Development of a Mindfulness-Based Treatment for the Reduction of Alcohol Use and Smoking Cessation

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TITLE: Development of a Mindfulness-Based Treatment for the Reduction of Alcohol Use and Smoking Cessation

Coordinating Center: H. Lee Moffitt Cancer Center

Protocol Version #25 Date: 7/1/21

1. PARTICIPANT SELECTION

1.1 Eligibility Criteria

Aim 1: Inclusion criteria will be ≥ 18 years of age; currently smoking ≥ 3 cigarettes per day for the past year; carbon monoxide level ≥ 8 ppm; should carbon monoxide level yield a result less than 8 ppm, the participant will be asked to submit a urine sample to determine cotinine levels and the result must be ≥ level 3 ; motivated to quit smoking and decrease alcohol use within the next 60 days; if male, consumes ≥ 5 drinks and if female, consumes ≥4 drinks on at least 1 occasion in the past month; willingness and ability to attend the 8 weekly group sessions; valid home address in the Tampa Bay area; functioning telephone number; and can speak, read, and write in English.

Aim 2: Inclusion criteria will be ≥ 18 years of age; currently smoking ≥ 3 cigarettes per day for the past year; motivated to quit smoking and decrease alcohol use within the next 60 days; if male, consumes ≥ 5 drinks and if female, consumes ≥4 drinks on at least 1 occasion in the past month; willingness and ability to attend the 8 weekly video group sessions; willingness and ability to use an email account for study materials; valid address; functioning telephone number; and can speak, read, and write in English.

1.2 Exclusion Criteria

Exclusion criteria will be contraindication for the nicotine patch; an active substance use disorder other than an alcohol use disorder; an active psychotic disorder; current use of tobacco cessation medications; pregnancy or lactation; and a household member already enrolled in the study. In rare cases, study staff might exclude a participant for a reason not specified here (e.g., arrives intoxicated for multiple sessions).

1.3 Inclusion of Women and Minorities

Both men and women and members of all races and ethnic groups are eligible for this trial.

1.4 Recruitment

Participants will be recruited through print and media ads within the state of Florida. This will include radio and TV ads, recruitment through social media, general online advertising, and advertising on local busses. Flyers will be distributed throughout the local Tampa-Bay community, including to primary care offices, wellness programs/clinics, and physicians (face-to-face meetings or presentations will occur as requested by the physicians/staff). We will also reach out to human resources departments of local business for them to distribute our study flyers to potentially interested employees. Additionally, we will be distributing flyers through avenues of the legal system, including, but not limited to, social services departments and district courts. We will contact ineligible participants from prior studies at TRIP via our existing and longstanding database of participants who have given us permission to contact them for future research. TrialFacts will also be used to recruit participants. Participants recruited through TrialFacts will be invited to complete a brief online survey and/or telephone pre-screening conducted by TrialFacts staff, which will include basic eligibility criteria. Our study team will then reach out to potentially eligible participants to complete a full study screen.

Finally, we will leverage our relationship with The Tampa Bay Community Cancer Network (TBCCN), a network of community-academic partners, which is led by two senior faculty

members in our program. Established in 2005, TBCCN addresses critical access, prevention and control issues among medically underserved, low-literacy and low-income populations in the Tampa Bay and surrounding catchment area. It is comprised of over 28 diverse partner organizations, including community clinics (e.g., federally qualified health centers, health departments, social service organizations, grassroots, faith-based and adult education groups) and Moffitt. Thus, during the first 3 months of this grant, we will determine which community or clinical organizations of TBCCN might be further interested in advertising our study to their members. Establishing these targeted relationships will not only bolster recruitment (including the possibility to hold group sessions at their locations), but would hopefully lead to maintainable relationships that extend beyond this grant period.

2. STUDY DESIGN AND METHODS

Aim 1.

Project Overview. The primary goal of Aim I is to modify an existing treatment – MBRP – to include a focus on smoking cessation and reducing alcohol use (MBRP-SA). In this section we include a description of MBRP and the proposed modifications to the original protocol to include a focus on smoking abstinence and reduced alcohol use (Study 1).

MBRP Overview. MBRP was designed to target key components in the relapse prevention process, with a specific focus on negative mood and craving. Principles of the treatment were derived MBRP[139] and MBCT.[140] MBRP-SA will use the same session structure as MBRP, with 8 weekly in-person group sessions that are 2 hours each. Group sizes for MBRP-SA will be 8-10 participants. The current study will follow the existing treatment manual for MBRP,[141] with necessary modifications as described in the following section. The core aims of MBRP are to aid individuals in developing an awareness of the present moment and the ability to shift attention (i.e., the opposite of being on autopilot) and to increase tolerance of emotional, cognitive, and physical states that are unpleasant or negative. The mindfulness practices within MBRP teach individuals how to hone these skills, which allows them to better manage substance use craving when it does occur. Examples of these practices include mindfulness meditation, mindful movement, body scan, and awareness of the senses.

Sessions 1 and 2 of MBRP focus on providing a rationale for how mindfulness can be related to craving and mood, discussing the tendency to be on “autopilot”, and increasing awareness of internal and external triggers for substance use. In these sessions, exercises are designed to aid participants in understanding how to “sit with” discomfort, which provides for the opportunity to mindfully choose a response, instead of impulsively responding. Sessions 3 and 4 aim to increase participants’ awareness of habitual responding in order to expand their options for coping when experiencing a craving. One particularly relevant exercise is SOBER (Stop, Observe, Breathe, Expand, Respond) Breathing Space, which is practiced in session and participants are encouraged to utilize this skill as part of their daily activities. Session 5 focuses on the ability to balance acceptance with the need to take skillful action. Session 6 highlights the importance of decentering from thoughts, and noticing “thoughts are just thoughts” and not fact. Sessions 7 and 8 discuss self-care, generalizing the skills learned in treatment to daily life, and increasing social support networks. Loving-kindness meditations are also introduced as a way to cultivate self-compassion and forgiveness. As participants progress through MBRP, home practices are introduced and built upon each week. Examples of formal home practice include body scans, sitting meditation, walking meditation, and mindful movement. Integrating mindfulness into daily activities is encouraged via informal exercises (e.g., awareness of brushing teeth, washing hands, SOBER breathing space). Participants will be sent

