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Mindfulness-Based Relapse Prevention for Alcohol Dependence: Findings from a Randomized Controlled Trial.

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Abstract

OBJECTIVES: To assess the effects of mindfulness-based relapse prevention for alcohol dependence (MBRP-A) intervention on drinking and related consequences.

METHODS: 123 alcohol-dependent adults in early recovery, recruited from outpatient treatment programs, were randomly assigned to MBRP-A (intervention plus usual-care; N=64) or Control (usual-care-alone; N=59) group. MBRP-A consisted of eight-weekly sessions and home practice. Outcomes were assessed at baseline, 8 weeks and 26 weeks (18 weeks post-intervention), and compared between groups using repeated measures analysis.

RESULTS: Outcome analysis included 112 participants (57 MBRP-A; 55 Control) who provided follow-up data. Participants were 41.0±12.2 years old, 56.2% male, and 91% white. Prior to “quit date,” they reported drinking on 59.4±34.8% (averaging 6.1±5.0 drinks/day) and heavy drinking (HD) on 50.4±35.5% of days. Their drinking reduced after the “quit date” (before enrollment) to 0.4±1.7% (HD: 0.1±0.7%) of days. At 26 weeks, the MBRP-A and control groups reported any drinking on 11.5±22.5% and 5.9±11.6% of days and HD on 4.5±9.3% and 3.2±8.7% of days, respectively, without between-group differences ($p > 0.05$) in drinking or related consequences during the follow-up period. Three MBRP-A participants reported “relapse,” defined as three-

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consecutive HD days, during the study. Subgroup analysis indicated that greater adherence to session attendance and weekly home practice minutes were associated with improved outcomes.

CONCLUSIONS: MBRP-A as an adjunct to usual-care did not show to improve outcomes in alcohol-dependent adults in early recovery compared to usual-care-alone; a return to drinking and relapse to HD were rare in both groups. However, greater adherence to MBRP-A intervention may improve long-term drinking-related outcomes.

Keywords

Alcohol dependence; alcoholism; mindfulness; meditation; relapse prevention

1. INTRODUCTION

In 2015, 6.2% of U.S. adults met criteria for alcohol use disorder (Substance Abuse and Mental Health Services Administration [SAMHSA], 2015), which included, according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (2000), alcohol abuse (mild severity) and alcohol dependence (higher severity).

Although treatment of alcohol use disorder improves outcomes, it presents clinical challenges. Even when an alcohol-dependent individual is motivated to change and receives treatment, relapse affects up to 40-60% of treated individuals, especially in the early recovery period (Hunt, Barnett, & Branch, 1971; McLellan, Lewis, O'Brien, & Kleber, 2000; Miller, Walters, & Bennett, 2001; Moos & Moos, 2006; Weisner, Matzger, & Kaskutas, 2003), suggesting a benefit of early intervention. Although standard-of-care treatment for alcohol dependence typically includes relapse prevention interventions (Hendershot, Witkiewitz, George, & Marlatt, 2011), high relapse rates indicate that the existing treatments are not sufficiently effective, at least for some individuals. With stress being one of the known relapse risk factors, there is urgent need for development of new therapies that strengthen relapse prevention skills and improve stress coping (Penberthy et al., 2015; Li et al., 2017), providing additional support for sustained recovery among those with alcohol dependence.

Mindfulness-based interventions have been proposed as adjunctive treatments targeting relapse prevention in substance use disorders (Bowen, Chawla, & Marlatt, 2010). Improved emotion regulation, reduced stress reactivity, and decreased risk of relapse in high-risk situations have been hypothesized and documented as possible mechanisms, through which mindfulness-based interventions may impact substance use-related outcomes (Garland, Gaylord, Boettiger, & Howard, 2010; Witkiewitz, Bowen, et al., 2014; Koob et al., 2014; Kober, Brewer, Height, & Sinha, 2017; Li et al., 2017; Priddy et al., 2018; Davis et al., 2018). Several studies of mindfulness-based interventions, including Mindfulness-Based Relapse Prevention (MBRP), for a broad spectrum of substance use disorders have shown beneficial findings for reducing relapse risk, frequency and amount of substance misuse, craving, drug and alcohol-related consequences, mental health symptoms, and physical health problems (Bowen et al., 2009; Bowen et al., 2014; Witkiewitz & Bowen, 2010; Witkiewitz, Warner, et al., 2014). Overall, the existing evidence highlights the promise of mindfulness-based treatments while underscoring the need for further, rigorous research on

their efficacy in substance use disorders, including alcohol dependence (Grant et al., 2017; Li, Howard, Garland, McGovern, & Lazar, 2017; Zgierska et al., 2009).

