



A smartphone app-based mindfulness intervention to enhance recovery from substance use disorders: Protocol for a pilot feasibility randomized controlled trial

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ABSTRACT

Background: Poor long-term recovery outcomes after treatment (e.g., readmission to inpatient treatment) are common among individuals with substance use disorders (SUDs). In-person mindfulness-based treatments (MBTs) are efficacious for SUDs and may improve recovery outcomes. However, existing MBTs for SUD have limited public health reach, and thus scalable delivery methods are needed. A digitally-delivered MBT for SUDs may hold promise.

Methods: We recently developed Mindful Journey, a smartphone app-based adjunctive MBT for improving long-term recovery outcomes. In this paper, we present details on the app and describe the protocol for a single-site pilot feasibility randomized controlled trial of Mindful Journey. In this trial, individuals ($n = 34$) in an early phase of outpatient treatment for SUDs will be randomized to either treatment-as-usual (TAU) plus Mindful Journey, or TAU only. The trial will focus on testing the feasibility (e.g., engagement) and acceptability of the app (e.g., perceived usability and helpfulness for recovery), as well as feasibility of study procedures (e.g., assessment completion). The trial will incorporate ecological momentary assessment before and after treatment to assess mechanisms in real-time, including mindfulness, craving, difficulties with negative emotion regulation, and savoring. To examine the sensitivity to change of outcomes (substance use, substance-related problems, and psychological distress) and mechanism variables (noted above), we will test within-treatment-condition changes over time.

Discussion: The proposed pilot trial will provide important preliminary data on whether Mindful Journey is feasible and acceptable among individuals with SUDs.

Trial registration: ClinicalTrials.gov NCT05109507.

1. Introduction

Substance use disorders (SUDs) are prevalent and linked with a large public health burden [1]. One of the most pressing and unsolved issues facing the SUD treatment field is the high rates of poor long-term recovery outcomes following treatment. Notably, about 50% of individuals return to any substance use [2–7], 40% return to multiple occasions of use [8,9], and 50% are readmitted to inpatient programs

within 1-year after treatment [10–12]. Hence, although there have been advances in treatments for SUDs [13], rates of poor recovery outcomes remain unacceptably high. Novel and more effective approaches are needed to facilitate long-term recovery.

Novel approaches may be most effective if they target core processes underlying SUDs [14]. Research indicates that negative affect [15–18], craving [18–22], and anhedonia [16,23,24] predict greater substance use. Accordingly, interventions are needed that help individuals cope

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adaptively with these processes. Mindfulness-based treatments (MBTs) for SUDs are promising and may be suitable for enhancing regulation of affective states [25,26]. MBTs for SUDs involves systematic mindfulness training to promote the ability to intentionally bring an open, curious, and accepting awareness to momentary experiences (e.g., thoughts, emotions, craving, sights, sounds, taste). Meta-analyses show that MBTs for SUDs are efficacious for increasing abstinence, reducing substance use frequency, and improving psychological functioning [18,27,28].

Unfortunately, current MBTs for SUDs have limited public health reach [29]. MBT protocols, which include closed-cohort 2-h group sessions [30,31], are often difficult to implement in community treatment settings given rolling admission of most community treatment programs. Additionally, there is a shortage of well-trained MBT therapists. Digital delivery may be a promising option for expanding the reach of MBTs for SUDs. Currently, 90% of American adults use the Internet and 83% own mobile smartphones [32]. And importantly, digital interventions may require lower costs to deliver than in-person treatments [33]. Research suggests that digital interventions are viable among clinical populations [34], including those with SUDs [35]. However, there are no available digital MBTs for promoting long-term recovery from SUDs—except for nicotine use disorder, for which there are several studies demonstrating the efficacy of web- and app-based MBTs for promoting long-term smoking cessation [36,37].

Overall, digital MBTs for SUDs may hold promise for enhancing long-term recovery. Notably, MBTs—with its relatively broad focus on regulation of negative affect and positive affect, in addition to craving—may be effective in promoting improvements in psychosocial functioning and well-being, in addition to substance-related outcomes. Indeed, SUD recovery is defined by NIH as a *multi-dimensional* process of change involving remission from SUDs, reduction in substance use, and improvements in psychosocial functioning [38]. Interventions for SUDs should ideally lead to improvements in all of these domains, instead of a narrow focus on abstinence from substances.

Our team recently developed Mindful Journey, a smartphone app-based adjunctive MBT for promoting *multi-dimensional* recovery from SUDs. In this paper, we first provide an overview of the app, followed by a description of the protocol for a pilot feasibility randomized controlled trial.

2. Methods

2.1. Overview of Mindful Journey

Existing interventions informing development. Mindful Journey is primarily based on Mindfulness-Based Relapse Prevention (MBRP) [30], while also drawing from Acceptance and Commitment Therapy (ACT) [36,39], Mindfulness-Oriented Recovery Enhancement (MORE) [31], Regulation of Craving Training (ROC-T) [40] and Dialectical Behavior Therapy (DBT) [41]. We also drew upon an existing evidence-based digital intervention for SUDs called Computer-Based Training in Cognitive Behavioral Therapy (CBT4CBT) [42], which includes narrator-guided, video-based content in a series of 30- to 45-min modules. Mindful Journey is designed to target several mechanisms, including mindfulness [43], craving [40,44], difficulties with negative emotion regulation [25,45], and savoring [46]. Mindful Journey is designed to support multi-dimensional recovery, rather than having a narrow focus on abstinence. Mindful Journey aims to support clients with a range of treatment goals, including both abstinence and non-abstinence goals (e.g., reductions in substance use). For example, the app includes question prompts that ask clients what their recovery goals are, and the app provides a variety of responses clients can choose among, including non-abstinence goals (e.g., improve my relationships, reduce my substance use). Furthermore, the app has example clients who have non-abstinence goals, such as a client who has the goal of reducing his cannabis use.