Table 1. MBRP Session Topics	
Week 1	Automatic Pilot and Relapse
Week 2	Awareness of Triggers and Craving
Week 3	Mindfulness in Daily Life
Week 4	Mindfulness in High-risk Situations
Week 5	Acceptance and Skillful Action
Week 6	Seeing Thoughts as Thoughts
Week 7	Self-care and Lifestyle balance
Week 8	Social Support and Continuing Practice

an email each week including the handouts from the session as well as links to the audio files of the meditations practiced during the group. Table 1 provides session topics for MBRP.

MBRP-SA Development. The primary adaptation for MBRP-SA will be to tailor some the session content and discussions to smoking cessation and alcohol use. These changes will be primarily guided by the existing literature (e.g., studies on mindfulness-based treatments for smoking cessation) and the experience/knowledge of the investigative team. It should be noted that MBRP already addresses some of the primary underlying mechanisms of smoking cessation and reduced alcohol use (e.g., managing negative affect and craving) and that the extant literature indicates that key behavior modification constructs (e.g., self-efficacy) are impacted by mindfulness.[45,50,67,76] Therefore, we will not modify the core components of MBRP, but instead supplement the existing protocol with content unique to smoking and alcohol use.

Content Modifications. Content modifications listed here fall into 3 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. Modifications are based on the existing literature, ability of content to address underlying behavior-change mechanisms (e.g., motivation) and Co-I Dr. Wetter's experience developing and testing a mindfulness-based cessation intervention.[58] **SMOKING-SPECIFIC**: Quit date. Research regarding smoking cessation indicates that motivation can be enhanced by setting a specific quit date.[142] Therefore, MBRP-SA will set the smoking quit date at Session 5, which is supported by existing mindfulness-based cessation treatments (e.g., [58]). 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.[143-145] MBRP-SA will acknowledge and process this type of cognition in Session 3. Diet and Weight Gain. Many individuals endorse motivation to continue smoking for weight control purposes,[144] and therefore we will include information on this topic in Session 3. Nicotine Patch. Current guidelines for smoking cessation indicate that when provided with a combination of nicotine replacement therapy and counseling, chances of success are greatest.[142] Thus, participants will be

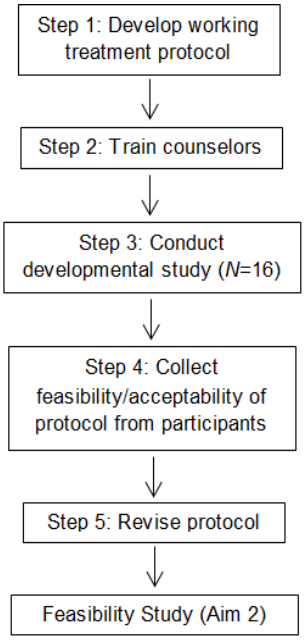

Figure 3. Treatment Development Flow

provided with nicotine patches at the end of Session 4, with the intention to begin using them at Session 5. Psychoeducation about patch use will occur at Session 4. Mindful Smoking is a mindfulness activity that brings awareness to the act of smoking a cigarette. An introduction to this will occur at the end of Session 2, and the actual practice will be conducted right before the beginning of Session 3 group. Participants will be encouraged to continue mindful smoking until their quit day at Session 5. **ALCOHOL-SPECIFIC**: Reduced alcohol use. Alcohol use will be monitored at each treatment session. A discussion of goals related to reduced drinking will begin at Session 1 and continue through Session 5. Participants will be encouraged to set realistic drinking goals for themselves, which is consistent with a harm reduction approach to alcohol use and fits within the framework of social determination theory.[146,147] Participants will be encouraged to implement drinking goals at Session 5 (to coincide with the smoking quit date), although many people may have already decreased use. At the orientation session, participants will be provided with a handout with psychoeducational information on alcohol use, and they will be encouraged to use this when deciding what their alcohol use goal will be. **CO-USE**: Psychoeducation on the health impacts of cigarette and alcohol use. Consistent with recommendations,[142] participants will be provided with psychoeducation 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, decrease risk of cancer development) will also be discussed and provided. Relationship between smoking and drinking. Given common underlying mechanisms of the co-use of alcohol and smoking exist (e.g., cue-induced craving, positive and negative reinforcement),[11-16] discussions related to the inter-connected relationship among smoking and alcohol use will be conducted. This discussion will also include a focus on previous attempts to change either or both behaviors by participants. We will also highlight that continued alcohol use may serve as a trigger for relapse. Discussions regarding whether complete abstinence is the best option for some participants will be conducted. We believe this added content will aid participants in making the best decision regarding their own co-use. These discussions will occur at Session 2.

Procedures. The treatment development procedures will follow an iterative multi-step process (see Figure 3) based on the treatment development literature.[148,149] Step one will develop a good working treatment protocol based on the above content modifications. Because an already well-developed treatment manual exists for MBRP,[141] we anticipate that this can be done fairly quickly. Step two will involve training counselors in the new protocol (see Treatment Delivery section in Study 2 for additional detail on counselor training). Step three will entail administering the protocol to a small group of participants (N=16) to receive feedback on MBRP-SA. We expect to enroll about 8 participants per group in order to run 3 groups. Eligibility criteria and study procedures will be identical to that outlined in Study 2 below, with the only exception being that participants will not complete the follow-up visits and will not complete the breath counting task.