Only a limited number of pilot-level studies have assessed mindfulness-based interventions in those with alcohol dependence (Crescentini, Matiz, & Fabbro, 2015; Garland, et al., 2010; Garland, Schwarz, Kelly, Whitt, & Howard, 2012; Zgierska et al., 2008), a group with high exposure to potential relapse triggers due to alcohol's wide availability and social acceptance of its use as well as its commercial promotion. In an uncontrolled pilot trial ($N=19$), conducted by our team to assess the effects of a tailored MBRP intervention, alcohol-dependent participants who had been in early recovery at the time of enrollment reported abstinence on $94.5\pm7.4\%$ of days throughout the 16-week assessment period as well as reduced severity of depression, anxiety and stress symptoms at 16 weeks compared to baseline ($p<0.05$) (Zgierska, et al., 2008).

The current RCT built on the pilot study and tested the effects of an MBRP-based intervention for alcohol dependence (MBRP-A) in alcohol-dependent individuals (Zgierska, Shapiro, Burzinski, Lerner, & Goodman-Strenski, 2017), hypothesizing that, by improving stress coping and reducing stress, the MBRP-A, adjunctive to usual-care, would reduce alcohol consumption (primary outcome) and drinking-related consequences (secondary outcome) when compared to usual-care-alone.

2. MATERIAL AND METHODS

2.1. Trial Design

This 26-week parallel-arm phase-2 RCT was approved by the University's Health Sciences Institutional Review Board (IRB) and registered with [ClinicalTrials.gov](https://clinicaltrials.gov) prior to participant enrollment. It evaluated the efficacy of the MBRP-A intervention, adjunctive to usual-care (MBRP-A group), compared to usual-care-alone (waitlist control group), for alcohol relapse prevention.

2.2. Participants

The study participants were alcohol-dependent adults in early recovery who had entered an addiction treatment program (Zgierska, et al., 2017). Eligibility, determined by self-report, included: age 18 years or older; English fluency; diagnosis of alcohol dependence confirmed by the Structured Clinical Interview for DSM-IV-TR Axis 1 Disorders (SCID) (First, Spitzer, Gibbon, & Williams, 2002); being in early recovery, defined by a drinking "quit date" within the prior 2-14 weeks; completion of 2 weeks of outpatient treatment for alcohol dependence (defined as 2 or more therapy sessions/week) in one of 8 treatment programs; and elevated Perceived Stress Scale-10 total score ≥ 14 (Cohen, Kamarck, & Mermelstein, 1983; Cohen & Williamson, 1988). The latter criterion was included because stress is a known relapse risk factor and its reduction had been hypothesized to serve as the primary mechanism underlying the MBRP-A's effects on relapse prevention (Breese et al., 2005). Because most cases of relapse occur during the first 12 weeks of recovery engagement efforts (Hunt, et al., 1971), the initial eligibility criteria included individuals with an alcohol "quit date" of up to 12 weeks prior to enrollment; however, with the funding

agency and the IRB's approval, "quit date" period was extended to 14 weeks after the study start date to facilitate recruitment. Exclusion criteria included: inability to reliably participate (e.g., geographic relocation); current meditation practice; current pregnancy; pre-existing schizophrenia, delusional or bipolar disorders; or meeting the SCID-based criteria for "active" (past 2 weeks) drug use disorder.

2.3. Intervention

2.3.1. Usual-care—At baseline, all participants were engaged in usual-care, delivered at one of the collaborating treatment programs. Usual care was comprised of individual and/or group outpatient therapy for alcohol dependence, with primary therapeutic modalities including twelve-step facilitation, motivational enhancement, relapse prevention and cognitive behavioral therapy (CBT); encouragement to participate in mutual self-help meetings was a part of usual care-based recommendations.