Core features. The core feature of the app is 15 sequential lessons

(~30–45 min each). Each of the 15 lessons includes several animated videos, one or two audio-guided mindfulness practices, and question prompts (see Table 1 for a summary of lessons). The lessons center on two core acronym-based mindfulness tools: “BOAT,” which stands for “Breath, Observe, Accept, Take a Moment” and is useful for regulating negative affect, pain, and craving; and “SOAK,” which stands for “Stop, Observe, Appreciate, Keep Curious” and is useful for savoring pleasant experiences and cultivating a range of positive emotions, such as contentment, gratitude, calm, and a sense of meaning. Mindful Journey has an overarching nautical theme. Recovery is likened to a journey or voyage one might take on a boat, with storms and strong waves coming and going, and one doing the best one can to ride out the waves. And, during the journey, one can also pause to “soak” in the sun when it is shining.

Animated videos. Our team created the animated videos using the Powtoon animation program [47]. The lessons include animated avatars of several fictional clients who provide testimonials and model ways of applying mindfulness skills. There are also animated avatars of two narrators/therapists who guide participants through the lessons and are the therapists in clips of individual and group therapy sessions with fictional clients. The animated videos are typically 1- to 4-min long and include a mix of moving animated illustrations and scenes, still graphics, and presentation of text, diagrams, charts (See Fig. 1 for example visuals).

Audio-guided mindfulness practice and question prompts. The mindfulness practices in Mindful Journey are drawn from MBRP and the aforementioned other MBTs. They are typically 5- to 10-min long. These are typically followed by a variety of prompts, including quiz items, reflection questions (e.g., What did you notice?), and prompts to elicit plans to apply skills in daily life.

The practice journey. After completing the 15 lessons, participants are directed to a “15-Day Practice Journey,” which involves a sequence of 15 audio-guided mindfulness practices (see Table 2 for an overview of the practices). At the beginning of each practice, the narrator provides a brief welcoming comment, and at the end the narrator commends the participant for practicing and provides a brief mindfulness “tip,” such as reminding participants that mindfulness is like a muscle that gets stronger over time with ongoing practice. After the 15th practice, participants are provided with detailed instructions on how to begin their own *self-guided* practice routine—which involves using the other resources in the app (described below).

Other sections of the app. The app also includes a “Cope Now” section with 2-min on-the-go audio-guided mindfulness practices for coping with momentary challenges (e.g., craving), an “All Practices” section with a library of audio-guided meditation practices that can be repeated, and a “Track” section with options to self-monitor and record recovery milestones (e.g., days sober). The Cope Now section includes a “Help Me Cope” button which contains a list of momentary challenges (e.g., low energy/feeling down, craving) and recommendations for ways to cope (e.g., practice the SOAK/BOAT). The “All Practices” also has a “Help Me Choose” button offering a list of situations (e.g., slip or setback) and recommendations for a related guided mindfulness practice (e.g., Bouncing back from a setback).

Resources used during development. Our team prioritized the use of low-cost resources for building Mindful Journey, in the interest of making the app sustainable. We used Powtoon [47] (~\$400/year) for creating the animated videos and the Qualtrics survey building tool [48] (~\$1500/year) to create the lessons. All the videos are hosted on Vimeo (~\$300/year). We used Thinkable [49] (~\$450/year), a web-based program for building and publishing smartphone apps. Of note, the app is available on both iOS and Android smartphones.

Phone coaching. We will pair Mindful Journey with brief manualized remote phone coaching. The purpose of the remote coaching is to provide a *minimal* level of general support (e.g., praise for engagement and encouragement to keep using the app) and technical support (e.g., answering questions about how to use the app or navigate any technical

Table 1
Overview of the 15 core lessons in Mindful Journey.