Compensation and Retention Procedures. Participants will be financially compensated for completing the assessment measures, and for the costs associated with participation such as transportation, child care, etc. Participants will receive $10 at the Orientation visit whether they are found to be eligible or not. The first 4 treatment visits will be paid at $15 per session, sessions 5-7 will pay $20 per session, and session 8 and the follow-up will pay out $25 per session. Participants will be compensated with a $10 gift card for completing the 16-week post-cessation follow-up call. For Visits 5 and 8, participants who arrive a half-hour early will receive a $5 bonus at the end of their visit.

Step four will include extensive querying of participants as to the appropriateness, acceptability, usefulness, etc. of all materials, assessments, procedures, and treatment. Some questions will mimic the acceptability questions outlined below for Study 2. However, more specific detail regarding MBRP-SA will also be gathered. A focus group will be conducted by the PI with participants on topics related to the content modifications outlined above (e.g., understandability of content and what information was most/least helpful regarding smoking and alcohol use), along with other general treatment-related issues (e.g., barriers to enrolling in the

treatment, concerns about logistically attending sessions, and appealing features of the treatment). Step five will include revising the treatment procedures and content based on the results from each cohort of development testing. Table 2 provides an overview of the timeline for Study 1.

Statistical Considerations. The primary goal of Study 1 is to develop MBRP-SA. Qualitative analysis of focus group will be the primary form of evaluation. The focus group will be audio-recorded and verbatim transcripts created for content analysis.[150] Using hand coding, the goal will be to identify key themes/textual units related to mindfulness and response to the treatment. Results from the qualitative interviews will be analyzed using the interview transcripts and content analysis. Content analysis will be conducted using an "intuitive" or "immersion/crystallizing" analysis plan, whereby the researcher reviews all data and pulls out those aspects most relevant to the research questions.[151] The research team will identify key themes as they read through the interview transcripts. Descriptive statistics of quantitative measures will supplement the qualitative analysis. These may provide information for identifying aspects of implementation that require change prior to the feasibility study (Study 2).

Aim 2.

*Note: All procedures reported for Aim 2 will be conducted remotely, primarily via zoom and phone calls (but also via mailouts, emails, and text messages as appropriate). Group treatment sessions (MBRP-SA and CBT) will be conducted via zoom.

Project Overview. The primary goal of Study 2 is to measure benchmarks regarding the feasibility and acceptability of the MBRP-SA protocol created in Study 1. Participants (N=64) will be randomized to either MBRP-SA or CBT and tracked from 5 weeks pre-quit through 16 weeks post-quit. The first follow-up appointment will be a phone call scheduled at 8 weeks post-cessation (±5 days). The second follow-up appointment will be a phone call scheduled at 16 weeks post-cessation (±5 days). Table 4 provides a timeline of all procedures and assessments. Details are presented in the subsequent sections. Administering the battery of assessments below according to this timeline mimics the procedures for a future, large-scale R01 efficacy trial and will allow for the evaluation of feasibility for completing all procedures.

Recruitment. Participants will be recruited through print and media ads within the state of Florida and Georgia. This will include radio and TV ads, and recruitment through social media. Flyers will be distributed throughout the community, including to primary care offices and physicians. These methods mimic the successful recruitment methods for this population in past studies conducted at TRIP. All methods used in Recruitment section above will be used here

Telephone Screening. Interested participants will be contacted via phone and provided a detailed overview of the study. Following verbal informed consent, potential participants will be screened for inclusion/exclusion criteria. Participants will complete the eligibility screening, including the MINI for Alcohol Use, Substance Use, and Psychotic Disorders for DSM-V for diagnostic information. The TLFB will confirm participants meet the alcohol criteria for the past month. Eligible participants will then be scheduled for a phone orientation session.

Table 3. Aim 1 Study Procedures Overview	Pre-cessation Week						Post-cessation Week					
	Phone Screen	**-5 Orientation**	**-4 Start of Tx**	**-3**	**-2**	**-1**	**0 Quit Day**	**1**	**2**	**3 End of Tx**	**8 Follow Up**	**16 Follow Up**
Telephone Screening	X											
TREATMENT (Tx) PROCEDURES												
MBRP-SA or CBT Delivery			Tx 1	Tx 2	Tx 3	Tx 4	Tx 5	Tx 6	Tx 7	Tx 8		
Nicotine Patch Dispensation						X	X	X	X	X	X	
DEMOGRAPHICS / MENTAL HEALTH												
Demographics		X										
MINI Psychotic Disorders, Alcohol, and Substance Use Disorders for DSM-5		X										

ALCOHOL USE MEASURES												
Alcohol Use Goals			X			X				X	X	
Alcohol Use History		X										
Patient Health Questionnaire–Alcohol Use		X					X			X	X	
Penn Alcohol Craving Scale		X					X			X	X	
Alcohol Abstinence Self Efficacy		X					X			X	X	
Drinking Motives Questionnaire - Revised		X					X			X	X	
SMOKING MEASURES												
Smoking Use and History		X										
Brief Wisconsin Inventory of Smoking Dependence Motives		X					X			X	X	
Wisconsin Smoking Withdrawal Scale		X					X			X	X	
Self-Efficacy Scale-Smoking		X					X			X	X	
MINDFULNESS												
Five Facet Mindfulness Questionnaire		X					X			X	X	
Toronto Mindfulness Scale		X	X	X	X	X	X	X	X	X	X	
NEGATIVE AFFECT / DEPRESSION / STRESS / ANXIETY												
Center for Epidemiological Studies Depression Scale Revised		X					X			X	X	
Distress Tolerance Scale		X					X			X	X	
Perceived Stress Scale		X					X			X	X	
Positive and Negative Affect Scale		X	X	X	X	X	X	X	X	X	X	
BEHAVIORAL TASK												
Breath Counting		X									X	
ALCOHOL USE AND SMOKING STATUS / BIOCHEMICAL VERIFICATION												
Timeline Followback		X	X	X	X	X	X	X	X	X	X	X
Carbon Monoxide (CO)		X	X	X	X	X	X	X	X	X	X	
Urinalysis hCG, as applicable		X										
Urine Cotinine as applicable		X										
Blood Alcohol Content (BAC)		X	X	X	X	X	X	X	X	X	X	
FEEDBACK FROM PARTICIPANTS												
End of Treatment Feedback Questionnaire										X		
WAI-SR Client Version Modified										X		
Follow-up Feedback Questionnaire											X	