2.3.2. MBRP-A Intervention—Participants in the MBRP-A group additionally received the MBRP-A intervention (Zgierska, et al., 2017). MBRP-A was adapted, with the MBRP's developers' feedback and permission, from the MBRP program for substance use disorders (Bowen, et al., 2010), which, in turn, was modeled after Mindfulness-Based Stress Reduction (Kabat-Zinn, 1990). To tailor MBRP-A to the needs of individuals with alcohol dependence, the MBRP's focus on broader substance use was adapted to center on alcohol-specific content. The MBRP-A intervention was found to be feasible, acceptable, safe among adults with alcohol dependence, and delivered with high treatment fidelity (Zgierska, et al., 2017).

MBRP-A consisted of 8 weekly, two-hour group-therapy sessions, led by a trained and experienced therapist, and provided intensive training in mindfulness meditation, linking it to cognitive-behavioral relapse prevention skills (Table 1). Each session included: check-in, home practice review, practice and discussion of two to four practice techniques, and recommendations for further home practice. MBRP-A participants were asked to engage in both formal (e.g., body scan meditation, for 30 minutes/day on 6 days/week) and brief, informal (e.g., mindfulness of daily activities, daily) home mindfulness practice during the entire 26-week study. MBRP-A participants received session-specific handouts, a meditation cushion, and CDs with guided meditations: one with study-recorded body scan and loving-kindness practices, and four commercially-produced (Kabat-Zinn, 1996) for formal home practice. Additional details of usual-care and the MBRP-A intervention are described elsewhere (Zgierska, et al., 2017).

2.4. Study Setting and Procedures

Initial screening took place by phone. The final screening, enrollment and assessment procedures occurred at the University's Clinical Research Unit. MBRP-A was delivered in a large and quiet conference room in a local hospital.

Interested individuals who met the initial screening criteria were invited for in-person screening, during which eligibility criteria (presence of alcohol dependence; absence of an active drug use disorder) were reassessed with the SCID (First, et al., 2002) by the trained

study coordinator. The study coordinator then completed the informed consent and enrollment procedures, followed by collection of baseline data, and finally randomization. The sealed randomization envelopes (1:1 randomization scheme) were prepared by the study statistician and distributed consecutively to participants who completed their baseline assessment.

Once randomized, participants were reminded about follow-up assessments, with MBRP-A participants additionally informed about the MBRP-A details, and control participants about the option to receive the intervention after completing the study. During the assessment visits, participants first filled out the surveys with the study coordinator, followed by a venous blood sample collection by the nurse for biomarkers, then received remuneration, up to \$120 for the completion of all assessments. Those unable to complete the full follow-up visit were asked to complete as much as possible (e.g., surveys by phone; blood draw). Due to the resource limitations, the interventionists and assessors were not blinded to group status.

2.5. Outcome Measures

Outcome measures were collected at baseline, 8-week follow-up (F1; post-intervention), and 26-week follow-up (F2; 18 weeks post-intervention). This manuscript details results stemming from main outcomes measures, which are described below.

2.5.1. Alcohol consumption—Alcohol consumption (primary outcome) was assessed with the Timeline Followback method, a validated, reliable measure of substance use (Fals-Stewart, O'Farrell, Freitas, McFarlin, & Rutigliano, 2000; Sobell & Sobell, 1992). Daily alcohol use data (number of standard drinks/day) were collected for 6 months prior to the self-identified "quit date" ("baseline"), from the "quit date" to the study enrollment date ("quit-to-enrollment"), and then during the entire study. These data enabled a calculation of variables describing the pattern of alcohol consumption: % drinking days and % heavy drinking (HD) days during each assessment period, and time to relapse to drinking (three-consecutive HD days) during the follow-up period. HD was defined as 5+ drinks/day for men, and 4+ drinks/day for women (National Institute on Alcohol Abuse and Alcoholism [NIAAA], n.d.).

2.5.2. Drinking-related consequences—Drinking-related consequences (secondary outcome) were measured using the 50-item valid and reliable Drinker Inventory of Consequences (Anderson, Gogineni, Charuvastra, Longabaugh, & Stein, 2001; Forcehimes, Tonigan, Miller, Kenna, & Baer, 2007; Miller, Tonigan, & Longabaugh, 1995), which assesses the presence and extent of various drinking-related consequences. At baseline, the Inventory evaluated whether a given consequence occurred during one's lifetime (yes/no; score range: 0-45). In addition, at baseline ("past 3 months") and each follow-up ("past month"), it evaluated the frequency of a given consequence (0-3 Likert scale), yielding a total score (range: 0-135) and 5 subscale scores, with higher scores indicating worse consequences.