Lesson number and name	Core learning objectives	Audio-guided mindfulness meditation practices
1 Getting Started	<ul style="list-style-type: none"> Define mindfulness. Identify ways in which mindfulness in plays a role in recovery. Practice guided mindfulness exercises. Explain the steps of the BOAT (Breathe, Observe, Accept, Take a Moment). Describe how to use the Mindful Journey app. 	<ul style="list-style-type: none"> Body and breath practice BOAT practice
2 Responding with Awareness	<ul style="list-style-type: none"> Define automatic pilot. Describe the role of automatic pilot in substance use. Identify and define the three components of the triangle of awareness (thoughts, emotions, sensations). Practice mindfulness after thinking about challenging personal situation. Explain how to use the BOAT in daily life. 	<ul style="list-style-type: none"> Brief BOAT BOAT with imaginal exposure to challenging situation
3 Coping with Cravings	<ul style="list-style-type: none"> Define craving. Practice mindfulness while viewing images that may elicit craving. Describe the similarity of cravings with ocean waves. Explain how mindfulness can be applied to a situation that elicits craving. 	<ul style="list-style-type: none"> BOAT Exercise – Food Cravings (with visual display of food images) BOAT Exercise – Substance Cravings (with visual display of distal cue images)
4 Riding the Wave	<ul style="list-style-type: none"> Define a trigger and describe the roles of triggers in substance use. Identify personal triggers. Practice mindfulness after thinking about a situation that triggers craving for substances. Create a plan for coping with triggers 	<ul style="list-style-type: none"> BOAT with imaginal exposure to substance craving
5 Emotions as Visitors	<ul style="list-style-type: none"> Identify types of difficult emotions and describe how they play a role in substance use. Practice mindfulness of one's current emotions before and after listening to a poem about emotions as guests. Explain how difficult emotions are similar to guests or visitors. Describe the role of mindfulness, particularly the component of acceptance, in the process of coping with difficult emotions. 	<ul style="list-style-type: none"> Mindfulness of emotions with reading of the Guest House [30]
6 Seeing Thoughts as Thoughts	<ul style="list-style-type: none"> Define thoughts. Differentiate thoughts from body sensations and emotions. Describe the role of thoughts in the relapse cycle [30]. 	<ul style="list-style-type: none"> Walking Down the Street Exercise [30] Mindfulness of Thoughts

Table 1 (continued)

Lesson number and name	Core learning objectives	Audio-guided mindfulness meditation practices
7 Practicing Self-Compassion	<ul style="list-style-type: none"> Practice mindfulness of thoughts after hearing about an imaginary ambiguous situation. Practice mindfulness of current thoughts while using the breath as an anchor for attention to return to. Describe the role of self-criticism in the relapse cycle. Practice mindfulness while offering compassionate words to other people and oneself. Explain how self-compassion can facilitate recovery. Create a brief self-compassion reminder statement. Practice mindfulness while mentally reciting one's self-compassion reminder. 	<ul style="list-style-type: none"> Compassion Practice Self-Compassion reminder exercise
8 Exploring Your Needs	<ul style="list-style-type: none"> Describe types of needs that human beings have in life. Explain how substance use is related to trying to meet one's needs. Practice mindfully reflecting on one's own personal needs that may underlie craving and substance use. Explain how the BOAT can be used as a tool to check-in with one's needs in the moment. 	<ul style="list-style-type: none"> Exploring Your Needs Practice Brief BOAT
9 Taking Care of Your Body	<ul style="list-style-type: none"> Explain the importance of self-care in recovery, including taking care of one's body. Practice mindfulness while engaging in gentle movements and stretches, as well as while intentionally resting one's body. 	<ul style="list-style-type: none"> Mindful Movement Mindful Rest
10 Being Curious	<ul style="list-style-type: none"> Explain the steps of the SOAK (Stop, Observe, Appreciate, Keep Curious). Describe the role of the SOAK in recovery. Define curiosity. Explain how the SOAK can be used in daily life. Practice mindfulness after thinking about a pleasant situation. Describe how the BOAT and the SOAK are both mindfulness tools one can use in different situations. Creating a specific plan for engaging in a pleasurable activity over the next week and planning to practice the SOAK in this situation. 	<ul style="list-style-type: none"> SOAK practice Brief SOAK exercise with visual display of vivid photos.
11 Savoring Positive Experiences	<ul style="list-style-type: none"> Explain how the SOAK can be used in daily life. Practice mindfulness after thinking about a pleasant situation. Describe how the BOAT and the SOAK are both mindfulness tools one can use in different situations. Creating a specific plan for engaging in a pleasurable activity over the next week and planning to practice the SOAK in this situation. 	<ul style="list-style-type: none"> Brief SOAK practice SOAK practice with imaginal exposure to pleasant situation

(continued on next page)

Table 1 (continued)

Lesson number and name	Core learning objectives	Audio-guided mindfulness meditation practices
12 A Healthy Relationship with Positive Emotions	<ul style="list-style-type: none"> • Explain how a relentless pursuit of positive emotions can be problematic and trigger substance use. • Describe the difference between letting positive emotions come and go versus chasing them or clinging to them. • Practice mindfulness after thinking about a situation that triggers intense desire for more positive emotions. • Explain how not allowing oneself to feel positive emotions can also be problematic. • Practice mindfully reflecting on ways of welcoming positive emotions and recognizing one is deserving of them. 	<ul style="list-style-type: none"> • Letting Positive Emotions Come and Go (with imaginal exposure to situation triggering intense desire for more positive emotions) • Welcoming positive emotions
13 Exploring New Positive Emotions	<ul style="list-style-type: none"> • Identify other types of positive emotion words besides happy, such as love, interest, calm, amusement, confidence, or meaning. • Write about a specific activity that might bring about a one of these other types of positive emotions. • Practice mindfulness after writing and thinking about this specific activity. • Explain how connecting with a variety of positive emotions is important during recovery. • Explain how positive emotions and negative emotions can be felt at the same time. 	<ul style="list-style-type: none"> • Brief SOAK • Getting to Know Positive Emotions (includes SOAK)
14 Connecting with Your Values	<ul style="list-style-type: none"> • Define values and describe their role in the recovery process. • Practice mindfully reflecting on personal values in key domains of life. • Explain the connection between mindfulness and making choices guided by our values. • Practice mindfully reflecting on values after thinking about a situation that triggers craving. 	<ul style="list-style-type: none"> • Values Practice • Brief BOAT with imaginal exposure to situation eliciting craving to use substances.
15 The Journey Ahead	<ul style="list-style-type: none"> • Mindfully reflect on one's recovery journey so far and the journey ahead. • Describe the impact of mindfulness practice on the brain. • Explain the importance of a regular mindfulness practice routine. • Describe how the BOAT and the SOAK are both mindfulness tools one can use in different situations. 	<ul style="list-style-type: none"> • Reflecting on Your Journey • Serenity Prayer Exercise

