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# Pilot randomized controlled trial of mindfulness-based relapse prevention vs cognitive behavioral therapy for smoking and alcohol use

Christine Vinci [a,b,*], Steven K. Sutton [a,b], Min-Jeong Yang [a], Sana Baban [a], Rachel Sauls [a], Katie Witkiewitz [c], Karen O. Brandon [a], Marina Unrod [a], Thomas H. Brandon [a,b], David W. Wetter [d]

[a] Moffitt Cancer Center, 12902 USF Magnolia Dr., Tampa, FL 33612, United States
[b] University of South Florida, 4202 E Fowler Ave, Tampa, FL 33620, United States
[c] University of New Mexico, Logan Hall, Room 118, MSC 03-2220, Albuquerque, NM 87131, United States
[d] University of Utah and Huntsman Cancer Institute, 2000 Circle of Hope Dr., Salt Lake City, UT 84112, United States

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ABSTRACT

*Background:* The combined use of cigarettes and alcohol is associated with a synergistic increase in the risk of morbidity and mortality. Continued alcohol use during a smoking quit attempt is a considerable risk factor for smoking relapse. As such, there is a need for interventions that address both behaviors concurrently. Mindfulness-based interventions hold much promise for simultaneously addressing tobacco and alcohol use.
*Method:* This pilot study evaluated the feasibility and acceptability of a mindfulness-based intervention using a two-arm randomized controlled trial of Mindfulness-Based Relapse Prevention for Smoking and Alcohol (MBRP-SA) vs Cognitive Behavioral Therapy (CBT). Interventions were delivered via telehealth in a group setting; all participants received a 6-week supply of the nicotine patch. Participants (N = 69) were adults who smoked cigarettes who reported binge drinking and were motivated to both quit smoking and change their alcohol use. Primary outcomes were feasibility and acceptability of MBRP-SA compared to CBT. Changes in tobacco and alcohol use are also presented.
*Results:* Participants in MBRP-SA and CBT indicated that the treatments were highly acceptable, meeting a priori benchmarks. Feasibility was mixed with some outcomes meeting benchmarks (e.g., recruitment) and others falling below (e.g., retention). Participants in both conditions demonstrated significant reductions in tobacco and alcohol use at the end of treatment.
*Conclusions:* In sum, MBRP-SA had comparable outcomes to CBT on all metrics measured. Future research should evaluate the efficacy of MBRP-SA on smoking abstinence and drinking reductions in a large-scale, fully powered trial. This study was registered on clinicaltrials.gov (NCT03734666).

## 1. Introduction

The combined use of cigarettes and alcohol is associated with a synergistic increase in the risk of morbidity and mortality (Hart et al., 2010; Vaillant et al., 1991; Xu et al., 2007), and alcohol use in the context of smoking cessation presents a considerable risk for relapse to smoking (Kahler et al., 2010; Lam et al., 2013). To date, Cognitive Behavioral Therapy (CBT) is generally considered the gold standard for treating substance use disorders, and interventions for the combined use of cigarettes and alcohol have primarily used CBT/motivational interviewing (Ames et al., 2010; Baca and Yahne, 2009; Davis et al., 2013; Fridberg et al., 2015; Joseph et al., 2004; Kahler et al., 2008, 2010). Although promising, these studies are often limited by focusing on individuals with severe alcohol use (i.e., Alcohol Use Disorder [AUD]) (Baca and Yahne, 2009; Joseph et al., 2004) and/or young adults (Ames et al., 2010; Davis et al., 2013; Fridberg et al., 2015).

Mindfulness-based interventions for substance use have recently emerged with promising results for addressing smoking and alcohol use individually (S. Bowen et al., 2009; D.J. Bowen et al., 2009; Bowen et al., 2014, 2006; Brewer et al., 2011; Davis et al., 2007, 2014, 2015, 2013; Vidrine et al., 2016). Briefly, mindfulness interventions target increased awareness of experience, with an emphasis on cultivating a

* Correspondence to: 12902 USF Magnolia Dr., Tampa, FL 33612, United States.
*E-mail address:* christine.vinci@moffitt.org (C. Vinci).

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nonjudgmental perspective to ultimately change one's relationship with thoughts, emotions, and sensations (Creswell and Lindsay, 2014; Kabat-Zinn, 1990). Mindfulness interventions have been shown to reduce negative affect and decouple the link between negative affect and craving (Adams et al., 2015, 2014; Bowen and Marlatt, 2009; Cambron et al., 2020; Witkiewitz and Bowen, 2010; Witkiewitz et al., 2011). One large-scale study found that Mindfulness-Based Relapse Prevention (MBRP) resulted in fewer heavy drinking days through 12 months than CBT (Bowen et al., 2014). One potential explanation for the success of MBRP over CBT at the long-term follow-up is that mindfulness-based interventions provide skills that are meant to go beyond addressing the immediate concern of substance use. Instead, the mindfulness exercises are meant to apply to a variety of present-moment experiences (e.g., depression, anxiety, interpersonal stressors) that can lead to relapse. In other words, actively engaging in mindfulness has greater generalizability and may lead to greater long-term success than CBT. To our knowledge, only one pilot study, conducted in-person and among college students, has evaluated a mindfulness-based intervention for the combined use of tobacco and alcohol (Davis et al., 2013). Results found a reduction in smoking and alcohol use, although attrition was high.

MBRP was originally designed and tested as a group-based relapse prevention treatment to follow primary substance use disorder treatment (Bowen et al., 2011, 2014). MBRP addresses substance use broadly but does not directly address smoking cessation. Our team developed and evaluated a modified version of MBRP. We first modified MBRP to 1) ensure the intervention could be used as a primary treatment option for both smoking and alcohol use, and 2) incorporate smoking cessation, alcohol modification, and co-use treatment content. Next, we evaluated MBRP for Smoking and Alcohol (MBRP-SA) in a small single-arm pilot study; participant feedback was incorporated into the revised intervention (Hemenway et al., 2020).