2.5.3. Other measures—Demographic information, history (“lifetime” at baseline; interval at follow-up) of treatment for alcohol/drug use disorders, and history of participation in mutual self-help groups were obtained from all participants. The 10-item reliable and valid Perceived Stress Scale (Cohen, et al., 1983; Cohen & Williamson, 1988) evaluated perceived stress over “the past month” (0-4 Likert scale, maximum total score: 40). The total score (average score across items) of the 15-item Mindfulness Attention and Awareness Scale was used to measure mindfulness, using a 1-6 Likert scale (Brown & Ryan, 2003). Attendance at the MBRP-A sessions and logs of formal mindfulness practice (average minutes/day and days/week, enabling a calculation of weekly practice minutes) were collected from MBRP-A participants. Participant safety questions were asked at each study contact. Safety was additionally evaluated during the scheduled assessment visits with liver enzyme concentrations, measured from a venous blood sample, and with questions 15 and 63 from the Symptom Checklist-90-Revised (Derogatis, 1994), asking about the potential intent-to-harm self or others over “the past week.”

2.6. Statistical Methods

2.6.1. Sample Size—Sample size was calculated using estimates from previous studies of mindfulness and behavioral treatments for alcohol dependence (Anton et al., 2006; Baer, 2003; Grossman, Niemann, Schmidt, & Walach, 2004; Zgierska, et al., 2008). Based on the assumption that the MBRP-A group would report 20% fewer drinking days (Cohen’s $d=0.3$) than the control group, a sample size of 112 participants provides 80% power to detect a 20% difference in the percent of drinking days between the study arms with a type I error of 5%; the sample size accounted for up to 25% loss to follow-up. We exceeded our target sample size and enrolled 123 participants, with 112 participants completing at least one follow-up assessment.

2.6.2. Statistical Analysis—Outcome data were double-entered and managed using the University-hosted electronic secure database. Analyses were conducted using SAS (Version 9.4) for all randomized participants who completed at least one follow-up assessment ($N=112$). Over 91% of participants completed at least one follow-up and were included in the analysis. Results were presented as mean $\pm$ SD (standard deviation), unless indicated otherwise. A two-tailed $p<0.05$ was considered statistically significant. Unadjusted outcomes for the MBRP-A and control groups were compared at each follow-up time point with t-tests (or chi square tests, as appropriate). The primary efficacy analysis was conducted using repeated measures models, which adjusted for baseline values of the outcome measure, gender, age, race, and employment status. The two latter variables were included due to between-group differences in these variables at baseline. SAS PROC MIXED was used to construct a linear mixed effects model for each outcome. Cohen’s d was calculated to assess the magnitude of between-group differences in outcome change. Exploratory analyses additionally evaluated whether intervention protocol adherence (defined by 2 separate variables, session attendance and weekly minutes of formal home practice) was correlated with change in drinking-related outcomes at F1 and F2 (Pearson’s correlation). MBRP-A participants who were adherent to the intervention (based on the previously described thresholds, i.e., attendance at 4+ sessions; formal practice 150 minutes/week)

(Zgierska, et al., 2016a; Zgierska, et al., 2016b) were also compared to those less adherent and controls.

3. RESULTS

3.1. Participant Recruitment and Flow

Participants were recruited over a two-year span (January 2010 – January 2012).

Recruitment occurred through study fliers placed at the collaborating addiction treatment clinics, researchers visiting the clinics, and referral by the clinics' providers.

Among 359 individuals who expressed interest, 292 were screened, and 123 (64 MBRP-A, 59 controls) were eligible, enrolled, and provided baseline outcome data (Figure 1). During the study, seven (6 MBRP-A; 1 control) participants withdrew, six citing lack of time or changed life circumstances and one being withdrawn by the Principal Investigator (PI) due to mental health problem-related disruptiveness during the intervention sessions. Main outcome data were provided by 111 participants at F1 and 105 participants at F2, with 112 participants (57 MBRP-A, 55 controls) providing data for at least one follow-up and included in the outcome analysis (Figure 1).

3.2. Baseline Characteristics

3.2.1. Demographics—Participants ($N=112$, Table 2) were 41.0 ± 12.2 years old, 56.2% male, and 91.0% White. The majority (83.9%) reported college or graduate level education. Approximately half (55.4%) were employed and half (46.4%) reported annual income below \$20,000. Compared to controls, fewer MBRP-A participants were white ($p=0.074$) and employed ($p=0.036$).