Table 1 (continued)

Lesson number and name	Core learning objectives	Audio-guided mindfulness meditation practices
	<ul style="list-style-type: none"> • Practice mindfulness after listening to the Serenity Prayer 	

issues that arise) [50]. This decision was based on evidence that a minimal degree of remote clinician-based support can substantially increase engagement in app-based interventions [51]. The remote phone coaching will include weekly phone coaching call (typically 5–15 min), 3–4 text-based weekly reminders to use the app, and technical support as needed by phone or text. The phone coaching will not involve any mindfulness training, and instead involves general encouragement to use the app and praise for engagement. The phone coaches will be Bachelor's-level research staff trained by a licensed clinical psychologist, who also receive ongoing supervision. Participants will be encouraged by their phone coaches to complete about 3 lessons per week, while also using the additional features as desired.

3. Methods

3.1. Study design

The study design is a pilot feasibility randomized controlled trial with parallel assignment and 1:1 allocation to either (1) treatment-as-usual (TAU) plus Mindful Journey, or (2) TAU only (see Fig. 2 overview of study design). Participants will complete interview-based and self-report assessments at baseline, 2-weeks later at the randomization visit, midway through the 2-month active treatment period, post-treatment, and 2-months after the end of the treatment period. Additionally, participants will complete 2 weeks of ecological momentary assessment (EMA; described further below) before and immediately after the treatment period.

3.2. Participants

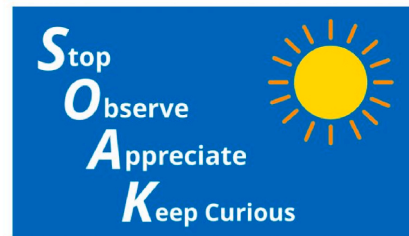
In the initial feasibility trial, participants will be recruited via flyers posted at the community-based addiction treatment clinic, located in the New Haven metropolitan area of Connecticut, that provides outpatient treatment for individuals with a range of SUDs. The target sample size is 34 participants, which is a small-to-moderate sized sample that is suitable for a preliminary single-site pilot trial focused on feasibility and acceptability, not efficacy. Participant inclusion criteria will include: (1) 18 years of age or older; (2) English-speaking; (4) in an early phase of treatment, as demonstrated by completing at least one month of SUD treatment in the past 4 months, and using their primary substance of choice in past 6 months; (5) not currently enrolled in residential/inpatient treatment; (6) willingness to be randomized; (7) willingness and ability to participate for the entire 18-week study period; (8) willingness to provide locator information for follow-up; and (9) own a working, WIFI-enabled smartphone. Exclusion criteria will include: (1) current psychotic disorder symptoms; (2) high suicide risk characterized by suicidal ideation with intent; (3) homicidal ideation posing imminent danger to others; (4) pending legal case, imminent incarceration, or a planned move that results in inability to commit to procedures during the entire study period; and (5) participation in the previously-conducted usability testing study. This study has received approval from the Institutional Review Board (IRB) at Yale School of Medicine.

3.3. Measures

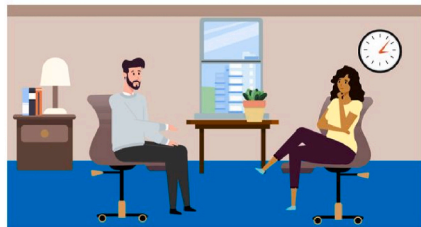
We will use measures with evidence of validity and reliability among individuals with SUDs (see Table 3). All interview-based measures will be administered by trained research staff. All self-report measures will

mindful journey

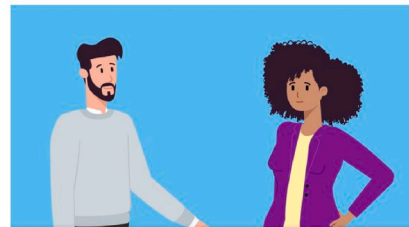
Didactic Videos on the BOAT and SOAK



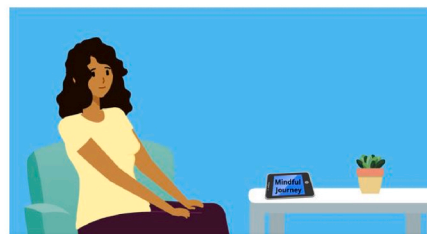
Therapist-Client Discussions



Narrator Guidance + Support



Client Testimonials



“Inside the Mind” Videos



Fig. 1. Example animations in the video clips of Mindful Journey.

Table 2

Overview of the 15-day Practice Journey after completing the lessons.

