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Development of a mindfulness-based treatment for smoking cessation and the modification of alcohol use: A protocol for a randomized controlled trial and pilot study findings

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ABSTRACT

The combined use of cigarettes and alcohol is associated with an increased risk of morbidity and mortality. Yet, efficacious interventions that address both behaviors concurrently are lacking. Smoking cessation and alcohol modification not only garner health benefits, but there is also value in addressing alcohol use in the context of smoking cessation to reduce the risk for smoking relapse. In this paper we describe the development of mindfulness-based relapse prevention for smoking cessation and alcohol modification (MBRP-SA) and pilot study findings (Phase 1). Next, details regarding the methods and design of an ongoing, randomized controlled trial, Project RISE (Phase 2), are described. MBRP-SA is a group-based intervention that consists of eight weekly treatment sessions. Results from the Phase 1 pilot study ($N = 21$ enrolled) indicated that participants planned to use the skills learned in their everyday activities and to address their smoking and alcohol goals. Based on the progression of Phase 1 cohorts, modifications were made to the inclusion/exclusion criteria and recruitment methods that will be implemented in Phase 2. Phase 2 will assess the feasibility and acceptability of MBRP-SA, delivered via live online groups, as a primary treatment option for smoking cessation and alcohol use modification.

1. Introduction

The use of cigarettes and alcohol is associated with numerous health problems. Cigarette smoking is the leading preventable cause of morbidity and mortality in the United States and is the primary cause of cancer development [1,2]. The combined use of cigarettes and alcohol is associated with a synergistic increase in risk of mortality [3–5]. Existing data indicate that people who drink alcohol are more likely to smoke cigarettes and vice versa [6,7]. Importantly, alcohol use presents a substantial risk for relapse in the context of smoking cessation [8,9], and effective interventions designed to address drinking during a quit attempt are needed.

Existing treatments for the co-use of smoking and alcohol have primarily focused on individuals with alcohol use disorder (AUD) [10–12]. Additional research is needed for those who do not meet criteria for AUD, as 1) such interventions can have broader reach, 2) risk of smoking relapse is likely to decrease if alcohol use has reduced or stopped (regardless of meeting AUD criteria), and 3) health problems due to alcohol use, including cancer development, have primarily been linked to the quantity/frequency of use (not necessarily AUD) [13–16]. Brief interventions have been tested among smokers with problematic levels of alcohol use (i.e., not AUD), but these studies often report a lack of sustained decreases over time for smoking and/or alcohol use [17–19] or restricted age range (e.g., young adults) [20]. The current study addresses these limitations by testing an intensive (8 week) intervention that targets adult cigarette smokers who want to both quit smoking and change alcohol use.

We posit that a mindfulness-based intervention (MBI) may be particularly effective for this population. MBIs are associated with increased tobacco abstinence [21–26] and decreased alcohol use

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[27–30]. Mindfulness is theorized to target several mechanisms central to changing substance use behavior [31], and empirical studies show mindfulness is associated with key constructs central to behavior change, including negative affect [21,32–37], positive affect [36,38–41], self-efficacy [35,42–44], and craving [35,45–48]. Mindfulness-based relapse prevention (MBRP), the intervention modified in the current study, has shown efficacy for reducing alcohol use, alcohol craving, and substance use [49–52]. There is only one small pilot study targeting both smoking and alcohol use with a mindfulness intervention among college students, which found increased tobacco abstinence and reduced drinking [53]. Importantly, this study found that alcohol use was significantly lower among those able to maintain tobacco abstinence, as opposed to those who continued to smoke.

The primary aim of the current study was to modify MBRP for adults who want to quit smoking and change their alcohol use, and then compare the revised treatment (MBRP-SA [smoking and alcohol]) to standard cognitive behavioral therapy (CBT). Drinking change goals (e.g., safe drinking, reduction) were set by the individual participants and abstinence from alcohol was not a target of the intervention, consistent with a harm reduction approach and fitting within the framework of self-determination theory [54,55]. This paper describes the intervention development process, study design of the randomized controlled trial (RCT; including changes due to COVID-19), and pilot results from the intervention development phase.

2. Method

2.1. Overview

The primary goal of Phase 1 was to modify an existing addiction treatment – MBRP [56] – to focus on smoking cessation and the modification of alcohol use (MBRP-SA), and to pilot test the revised protocol on a small sample. We include here a description of MBRP, modifications made to the original MBRP treatment manual, and data from the pilot study. The primary goal of Phase 2 was to evaluate benchmarks regarding the feasibility and acceptability of the MBRP-SA protocol. A description of the RCT that is ongoing is provided, including changes being made due to COVID-19.

2.2. Phase 1

MBRP has an established group treatment manual [57] that was used to guide the development of MBRP-SA. We refer the reader to that manual for a detailed overview of specific mindfulness practices, content, and examples of facilitator/client interaction [58]. It should be noted that MBRP was initially designed to prevent relapse to substance use, broadly, and was delivered as an aftercare treatment following residential or intensive outpatient treatment for substance use disorder, although it has demonstrated efficacy as the primary treatment following detoxification/stabilization [59] and effectiveness as an outpatient primary treatment for drinking reductions [60]. MBRP does not specifically discuss tobacco use or cessation (e.g., use of nicotine replacement therapy), and no published studies have included tobacco use as an outcome. That said, MBRP has demonstrated efficacy for reducing alcohol use, alcohol craving, and substance use [50,58,59,61]. Here, we describe our modifications to the treatment protocol. Table 1 provides the final content for each session of MBRP-SA.

2.2.1. Modifications to MBRP

The primary adaptation for MBRP-SA was to make the treatment content suitable for primary treatment for smoking cessation and the modification of alcohol use. Initial changes to the existing MBRP treatment manual were guided by the existing literature (e.g., studies on mindfulness-based treatments for smoking cessation) [22–26,62] and the clinical experience and knowledge of the investigative team. Modifications were also made following each cohort, based on feedback from participants and the experiences of the facilitators. Information presented here includes the final, revised treatment that is being utilized during Phase 2.

