 (6.3%)			
Hispanic	3 (18.8%)			
Multiracial	3 (18.8%)			
Combat experiences (summed score)	5.62 (2.73)			
AUDIT (mean)	12.6 (6.06)			
AUDIT (cut score 8+)	13 (81.2%)			
AUDIT (cut score 16+)	7 (43.8%)			
PTSD (cut score 33+)	16 (100%)	--	--	--
Primary outcomes (Past 30 days)				
Frequency of alcohol use	13.1 (8.48)	10.7 (8.09)	2.09 (0.03)	-0.54
Alcohol use problems	9.63 (7.00)	7.0 (7.82)	1.71 (0.05)	-0.44
PTSD symptoms (mean)	42.9 (15.5)	26.8 (12.3)	4.40 (.001)	-1.12
Reexperiencing	8.71 (4.58)	6.42 (3.32)	2.82 (0.01)	-0.74
Avoidance	5.29 (2.36)	3.28 (1.72)	3.54 (< 0.01)	-0.91
Negative alterations in mood	16.1 (6.74)	9.57 (5.72)	3.99 (<0.01)	-1.04
Hyperarousal	12.6 (4.75)	7.50 (4.01)	4.20 (<0.01)	-1.09
Mechanisms				
Emotion regulation				
Cognitive reappraisal	29.8 (5.25)	31.4 (3.36)	1.23 (0.24)	0.32
Expressive suppression	20.2 (4.36)	15.6 (4.89)	4.72 (< 0.01)	-1.22
Craving	9.63 (5.23)	6.57 (5.17)	2.02 (0.03)	-0.53
Perceived Stress	23.8 (5.22)	18.4 (6.5)	3.40 (< 0.01)	-0.88