Day	Mindfulness Practice
1	Body and Breath
2	Body Scan
3	Mindful Breathing
4	BOAT
5	Ride the Wave
6	Mindfulness of Emotions
7	Compassion Practice
8	Exploring Your Needs
9	Mindful Movement
10	Mindful Rest
11	Mindful Eating
12	SOAK
13	Letting Positive Emotions Come and Go
14	Exploring Positive Emotions
15	Values Practice

be administered on Qualtrics and completed on a study tablet. The acceptability items are based on the theoretical framework of acceptability [52].

3.4. Feasibility benchmarks

The measures of feasibility and benchmarks for success (in parentheses) include: (1) feasibility of randomization (80% of eligible participant will be randomized); (2) 90% of participants will accept their randomized assignment and continue with the study; (3) adherence to Mindful Journey (50% of randomized participants completing >50% of the 15 lessons); (4) completion rates for post-treatment and follow-up visits (50% of randomized participants completing each of these visits); and (5) completion rates for EMA at baseline and post-treatment (50% of randomized participants completing >50% of EMA surveys at baseline and post-treatment). Lesson completion will be automatically recorded within Qualtrics. These measures will provide data on feasibility of both the intervention and of data collection procedures. Benchmarks for treatment adherence and assessment completion were set at relatively low values for several reasons. First, this is the first pilot feasibility trial of Mindful Journey. Our intention at this early stage is to evaluate whether this intervention has preliminary promise, as demonstrated by at least moderately adequate treatment adherence and assessment completion. Future multi-site feasibility trials can set higher benchmarks, which would provide stronger justification for eventually conducting an efficacy trial. Second, engagement rates in digital MBT have been relatively low [53]. Third, individuals with chronic SUDs represent a complex population—often with co-occurring psychiatric disorders and challenging life circumstances (e.g., unstable housing)—

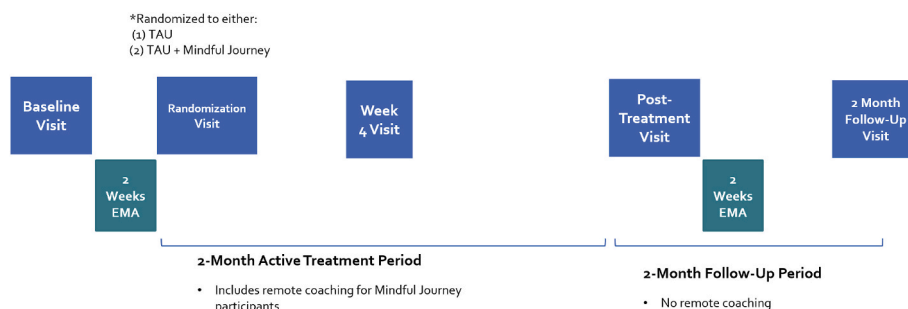


Fig. 2. Overview of study design.

which can influence treatment adherence and assessment completion [54]. We took this into account when setting benchmarks.

3.5. Acceptability benchmarks

The dimensions of acceptability assessed include willingness to engage (assessed prior to starting the intervention), usability, how understandable the content is, how engaging the content is, visual appeal, perceived helpfulness for SUD recovery, perceived skill acquisition, and perceived confidence implementing skills. The benchmark for success for all items is an average score >3 on a scale with response anchors: 1 = strongly disagree, 2 = disagree, 3 = neither disagree or agree, 4 = agree, and 5 = strongly agree. Again, given this is the first pilot feasibility trial of Mindful Journey, benchmarks for acceptability were relatively conservative. Our intention at this early stage is to evaluate whether this intervention has preliminary promise for acceptability.

3.6. Outcomes

The substance use outcomes examined – on a preliminary/exploratory basis – will include change in the frequency of primary substance use, and change in frequency of any substance use from baseline (3-month period prior to baseline) through end-of-treatment (end of week 8 post-randomization), and through the 2-month follow-up period (weeks 9–16 post-randomization). These outcomes will be based on data from the Timeline-Follow-Back Interview (TLFB) [55], which is commonly used in RCTs of SUD treatment. Although we are collecting data on substance use with EMA, it is only during the 2 weeks before and after treatment. Using the TLFB allows us to examine substance use over a longer period.

Additional outcomes examined will include change in substance-related problems as measured by the Short Inventory of Problems Revised (SIP-R) [56], and psychological distress as measured by the Brief Symptom Inventory (BSI) [57]. These outcomes will be examined from baseline through end-of-treatment and through the 2-month follow-up period.

3.7. Mechanisms

Mechanisms examined – on a preliminary/exploratory basis – will include baseline to post-treatment changes in average scores for EMA-measured mindfulness, craving, difficulties regulating negative affect, and savoring.

3.8. Procedures

Screening and baseline visit. A brief phone-based screener will be used to determine preliminary eligibility. This screener will include questions on age, recent SUD treatment, ownership of a smartphone, and ability to engage in an 18-week research study. Those initially eligible will be invited to attend an in-person baseline visit with trained research staff, in which the study will be described in more detail and informed

consent will be obtained. Then, participants will complete semi-structured interview-based assessments and self-report questionnaire measures, administered on Qualtrics. A breathalyzer test and urine drug screen will be administered, and participants will be instructed on how the EMA works and will complete a practice EMA survey. Of note, to validate the self-report data on substance use, we will assess the concordance between self-report substance use and biological data.