It should be noted that MBRP already addresses some of the primary underlying mechanisms of smoking cessation and alcohol use (e.g., managing negative affect and craving), and the extant literature indicates that key behavior modification constructs (e.g., self-efficacy) are impacted by mindfulness [35,63–65]. Therefore, the core components of MBRP were not modified, but instead the existing protocol was supplemented with content unique to smoking and alcohol use. Content modifications listed here fall into three categories: smoking-specific, alcohol-specific, and co-use. Given MBRP has already demonstrated efficacy for reduced alcohol use, most of these modifications focus on smoking and co-use content.

2.2.1.1. Smoking content changes. **Quit date**. Extant literature indicates that motivation can be enhanced by setting a specific quit date [66]. Therefore, MBRP-SA includes a quit smoking date at session 5, which is also supported by the existing literature on mindfulness-based treatments for smoking cessation [26]. This permits time for individuals to develop their mindfulness practice (sessions 1–4) while still providing ongoing support for 3 weeks after the quit day. **Losing a friend**. Many smokers report that smoking a cigarette represents a type of "friendship" and that quitting smoking is like losing a close friend [67–69]. MBRP-SA incorporates content related to this concept in session 3. **Diet and Weight Gain**. Many individuals endorse motivation to continue smoking for weight control purposes [68]; therefore, information on this topic is included in session 3. **Nicotine Patch**. Current guidelines for smoking cessation indicate the combination of nicotine replacement therapy and behavioral intervention are most effective in supporting cessation [66]. Thus, participants are provided with nicotine patches at the end of session 4, with the intention to begin using them at session 5. Psychoeducation about patch use occurs at session 4. **Mindful Smoking**. Mindful smoking is a mindfulness activity that brings awareness to the act of smoking a cigarette. An introduction to this occurs at the end of session 2, and the actual practice is conducted prior to the start of session 3. Participants are encouraged to continue mindful smoking until their quit day at session 5.

2.2.1.2. Alcohol content changes. **Modification of alcohol use**. A discussion of goals related to changing alcohol use begins at session 1 and continues through session 5. Participants are provided with a handout including psychoeducational information on alcohol use, and participants are encouraged to use this information to set realistic drinking change goals for themselves in session 1. Participants are encouraged to implement their drinking goal at session 5 (to coincide with the smoking quit date), although many people may have already changed use prior to this session.

2.2.1.3. Co-use changes. **Psychoeducation**. Consistent with recommendations [66], participants are provided with psychoeducational information on the impact of cigarette and alcohol use on their health at session 1. Information on the benefits of quitting smoking and reducing drinking (e.g., breathing becomes easier, decreased risk of cancer development) are also provided. **Relationship between smoking and drinking**. Given common underlying mechanisms of the co-use of alcohol and cigarettes (e.g., cue-induced craving, positive and negative reinforcement) [8,70–74], discussions related to the inter-connected relationship among smoking and alcohol use begin in session 2 and continue throughout the treatment. Discussions are integrated throughout the sessions as part of the inquiry process, where facilitators ask participants questions about their experiences with the practices. These discussions may include a focus on previous attempts to change either or both behaviors by participants, and discussions around how continued alcohol use may serve as a trigger for relapse. We believe this

Table 1
Session content of MBRP-SA.

Session 1 – Automatic Pilot and Relapse
- introductions
- group expectations for group, limits to confidentiality, and rules for confidentiality and privacy
- group structure and overview
- quitting smoking and alcohol goals
- raisin exercise
- what is mindfulness
- body scan exercise
Session 2 – Awareness of Triggers and Cravings
- review group rules
- body scan
- home practice review and common challenges
- walking down the street exercise
- urge surfing exercise
- mountain meditation
- introduction to mindful smoking
Session 3 – Mindfulness in Daily Life
- mindful smoking meditation
- home practice review
- breath meditation
- false refuge
- SOBER breathing space
Session 4 – Mindfulness in High-Risk Situations
- awareness of hearing and seeing
- home practice review
- sitting meditation: sound, breath, sensation, thought
- individual and common relapse risks
- sober breathing space in a challenging situation
- quit day prep
Session 5 – Acceptance and Skillful Action
- sitting meditation: sound, breath, sensation, thought, emotion
- sitting meditation
- home practice review
- quit day and alcohol modification goal
- sober breathing space in pairs
- sober breathing space in challenging situations
- acceptance and skillful action
- mindful walking
Session 6 – Seeing Thoughts as Thoughts
- mindful movement
- home practice review
- sitting meditation: thoughts
- thoughts and relapse
- relapse cycle
- sober breathing space
- preparing for the end of the course
Session 7 – Self-Care and Lifestyle Balance
- lovingkindness meditation
- home practice review
- daily activities exercise
- where does relapse begin?
- reminder cards
Session 8 – Social Support and Continuing Practice
- body scan
- home practice review
- the importance of support networks
- reflections on the course and intentions for the future
- concluding meditation and closing circle

Note. The end of each session consists of reviewing the home practice for that upcoming week and a very brief closing mindfulness exercise.

added content aids participants in making the best decision regarding their own co-use.

2.2.2. Pilot study

The MBRP-SA protocol was pilot tested with three cohorts of individuals ($N = 21$) and feedback from participants was used to make any additional modifications. These pilot study outcomes are presented in the results section.

2.2.3. Participants and recruitment

Inclusion and exclusion criteria are presented in Table 2. Three cohorts (5–8 participants each) were recruited as part of Phase 1. Recruitment methods for the first two cohorts of Phase 1 included print ads within the community and general online advertising. Flyers were distributed at primary care offices, wellness programs/clinics, and physician offices (face-to-face meetings or presentations were conducted as requested by the physicians/staff). We asked human resources departments of local businesses to distribute flyers to potentially interested employees. Participants from prior studies at our research clinic who gave permission to be contacted for future research were contacted. Finally, we collaborated with the Tampa Bay Community Cancer Network (TBCCN), which is a network of 28 diverse partner organizations, including community clinics and Moffitt Cancer Center. This network addresses critical access and prevention and control issues among medically underserved, lower-literacy and low-income populations in the immediate and surrounding catchment area. Organizations included federally qualified health centers, health departments, social service organizations, faith-based and adult education groups, and medical offices (e.g., dental offices). For cohort 3, a marketing and advertising company, Trialfacts, was used to recruit through social media (e.g., Facebook, YouTube). We also advertised on local buses.