We present here the results of a two-arm pilot randomized controlled trial (RCT) to compare MBRP-SA to CBT among adults who smoke cigarettes who reported binge drinking, and who wanted to quit smoking and modify their alcohol use. The goal of this study was to determine if MBRP-SA was comparable to CBT on the primary outcomes of feasibility and acceptability. Effects of both treatments on tobacco and alcohol use at end of treatment and follow-up are also presented. Due to the COVID-19 pandemic, the entire study was conducted remotely, allowing for the evaluation of the feasibility and acceptability of using telehealth to deliver both treatments.

## 2. Method

### 2.1. Participants

Participants were mainly recruited via Trialfacts (a recruitment company that utilized online ads, primarily Facebook and Google ads) and Craigslist ads in Florida and Georgia. The target sample size of 80 was determined based on existing recommendations for sample size estimates in feasibility studies (Hertzog, 2008; Lancaster et al., 2004) while accounting for attrition.

Study staff assessed eligibility based on the following inclusion criteria: (1) $\geq$ 18 years old, (2) $\geq$ 3 cigarettes per day (CPD) in the past year, (3) motivated to quit smoking and modify alcohol use within the next 60 days, (4) consumption of $\geq$ 4 (females) or $\geq$ 5 (males) alcoholic drinks on $\geq$ 1 times in the past month, (5) able to attend 8 weekly virtual group sessions, (6) able to use an email account for study materials, (7) valid home address and functioning telephone number, and (8) able to read, write, and speak in English. Exclusion criteria included: (1) contraindication for the nicotine patch, (2) active substance use disorder (other than AUD) or active psychotic disorder assessed by the Mini International Neuropsychiatric Interview (Sheehan et al., 1998), (3) current use of tobacco cessation medications, (4) pregnancy or lactation, and (5) household member already enrolled in the study. Recruitment started January 2020 and ended April 2021 with a pause from March 2020 through July 2020 due to COVID-19. The study protocol was approved by the institution's review board, Advarra. The study was registered on clinicaltrials.gov (NCT03734666).

### 2.2. Measures

#### 2.2.1. Baseline and weekly measures

Baseline measures included collection of demographic data (e.g., age, gender, race, sexual orientation, marital status, income, education, employment status, insurance status), measures of frequency/quantity of typical tobacco and alcohol use, and the Timeline Followback (TLFB) to assess daily smoking and alcohol use (Sobell and Sobell, 1992) in the past month to establish a baseline for changes in tobacco and alcohol use over time. Participants also completed weekly measures via REDCap, which included an item to assess weekly home practice.

#### 2.2.2. Feasibility and acceptability

Based on the extant literature (Arain et al., 2010; D.J. Bowen et al., 2009; Tickle-Degnen, 2013), feasibility outcomes included recruitment, retention, cost per eligible participant, number of completed treatment sessions, questionnaire completion, and homework completion. Acceptability was measured by the Client Satisfaction Questionnaire (Larsen et al., 1979) for general treatment satisfaction and the System Usability Scale (SUS) for usability of the telehealth component (Lewis and Sauro, 2009). See Table 3 for feasibility and acceptability benchmarks.

Additional questions were developed by the study team to explore intention to continue using the skills learned and perceived appropriateness of the treatments for smoking and alcohol use. Participants were also invited to complete interviews via phone call at the first follow-up with a study staff member to assess: the interventions' appropriateness/acceptability and usefulness, feedback on the telehealth component, and any other general feedback.

#### 2.2.3. Tobacco and alcohol use

The TLFB was completed via phone call at baseline, week 4, week 8, and two follow-ups. Participants were asked if they had smoked each day since the last assessment. If yes, they were asked how many cigarettes were smoked that day. Identical procedures were followed for alcohol drinks per day. Tobacco abstinence was defined as no cigarette smoking in the past 7 days (i.e., 7-day point prevalence abstinence [PPA]). For participants reporting 7-day PPA at the 16-week follow-up, abstinence was verified by a saliva cotinine sample (<10 ng/mL). Alcohol use variables derived from the TLFB included the percent of heavy drinking days ($\geq$4 drinks for women and $\geq$5 for men on a given day), percent days abstinent from alcohol (i.e., days where no alcohol use was reported), and number of drinks per day (including days without alcohol use).

### 2.3. Procedures

Participants were screened via phone for eligibility and provided with general information about practical aspects of the group treatment. Differences between the two conditions were not disclosed. If interested in the study, participants were then randomized to condition (MBRP-SA vs CBT), and study staff then shared the dates and times of group sessions. A separate individual orientation phone call that included the formal informed consent process was then scheduled. This ordering of procedures allowed time for study staff to mail-out the consent form and other orientation materials that would be reviewed during the call. In other words, randomization occurred prior to consent because condition-specific information would be provided verbally and via mail prior to the orientation phone call. As presented later in the CONSORT, this approach did not impact likelihood of consent and enrollment. If consented, a link to the baseline survey via REDCap was sent; 8–11 participants were consented to each group over 4 cohorts. Study

materials were mailed out that included: if needed, a tablet with a data plan (29 % of participants were sent a tablet), treatment handouts and headphones, and a CD with audio-recorded meditations (MBRP-SA only). All were then scheduled to attend a group Zoom orientation one week before treatment session 1, which included an introduction to Zoom features and etiquette, meeting the study team and other group members, and a brief treatment overview by the group facilitator.