Baseline and post-Treatment EMA. The EMA protocol at baseline and post-treatment will be the same and will consist of 4 brief surveys per day over 14 consecutive days. This includes a past-day survey delivered at 9am, and 3 additional surveys delivered randomly within 3 time-blocks: noon to 1:30pm (“midday survey”), 4pm to 5:30pm (“afternoon survey”), and 8pm to 9:30pm (“evening survey”). Each EMA survey takes approximately 3–5 min to complete. For the past-day survey, participants will have 9 h to complete it, with reminders every hour. For the other 3 surveys, participants will have 1 h to complete them with reminders every 15 min. All surveys will be administered via the Metricwire [58] smartphone app, which is HIPAA-compliant and uses smartphone notifications to notify participants to complete the surveys.

The past-day report includes items with the stem “Yesterday” to assess behaviors (e.g., substance use and related problems) occurring any time in the previous day. The past-day report also includes items with the stem “Late last night from 10:30 p.m. to when you fell asleep” to assess behaviors (e.g., substance use) and contextual features (e.g., cue and stressors) occurring at night after the evening survey. We will assess variables at night after the evening survey to facilitate exploratory lagged analyses (e.g., momentary craving during the evening predicting substance use late at night).

The midday, afternoon, and evening surveys include items with the stem “Right now” to assess momentary experiences (e.g., affect and craving) and processes (e.g., mindfulness, negative emotion dysregulation, and savoring). The midday survey includes items with the stem “Since waking up today until now” to assess recent behaviors (e.g., substance use) and contextual features (e.g., cue and stressors) occurring during the morning and/or early afternoon. The afternoon survey includes items with the stem “Since 2:30pm until now” to assess the same behaviors and contextual features occurring during the mid-to late-afternoon. And the evening survey includes items with the stem “Since 6:30pm until now” to assess the for those occurring during the evening.

Randomization visit. Participants will attend a randomization visit after the 2-week baseline EMA period. Another breathalyzer test and a urine drug screen will be administered at this visit, and participants will complete assessments. Further, participants will be randomized to a treatment condition with a computerized urn randomization program that balances treatment conditions on gender, race/ethnicity (racial/ethnic minority vs. White/non-Hispanic), and primary substance used (alcohol vs. other drugs). Participants randomized to receive Mindful Journey will be instructed on how to download the app on their smartphones, after which they will proceed to complete the first lesson (~45 min) in a private room at the clinic. Research staff will be available to answer any technical questions about how to use the app during this visit. After completing the first lesson, research staff will inform

Table 3
Summary of study measures.

Interview-Based Measures						
Construct	Measurement Instrument	Baseline Visit	Randomization Visit	Mid-tx Visit (week 4)	Post-Tx Visit	2-M F/U Visit
Psychiatric Diagnoses	Mini International Neuropsychiatric Interview (MINI) [61]	x				
Substance Use	Timeline Follow-Back (TLFB) [55]	x	x	x	x	x
Substance-Related Problems	Short Inventory of Problems Revised (SIP-R) [56]	x	x	x	x	x
Engagement in treatment services	Adaptation of the Treatment Services Questionnaire (TSQ) [62]	x	x	x	x	x
Suicidality	Columbia Suicide Severity Rating Scale (C-SSRS) [63]	x				
Homicidal Ideation	Items adapted from the Columbia Suicide Severity Rating Scale (C-SSRS) [63]	x				
Self-Report Measures						
Construct	Measurement Instrument	Baseline Visit	Randomization Visit	Mid-tx Visit (week 4)	Post-Tx Visit	2-M F/U Visit
Demographics and Addiction History (e.g., primary drug of choice, past treatment episodes)	Demographics and Addiction History Questionnaire [64]	x				
Mindfulness	Cognitive and Affective Mindfulness Scale-Revised (CAMS-R) [65]	x		x	x	x
Psychological Distress	Brief Symptom Inventory (BSI) [57]	x		x	x	x
Quantitative Ratings of Treatment Acceptability Dimensions	Treatment acceptability items based on the theoretical framework of acceptability (TFA) [66]	x			x	
Willingness to engage in program	"I am willing to try out a smartphone app that teaches mindfulness skills for improving one's recovery"	x				
Usability	"Overall, I thought the program was easy to use"				x	
Understandability	"Overall, the material covered in the program was clear and understandable"				x	
Engage-ability	"Overall, the program did a good job at keeping me engaged as I was going through it"				x	
Appeal of visual content	"Overall, I thought the visual content of the program was appealing and high quality"				x	
Helpfulness	"Overall, I found the program helpful for me and my recovery"				x	
Acquisition of skills	"Overall, I learned valuable skills after participating in the program"				x	
Confidence implementing skills	"I am confident in my ability to apply these skills in my daily life"				x	
Chronic Pain	Brief Pain Inventory (BPI) [67]	x		x	x	x
Biological Measures						
Construct	Measurement Instrument	Baseline Visit	Randomization Visit	Mid-tx Visit (week 4)	Post-Tx Visit	2-M F/U Visit
Urine drug screens		x	x	x	x	x
Breathalyzer		x	x	x	x	x
Smartphone-Based EMA Measures						
Construct	Measurement Items	Past Day Report	Midday, Afternoon, and Evening Reports			
Past Day Substance Use	Items assessing past day substance use (yes or no for each substance) "Yesterday, did you use any of the following substances ..."	x				
Recent Substance Use	Items assessing recent substance use during the period occurring after the last EMA survey to the current moment "Since waking up today until now, have you used any of the following substances ..."	x	x			
Recent Exposure to Drug Cues	Items assessing recent exposure to the sight of drugs or other people using drugs "Have substances been directly visible to you?" "Have you seen people, places, or things that triggered craving for substances?"	x	x			
Recent Exposure to stressors	Items assessing about exposure to stressors and severity of stressors "Has anything stressful happened to you?" "How stressful has this situation been?"	x	x			
Recent involvement in a pleasant activity	An item assessing recent involving in a pleasant activity "Have you been involved in a pleasant/enjoyable activity that does not involve substances?"	x	x			
Recent Use of the "BOAT" tool	An item assessing use of the BOAT tool * only participants randomized to Mindful Journey "I practiced the BOAT" (yes or no)	x	x			
Recent Use of the "SOAK" Tool	An item assessing use of the SOAK tool * only participants randomized to Mindful Journey "I practiced the SOAK" (yes or no)	x	x			
Momentary Positive Emotion	Items assessing momentary positive emotions (excited, grateful, sense of connection, happy, relaxed, sense of meaning/purpose)				x	