2.2.3.1. Telephone screening. Interested participants were contacted via phone and provided a detailed overview of the study. Potential participants were screened for inclusion/exclusion criteria. Eligible participants were scheduled for an in-person orientation session.

2.2.3.2. Orientation session. Upon arrival, participants completed the informed consent process for the collection of eligibility data. Next, they provided two breath tests, including a carbon monoxide (CO) test to confirm smoking status and a blood alcohol content (BAC) test to detect the presence of alcohol. Participants who had a BAC above 0.01 were not permitted to participate in the session but were encouraged to reschedule. The Timeline Followback (TLFB) [75,76] was administered to confirm participants met the alcohol inclusion criterion for the past month. The Mini International Neuropsychiatric Interview (MINI) for Substance Use and Psychotic Disorders [77] according to the DSM-5 was administered to obtain diagnostic information.

Eligible participants were provided a detailed description of the study via a PowerPoint presentation, were given an opportunity to ask questions, reviewed the written informed consent document (most of which was already presented via PowerPoint), and provided written informed consent for participation in the treatment study. These procedures were conducted in either a group or individual setting, depending on schedules and availability. Consented participants completed a series of self-report questionnaires. Individuals who were not eligible or declined to participate were provided with referrals for smoking cessation and alcohol treatment programs.

2.2.3.3. Treatment visit overview. Participants attended group treatment for eight weekly sessions. At the beginning of each visit, study staff collected CO and BAC. Any participant with a BAC > 0.01 was not permitted to participate in the session and was encouraged to schedule an individual makeup session in which they could listen to the session recording. Makeup sessions were intended to aid in treatment retention and ensure participants were receiving all group content. After completing the breath tests, participants completed self-report measures and the TLFB for tobacco and alcohol use. Participants were then escorted to the designated room for the group session. All participants received nicotine replacement therapy (NRT) and MBRP-SA, as described in more detail below.

2.2.3.3.1. NRT. The nicotine transdermal patch is the most widely used pharmacotherapy and the Treating Tobacco Dependence Clinical Practice Guideline [66] has identified it as frontline therapy. Patch therapy for participants who smoked >10 cigarettes per day (CPD) consisted of 6 weeks of 21 mg patches and 2 weeks of 14 mg patches. Patch therapy for participants who smoked <10 CPD consisted of 6 weeks of 14 mg patches and 2 weeks of 7 mg patches. Patch dispensation occurred at weekly treatment visits beginning at the end of visit 4. Participants were instructed to begin wearing the patch the same day as visit 5, the quit date.

2.2.3.3.2. MBRP-SA. MBRP-SA session content is described in detail above and in Table 1. There were 8 sessions (2 h each), with up to 8 participants in each group. Participants received an email within 24 h after each group session that included a summary of group content, session handouts as attachments (in case this format was preferred over the hard copies provided in group), and a web link to the meditations for that week. Headphones were provided to all participants at session 1, and CDs with meditations were distributed throughout the sessions (for those who would prefer to listen to the CD instead of via the web link).

2.2.3.4. Retention procedures. The following procedures were conducted to reduce attrition: pre-treatment mailouts to remind participants about the group and to provide information about what to expect from the group treatment; reminder phone calls or texts prior to all study sessions; requiring a functioning phone number and home address to contact participants by phone or mail as needed; and obtaining the name, address, and phone number of at least two contacts (i.e., relatives, friends) who could provide contact information for the participants, in case we were unable to contact them during the study. Participants were financially compensated for completing the assessment measures and for the costs associated with participation such as transportation, childcare, etc. Participants received compensation at each visit on an escalating payment schedule, ranging from $10 - $30 per visit. Participants could earn up to $200 by participating in the study. Participants were also provided with a light meal at the beginning of each group session.

Table 2
Inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
≥ 18 years of age	Contraindication for nicotine patch
Currently smoking ≥3 cigarettes per day for the past year	Active substance use disorder other than an alcohol use disorder
Carbon Monoxide level ≥ 8 ppm[a]	Active psychotic disorder
Cotinine levels ≥10 ng/ml (if CO is not ≥8 ppm)[a]	Regular use of other tobacco or nicotine products (cigars, e-cigarettes)[a]
Motivated to quit smoking within the next 60 days	Current use of tobacco cessation medications
Motivated to change alcohol use within the next 60 days	Pregnancy or lactation
If male, consumes ≥5 drinks; If female, consumes ≥4 drinks on at least 5 occasions in the past month[b]	Household member already enrolled in the study
Valid home address in the area[c]	
Functioning telephone number	
Can speak, read, and write in English	

[a] Criteria removed for RCT.
[b] Criterion changed to "If male, consumes ≥5 drinks; If female, consumes ≥4 drinks on at least 1 occasion in the past month" for RCT.
[c] Criterion changed to "Valid home address" for RCT.

2.2.4. Measures

Table 3 provides an overview of measures that were administered throughout the study, and we provide a summary of those measures below.

2.2.4.1. Demographics. The demographics questionnaire collected data such as gender, age, race, ethnicity, education, income, employment, partner status, and insurance status.

2.2.4.2. Alcohol measures. Alcohol use was captured via several self-report questionnaires, including an alcohol use history questionnaire (created by the team; assesses past year use, other household drinkers, etc.), alcohol craving [78], alcohol abstinence self-efficacy [79], and drinking motives [80].

2.2.4.3. Smoking measures. Assessment of tobacco use behaviors included smoking use history (onset of smoking, quit attempts, other household smokers, use of other products, etc.), motives for smoking [81], nicotine withdrawal symptoms [82], and smoking self-efficacy [83].

2.2.4.4. Mindfulness measures. Mindfulness was measured using self-report questionnaires that assessed state and trait mindfulness [84,85].

2.2.4.5. Affect/depression/stress measures. Depression [86], distress tolerance [87], stress [88], and affect [89] were assessed.