Participants attended 8 weekly group sessions via Zoom. Session 5 was designated as the smoking quit date as well as the day participants would implement their alcohol change goal (at the beginning of treatment participants developed their own unique goal for modifying their alcohol use). A weekly assessment was sent via REDCap two days before each group session. Participants completed follow-ups at 8 and 16 weeks post-quit date (5- and 8-weeks post-treatment). At 8 weeks, participants completed questionnaires via REDCap, a phone call for TLFB, and the interview. At 16 weeks, participants completed a phone call for TLFB. If abstinent at 16 weeks, a cotinine kit was mailed to biochemically confirm abstinence. Participants could earn up to $240 for completing study assessments. Additional details about the study procedures can be found in the protocol (Hemenway et al., 2020) and telehealth (Vinci et al., 2022) articles.

#### 2.3.1. Randomization

Participants were randomized using balanced-permuted block randomization with a block size of 4 following stratification by gender (male vs female), race/ethnicity (non-Hispanic White vs Other), and CPD at screening (<20 vs ≥20). The study statistician created the randomization sequences that were implemented within REDCap. Randomization occurred after eligibility was confirmed by staff.

#### 2.3.2. Treatment overview

Participants attended weekly 2-hour group sessions for 8 weeks via Zoom. All participants received the NicoDerm CQ patch with standard dosing recommendations. Patch use began on the quit date. Participants had access to a study website unique to their treatment condition that included all study handouts, staff contact information, and meditations (for MBRP-SA).

*2.3.2.1. MBRP-SA.*. MBRP-SA was developed based on MBRP, an empirically-supported treatment for relapse prevention of alcohol and other substance use (Bowen et al., 2011, 2014). MBRP-SA retained the core treatment components of MBRP, while supplementing content specific to smoking cessation, co-use of cigarettes and alcohol, and alcohol modification (Hemenway et al., 2020). Sessions 1–4 were designed to prepare participants for quitting smoking and implementing their alcohol change goal by session 5 (quit date). Sessions 5–8 built upon skills learned and prepared participants for using mindfulness skills once treatment sessions ended (Table 1; see protocol article for more details (Hemenway et al., 2020). Home practice was assigned at the end of each session and included daily mindfulness meditations.

**Table 1**
MBRP-SA and CBT Treatment Session Titles.

| Session | MBRP-SA | CBT |
|---|---|---|
| 1 | Automatic pilot and relapse | Motivation and strategies for quitting smoking and changing drinking |
| 2 | Awareness of triggers and craving | Addiction and triggers |
| 3 | Mindfulness in daily life | Preparing for life without cigarettes |
| 4 | Mindfulness in high-risk situations | Stress management and using the nicotine patch |
| 5 **(Quit date)** | Acceptance and skillful action | Quit date! Clearing the environment and withdrawal |
| 6 | Seeing thoughts as thoughts | Coping skills, stress, and social support |
| 7 | Self-care and lifestyle balance | Understanding the relapse process, weight gain, and relapse prevention |
| 8 | Social support and continued practice | Tapering off the patch and maintaining abstinence from smoking |

*2.3.2.2. CBT.* CBT sessions utilized a combination of standard tobacco treatment recommendations (Fiore, 2009) and traditional CBT skills (e.g., identification of triggers, coping skill development, cognitive restructuring (Vidrine et al., 2016) (Table 1). Home practice was assigned each week and included practicing the skills learned.

### 2.4. Treatment delivery and fidelity

Group facilitators in both MBRP-SA and CBT were PhD-level clinical psychologists. The MBRP-SA facilitator was required to have completed an intensive mindfulness training, have a daily mindfulness practice, and have attended a silent mindfulness meditation retreat. The CBT facilitator was trained in CBT. Weekly supervision with review of the video-recorded sessions was conducted to ensure treatment fidelity.

To test therapist-specific effects that could have occurred from having different facilitators for MBRP-SA vs CBT, participants completed the Working Alliance Inventory (Horvath and Greenberg, 1989) at the end of treatment. Treatment fidelity was assessed via the Mindfulness-Based Relapse Prevention Adherence and Competence Scale (MBRP-AC; (Bowen et al., 2021) for MBRP-SA and a modified version of the Cognitive Therapy Adherence and Competence Scale (CTACS; (Barber et al., 2003)) for CBT. Sessions were coded by two independent raters for each treatment. Inter-rater reliability was established at > 0.85 for each treatment prior to coding independently. Fifty percent of MBRP-SA and 47 % of CBT sessions were coded. To ensure coding consistency over time, 13 % of all coded sessions were coded by both raters. If discrepancies arose, a meeting was held to resolve any issues.

### 2.5. Data analysis

Feasibility and acceptability outcomes, with benchmarks (see Table 3), were determined a priori and before transitioning to telehealth delivery due to COVID-19. Feasibility benchmarks were determined for recruitment, retention through end of treatment and follow-up, costs per eligible participant, session completion, weekly questionnaire completion for sessions attended, and engagement in mindfulness home practice (for MBRP-SA). The CSQ was the primary measure of acceptability. Interview data were transcribed from audio to text and key themes were derived.

Baseline characteristics (i.e., age, gender, race, marital status, income, education, employment status, insurance status, frequency/quantity of tobacco and alcohol use, tobacco dependence, and Alcohol Use Disorder) were examined as potential predictors of session attendance in two separate sets of analyses including 1) attending 0 vs 1–3 vs ≥ 4 sessions or 2) 0–3 vs ≥ 4 sessions.

For all tobacco and alcohol use outcomes, we present descriptive results for completers (i.e., those who completed assessments). However, for biochemically confirmed abstinence at 16 weeks, we present both completers only and results from an intent-to-treat analysis of all enrolled participants. For those who did not return the cotinine kit, they were coded as smoking.