3.2.2. Clinical characteristics—Lifetime addiction treatment history (Table 3) obtained at baseline revealed that, on average, participants completed 4.8 ± 18.0 separate episodes of detoxification, 1.0 ± 1.6 episodes of residential treatment, and 2.3 ± 1.5 episodes of outpatient treatment. In addition, 86.6% attended mutual self-help meetings, averaging 232.4 ± 540.0 meetings. There were no statistically significant differences between the groups in their lifetime treatment experience.

At baseline (Table 3), prior to their alcohol “quit date,” participants ($N=112$) reported drinking on $59.4\pm34.8\%$ of days, averaging 6.1 ± 5.0 drinks/day, with HD on $50.4\pm35.5\%$ of days. Between the “quit date” and enrollment (39.9 ± 21.9 days on average), they reduced their drinking days to $0.4\pm1.7\%$ (averaging 0.02 ± 0.06 drinks/day) and HD days to $0.1\pm0.7\%$, with 90.2% reporting abstinence. They also reported numerous lifetime and recent (past 3 months) drinking-related consequences. There were no differences between groups on any of these baseline clinical characteristics ($p>0.05$; Table 3). In addition, the MBRP-A and control groups did not differ at baseline in their perceived stress (20.2 ± 6.5 versus 21.8 ± 6.9 , respectively; $p=0.213$) and mindfulness (3.7 ± 0.9 versus 3.6 ± 0.8 , respectively; $p=0.634$) scores.

3.3. MBRP-A intervention adherence

Intervention session attendance—Among the 57 analyzed MBRP-A participants, 5 did not participate in the intervention training. The remaining 52 MBRP-A participants attended, on average, 5.8 ± 2.2 out of 8 sessions, with 44 attending at least 4 sessions and 16 attending all 8 sessions.

Home practice adherence—Of the 57 analyzed MBRP-A participants, 57 reported at F1 and 54 reported at F2 on their home mindfulness practice. Among those who provided practice data, 94.7% reported a formal practice (174.0 ± 79.8 minutes/week over 5.3 ± 1.8 days/week) at F1 and 72.2% reported a formal practice (93.0 ± 64.9 minutes/week over 3.7 ± 2.2 days/week) at F2.

3.4. Follow-up outcomes

Interval addiction treatment history (Table 4) did not show statistically significant differences between the MBRP-A and control groups in the number of detoxification, residential or outpatient treatment episodes, or the number of attended mutual self-help meetings.

At 8 weeks, 29.8% of MBRP-A and 27.3% of control participants reported “any drinking,” and 17.5% of MBRP-A and 18.2% of control participants reported at least one HD day. At 26 weeks, the percentages of any drinking and HD rose to 38.5% and 26.9%, respectively among the MBRP-A and 37.7% and 24.5%, respectively, among the control participants, without between-group differences ($p = 0.05$; Table 4). During the 26-week trial, 3 MBRP-A group participants relapsed to drinking (i.e., had three-consecutive HD days). The groups did not differ in the number of drinks/day, and the percentage of drinking days or HD days at 8 and 26 weeks ($p = 0.05$). Similarly, they did not differ in the drinking-related consequence scores at either follow-up point ($p = 0.05$), with both groups reporting overall improvements compared to baseline.

The MBRP-A and control groups did not differ in the perceived stress scores at F1 (15.1 ± 5.7 versus 17.4 ± 7.8 , respectively; $p = 0.087$) and F2 (14.3 ± 6.4 versus 17.1 ± 8.3 , respectively; $p = 0.062$), with similar findings for the mindfulness scores at F1 (4.1 ± 0.8 versus 3.9 ± 0.9 , respectively; $p = 0.196$) and F2 (4.4 ± 0.7 versus 4.0 ± 1.0 , respectively; $p = 0.073$).

3.5. Outcome analyses

Repeated measures analysis indicated that, over the 26-week trial, there were no statistically significant between-group differences ($p = 0.05$) in alcohol consumption (number of drinks/day; % drinking days; % HD days) or the severity of drinking-related consequences; the change in perceived stress and mindfulness scores also did not differ between the groups ($p = 0.245$ and $p = 0.061$, respectively; Table 4).