2.2.4.6. End of treatment questionnaire. The End of Treatment Questionnaire (developed by the study team) was administered at the last treatment visit. This measure captured the intent to use the skills learned in treatment, preferences for and benefits of the skills learned, appropriateness of skills, and barriers to treatment. Intent to utilize skills were measured on a 10-point Likert scale ranging from 1 (No, not at all) to 10 (Yes, definitely). Appropriateness and likelihood of using skills were measured on a 5-point Likert scale ranging from 1 (Definitely unlikely/inappropriate) to 5 (Definitely likely/appropriate). Additionally, participants were asked about which meditation practices were the most useful and enjoyable. Options included: the Body Scan, Urge Surfing, Mountain Meditation, Sitting Meditation on the Breath, SOBER Breathing Space, Sitting Meditation on Sound, Breath, Sensation, and Thought, Mindful Movement, Sitting Meditation on Thoughts, and

Table 3
Phase 1 study procedures overview.

	Pre-cessation Week					Post-cessation Week				
	-10 – −5	-4	-3	-2	-1	0	1	2	3	4
	Orientation	Start of Tx				Quit Day			End of Tx	Follow Up
DEMOGRAPHICS / MENTAL HEALTH										
Demographics	X									
MINI Psychotic Disorders, Alcohol, and Substance Use Disorders for DSM-5[77][a]	X									
SMOKING MEASURES										
Smoking Use and History	X									
Brief Wisconsin Inventory of Smoking Dependence Motives [81]	X					X			X	X
Wisconsin Smoking Withdrawal Scale [82]	X					X			X	X
Self-Efficacy Scale-Smoking	X					X			X	X
ALCOHOL USE MEASURES										
Alcohol Use Goals[a]		X			X				X	X
Alcohol Use History	X									
Patient Health Questionnaire – Alcohol Use	X					X			X	X
Penn Alcohol Craving Scale [78]	X					X			X	X
Alcohol Abstinence Self Efficacy [79]	X					X			X	X
Drinking Motives Questionnaire – Revised [80]	X					X			X	X
MINDFULNESS										
Five Facet Mindfulness Questionnaire [84]	X					X			X	X
Toronto Mindfulness Scale [85]	X	X	X	X	X	X	X	X	X	X
AFFECT / DEPRESSION / STRESS										
Center for Epidemiological Studies Depression Scale Revised [86]	X					X			X	X
Distress Tolerance Scale [87]	X					X			X	X
Perceived Stress Scale [88]	X					X			X	X
Positive and Negative Affect Scale [89]	X	X	X	X	X	X	X	X	X	X
ALCOHOL USE AND SMOKING STATUS / BIOCHEMICAL VERIFICATION										
Timeline Followback[75, 76, 92][a]	X	X	X	X	X	X	X	X	X	X
Carbon Monoxide (CO)[a]	X	X	X	X	X	X	X	X	X	X
Urinalysis hCG, as applicable[a]	X									
Urine Cotinine as applicable[a]	X									X
Blood Alcohol Content (BAC)[a]	X	X	X	X	X	X	X	X	X	X
FEEDBACK FROM PARTICIPANTS										
End of Treatment Feedback Questionnaire									X	
Working Alliance Inventory – Short Revised Client Version Modified [90]									X	
Follow-up Questionnaire[a]										X

Note. Tx = "Treatment".

[a] Procedure modified from Phase 1 to Phase 2 (see text for details).

Loving Kindness.

2.2.4.7. Working alliance inventory. The quality of the alliance between the participant and the facilitator was assessed [90].

2.2.4.8. Follow-up questionnaire. The Follow-Up Questionnaire was administered at the in-person follow-up visit. This measure was developed by the study team and assesses skill maintenance since the end of treatment.

2.2.4.9. Acceptability. Acceptability of the treatment was assessed through participant satisfaction (via the Client Satisfaction Questionnaire [91]), intention to continue using the skills learned from the treatment (via the End of Treatment Questionnaire developed for this study), and perceived appropriateness of the treatments for smoking and alcohol use (also via the End of Treatment Questionnaire). Although these data were collected in Phase 1, these measures will be formally examined during the RCT in Phase 2.

2.2.4.10. Smoking and alcohol use. Tobacco abstinence and alcohol use was collected in Phase 1 and will be examined more closely in Phase 2 to determine whether changes in smoking and drinking occurred over the course of the study. Below the data collection process for Phase 1 is described (Phase 2 is described later).

2.2.4.11. Tobacco abstinence. The TLFB was used to record daily, retrospective self-reported smoking data [75,76]. The TLFB collected smoking data from the past four weeks at the orientation visit, past week use at each subsequent visit, and past week use at the in-person follow-up visit. A calendar was provided to participants, and they indicated any key events that occurred on certain dates to aid their memory. Participants then indicated how many cigarettes they smoked each day.

2.2.4.12. Alcohol use. The TLFB was used to determine daily, recent alcohol use via self-report [75,76,92]. Procedures for reporting alcohol use are the same as described above for reporting smoking. Participants completed an Alcohol Goals Form at orientation, session 4, session 8, and the in-person follow-up. At baseline, this form asked participants to indicate their alcohol use goal. At session 4, participants again completed this form, in case they decided to modify their goal. At session 8 and at follow-up, participants indicated whether or not they were able to achieve their stated goal from session 4.

2.2.5. Open-ended program feedback

Feedback on MBRP-SA was gathered from each cohort. Specifically, participants were asked to return to the clinic one week after the last treatment session to provide written and verbal feedback. Verbal feedback was collected in a group format and focused on questions surrounding program materials (e.g., treatment session handouts), logistics of the study procedures, and barriers that occurred throughout the study. Feedback provided from this group will be discussed in our Results section.

2.3. Phase 2

Phase 2 will comprise the RCT, Project RISE (**R**eaching and **I**nspiring **S**top Smoking and Alcohol Reduction **E**fforts), which will compare MBRP-SA to CBT for smoking cessation and alcohol modification. Primary differences from Phase 1 include the randomization component, provision of CBT, and timing of follow-up visits. At the beginning of Phase 2 the COVID-19 pandemic began and the decision was made, in conjunction with the study sponsor, to provide all phases of the research and treatment protocol remotely (e.g., REDCap and telephone-based data collection, video conferencing for group sessions). Additionally, the order of measures and procedures has been modified slightly in Phase 2 due to remote procedures (e.g., a Zoom Orientation session was added to help acclimate participants to the technology).