For tobacco and alcohol use outcomes, the within-group reduction rate was calculated by comparing past 7-day use at baseline to past 7-day use at end of treatment (we were not powered for between-group analyses). For alcohol use, we additionally mapped changes in drinking onto the World Health Organization's guideline for alcohol consumption (World Health Organization, 2000), which categorizes consumption at a given timepoint into four health risk levels for acute problems: Low (1–40 g for males/1–20 g for females), Medium (41–60 g for males/21–40 g for females), High (61–100 g for males/41–60 g for females), and Very High (101 +g for males/61 +g for females). Using

the National Institute on Alcohol Abuse and Alcoholism's definition of a standard drink as having ~14 g of pure alcohol, the past 7-day average number of drinks was multiplied by 14 to determine risk level at both baseline and end of treatment.

## 3. Results

### 3.1. Sample characteristics

Of the 250 participants assessed for eligibility, 121 were randomized to either CBT (n = 60) or MBRP-SA (n = 61). Of those, 34 consented to participate in CBT and 35 in MBRP-SA. Primarily due to COVID-19 pandemic-related cost overruns, we were unable to run an additional cohort of groups to reach our desired N of 80 consented participants. Fig. 1 presents the study CONSORT, including reasons for ineligibility and participation through follow-ups.

Of the 69 participants who consented, 67 completed baseline measures and were considered enrolled in the study. Table 2 presents the demographic characteristics for the entire sample and by condition. Participants were majority female, non-Hispanic/Latino, and White. Only one baseline characteristic predicted session attendance. Participants who attended 4–8 sessions (vs 0–3 sessions) were significantly older (47.8 vs 42.9 years of age; $p = .044$).

### 3.2. Treatment fidelity

Results from the Working Alliance Inventory (1–5 Likert scale) showed that participants in both conditions had a strong alliance with their group facilitator (M=4.27, SD=0.72 for CBT and M=4.19, SD=0.53 for MBRP-SA). Both facilitators were highly adherent to each manualized treatment (for detailed results from the CTACS and MBRP-AC, see Supplemental Material 1).