3.6. MBRP-A intervention adherence and outcomes

To evaluate the potential impact of intervention adherence on drinking-related outcomes, the MBRP-A participants ($N = 57$) were divided into subgroups based on their session attendance (more adherent participants attended 4+ sessions, $n = 44$) and weekly home

practice minutes (more adherent participants reported a practice time of, on average, 150+ minutes/week, $n=40$). A 3-group repeated measures analysis examined between-group differences for the MBRP participants who were more adherent to the intervention protocol compared to the MBRP participants who were less adherent and the controls; no differences ($p > 0.05$) were found between the groups in any of primary outcomes.

In addition, Pearson bivariate correlations evaluated the relationship between session attendance and weekly home practice minutes, and the changes in drinking-related outcomes at each follow-up. When considering all MBRP-A participants ($N=57$), session attendance correlated with home practice minutes ($r=0.523$, $p<0.001$). Neither session attendance nor home practice time were correlated ($p > 0.05$) with the changes in the drinking-related outcomes at F1. At F2 though, increase in practice minutes correlated to reduced percent drinking days (from post-quit to F2, $r=-0.304$, $p=0.030$).

When focusing on MBRP-A participants who attended 4 or more intervention sessions ($n=44$), both session attendance ($r=-0.344$, $p=0.022$) and home practice minutes ($r=-0.304$, $p=0.045$) were correlated with changes in percent drinking days from post-quit to F1. Session attendance was also correlated with changes in percent HD days from post-quit to F1 ($r=-0.389$, $p=0.009$). Practice minutes was correlated with changes in percent drinking days ($r=-0.366$, $p=0.019$) and percent HD days ($r=-0.348$, $p=0.026$) from post-quit to F2.

3.7. Adverse events

No serious or unanticipated safety or health-related concerns or adverse events were noted during the study (Zgierska, et al., 2017). Because elevated liver enzyme values and depressed mood with intent to harm were anticipated to be more prevalent in those with alcohol dependence than in the general population, they were assessed as a part of the study safety protocol, which also addressed the management of such findings. Participants with elevated liver enzyme concentrations (35 individuals in total, with 11 having abnormal results on more than one assessment) were contacted by phone by the PI to discuss the results, then sent a summary letter. Thirty-four participants with “positive screen” for a potential intent-to-harm (questions 15 and 63 of the Symptom Checklist-90-Revised (Derogatis, 1994)), including 12 participants with an abnormal screen at more than one assessment period, were called and assessed by a study clinician, typically the PI, and were all cleared for safety.

4. DISCUSSION

Our 26-week RCT did not find statistically significant between-group effects in any of our primary outcome analyses. The lack of between-group effects was surprising, given the promising findings of several other individual trials assessing similar mindfulness-based treatments (Bowen, et al., 2009; Bowen, et al., 2014; Garland, Roberts-Lewis, Tronnier, Graves, & Kelley, 2016; Witkiewitz, et al., 2014), including our pilot study (Zgierska, et al., 2008), and the conclusions of a recent systematic review and meta-analysis by Li et al. (2017) that reported an overall positive impact of mindfulness-based intervention on substance use-related outcomes across studies with heterogeneous design and interventional methodologies. However, our primary results are overall consistent with those of another

recent meta-analysis by Grant et al. (2017), which focused on MBRP and showed no statistically significant improvement in relapse rates or frequency of substance use in those with substance use disorders when a meta-analytic approach was implemented.

Although the absence of statistically significant differences in drinking-related outcomes can suggest the lack of MBRP-A efficacy, at least in the population assessed in our trial, it is important to note that, overall, both the MBRP-A and usual-care groups evidenced favorable outcomes when compared to previous research (Project MATCH Research Group, 1997; Anton, et al., 2006), including our pilot study ($N=19$), which showed that 47% of participants stayed abstinent through the 16 week follow-up period (Zgierska, et al., 2008). In the current RCT, over 60% of participants across both groups reported abstinence throughout the 26-week study; among those who reported any drinking, approximately 25% reported heavy drinking, yet only 3 participants engaged in more sustained heavy drinking (i.e., on at least 3 consecutive days).