(continued on next page)

Table 3 (continued)

Smartphone-Based EMA Measures			
Construct	Measurement Items	Past Day Report	Midday, Afternoon, and Evening Reports
Momentary Negative Emotion	Items asking about momentary negative emotions (Sad, Angry, lonely, ashamed, anxious, bored)		x
Momentary Physical Pain	An item assessing intensity of momentary pain “Please rate your pain”		x
Momentary Mindfulness	Items assessing momentary mindfulness, adapted from the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R) [65] “I am able to focus on the present moment” “I can notice my thoughts and feelings without judging them” “I am able to accept the thoughts and feelings I am having”		x
Momentary Difficulties in Emotion Regulation	3 items from the State Difficulties in Emotion Regulation Scale (S-DERS) [68] “I am having difficulty controlling my behaviors” “My emotions feel out of control” “I believe I will continue feeling this way for a long time”		
Momentary Savoring	3 items assessing momentary savoring adapted from the Savoring Beliefs Inventory (SBI) [69] “I feel fully able to appreciate good things” “I can’t seem to capture joy of happy moments” “I find it easy to enjoy myself when I want to”		x
Momentary Craving	Single item assessing intensity of momentary drug craving “I crave or desire alcohol or drugs”		x

participants that they will continue to use the app during the 2-month treatment period, with the support of weekly remote coaching. The recommended pace for using the app is 3 lessons per week and participants will have the choice to complete the lessons at home, on-the go (e. g., on the bus), or in a private room at the clinic. To complete the lessons, participants will need Internet access via a data plan or Wi-Fi connection. Participants randomized to treatment-as-usual only will only complete assessments at the randomization visit.

Mid-treatment, post-treatment, and 2-month follow-up visits. After the randomization visit, participants will attend three additional study visits: 1) during week 4 (mid-treatment) of the 2-month treatment period; 2) post-treatment (within 2 weeks after the end of the treatment period); and 3) 2-months after the end of the treatment period. At each visit, a breathalyzer test and a urine drug screen will be administered, and participants will complete assessments.

Compensation. Participants will be compensated up to \$492 in total for completing study assessments. This includes \$70 for the baseline visit, up to \$81 dollars each for the baseline and post-treatment EMA (\$1 per survey and bonus of \$25 for completing 75% or more of baseline EMA surveys), \$50 each for the randomization, mid-treatment, and post-treatment visit, \$30 for completing all 15 Mindful Journey lessons, and \$80 for completing the 2-month follow-up visit. A bonus payment for EMA will be included given the evidence that incentives for high completion of surveys increases completion rates [59]. The bonus payment for completing all 15 lessons will be included to promote adherence to the intervention. Adherence to Mindful Journey is being incentivized because we are in an early phase of treatment development and testing and want to ensure that participants are exposed to the intervention and can therefore provide ratings on its acceptability.

3.9. Treatment conditions

Treatment-as-usual (TAU). Participants in this condition will not have access to the Mindful Journey app and will continue with TAU at the community-based clinic. TAU entails outpatient therapy, including an intensive outpatient treatment (typically 3–4 days per week of 2–3 h therapy sessions), and aftercare outpatient treatment (1–2 days per week of 1-h therapy sessions). Most of the therapy sessions are group based and group topics include motivational enhancement, concepts and skills related to the Alcoholics/Narcotics Anonymous 12-step program, anger management, communication skills, changing social networks, psychoeducation about addiction, and general relapse prevention skills (e.g., identifying warning signs). Individual sessions

primarily focus on case management. Urine drugs screens are regularly administered. The clinic does not offer mindfulness-based treatment. Clinical staff generally aim to help clients achieve abstinence from substances. However, clinical staff are also flexible in meeting clients where they are, and supporting non-abstinence goals, such as reductions in substance use. Additionally, clinical staff aim to support clients in improving psychosocial functioning.