### 3.3. Feasibility and acceptability

Table 3 presents detailed feasibility and acceptability outcomes by

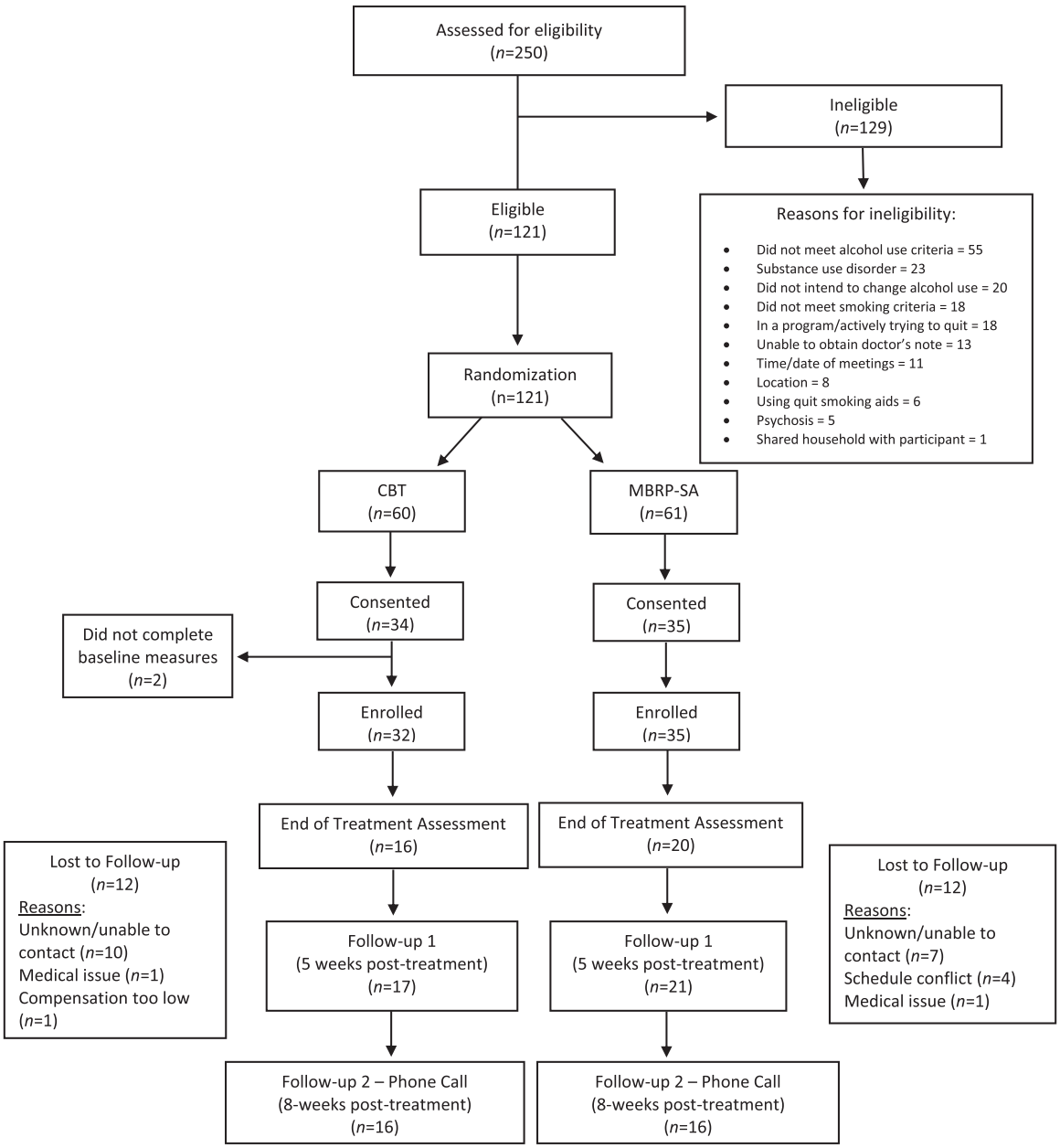


**Fig. 1.** CONSORT Diagram.

**Table 2**
Participant Characteristics.

| Characteristic / Level | M (SD) or N (%) All (N = 67) | CBT (N = 32) | MBRP-SA (N = 35) | p-value |
|---|---|---|---|---|
| Age | 44.1 (9.5) | 43.3 (9.3) | 44.7 (9.8) | 0.534 |
| Gender | | | | |
| Female | 46 (69 %) | 23 (72 %) | 23 (66 %) | 0.891 |
| Male | 20 (30 %) | 9 (28 %) | 11 (31 %) | |
| Transgender Male | 1 (1 %) | 0 (0 %) | 1 (3 %) | |
| Sexual Orientation | | | | |
| Heterosexual | 54 (81 %) | 28 (88 %) | 26 (74 %) | 0.437 |
| Gay or Lesbian | 7 (10 %) | 3 (9 %) | 4 (11 %) | |
| Bisexual | 5 (7 %) | 1 (3 %) | 4 (11 %) | |
| Other | 1 (1 %) | 0 (0 %) | 1 (3 %) | |
| Ethnicity | | | | |
| Non-Hispanic/Latino | 59 (88 %) | 28 (88 %) | 31 (89 %) | 1.00 |
| Hispanic/Latino | 8 (12 %) | 4 (13 %) | 4 (11 %) | |
| Race | | | | |
| White | 43 (64 %) | 20 (63 %) | 23 (66 %) | 0.651 |
| Black/African American | 18 (27 %) | 8 (25 %) | 10 (29 %) | |
| Other | 6 (9 %) | 4 (13 %) | 2 (6 %) | |
| Marital Status | | | | |
| Married, Partnered, or Living Together | 25 (37 %) | 15 (47 %) | 10 (29 %) | 0.557 |
| Single | 28 (42 %) | 13 (41 %) | 15 (43 %) | |
| Divorced, Separated, or Widowed | 14 (20 %) | 4 (12 %) | 10 (29 %) | |
| Annual Household Income | | | | |
| Less than $20,000 | 26 (39 %) | 10 (31 %) | 16 (46 %) | 0.334 |
| $20,000-$49,999 | 22 (33 %) | 11 (34 %) | 11 (31 %) | |
| $50,000 or more | 18 (27 %) | 11 (34 %) | 7 (20 %) | |
| Unknown | 1 (1 %) | 0 (0 %) | 1 (3 %) | |
| Education | | | | |
| High school diploma or less | 19 (28 %) | 8 (25 %) | 11 (31 %) | 0.667 |
| Some college | 16 (24 %) | 6 (19 %) | 10 (29 %) | |
| Associate/ Undergraduate degree | 21 (31 %) | 12 (38 %) | 9 (26 %) | |
| Graduate/Professional degree | 6 (9 %) | 3 (9 %) | 3 (9 %) | |
| Unknown | 5 (7 %) | 3 (9 %) | 2 (6 %) | |
| Employed: Full- or Part-time | 39 (58 %) | 20 (63 %) | 19 (54 %) | 0.621 |
| Insurance | | | | |
| Medicare, Medicaid, Private, Other | 47 (70 %) | 24 (75 %) | 23 (66 %) | 0.437 |
| Uninsured | 20 (30 %) | 8 (25 %) | 12 (34 %) | |
| Cigarettes smoked per day | 16.2 (8.6) | 15.1 (6.5) | 17.1 (10.2) | 0.327 |
| Time to first cigarette after waking | | | | |
| Less than 5 min | 34 (51 %) | 16 (50 %) | 18 (51 %) | 0.224 |
| 6–30 min | 25 (37 %) | 13 (41 %) | 12 (34 %) | |
| 31–60 min | 4 (6 %) | 3 (9 %) | 1 (3 %) | |
| More than 60 min | 4 (6 %) | 0 (0 %) | 4 (11 %) | |
| Average drinking days per week | 3.8 (1.8) | 3.7 (1.8) | 3.8 (1.8) | 0.801 |
| Average drinks per drinking day | 4.7 (2.8) | 4.2 (2.4) | 5.1 (3.1) | 0.234 |
| Alcohol Use Disorder* (% yes) | 28 (42 %) | 9 (28 %) | 19 (55 %) | 0.055 |
| Binge drinking days in past month: Female | | | | |
| 3 or fewer | 18 (40 %) | 14 (63 %) | 4 (17 %) | 0.006 |
| 4–10 | 15 (33 %) | 4 (18 %) | 11 (48 %) | |
| 11 or more | 12 (27 %) | 4 (18 %) | 8 (35 %) | |
| Binge drinking days in past month: Male | | | | |
| 4 or fewer | 7 (37 %) | 3 (33 %) | 4 (40 %) | 0.608 |
| 5–10 | 8 (42 %) | 5 (56 %) | 3 (30 %) | |
| 11 or more | 4 (21 %) | 1 (11 %) | 3 (30 %) | |

Note. * = Diagnosed with the MINI International Neuropsychiatric Interview for the DSM-5. p-values for continuous variables calculated from t-test; p-values for categorical variables calculated from Fisher's Exact test. Tobacco and alcohol use data reported here asked about use "most of the time" and was gathered to describe general use within the sample.

condition at both end of treatment and follow-up. We recruited an average of 25.5 eligible participants per month when actively recruiting for a given cohort. Total recruitment costs were $38,380, with each eligible participant costing $572.84 to recruit. Retention from enrollment through the end of treatment and follow-up was about 50 % for both conditions. Regarding session completion, 34 % in CBT and 43 % in MBRP-SA completed all 8 sessions, and 47 % in CBT and 57 % in MBRP-SA completed at least half of all sessions. For MBRP-SA, 76 % of participants reported engaging in mindfulness meditations on 4 or more days per week. For those attending sessions, measures completion was 98 % for CBT and 99 % for MBRP-SA.