Table 4. Aim 2 Study Procedures Overview	Pre-cessation Week						Post-cessation Week					
	Phone Screen	**-5 Orientation**	**-4 Start of Tx**	**-3**	**-2**	**-1**	**0 Quit Day**	**1**	**2**	**3 End of Tx**	**8 Follow Up**	**16 Follow Up**
Telephone Screening	X[a]											
TREATMENT (Tx) PROCEDURES												
MBRP-SA or CBT Delivery			Tx 1	Tx 2	Tx 3	Tx 4	Tx 5	Tx 6	Tx 7	Tx 8		
Nicotine Patch Dispensation						X	X	X	X	X	X	
DEMOGRAPHICS / MENTAL HEALTH												
Demographics		X										
MINI Psychotic Disorders, Alcohol, and Substance Use Disorders for DSM-5	X[a]											
ALCOHOL USE MEASURES												
Alcohol Use Goals			X[a]			X[a]				X[a]	X[a]	X[a]
Alcohol Use History		X										
Patient Health Questionnaire–Alcohol Use		X					X			X	X	
Penn Alcohol Craving Scale		X					X			X	X	
Alcohol Abstinence Self Efficacy		X					X			X	X	
Drinking Motives Questionnaire - Revised		X					X			X	X	
SMOKING MEASURES												
Smoking Use and History		X										

Brief Wisconsin Inventory of Smoking Dependence Motives		X					X			X	X	
Wisconsin Smoking Withdrawal Scale		X					X			X	X	
Self-Efficacy Scale-Smoking		X					X			X	X	
MINDFULNESS												
Five Facet Mindfulness Questionnaire		X					X			X	X	
Toronto Mindfulness Scale		X	X	X	X	X	X	X	X	X	X	
Avoidance and Inflexibility Scale		X					X			X	X	
NEGATIVE AFFECT / DEPRESSION / STRESS / ANXIETY												
Center for Epidemiological Studies Depression Scale Revised		X					X			X	X	
Distress Tolerance Scale		X					X			X	X	
Perceived Stress Scale		X					X			X	X	
Positive and Negative Affect Scale		X	X	X	X	X	X	X	X	X	X	
ALCOHOL USE AND SMOKING STATUS / BIOCHEMICAL VERIFICATION												
Timeline Followback	X[a]					X[a]				X[a]	X[a]	X[a]
Saliva Cotinine												X
FEEDBACK FROM PARTICIPANTS												
Client Satisfaction Questionnaire										X		
End of Treatment Feedback Questionnaire										X		
WAI-SR Client Version Modified										X		
Feasibility of Technology Survey										X		
System Usability Scale										X		
Follow-up Feedback Questionnaire											X	

[a] = data collected during phone call (vs REDCap)

Phone Orientation Visit. Study personnel will call the participant at their scheduled session time and provide a detailed description of the study and obtain verbal consent. A copy of the informed consent and a PowerPoint describing the study in detail will be mailed and/or emailed to participants before the orientation session. If the participant decided to consent to the study, a series of self-report questionnaires to complete will be emailed to them(see Aim 3 below). Individuals who are ineligible or decline to participate will receive self-help materials and referrals for smoking cessation and alcohol use programs.

Zoom Orientation Visit. Consented participants will be scheduled for a group Zoom Orientation session one week before the first treatment session. Prior to the visit, participants will be provided a packet of instructions on how to access and navigate the video-conferencing app, Zoom, and additional materials related to the study (e.g. session handouts, welcome materials). Tablets, webcams, and/or microphones will be provided to participants on an as-needed basis. This orientation session will take place via Zoom. During this session, participants will be provided with a training on how to use video-conferencing app and will discuss the other relevant materials sent to participants in preparation for the first treatment visit. Prior to all Zoom visits in the study, participants will join a waiting room before they are admitted to the group, where they will see banners with reminders about sessions content, privacy standards, etc. This procedure will be followed for all treatment sessions as well as the Zoom Orientation session.

Randomization. Three stratification variables will be included: gender (men vs women), race/ethnicity (non-Hispanic White vs Other), and smoking rate (20+ cigarettes per day [CPD] vs less than 20). Within these 8 cells, eligible participants will be assigned to the two treatments using balanced-permuted block randomization with a block size of 4.

Compensation and Retention Procedures. Participants will be financially compensated for completing the assessment measures, and for the costs associated with participation such as child care, etc. Participants will receive a $10 gift card after completing measures sent after the Orientation visit, and will receive an additional $5 bonus gift card if they complete it in 24 hours. Participants who decline to consent to the study during the Orientation visit will receive a $10 gift card. Participants will receive $10 for completing the Zoom Orientation visit. For measures completed prior to visits 1-4, 6, and 7, participants will receive a $5 gift card, and a $5 bonus gift card if they complete them within 24 hours.. For measures completed prior to visits 5 and 8, participants will receive a $20 gift card, and a $10 bonus gift card if they complete the measures

within 24 hours. For completing the phone call assessment prior to visits 5 and 8, participants will be compensated with a $15 gift card. Payment for these visits differ based on the length (e.g., participants are compensated more when asked to complete lengthier questionnaire packets). Participants will be compensated with a $20 gift card for completing the first follow-up call and measures, and will receive a $10 bonus gift card if they complete the measures within 24 hours. For completing the second follow-up call (16 weeks post-cessation), participants will receive a $25 gift card. Participants will receive a $10 bonus for sending back a saliva sample to confirm tobacco abstinence. For any unreturned iPads after a period of two months of phone calls/emails from staff, a $50 gift card incentive will be offered for the return of the iPad.