2.3.1. Participants

Phase 2 participants ($N = 64$) will be randomized to MBRP-SA or CBT in a 1:1 ratio ($n = 32$ in each group). Inclusion and exclusion criteria are presented in Table 2. Based on recruitment from Phase 1 and to facilitate recruitment in Phase 2, some criteria were changed. Details surrounding changes to the inclusion and exclusion criteria will be discussed further in the Results section and the changes from Phase 1 to Phase 2 are indicated in the Table with an asterisk.

2.3.2. Procedures

2.3.2.1. Recruitment. Given the circumstances surrounding COVID-19, we have modified our recruitment procedures to expand beyond the local area. We will maintain those recruitment procedures from Phase 1 that best fit procedural changes implemented in Phase 2 due to COVID-19 (e.g. flyers at local business, bus ads, healthcare partners). Otherwise, recruitment is planned to primarily take place via Trialfacts.

2.3.2.2. Randomization. Sixty-four participants will be randomized to either MBRP-SA ($n = 32$) or CBT (n = 32). Three stratification variables will be included: gender (men vs women), race/ethnicity (non-Hispanic White vs Other), and smoking rate (20+ CPD vs less than 20). Within these eight cells, eligible participants will be assigned to one of the two treatments using balanced-permuted block randomization with a block size of four.

2.3.2.3. Telephone screening. Interested participants will be contacted via phone and provided a detailed overview of the study as performed in Phase 1. Potential participants will be screened for inclusion/exclusion criteria. However, all eligibility data will be collected in the phone screen during Phase 2, rather than at the orientation session. Eligible participants will then be scheduled for a phone call with a staff member to orient them to the study. Procedures for participants who are not eligible or those who decline to participate will be identical to Phase 1.

2.3.2.4. Orientation sessions. A study staff member will conduct a phone call with participants to obtain verbal consent and orient participants to the study. Consented participants will be provided with a study schedule via mail, will complete the first Alcohol Goals Form, and the TLFB for smoking and alcohol use. They will then be sent an electronic link to complete a series of self-report questionnaires (see Table 3). Individuals who decline to participate will be provided with referrals for smoking cessation and alcohol use programs.

Participants will then be scheduled to attend a Zoom orientation session with study staff, the treatment facilitator, and fellow participants for the purpose of training in the video-conferencing software, video-conferencing etiquette, initial introductions to group members and study staff, and to be informed of any materials they should have on hand for their first treatment session. The Zoom orientation session is planned to take place one week before the first treatment session, and participants will receive a mailout with needed materials prior to the Zoom orientation. Prior to being admitted to the Zoom orientation session, participants will be asked to verify their date of birth to confirm their identity. Before entering any Zoom call (both Zoom orientation and group sessions), participants will view a banner that includes a reminder for group expectations (e.g., being in a private, quiet location for group). We will follow the American Psychological Association guidelines for telepsychology in all aspects of treatment delivery [93].

2.3.2.5. Treatment visit overview. Participants will attend group treatment for eight weekly sessions via the video-conferencing app Zoom. All participants will receive NRT as described above (with the only

difference being that it will be delivered via mail) and either MBRP-SA or CBT, as described in more detail below.

2.3.2.5.1. MBRP-SA. MBRP-SA session content is described in detail above and in Table 1. There will be 8 sessions (2 h each), with 8–10 participants in each group. The procedure for sending weekly emails will be identical to those in Phase 1. Headphones will be mailed to all participants prior to session 1, and CDs with meditations will also be mailed (for those who would prefer to listen to the CD over the web link). Given the remote nature of Phase 2 and in an attempt to maintain participant engagement, participants will also be provided with a link to a study-specific website that contains relevant study materials (e.g., links to handouts, audio files of meditations).

2.3.2.5.2. CBT. CBT is a well-established and commonly used treatment for substance use disorders that primarily utilizes a problem solving and coping skills approach rooted in relapse prevention theory [66,94]. Session content will generally follow the manual used in prior studies combined with standards from the Treating Tobacco Use and Dependence: Clinical Practice Guideline (e.g., setting a quit date, providing NRT) [66]. CBT will consist of 8 sessions (2 h each), with 8–10 participants in each group. Thus, participants in both MBRP-SA and CBT will be matched on treatment contact time. All treatment activities focus on promoting/maintaining smoking abstinence and modifying alcohol use, with specific treatment objectives for each session. Participants will receive weekly emails that contain a summary of the session content and session handouts for their review (similar to the MBRP-SA group). Participants will be provided with a link to a website containing relevant study materials. The CBT and MBRP-SA websites are identical except for inherent differences between the treatments (e.g., different handouts; no meditations available for CBT group).

CBT session content varies over the 8 treatment sessions and builds upon what is learned in prior sessions. During session 1, participants will discuss reasons for smoking and drinking, as well as the benefits of quitting smoking and changing alcohol use. In session 2, the group will discuss identifying and coping with high-risk situations. Session 3 will focus on their alcohol change goal, as well as changing thoughts that undermine smoking abstinence and alcohol modification. Session 4 will cover stress management and preparing for the quit day. During session 5 (quit day), the group will discuss preparing for success by discussing future challenges related to quitting, including withdrawal. Session 6 will focus further on coping skills, managing stress, and enlisting social support. Session 7 will cover managing weight gain and anticipating threats to smoking abstinence. Finally, in session 8, the group will discuss preparation for the end of the treatment, as well as how to maintain the gains they have achieved in treatment. Home practice will be assigned each week, based on that week's content.

2.3.2.6. Follow-up phone calls. Participants will be contacted by phone for an individual follow-up session eight weeks post their quit date (i.e., five weeks following session 8). Participants will complete the TLFB for tobacco and alcohol use and the Alcohol Goals Form (see Table 3). A subset of participants will be invited to complete in-depth interviews during this visit. General response to treatment will be assessed, including what they found most and least helpful. Participants will specifically be queried on the appropriateness, acceptability, usefulness, etc. of the intervention, as well as other general treatment-related issues (e.g., barriers to enrolling in treatment).

At 16 weeks post-quit date (i.e., eight weeks following the first follow-up call), participants will receive a final follow-up call. The study staff will administer the TLFB for tobacco and alcohol use and the Alcohol Goals form. Participants who report tobacco abstinence at their 16-week follow-up will be mailed a test kit to measure cotinine via saliva for biochemical verification of tobacco abstinence.