The CSQ results indicated very high treatment satisfaction (97 % with a score of ≥3.0), and the SUS scores indicated high usability of the telehealth component of treatment (77 % with a score of ≥70.0). Participants had high ratings for intention to use skills learned and perceived appropriateness of treatment for smoking and alcohol. There were no statistically significant differences between conditions on any acceptability outcome. There were very few differences between conditions for feedback about the intervention and telehealth components (see Supplementary Material 2). Participants reported that specific intervention content, accountability/support of the group, and patches were most helpful, and that they would recommend the treatments to family/friends. The telehealth component was cited as convenient, and participants noted various benefits of having a Zoom orientation prior to treatment. Challenges included issues with connectivity, having distractions in the home, and length/timing of sessions.

### 3.4. Tobacco and alcohol use

Table 4 presents the results for CPD, 7-day self-reported PPA, percent heavy drinking days, percent days abstinent, and drinks per day from baseline through follow-up. Note that percent values were calculated based on the entire sample. When comparing past 7-day CPD at baseline and end of treatment, the reduction rates were 79.3 % in CBT and 91.3 % in MBRP-SA. Paired sample t-tests revealed that CPD reduction was significant within each group, $t(14) = 6.20$, $p < .001$ in CBT; $t(17) = 8.19$, $p < .001$ in MBRP-SA. At the 16-week follow-up, biochemically confirmed abstinence for completers only was 6.3 % ($n = 1/16$) for CBT and 35.7 % ($n = 5/14$) for MBRP-SA. ITT analysis resulted in 3.1 % ($n = 1/32$) for CBT and 14.3 % ($n = 5/35$) for MBRP-SA.

Regarding change in percent of heavy drinking days from baseline to end of treatment, the mean reduction rates were 34.7 % and 27.0 % in CBT and MBRP-SA, respectively. The reduction was significant within each group, $t(13) = 4.57$, $p < .001$ in CBT; $t(17) = 3.13$, $p < .01$ in MBRP-SA. The average reduction in drinks per day in past 7-days from baseline to end of treatment was 84.6 % and 72.4 % in CBT and MBRP-SA, respectively. The reduction was significant within each group, $t(13) = 4.76$, $p < .001$ in CBT; $t(17) = 2.85$, $p < .05$ in MBRP-SA. WHO risk level analyses demonstrated that most participants in both conditions who consumed alcohol at moderate to very high levels at baseline were either abstinent or low risk at end of treatment (Table 5). Finally, of those who reduced CPD, 87.9 % (n = 29; 13 in CBT, 16 in MBRP-SA) also reported reductions in drinks per day, whereas 9.1 % (n = 3; 1 in CBT, 2 in MBRP-SA) reported no change. No participants reported an increase in drinks per day.

## 4. Discussion

This pilot, two-arm RCT evaluated the feasibility and acceptability of group-based MBRP-SA vs CBT, delivered via telehealth, among those who were seeking to quit smoking and change alcohol use. All participants also received a 6-week supply of the nicotine patch. Results indicated high acceptability and mixed feasibility for both treatments. Retention rates and recruitment costs did not meet expectations in either condition. Importantly, tobacco and alcohol use reductions in both conditions were substantial from baseline to end of treatment. Overall,

**Table 3**
Feasibility and acceptability outcomes.

| | Variable | Scale | Benchmark | Overall | CBT | MRBP-SA |
|---|---|---|---|---|---|---|
| | | | | **N=67** | **n=32** | **n=35** |
| FEASIBILITY | **Recruitment*** (eligible per month) | - | 8 | 25.5 | - | - |
| | **Retention** | | | | | |
| | Baseline → End of Treatment | - | 80% | 54% | 50% | 57% |
| | Baseline → Follow-up 2 | - | 70% | 48% | 50% | 46% |
| | **Costs per eligible participant*** | - | <$100 | $572.84 | - | |
| | **Session completion** | | | | | |
| | 8 sessions | - | ≥40% | 39% | 34% | 43% |
| | ≥ 4 sessions | - | ≥60% | 52% | 47% | 57% |
| | **If attended session, questionnaire completion that week** | - | 90% | 99% | 98% | 99% |
| | **MBRP-SA weekly meditation completion** | - | > 3.5 days per week | - | - | 76% meditated ≥4 days per week |
| ACCEPTABILITY | | | | **N=35** | **n=16** | **N=19** |
| | **Client Satisfaction Questionnaire** | - | >80% score ≥3.0; 1-4 | 97% | 100% | 94% |
| | **System Usability Scale** | 0-100 | - | 79.9 (16.0) | 85.3 (15.5) | 74.5 (15.1) |
| | **Plan to continue to use the skills learned in treatment** | | | | | |
| | End of Treatment | 1-10 | - | 9.7 (0.7) | 9.7 (0.7) | 9.7 (0.7) |
| | Follow-up 1 | 1-10 | - | 9.0 (2.0) | 9.3 (1.5) | 8.7 (2.4) |
| | **Will use the skills to abstain from tobacco** | | | | | |
| | End of Treatment | 1-5 | - | 4.9 (0.3) | 4.9 (0.3) | 4.9 (0.3) |
| | Follow-up 1 | 1-5 | - | 4.5 (1.0) | 4.7 (0.6) | 4.4 (1.3) |
| | **Will use the skills toward alcohol reduction** | | | | | |
| | End of Treatment | 1-5 | - | 4.6 (0.7) | 4.4 (0.8) | 4.7 (0.6) |
| | Follow-up 1 | 1-5 | - | 4.3 (0.9) | 4.4 (0.7) | 4.3 (1.1) |
| | **Treatment was appropriate for smoking cessation** | | | | | |
| | End of Treatment | 1-5 | - | 4.8 (0.5) | 4.9 (0.3) | 4.8 (0.5) |
| | Follow-up 1 | 1-5 | - | 4.7 (0.9) | 4.9 (0.3) | 4.5 (1.2) |
| | **Treatment was appropriate for alcohol reduction** | | | | | |
| | End of Treatment | 1-5 | - | 4.6 (0.7) | 4.5 (0.8) | 4.6 (0.7) |
| | Follow-up 1 | 1-5 | - | 4.2 (1.0) | 4.3 (0.9) | 4.1 (1.1) |