This payment schedule will apply only to Aim 2. We will also conduct the following procedures to reduce attrition: reminder phone calls or texts prior to all study visits, flexible scheduling of the group sessions (e.g., evenings, various days of the week) to accommodate different schedules, 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 2 collaterals (i.e., relatives, friends) who can provide contact information for the participants, should we be unable to contact them during the study. Participants who are unable to complete the measures or phone assessments will be mailed the materials to complete.

Treatment Overview. All participants will receive nicotine replacement therapy (NRT) and either MBRP-SA or CBT. Table 4 provides an overview of all treatment and follow-up visits.

NRT**.** The nicotine transdermal patch is the most widely used pharmacotherapy and the Treating Tobacco Dependence Clinical Practice Guideline has identified it as frontline therapy.[142] The patch is safe, tolerable, and available over-the-counter. Patch therapy for participants who smoke >10 CPD will consist of 6 weeks of 21 mg patches and 2 weeks of 14 mg patches. Patch therapy for participants who smoke 5-10 CPD will consist of 6 weeks of 14 mg patches and 2 weeks of 7 mg patches. Patch dispensation will occur at weekly treatment visits. Participants receive only the number of patches needed to last until the next visit plus several extra patches should one fall off, become torn, etc, or should the visit be delayed. Based on our previous research, compliance is improved when participants are provided with only enough patches to last until the subsequent visit. A reduction in dosage or cessation of the patch regimen will be implemented for any participants who show signs of being on too high of a dose, which is expected for very few participants since blood nicotine levels are usually much lower on the patch than while smoking. Note that for Aim 2, patches will be mailed each week.

MBRP-SA and CBT. MBRP-SA was already described above. CBT is a well-established and commonly used treatment for substance use behaviors that primarily utilizes a problem solving and coping skills approach rooted in relapse prevention theory,[152] combined with standards from the Guideline.[142] Session content will generally follow the manual used in the original MBRP RCT[64], the MBAT RCT[58], and standards from the Guideline (e.g., setting a quit date, providing NRT).[142] CBT will consist of 8 sessions (2 hours 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 reducing drinking, with specific treatment objectives for each session. Participants will receive weekly emails that outline the group session as well as include relevant links and attached handouts for their review. Participants will also receive referrals for mental health and substance use at the end of treatment.

Treatment Delivery and Fidelity. Explicit therapist selection criteria, extensive training, and on-going monitoring and supervision of treatment delivery, fidelity, and therapist competence will ensure that treatments are of the highest quality, follow the protocols precisely, and prevent counselor drift and contamination.

Selection Criteria. For both MBRP-SA and CBT, therapists must 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, therapists also need to: complete the 5-day intensive MBRP 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 (see below for more detail).

Training, Supervision, Adherence. As reported above, counselors providing MBRP-SA will already have a strong background in mindfulness-based techniques. Counselor training in CBT and the smoking cessation and alcohol use portion of MBRP-SA will be conducted by Drs. Vinci and Brandon, who have extensive experience in delivering behavioral treatments for nicotine dependence and alcohol use. This training will include a focus on smoking and alcohol use through readings of the MBRP-SA and CBT manuals, practicing and role playing each session of MBRP-SA and CBT, and working through anticipated issues that might arise during sessions. Training will occur in a regular series of half-day blocks (1-2 per week) with the counselor studying and role-playing between training sessions. Training will continue until the counselor reaches performance criteria for competence and adherence to the protocols, which will be made on counselor rating forms during mock counseling sessions using the validated Mindfulness-Based Relapse Prevention Adherence and Competence Scale (MBRP-AC)[153] for MBRP-SA and a modified version of the Cognitive Therapy Adherence and Competence Scale (CTACS) for CBT.[154] To ensure fidelity to the MBRP-SA treatment once participants are enrolled in the study, we will follow the recommended supervision guidelines for MBRP. This will involve weekly supervision with MBRP-trained clinicians to review tapes, discuss miscellaneous counseling issues, and problem-solve as needed. These supervision sessions will ensure that MBRP-SA is being delivered consistent with the spirit of MBRP. CBT counselors will follow identical supervision procedures.

Treatment Fidelity. To monitor therapist adherence and competence to the protocol and to prevent drift, all sessions will be recorded and a random sample of 10% will be rated by the investigators using the MBRP-AC and CTACS. Additionally, applicable staff at the University of New Mexico will receive audio recordings of the sessions to further monitor therapist adherence to the protocol. A counselor who falls below performance criteria will receive additional training. In order to observe any counselor-specific characteristics that may be unique to some groups and not others, participants will complete a measure at the final treatment session that assesses topics relevant to their therapist such as, warmth, empathy, credibility, confidence, trustworthiness, and responsiveness to questions. The audio recordings may also be used for participants who miss a group session. They may come into the research facility to listen to the audio recording from group to make up the missed session. Finally, homework completion will be monitored weekly via questionnaire to assess treatment adherence (e.g., amount of time each day spent meditating, types of mediations practiced each week).

Benchmarks for Feasibility and Acceptability. Table 5 provides a list of benchmarks that are the primary outcomes for Study 2. The development of these benchmarks was informed by the extant literature on feasibility measurement.[155-157] In addition to the measurable outcomes below, other areas to be monitored include the ability to: randomize participants to group, effectively screen for eligibility criteria, organize all questionnaires to be completed in-full for thorough data processing and analysis, and 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.