2.3.2.7. Retention procedures. The reminder procedures, participant and collateral contact information described for the Phase 1 pilot study will be implemented in Phase 2. Additionally, participants who miss one or more treatment sessions will be encouraged to makeup the session by listening to the session recording. Participants will also be compensated for completing assessment measures during Phase 2.

2.3.3. Measures

Below our primary outcome measures are described. All measures administered in Phase 2 are identical to those administered in Phase 1 unless otherwise specified. Each week, participants will be sent a link to complete a brief set of measures via REDCap. A study staff member will contact the participant by phone to complete the TLFB for tobacco and alcohol use and the Alcohol Goals Form before sessions 4 and 8 and at follow-up (see Table 3).

2.3.3.1. Acceptability and feasibility. Our primary aim of Phase 2 is to assess the acceptability and feasibility of MBRP-SA (see Table 4). To measure the acceptability of treatment, we will be utilizing the same measures as described in Phase 1.

Feasibility will be measured by accrual rates, retention, cost of recruitment, questionnaire completion, and homework completion. The number of call attempts for each participant will be recorded, as well as reasons for ineligibility. The development of these outcomes was informed by the extant literature on feasibility measurement [46,95,96].

In addition to the measurable outcomes mentioned above, other areas that will be monitored include the ability of study staff to: randomize participants to each group, effectively screen for eligibility criteria, organize all questionnaires to be completed for thorough data processing and analysis, and to schedule participants for treatment sessions and follow-ups. For any participant who drops out early, a structured phone interview will be attempted to determine reasons for withdrawal and overall reaction to the treatment protocol.

2.3.3.2. Follow-up questionnaire. The Follow-Up Questionnaire will be administered at the 8-week follow-up call in Phase 2.

2.3.3.3. Smoking and alcohol use. Tobacco abstinence and alcohol use outcomes will be collected in Phase 2 and will follow the similar

Table 4
Measurable benchmarks.

Outcome Measure	Description of Outcome to be Evaluated	Measure and/or Expected Outcome
Acceptability	Participant Satisfaction	Client Satisfaction Questionnaire [91] (satisfaction of ≥80%)
	Intention to continue using skills learned	Questionnaire developed for this study
	Perceived appropriateness of the treatments for smoking and alcohol use	Questionnaire developed for this study
Feasibility	Accrual	For recruitment, the cost of each participant will be ≤$100
	Completed sessions	≥40% of participants will complete all 8 sessions; ≥60% will complete between 4 and 7 sessions
	Homework Completion	For MBRP-SA, participants will engage in mindfulness home practice a minimum of 3.5 days per week
	Screening/eligibility for study	Record number of call attempts for each participant and reasons for ineligibility
	Recruitment	Recruit 8 eligible participants per month
	Retention	Retain 80% through end of treatment, 70% through follow-up
	Questionnaire completion	For sessions attended, 90% of questionnaires will be completed

procedures as Phase 1 (e.g., TLFB).

2.3.3.4. Tobacco abstinence. To determine tobacco abstinence in Phase 2, 7-day point prevalence abstinence will be used, which is a combination of a self-report of no smoking in the last 7 days, combined with biochemical verification of no smoking (via saliva cotinine) at the 16-week follow-up.

2.3.3.5. Alcohol use. From the TLFB, the primary outcome of interest is the percent of heavy drinking days. Other alcohol use outcomes, such as percentage of days abstinent from alcohol and drinks per drinking day, will also be derived.

2.3.4. Treatment delivery and fidelity

2.3.4.1. Facilitator selection criteria. For both MBRP-SA and CBT, group facilitators will have a minimum of a Master's degree in counseling, psychology, social work, or a related field and experience running group therapy. For MBRP-SA, facilitators also need to: complete an intensive mindfulness training, have a daily formal and informal mindfulness practice, and attend, or have attended a silent meditation retreat. For CBT, therapists must have been trained in CBT. The decision to utilize different therapists for each treatment was made to decrease the likelihood of treatment crossover and subsequent treatment contamination if a therapist provided both treatments. Although we are aware that the risk in using different therapists may allow for therapist-specific effects to occur, we believe that MBRP-SA and CBT would be difficult to provide concurrently while adhering to both protocols. Therapist-specific effects will be evaluated via the Working Alliance Inventory [90].

2.3.4.2. Supervision and treatment fidelity. To ensure fidelity to the MBRP-SA and CBT manuals, weekly supervision with the opportunity to review recordings will be conducted. Discussions related to issues that arise during the group will be conducted during these meetings as well. To monitor facilitator adherence and competence to the protocol, all sessions will be recorded and a random sample of 10% will be rated using the Mindfulness-Based Relapse Prevention Adherence and Competence Scale (MBRP-AC) [97] for MBRP-SA and a modified version of the Cognitive Therapy Adherence and Competence Scale (CTACS) [98] for CBT. In order to observe any facilitator-specific characteristics that may be unique to some groups and not others, results from the Working Alliance Inventory [90] will be examined.

2.3.5. Planned analyses

2.3.5.1. Sample size. Randomizing 64 participants to MBRP-SA or CBT will provide sufficient data for assessing feasibility of the RCT, based on existing recommendations in the literature for sample size estimates in feasibility studies [99,100].

2.3.5.2. Analytic plan. Descriptive statistics of demographics, smoking history, and alcohol history variables will be calculated, and group comparisons will be performed. Descriptive statistics and effect sizes for primary outcomes will be calculated (Cohen's h for tobacco abstinence and Cohen's d for drinking outcomes). Although underpowered to detect small- or medium-sized effects, we will use regression analyses to examine whether primary outcomes vary by sex. These analyses will include a treatment group (MBRP-SA vs. CBT), sex, and the treatment group by sex interaction. Logistic regression will be used for the tobacco abstinence outcome and linear regression will be used for the drinking outcomes. If there is an effect of treatment cohort (i.e., the subset of participants who are treated together), as indicated by the intraclass correlation coefficient is >0.10, then we will use multilevel models to adjust for clustering within cohorts.

Feasibility and acceptability will be assessed by the multiple indices described above. Each index will either be compared to published norms (e.g., CSQ) or based on our prior experience with clinical trials. Table 4 includes benchmarks of feasibility and acceptability determined a priori. Evaluation of all indices will inform and guide modification prior to the proposal of a full scale RCT.