Note. Values are Mean (Standard Deviation) or percentages for all variables. CBT=Cognitive Behavioral Treatment; MBRP-SA=Mindfulness-Based Relapse Prevention for Smoking and Alcohol; there were no significant differences between CBT and MBRP-SA on any acceptability outcomes. *N = 69 (CBT=34; MBRP=35).

**Table 4**
Tobacco and Alcohol Use Results.

| | Tobacco Use: CPD (Mean, SD) | | Tobacco Use: % 7-day PPA* | | Alcohol Use: % Heavy Drinking Days* | | Alcohol Use: % Days' Abstinent* | | Alcohol Use: Drinks Per Day (Mean, SD) | |
|---|---|---|---|---|---|---|---|---|---|---|
| | CBT | MBRP-SA | CBT | MBRP-SA | CBT | MBRP-SA | CBT | MBRP-SA | CBT | MBRP-SA |
| **Baseline** | 15.78 (7.30) | 19.49 (9.09) | 0% | 0% | 35.2% | 37.6% | 46.7% | 45.6% | 2.60 (1.73) | 3.73 (4.09) |
| **n** | 31 | 34 | 31 | 34 | 30 | 34 | 30 | 34 | 30 | 34 |
| **Quit Day** | 2.05 (3.13) | 2.01 (4.18) | 28.1% | 25.7% | 3.4% | 3.0% | 76.5% | 91.7% | 0.53 (0.73) | 0.33 (0.72) |
| **n** | 17 | 20 | 17 | 20 | 17 | 19 | 17 | 19 | 17 | 19 |
| **EOT** | 2.23 (4.21) | 1.84 (3.78) | 31.3% | 34.3% | 6.3% | 4.0% | 82.1% | 87.3% | 0.72 (1.38) | 0.41 (0.78) |
| **n** | 16 | 18 | 16 | 18 | 16 | 18 | 16 | 18 | 16 | 18 |
| **Follow-up 1** | 3.09 (5.31) | 2.89 (4.06) | 25% | 22.9% | 4.5% | 5.0% | 85.7% | 88.2% | 0.42 (0.70) | 0.41 (0.92) |
| **n** | 16 | 18 | 16 | 18 | 16 | 17 | 16 | 17 | 16 | 17 |
| **Follow-up 2** | 3.81 (5.99) | 7.16 (8.44) | 25% | 17.1% | 4.6% | 5.1% | 86.8% | 82.5% | 0.39 (0.65) | 0.52 (0.89) |
| **n** | 16 | 14 | 16 | 14 | 16 | 14 | 16 | 14 | 16 | 14 |

Note. n = number of participants who fully completed the Timeline Followback. * = the % values were calculated based on the entire sample (n = 32 in CBT, n = 35 in MBRP-SA). EOT = end of treatment; CPD = cigarettes per day; PPA = point prevalence abstinence; CBT = Cognitive Behavioral Therapy; MBRP-SA = Mindfulness-Based Relapse Prevention for Smoking and Alcohol. All outcomes were calculated based on data gathered from the past 7 days via the Timeline Followback. At baseline, 2 participants' baseline data were unavailable given their delayed participation and 1 participant's alcohol data at baseline was entirely missing.

**Table 5**
Alcohol consumption risk level analysis (%, n).

| | | Risk Level | | | | |
|---|---|---|---|---|---|---|
| | | 0 (abstinent) | 1 (low) | 2 (moderate) | 3 (high) | 4 (very high) |
| **Baseline** | **N** | | | | | |
| CBT | 30 | 0.00% (0) | 46.67% (14) | 23.33% (7) | 23.33% (7) | 6.67% (2) |
| MBRP-SA | 34 | 5.88% (2) | 26.47% (9) | 26.47% (9) | 26.47% (9) | 14.71% (5) |
| **End of Treatment** | | | | | | |
| CBT | 14 | 26.67% (8) | 13.33% (4) | 3.33% (1) | - | 3.33% (1) |
| MBRP-SA | 18 | 35.29% (12) | 11.76% (4) | 5.88% (2) | - | 0.00% (0) |

Note. Risk level analysis based on drinks per day in the past 7 days at baseline and end of treatment.

MBRP-SA had comparable outcomes to CBT on all measures, suggesting that future research should evaluate MBRP-SA's efficacy on smoking abstinence and alcohol use in a fully powered RCT.

Feasibility metrics were surpassed for several outcomes including recruitment, measure completion, and home practice completion. Additionally, participants in MBRP-SA met/marginally met session attendance benchmarks with 43 % of participants completing all 8 sessions and 57 % completing ≥ 4 sessions. CBT was below session attendance benchmarks at 34 % and 47 %, respectively. Some CBT cohorts had low session attendance at the first few sessions, which likely impacted attendance throughout. It is also possible that factors not objectively measured (e.g., group cohesion) may have differed between treatments.