We will invite a subset of participants (N=16) back for in-depth interviews, and questions will mimic those from the interviews we will conduct as part of Aim 1. Interviews will be audio-recorded and transcribed for content analysis. We will specifically query participants on the appropriateness, acceptability, usefulness, etc. of the intervention, as well as other general treatment-related issues (e.g., transportation; barriers to enrolling in treatment). The analysis of these data will also model what we have written for Aim 1.

Table 5. Measureable Benchmarks

Area of Interest	Description of Outcome to be Evaluated	Measure and/or Expected Outcome
Acceptability	Participant Satisfaction	Client Satisfaction Questionnaire[158] (satisfaction of ≥80%)
	Intention to continue to use skills learned from the treatments	Questionnaire developed for this study
	Perceived appropriateness of the treatments for smoking and alcohol use	Questionnaire developed for this study
Demand	Accrual rates for study	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 homework at a minimum of 3.5 days per week*
Implementation/ Practicality	Screening/eligibility for study	Record number of call attempts for each participant and reasons for ineligibility
	Recruitment	Recruit 8 eligible participants per month; 60% of recruitment will be completed by the end of year 2
	Retainment	Retain 80% through end of treatment, 70% through follow-up
	Questionnaire completion	For sessions attended, 90% of questionnaires will be completed

Note. * based on data from Bowen et al., 2014; Vidrine et al., 2016; Witkiewitz et al., 2014[64,66,107]

Aim 3.

The primary goal of Aim 3 is to collect and examine descriptive data on proximal variables associated with smoking abstinence and reduced drinking (e.g., negative affect, craving), as well as distal variables (smoking abstinence, heavy alcohol use) from Study 2. Aim 3 will be underpowered to test for any main effects of treatment on clinical outcomes. Nonetheless collecting these data will contribute to our assessment of feasibility and will provide guidance as we determine the sample size for a full-scale efficacy trial.

Rationale for Assessment Strategy and Methodology. Several major considerations guided our assessment procedures. First, assessment selection criteria included established reliability and validity. Second, assessments had to either a) represent hypothesized treatment mechanisms/effects or b) have been empirically demonstrated to predict smoking abstinence and/or reduced drinking. Third, to reduce the inconvenience associated with completing the assessments we will provide compensation for participants' time and provide snacks and beverages at all visits. In sum, our assessments comprehensively assess all necessary variables, the ability of the team to implement these procedures, and participant completion of the measures. Such information will inform future methods for a larger efficacy trial.

Demographics/Description of Sample Measures. Demographics Questionnaire collects data on gender, age, race, ethnicity, education, income, employment, partner status, insurance status, and preferred language. MINI International Neuropsychiatric Interview DSM-5 is a semi-structured interview to assess for the presence of psychiatric disorders and substance use disorders and will be used in the current study to describe the sample and determine eligibility criteria. The following modules will be administered: I. Alcohol Use Disorder, J. Substance Use Disorder (Non-Alcohol), and K. Psychiatric Disorders and Mood Disorder with Psychotic Features.

Alcohol Use Measures. Alcohol Use History will collect information on past year alcohol use (e.g., quantity/frequency of use, typical alcoholic drinks consumed), alcohol use history (e.g., age of first drink), other household drinkers, number of friends/family who drink, and treatment

history. As part of the inclusion/exclusion criteria, participants will also be asked if they have a history of experiencing severe alcohol withdrawal symptoms and if they are motivated to reduce their drinking in the next 60 days. Penn Alcohol Craving Scale (PACS) consists of 5 self-report items assessing the intensity, duration, and frequency of craving, the ability to resist alcohol, and average level of craving in the past week.[160] Alcohol Abstinence Self-Efficacy Scale (AASE) evaluates an individual's confidence to abstain from drinking according to 4 different scenarios: negative affect, social/positive, physical and other concerns, and withdrawal.[161] Drinking Motives Questionnaire Revised (DMQ-R) utilizes self-reported data to measure drinking motives including social, enhancement, coping, and conformity.[179] At baseline, on the quit day, and at the follow-up visit, participants will be asked about their alcohol reduction goal, and any progress toward achieving their chosen alcohol reduction goal.

Smoking Measures. Smoking Use and History will collect information on the onset of regular smoking, smoking behavior (e.g., CPD, years spent smoking, time to first cigarette in the morning), smoking history (e.g., age smoked first cigarette), quit attempts, other household smokers, number of friends/family who smoke, and use of other tobacco products (e.g., e-cigarettes, cigars, hookah, snus). Participants will also be asked if they are motivated to quit smoking in the next 60 days, as part of the inclusion/exclusion criteria. Brief Wisconsin Inventory of Smoking Motives (WISDM) is a 37-item self-report measure used to assess nicotine dependence as a multi-dimensional construct via 11 different smoking motives.[162] Wisconsin Smoking Withdrawal Scale (WSWS) includes 7 subscales assessing nicotine withdrawal symptoms according to 28 items.[163] Self-efficacy Scale - Smoking is a 20-item self-report measure that determines an individual's level of confidence for not smoking in positive/social situations, negative affect situations, and out of habit.[164]

Mindfulness Measures. Five Facet Mindfulness Questionnaire (FFMQ) is a 39-item Likert-scale measure assessing 5 facets of trait mindfulness.[40] Toronto Mindfulness Scale (TMS) is a 13-item Likert-scale self-report measure of state mindfulness.[41] The TMS yields two factors: Curiosity and Decentering.