Several aspects of the study design may help explain these findings. Because we enrolled individuals who were committed to quitting drinking, with up to 14 weeks of sobriety at entry into the study, and who already entered professional treatment for alcohol dependence, these eligibility criteria could have led to a selection-bias, favoring “good outcomes.” Research has shown that past abstinence predicts future abstinence (Charney, Zikos, & Gill, 2010; Gueorguieva, Wu, Fucito, & O’Malley, 2015; Gueorguieva et al., 2014; Vielva & Iraurgi, 2001), with one study noting that 4 weeks of abstinence predicted abstinence at 12 weeks (Charney, et al., 2010). In our trial, 71.5% ($n=80$) of participants reported at least 4 weeks of continuous sobriety at enrollment. Engagement in professional treatment and mutual self-help groups, reported at baseline by 100% and 86.6% of the study participants, respectively, could also have influenced outcomes (Bond, Kaskutas, & Weisner, 2003; Magura, Cleland, & Tonigan, 2013; Pagano, White, Kelly, Stout, & Tonigan, 2013). In addition, all participants received usual-care for alcohol dependence, which has been shown to contain “common factors” (e.g., alliance/group cohesion, positive outcome expectations) that can account for a relatively large percentage of outcome variance (Wampold & Imel, 2015). These “common factors” could have introduced substantial “noise” in the data, making it more difficult to detect effects specific to MBRP-A (Goldberg et al., 2018).

Participant engagement efforts may have exerted additional therapeutic effects (Michie et al., 2012), promoting similar gains in both study arms. All participants were contacted by phone up to four times prior to each study visit for scheduling, frequently sharing their struggles during these communications with the research coordinator; research personnel were trained to listen with empathy, which has demonstrated therapeutic value (Elliott, Bohart, Watson, & Greenberg, 2011). In addition, an abnormal elevation in liver enzyme levels or presence of self-reported potential intent to harm led to a by-phone evaluation by a study clinician, usually the PI. Because these abnormal findings can be caused by active drinking (in fact, this was often the case), such an evaluation could have served as counselling participants across both groups to reduce/quit drinking. Alcohol research protocols have been hypothesized to replicate elements of alcohol brief interventions (Clifford & Maisto, 2000), and research has found that higher frequency and intensity of study contacts have been linked to reductions in drinking and related consequences (Clifford, Maisto, & Davis, 2007).

Telephone-based continuing care has also been shown to support sustained abstinence from alcohol use following treatment (McKay et al., 2004; Pelc et al., 2005). It is therefore likely that engagement efforts in the study provided therapeutic benefit for participants in both groups, potentially obscuring any intervention effects.

Decrease in stress reactivity is one of the hypothesized mechanisms underlying the efficacy of mindfulness-based interventions in reducing relapse risk (Garland et al., 2010; Witkiewitz et al., 2014; Koob et al., 2014; Kober et al., 2017; Li et al., 2017; Priddy et al., 2018; Davis et al., 2018). It is possible our findings could be due to the insufficient efficacy of our intervention in improving stress coping and reducing stress reactivity, especially since both groups decreased their perceived stress scores to a similar degree. It is also plausible that the perceived stress scale used was not sensitive enough to detect subtle between-group differences in stress severity change; recent meta-analysis by Li et al. (2017) suggests that the Perceived Stress Scale may be less sensitive for capturing change than other stress assessment surveys.

Despite our null principal findings, informal participant feedback suggests the utility of the intervention (Zgierska, et al., 2017). Treatment providers reported receiving positive comments from clients about the intervention's usefulness for recovery, a fact that has likely contributed to the implementation of the MBRP-A-based strategies into the usual-care treatment protocols in many of the treatment programs, which collaborated in this study (personal communication). Incorporation of the MBRP-A elements into regular treatment could have "contaminated" the usual-care that the study participants had received and, thereby, influenced the study results. The spontaneous dissemination of our intervention into practice in the collaborating addiction treatment programs, which already utilized traditional behavioral approaches such as CBT, suggests that MBRP-A may fill a recovery gap that is meaningful to at least some clients. This assumption is corroborated by our subgroup analysis findings, which suggested that participant adherence to the MBRP-A intervention can positively impact outcomes; better attendance at the training sessions and spending more time in home practice could generate a difference in results (Parsons, et al., 2017). The MBRP-A intervention may not be broadly acceptable to treatment-seeking individuals, as suggested by clinical experience and our findings showing a higher attrition rate among the MBRP-A versus control participants, and the fact that 5 MBRP-A participants did not participate in the intervention sessions; this could have further impacted our findings.