Both recruitment costs and retention rates fell below benchmarks. Given our ability to recruit broadly throughout the states of Florida and Georgia when we shifted to telehealth delivery, recruitment costs primarily went towards online and social media-based advertisements (vs historically low-cost approaches such as posting flyers in the community when recruiting for in-person studies). Additionally, given we recruited cohorts within 4-week increments, we chose to turn our advertisements "on and off" as needed. This seemed like the most efficient way to leverage motivation to quit (i.e., not requiring participants to wait months until the next cohort began), and at the same time required that we utilize recruitment methods that were possibly more expensive to guarantee enough participants to enroll in each group. As such, recruitment costs were high, and future trials utilizing online advertisements for difficult-to-reach populations should consider this in the study design phase.

We retained 54 % of enrolled participants through the end of treatment assessment and 48 % through the second follow-up, with similar rates across both conditions. Previous trials with similar populations have discussed challenges with retention (Ames et al., 2010; Davis et al., 2013). For instance, in the only other trial for group-based mindfulness among those who smoke and binge drink, retention was about 50 % (Davis et al., 2013). One notable difference between the current study and all previous trials (i.e., not just with mindfulness) conducted with this population in a group setting is that all treatment sessions were held via Zoom and all assessments were conducted via REDCap and/or phone call. Thus, it appears that attrition in this population is high regardless of treatment delivery modality, and reasons for attrition may not be easily mitigated via telehealth (e.g., medical emergencies, scheduling conflicts). Nonetheless, interview results revealed that the increased accessibility/convenience that came with Zoom sessions facilitated participation.

Among clients who completed treatment, satisfaction ratings for both treatments were very high. Participants also indicated that the skills were helpful for quitting smoking and to address their alcohol use goals, and that the treatment content was appropriate for their treatment needs. System usability was high, supporting the telehealth component. Interview results further supported high acceptability, as participants indicated that the treatments met their smoking and alcohol goals, and that they were very likely to recommend the treatment to family/friends.

Both conditions were very successful in significantly reducing CPD. A similar pattern was observed for self-reported 7-day PPA through follow-up. Of note, participants in MBRP-SA had a descriptively higher biochemically confirmed PPA at the 16-week follow-up, which is similar to previous studies with this type of population and group-based treatment (Ames et al., 2010; Davis et al., 2013). MBRP-SA participants also had higher session attendance, which could drive higher abstinence rates. That said, there was an inconsistent return rate of cotinine samples between conditions (6/7 samples returned for MBRP-SA and 2/5 returned for CBT). These discrepant cotinine return rates, combined with the small sample size, warrants caution in the interpretation of tobacco abstinence results. Self-reported abstinence was higher than biochemically confirmed abstinence, which may have been due to various factors including misreporting by the participant or change in smoking status (e.g., at time of phone call participant was abstinent but had started smoking by the time they received the saliva kit in the mail).

Both MBRP-SA and CBT had significant reductions in percent heavy drinking days and drinks per day, which is notable considering that neither treatment prescribed drinking reductions (e.g., someone may have wanted to decrease risky drinking behavior vs quantity). When further evaluating alcohol use in the context of the WHO guidelines, participants in both conditions reported no or low-risk drinking at the end of treatment compared to high and very high levels of use at baseline. Our findings are consistent with previous studies evaluating alcohol use within smoking cessation treatments (Ames et al., 2010; Davis et al., 2013; Kahler et al., 2008, 2010; Toll et al., 2015). This is the first study with adults (vs young adults) enrolled in group treatment via telehealth to observe such changes, suggesting that MBRP-SA and CBT delivered via telehealth are beneficial in reducing alcohol use.

Overall, MBRP-SA had comparable results to CBT, which is often considered the gold standard treatment. When considering previous research demonstrating the long-term success of MBRP over CBT (Bowen et al., 2014), future research building from this study should examine MBRP-SA vs CBT in a fully powered trial to determine long-term treatment efficacy of MBRP-SA for tobacco and alcohol use, as well as to evaluate various treatment moderators. Additional future avenues of research include a mechanistic trial of MBRP-SA to determine active treatment ingredients (e.g., role of acceptance/nonjudgment as a treatment component), and how to prevent attrition among this challenging population (e.g., integrating different treatment modalities such as phone counseling or smartphone apps to encourage connection between sessions).

Limitations include consideration that this study took place near the beginning of the COVID-19 pandemic, so familiarity with Zoom and similar platforms may be greater now in the general population. It is also unknown how tobacco and alcohol use may differ if this study occurred outside of the pandemic. Generalizing the results to other populations not studied here (e.g., those who smoke but do not drink) should be limited. Additionally, we reported outcomes only for those who

completed the intervention. Considering the high rates of attrition, caution is warranted in the interpretation of tobacco abstinence, as it is possible that those who stopped participating in the study were more likely to have started smoking again and therefore data would not be missing at random. Finally, the sample was not powered to conduct analyses of group differences on tobacco or alcohol use.

Strengths of this study include the RCT design implemented via telehealth, inclusion of a population that includes a range of problematic alcohol users (i.e., not restricted to those with AUD), the implementation of several treatment fidelity components including the fidelity coding of > 50 % of sessions in each condition, high fidelity for the delivery of both treatments, and biochemical confirmation of tobacco abstinence at follow-up. Overall, results support telehealth as a treatment modality for the delivery of MBRP-SA and CBT for smoking cessation and alcohol use. Findings also indicate that both treatments were highly accepted and moderately feasible, with very promising tobacco and alcohol use reductions observed over time.

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## Contributors

CV obtained funding, originated the project idea, oversaw data collection, wrote the first draft of the manuscript, and edited the manuscript. SS oversaw data analysis and edited the manuscript. MJY and RS assisted with data analysis and edited the manuscript. SB assisted with data collection, data analysis, and edited the manuscript. KW, THB, and DW contributed to the original project idea and edited the manuscript. KOB and MU were the treatment facilitators and edited the manuscript.

## Conflict of interest

THB is on the advisory board for Hava Health, Inc.

## Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.drugalcdep.2023.109768.

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