Negative Affect/Depression/Stress/Anxiety Measures. Center for Epidemiological Studies Depression Scale (CESD) is a 20-item self-report questionnaire that assesses depressive symptoms experienced within the past week.[165] Distress Tolerance Scale (DTS) is a 15-item, Likert-scale self-report measure of an individual's perception of his/her own emotional distress tolerance.[166] Perceived Stress Scale (PSS) is a widely used self-report measure that assesses the degree to which participants find their lives to be stressful.[167] Positive and Negative Affect Scale (PANAS) is a 20-item self-report Likert-scale measure that assesses an individual's positive and negative affect at a given point in time.[168]

Alcohol and Smoking Outcomes. Alcohol Use. The Timeline Followback (TLFB)[171-173] will be used to determine daily, recent alcohol use via retrospective self-report. A calendar is provided to participants, and they indicate any key events that occurred on certain dates to aid their memory. Participants then indicate how much alcohol they drank on each day. The TLFB has been widely used, evaluated, and has strong psychometric properties.[171-173] The TLFB will collect alcohol use from the past 4 weeks at the phone screen. The TLFB will be administered at each of the following visits and will ask participants to report their use since the last time they completed the TLFB: before visits 4 and 8, and at the 8-week and 16-week follow-up. From the TLFB, the primary outcome measure derived will be the percent of heavy drinking days (defined as: on a single occasion, ≥5 drinks for men and ≥ 4 drinks for women). Other alcohol use outcomes, such as percent days' abstinent and alcoholic drinks per drinking day, will also be derived.

Smoking Abstinence. To determine smoking abstinence, we will use the 7-day point prevalence, which is a combination of a self-report of no smoking in the last 7 days, combined with a biochemical verification of abstinence viasaliva cotinine. . Participants who report abstinence will be mailed a saliva cotinine kit to confirm abstinence at their 16-week follow-up call. The TLFB will be used to collected tobacco use throughout the study, and the schedule will mimic that used to collect alcohol use.

G. Data Management and Statistical Considerations for Study 2

To ensure participant confidentiality, no unique identifiers will be recorded into the dataset to be analyzed. Data will be collected via REDCap. The entered and reviewed data will be transferred monthly to a SPSS database.[174]

Sample Size. Randomizing 64 participants to MBRP-SA and 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.[175,176] A full set of statistical analyses focusing on treatment differences will be performed as part of the feasibility assessment. However, the sample size will not be sufficient for detecting treatment differences for anything less than large effect sizes (e.g., Cohen's d $\geq$ .72) for simple, two-group comparisons of a continuous variable with alpha=.05, power $\geq$ .80, and a two-tailed test. Binary variables assessed under the same testing conditions would require an OR $\geq$ 5.95.

Data Analysis Overview. Analyses will be conducted with SPSS and SAS version 9.4[174] and Mplus Version 7.[177] Descriptive statistics of demographics, smoking history, and alcohol history variables will be calculated and group comparisons will be performed. Descriptive statistics of all study measures (i.e., proximal and distal measures of alcohol use and smoking) will be calculated. Although underpowered to detect small- or medium sized sex differences, all analyses will examine sex as a covariate. Furthermore, analyses will include treatment group (i.e., each subset of participants who are treated with MBRP-SA or CBT together) when the intraclass correlation coefficient is > 0.10.

Aim 2 - Evaluate benchmarks regarding feasibility and acceptability. Feasibility will be assessed by the multiple indices described in Table 5. Each index will either be compared to published norms (e.g., CSQ) or our prior experience with clinical trials. We expect to recruit adequate numbers of eligible participants during the study timeframe with efficient cost expenditures, retain at least 80% through the end of treatment, and retain at least 70% through the end of the study. Treatment acceptance and satisfaction are expected to be 80% or higher, and participants are expected to comply with treatment requirements. The team will determine whether corrective actions for future studies are needed when an index suggests underperformance. Evaluation of all indices will inform and guide modification prior to the proposal of a full-scale RCT.

Aim 3 - Collect and examine descriptive data on proximal and distal variables associated with alcohol use and smoking. Descriptive statistics of proximal measures (e.g., negative affect, self-efficacy) will be presented in figures to review change over time and treatment differences. Generalized estimating equations (GEE) will be used to fit population-averaged models with the main variables of treatment, time, and their interaction. An AR(1) working correlation matrix will be used with r=.70. Covariates and potential confounding variables will be included, as warranted. This approach preserves data for analysis by avoiding listwise deletion of observations when at least one dependent variable was observed. Qualitative analyses (e.g., thematic analysis) may also be conducted on aspects of the treatment process.

A similar approach to analysis will be taken for the primary outcomes (the distal measures). TLFB will be used to derive a measure of heavy alcohol use and the 7-day point prevalence will be created for smoking abstinence at five targeted 1-week periods prior to a session: start of treatment (week -4), quit date (week 0), end of treatment (week +3), and two follow-ups (week +8 and week +16). Descriptive statistics will be presented in figures. GEE with an AR(1) working correlation matrix (r=.60) will be used to assess the effects of treatment, time (-4, 0, +3, +8, +*16*), and their interaction on the primary outcome measures. Means, percentages, and 95% confidence intervals will provide useful guidance as we determine sample sizes for a full-scale RCT. There is not adequate power to detect small- to medium-sized treatment group differences given the sample size. However, we would interpret any within-subject decreases in the number of heavy drinking days from pre- to post-treatment and/or any within-subject increases in smoking abstinence as evidence that the MBRP-SA intervention may be beneficial for these two problematic health behaviors. Given the small sample size, these changes are not likely to be significant. However, sample means and standard deviations will provide valuable data for

estimating sample size in a large-scale RCT. Changes in craving, self-efficacy, and general use of alcohol and smoking will also be examined as proximal outcomes that will also inform the development of a large-scale trial.

3. REGULATORY AND REPORTING REQUIREMENTS

3.1 Institutional Review Board

No subject is to be enrolled on this protocol until the Center's Institution Review Board has approved it.

3.2 Monitoring

Monitoring plan development for this project is commensurate with the risks proposed by the project. Monitoring will be ongoing by the principal investigator (PI-Dr. Vinci), and the Institutional Review Boards (IRB) of Advarra. Overall, the plan for monitoring includes: 1) Monitoring the progress of the study; 2) Assuring compliance with the requirements for reporting adverse events that may occur during the study; and 3) assuring data accuracy and protocol compliance. For all study protocols, the PI is responsible for the reporting of adverse events to the IRB.