TAU plus Mindful Journey. Details on Mindful Journey were provided above. Participants in this treatment condition will continue with TAU while also having access to the Mindful Journey app. Additionally, participants will receive weekly phone coaching during the 2-month treatment period. After the treatment period, participants will have continued access the app throughout the follow-up period, but without phone coaching.

3.10. Statistical analyses

Feasibility and acceptability. We will conduct descriptive analyses to compute mean scores and frequencies for the feasibility and acceptability measures. These will serve as the primary outcomes for this trial.

Outcomes and Mechanisms. The current study is a feasibility trial and is not fully powered to detect efficacy. Consistent with the NCCIH research framework, we will not test for efficacy (e.g., between-treatment-condition analyses), and instead, as exploratory analyses, we will descriptively compute mean scores at each timepoint and then compute within-treatment-condition mean changes in outcomes and mechanism variables from baseline to each subsequent assessment timepoint. We will compute the within-condition Cohen’s *d* effect sizes for changes in outcomes and mechanisms over time from baseline to each timepoint. Analyses will be conducted with the intent-to-treat sample. These preliminary analyses will allow us to examine both sensitivity to change of outcomes and mechanisms, as well as when these changes may be occurring (e.g., during treatment and/or during follow-up). This in turn, will inform the design of future trials that will test efficacy.

4. Discussion

Recovery from SUDs is often a complex, long-term process. Poor recovery outcomes after an initial treatment episode (e.g., return to using substances on multiple occasions or readmission to inpatient treatment) remain common [2–5]. There remains a need for innovative strategies to reduce improve long-term recovery outcomes, including

psychological well-being. Over the past several decades, a culmination of evidence suggests that negative affect [15–18], craving [18–22], and anhedonia [16,23,24] may underlie poor recovery outcomes. Mindfulness-based treatment (MBT), which has a focus on observing negative and positive affect and craving with nonjudgmental and nonreactive awareness, may be a suitable approach for promoting recovery. Indeed, in-person MBTs are effective for reducing substance use, substance-related problems, and psychological distress [18,27,28]. Nevertheless, to date there are no *digital* MBTs for promoting recovery in SUDs. This is unfortunate because digital interventions may overcome implementation barriers and can be easily, widely, and economically disseminated. To fill this gap, our team recently developed Mindful Journey, a novel adjunctive smartphone app-based mindfulness treatment for promoting long-term recovery from SUDs.

We also described the protocol for a pilot feasibility randomized controlled trial of Mindful Journey, in which individuals in an early phase of receiving outpatient treatment for SUD are randomized to either treatment-as-usual plus Mindful Journey or treatment-as-usual only. The trial will focus on testing the feasibility of the app (e.g., engagement with the app), feasibility of study procedures (e.g., assessment completion), and the acceptability of the app (e.g., perceived usability and helpfulness for recovery). As exploratory aims, we will also examine sensitivity to change of recovery outcomes and mechanisms, by computing mean scores at each timepoint and within-treatment-condition changes over time. We will not test for efficacy because this trial is not powered to do so. One innovative feature of the trial is the incorporation of ecological momentary assessment (EMA) before and after the active treatment period. EMA affords the opportunity to measure targeted mechanisms in real-time, including mindfulness, craving, difficulties with negative emotion regulation, and savoring.

One limitation of the current trial is the fact that it is underpowered to detect between-group differences. Additionally, as compared to an open trial in which all participants engage in Mindful Journey and provide acceptability ratings, the current randomized design only has a subset of participants engage in Mindful Journey and provide acceptability ratings. Hence, with the current design, another limitation is that we are obtaining data on acceptability from a smaller sample. With these limitations in mind, it is important to note that a strength of the randomized design is that we are able to evaluate feasibility metrics related to randomization, such as (1) percentage of participants eligible after the baseline session who proceed to be randomized 2 weeks later; and (2) percentage of participants who accept their randomized assignment and continue with the study. As such, our design allows us to evaluate the risk that participants randomized to TAU may be upset that they are not receiving the app and may drop out of the study. The feasibility metrics related to randomization are important to evaluate before proceeding to a fully-powered randomized controlled efficacy trial. Indeed, this type of design – and the collection of such metrics – is consistent with the NCCIH’s model for developing mind-body interventions [60].

Importantly, this single-site feasibility trial will provide foundational data to inform next steps in the treatment development process. If the trial results in adequate feasibility and acceptability, a next step may be conducting a multi-site feasibility trial, which would be a precursor to a full-scale multi-site efficacy trial.

In summary, this paper provides an overview of a novel app-based mindfulness treatment for SUD and outlines the protocol for a pilot randomized controlled trial focusing on feasibility and acceptability outcomes. The findings from this trial will provide important preliminary data on whether this app is feasible and acceptance among individuals in an early phase of treatment for SUD.

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CRediT authorship contribution statement

Corey R. Roos: Writing – review & editing, Writing – original draft, Project administration, Methodology, Funding acquisition, Conceptualization. **Jonathan Bricker:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization. **Brian Kiluk:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization. **Timothy J. Trull:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Sarah Bowen:** Writing – review & editing, Funding acquisition, Conceptualization. **Katie Witkiewitz:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Hedy Kober:** Writing – review & editing, Supervision, Methodology, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available upon request.

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