3. Results

3.1. Participant characteristics

The Phase 1 results are described here. Fig. 1 displays the CONSORT diagram for Phase 1. A total of 21 participants consented to the study. Of those consented participants, 15 completed the first treatment visit, nine completed five treatment visits, eight completed all eight treatment visits, and seven completed the follow-up.

The characteristics of consented participants are shown in Table 5. About half were female, the majority were white and not Hispanic or Latino. About half of participants reported an annual income of less than $20,000 and about 43% had a high school diploma equivalent or less. At baseline, the average number of cigarettes smoked was about a pack per day. Participants drank alcohol, on average, more than half the days per month and on average engaged in binge drinking (defined as 4 or more drinks for women, 5 or more drinks for men) on those drinking days. The demographics of the participants ($n = 7$) who completed all visits and those who did not complete all visits through follow-up ($n = 14$) are presented in Table 5 for comparison purposes.

3.2. Recruitment challenges/progression of 3 cohorts

Phase 1 recruitment was conducted in three cohorts. In the first cohort utilizing the recruitment methods stated above, with the exception of Trialfacts and bus ads, a total of six participants were enrolled. In cohort 2, we continued to utilize the same recruitment methods employed in cohort 1 and continued to expand methods to community organizations (e.g., dentist offices, community clinics). During this cohort, there was a slowdown in recruitment and retention. Although five participants were consented, only one participant attended the first treatment session. Due to challenges with recruitment in cohorts 1 and 2, the following procedures were implemented to increase enrollment during cohort 3: 1) expanded recruitment methods (city buses and Trialfacts) and 2) modified inclusion and exclusion criteria (modified alcohol use criteria from five binge drinking days per month to three per month). With the implementation of these new methods, recruitment improved, and 10 participants were consented in cohort 3.

3.3. End of treatment questionnaire

The End of Treatment Feedback Questionnaire was administered during the last treatment visit for cohort 3 of Phase 1 ($n = 4$). Five participants attended the last visit, but one participant did not complete the measure. Participants reported that they planned to continue utilizing the skills they learned in the treatment overall (M = 8.50, SD = 2.38), with 75% of participants reporting a nine or above on this scale. Also, 75% of the participants reported they intended to use the skills in their everyday activities. Participants reported that they were very likely to use the skills for abstaining from tobacco (M = 4.00, SD = 1.41) and supporting their alcohol modification goal (M = 4.50, SD = 1.00).

The meditations participants reported as the most useful were the Body Scan, the Sitting Meditation on the Breath, and SOBER Breathing Space. Most enjoyable meditations included the Body Scan, SOBER Breathing Space, Urge Surfing, and the Sitting Meditation on Thoughts. Three participants described their surroundings and environment as the biggest barrier for completing daily meditations (e.g., "noise at home", "surroundings"). Half of the participants expressed that the group component was their favorite part of the treatment, while the other half reported the mindfulness component (i.e., meditations) was their

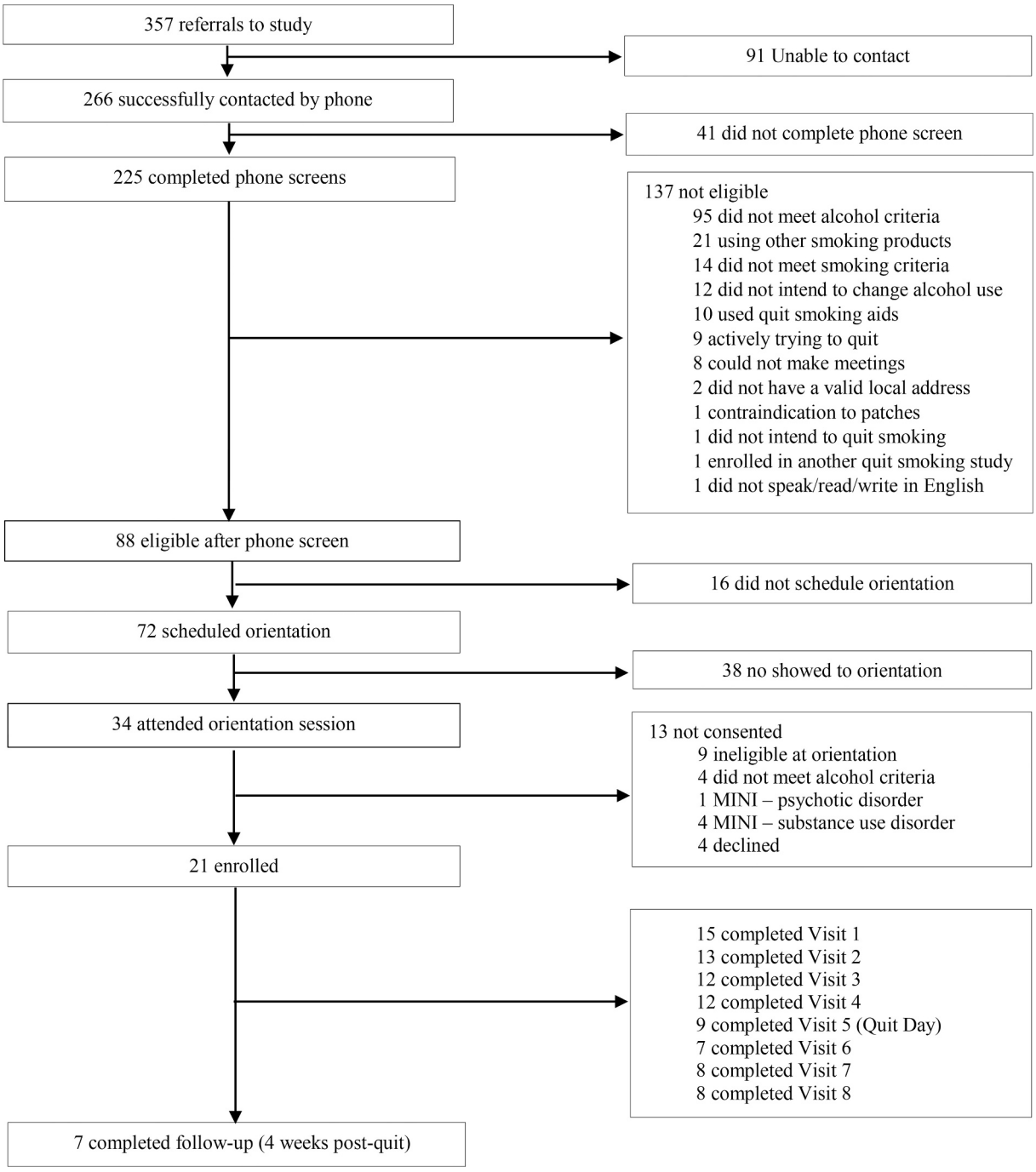

Fig. 1. Phase 1 consort.

favorite part of the treatment.