Dr. Vinci will oversee the implementation of the study and daily monitoring. This will include weekly meetings to discuss any issues related to the progression of the project and factors that may affect the outcome, including a review of data quality and security, recruitment, and retention. Adverse events will also be discussed. A brief report will be created and submitted annually for the study record and submitted to the Chesapeake IRB. For any problems that may arise, Dr. Vinci will consult with the co-investigators to discuss how to best proceed.

3.3 Informed Consent

The investigators and the research associated are responsible for obtaining consent by the participants. The consent process will be conducted remotely, and a waiver of written consent will be requested from the IRB to allow us to obtain verbal consent. Informed consent will be obtained over the phone prior to entry of any participant.

3.4 Investigator Study Files

Research records for patients on this study are the responsibility of the investigator. They will be available for review by the sponsors of the trial, health care personnel involved in this study, the IRB, DHHS, and the FDA.

Sources of Materials

Data collected from participants for research purposes include a saliva testing for Cotinine (a nicotine metabolite) and self-report measures and interview data that collect demographic, medical history, psychiatric symptoms, smoking-related information, alcohol-use information, and questions about personality traits and current affective and cognitive states. Data will be collected electronically via REDCap. The treatment sessions for the MBRP-SA group involve mindfulness (meditation) practice that is tailored to smoking cessation and reducing alcohol use. The treatment sessions for the CBT group involve coping and reappraisal skill training that is tailored to smoking cessation and reducing alcohol use. Participants will be asked about the feasibility and acceptability of the treatments, in addition to monitoring their homework practice each week.

Potential Risks

Minimal risks are anticipated for this study. Data including self-report, interview (psychological and medical), and biological samples (e.g., saliva) involve risk of breaches in confidentiality. Although everyone will be asked to keep the information shared during the group sessions confidential and to maintain anonymity outside of sessions, a breach of confidentiality is always possible. Participants will always be given the option to refuse to answer any questions on the measures that may be distressing. Successful abstinence may cause irritability, anxiety, general distress and difficulty concentrating. The nicotine patch that participants will wear beginning on the quit date will be the appropriate dose for their level of smoking, and the patch should aid in the management of withdrawal symptoms. The nicotine patch and smoking cessation counseling have been shown to be safe and effective for smokers attempting to quit. However, side effects to the patch may occur and include skin irritation/ rash, nausea, dizziness, dry mouth, diarrhea, nervousness, headache, vivid dreams or sleep disturbances, irritability, and irregular heartbeat.

Protections Against Risks

We believe that this study poses minimal risks. Potential side effects from the nicotine patch will be closely monitored by study staff and the PI. Participants will be told of potential allergic reactions and side effects in response to the patch and nicotine side effects, and also told that they are free to remove the patch at any point in time. Should participants feel any possible side effects, they will be advised to discontinue the patch, and also told that they can call the PI and study staff. Counseling will be provided by clinicians who have received ample training regarding ethical principles of counseling. Emergency procedures will be in place should any psychiatric emergency arise during the screening and/or treatment processes. Although this is likely to be very rare, all study personnel and counselors will be trained in these procedures. Should a person drop-out of treatment early, community referrals for smoking, alcohol use, and mental health services will be provided. To ensure that any data (e.g., psychological, medical, personal) collected from this study remains confidential, hardcopy and electronic storage of data will be identified by participant number, so that data will not be directly associable with names. Association between participant names and numbers will not be kept in the same location as the data. Electronic files will be protected by password access, and hard copies will remain in a locked cabinet when not in use. Saliva samples will be discarded and have no identifying information after analyses.

Any electronic data will be stored on internal drives and in password-protected files without participant identifiers. Storage of any paper files will be kept in locked filing cabinets. Only study personnel will have access to these files.

6.5. Data and Safety Monitoring Plan

The PI, Dr. Christine Vinci, will be responsible for executing the Data and Safety Monitoring Plan (DSMP), and complying with all reporting requirements. The PI will provide a summary of the Data and Safety Monitoring (DSM) report to NIH as requested. The DSM report may include participants' sociodemographic characteristics, recruitment rates, any quality assurance or regulatory issues during the past year, summary of Adverse Events (AEs) and Serious Adverse Events (SAEs), unanticipated problems, and any actions or changes with respect to the protocol. The DSM report to NIH may also include results of any interim data analyses.

Questionnaire/interview data will be collected using paper forms and will only be identified with the participant's study ID. Study staff will keep the codes that link the name of the participant and the study ID confidential in a password-protected file. Data accuracy will be subject to random audit. Data management reports will be made to the PI on an ongoing basis, which may include data entry progress, error rates, range checks, and general descriptive

statistics. The investigators will conduct all data analyses using SPSS and/or SAS software.

Trained study staff will monitor participants closely throughout each treatment session, and either the study PI or a Co-Investigator will be at the study site to address any concerns that arise. Research staff will report Adverse Events (AE) to the PI and capture the AE data in Oncore, Moffitt's Clinical Trials Database. Serious Adverse Events (using the FDA definition of SAEs) will be reported according to the requirements of NIH, Moffitt's Protocol Monitoring Committee, and the IRB. Any IRB actions in relation to this protocol will also be reported to NIH.

In the event, and only in the event, that study staff must work from home due to mandated orders (e.g., COVID-19 stay home orders), documents that contain protected health information may be temporarily kept at a personal residence for data entry and analysis. Documents will be secured in such a manner that they will be protected from being accessed by other individuals and pets who live in or visit the home. Any remote meetings (e.g., zoom meeting) or conference calls where protected health information may be discussed will be performed in a location that does not have listening devices (e.g., amazon echo) and are not likely to be overheard by those who live in or visit the personal residence.

4. STATISTICAL CONSIDERATIONS

Each Aim above outlines the analytic plan.

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