3.4. Program feedback

Across the three cohorts, a total of 7 participants completed the program feedback component at the follow-up visit. Information collected from the first cohort of participants primarily included modifications on session handouts (e.g., simplifying content; modification of visuals), although all cohorts were given the opportunity to provide feedback on the handouts. Regarding access to meditations, the majority of participants indicated a preference for accessing meditations online, rather than a physical CD. A small subset of participants reported using both the CD and the link to listen to meditations every week. Participants reported they would prefer to receive text message reminders for group sessions, as opposed to the traditional reminder phone calls. Additionally, participants responded with positive feedback on receipt of the weekly emails (e.g., felt more connected). Overall, participants reported they would recommend the treatment program to others. Regarding recruitment, a few participants encouraged the continued use of advertisements on the city buses, as well as using word-of-mouth.

4. Discussion

Phase 1 of this study consisted of modifying MBRP to be a primary treatment option for smoking cessation and the modification of alcohol use (MBRP-SA) and a pilot study to inform treatment modification. Open-ended feedback was received on the mindfulness treatment and procedures, which was incorporated into the RCT protocol. Specifically,

Table 5
Demographic characteristics.

Characteristic	M (SD) or N (%)		
	All Participants N = 21 M(SD) or n (%)	Participants who completed through follow-up n = 7 M(SD) or n(%)	Participants who did not complete through follow-up n = 14 M(SD) or n(%)
Age	51.40 (10.71)	53.60 (9.47)	50.29 (11.46)
Gender (female)	10 (47.62%)	3 (42.86%)	7 (50%)
Ethnicity (Hispanic/ Latino)	2 (9.52%)	1 (14.29%)	1 (7.14%)
Race			
- Black/African American	7 (33.33%)	2 (28.57%)	5 (35.71%)
- White	12 (57.14%)	4 (57.14%)	8 (57.14%)
- Other	1 (4.76%)	1 (14.29%)	0 (0.00%)
- Unknown	1 (4.76%)	0 (0.00%)	1 (7.14%)
Income (less than $20,000)	11 (52.38%)	5 (71.43%)	6 (42.86%)
Education			
- High school or less	9 (42.86%)	3 (42.86%)	6 (42.86%)
- More than high school	12 (57.14%)	4 (57.14%)	8 (57.14%)
Cigarettes per day	21.05 (11.36)	14.60 (7.16)	24.29 (11.87)
Average drinking days per month[a]	17.81 (9.03)	13.10 (5.92)	20.14 (9.57)
Average drinks per drinking day[a]	6.41 (4.16)	6.50 (4.45)	6.37 (4.19)

Note. M = Mean; SD = Standard Deviation.
[a] Timeline Followback data collected at the orientation session.

the following changes were incorporated into the Phase 2 protocol based on Phase 1 results: provide both physical and electronic access to meditations in the MBRP-SA group, implement text reminders for each visit, and continue to send weekly emails for each condition with links to study materials. This information may be useful for other studies looking to administer group-based mindfulness treatment to similar populations. Phase 2 (currently ongoing) includes an RCT to compare MBRP-SA to CBT. After the completion of the Phase 1 pilot study, the COVID-19 pandemic occurred. At the time this manuscript was written, our team had translated all in-person procedures to remote procedures. These modified procedures for Phase 2 are described above.

In addition to treatment development, Phase 1 allowed the study team to address recruitment and retention issues in advance of the RCT. Modification of the inclusion/exclusion criteria, which included a change to the number of binge drinking episodes per month, was successful in increasing enrollment. For Phase 2, the inclusion and exclusion criteria were further modified based on recruitment in Phase 1, along with the transition to remote procedures. First, our alcohol use inclusion criteria were modified to now include participants who binge drink once a month. We recognize lowering the number of occasions of binge drinking may affect the ability to detect treatment effects on alcohol modification (e.g., from baseline to end of treatment). However, by broadening the alcohol use criteria, we may increase the external validity of the RCT results. Second, participants who regularly use other tobacco (e.g., cigars, cigarillos) and nicotine (e.g., e-cigarettes) products will be allowed to participate, in order to have a more representative sample of current tobacco users. Conducting groups via video conferencing eliminates transportation barriers to participation and allows a greater reach beyond the immediate area.

In Phase 1, participants who completed all treatment visits, as compared to those who did not, smoked fewer cigarettes per day and drank fewer days per month at baseline. Participants who completed all visits also were more likely to report an annual income of less than $20,000. Although no formal comparative analyses were conducted between participants who completed the study and participants who did not, this initial observation will be further explored at the conclusion of the RCT. Specifically, we will examine demographic and pre-treatment substance use characteristics that are associated with treatment completion in order to address any issues in a larger RCT.

For Phase 2, feasibility and acceptability of the MBRP-SA treatment will be the primary outcomes. Findings will inform the development of a large-scale efficacy trial to evaluate differences in smoking and alcohol use for MBRP-SA and CBT. That trial would be the first large-scale study to evaluate an MBI that concurrently targets cigarette smoking and alcohol use as a primary treatment for changing both behaviors in adults. Such a trial will be able to examine moderator variables to determine whether individual characteristics are predictive of greater success in one treatment than the other (e.g., are women in MBRP-SA more likely to quit smoking than women in CBT), with such tailoring ultimately contributing to personalized medicine. Additionally, our modified procedures due to COVID-19 provides us with the opportunity to collect data on delivering these interventions via video-conferencing, which we are hopeful will ultimately result in a more scalable treatment option with greater reach into the community.

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