Limitations/Generalizability

The sample size may not have been large enough to adequately power the study in this early-stage RCT. Lack of blinding of research personnel (assessors, therapists) and participants may have introduced bias and impacted findings. Because treatments for alcohol dependence exist and because untreated alcohol dependence can have dire health consequences, the MBRP-A was conceptualized as an adjunctive therapy. Therefore, all participants across both groups received an evidence-based usual care, provided through their addiction treatment programs; they were also subject to intensive engagement efforts. Both usual care and engagement efforts could have affected results, attenuating the specific impact of the MBRP-A intervention. Because the intervention was primarily delivered by one therapist

(Zgierska, et al., 2017), the effectiveness of the intervention was necessarily impacted by the effectiveness of this particular therapist; it is possible that a different pattern of results could have emerged with a different therapist (Wampold & Imel, 2015). In addition, the study sample was comprised of predominantly white, well-educated and already-treated individuals with a “quit date” between 2-14 weeks prior to enrollment who had self-selected to participate in a trial of mindfulness meditation, thus possibly limiting the generalizability of our findings to others with alcohol dependence.

Future Directions

Therapies that target relapse prevention and maintenance of remission are vital to success in long-term recovery from addiction. While the current study did not show differential effects of the intervention relative to control, participant and provider feedback on its benefits was encouraging, conveying a need for further evaluation of this type of intervention. It is possible that, with a more rigorous design or use of different outcome measures, the beneficial effects would become more apparent or be better captured. It is also possible that mindfulness-based therapy is better suited for select subgroups of individuals with alcohol dependence. Identifying “responder” baseline characteristics (e.g., those in very early recovery or those with substantially elevated perceived stress scores) that result in better efficacy, which our study was not powered to investigate, or introducing mindfulness to a different clinical population (e.g., those not already engaged in formal addiction treatment), could possibly yield different results.

5. CONCLUSION

MBRP-A, adjunctive to usual care, was not shown to provide additional benefit for recovery maintenance in individuals with alcohol dependence, compared to usual addiction-specialty care, though intervention adherence may improve long-term drinking-related outcomes. In this study, both the intervention group and the control group had favorable drinking-related outcomes. More research is needed to adequately quantify potential therapeutic benefits or perhaps the optimal timing of introduction of this intervention.

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Abbreviations:

DSM-IV:	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
HD:	Heavy Drinking
MBRP:	Mindfulness-Based Relapse Prevention
MBRP-A:	Mindfulness-Based Relapse Prevention for Alcohol Dependence
PI:	Principal Investigator
RCT:	Randomized Controlled Trial
SCID:	Structured Clinical Interview for DSM-IV-TR Axis 1 Disorders

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Highlights

- MBRP-A plus usual care and usual care alone resulted in similar health benefits.
- Addition of MBRP-A to usual care did not further improve drinking-related outcomes.
- Greater MBRP-A intervention adherence was associated with better outcomes.

Figure 1.
The CONSORT study flow diagram.

Table 1.

Mindfulness-Based Relapse Prevention for Alcohol Dependence (MBRP-A): Outline of the Concepts Taught at the Weekly Intervention Sessions.

Mindfulness-Based Relapse Prevention for Alcohol Dependence (MBRP-A)	
Session	Brief Description
1	Introduction to MBRP-A: mindfulness meditation and MBRP-A introduction, autopilot versus mindfulness, relapse and mindfulness
2	Craving and triggers: typical challenges with meditation, awareness of the tendency to judge day-to-day experiences, reaction versus mindful response to triggers, cravings, and urges
3	Daily mindfulness: brief mindfulness practices for daily life, self-awareness of mind/body feelings and sensations (including the inner experience of craving)
4	Mindfulness in high-risk situations: identifying personal thoughts, emotions, and sensations that arise in high-risk situations, mindfulness during thoughts, emotions, and sensations that are uncomfortable
5	Acceptance and change: Unconditional self-acceptance, acceptance of unpleasant mind/body states, coping with challenging interpersonal interactions
6	Thoughts: thoughts and relapse, understanding thoughts, identifying thought patterns that may lead to relapse, lapse versus relapse
7	Taking care of oneself and life balance: Relapse warning signs, coping behaviors, coping plan, forgiveness of self and others, compassion
8	Balance in daily life: support networks, mindful living as a facilitator of life balance, challenges in asking for help, reflection on MBRP-A intervention, looking to the future

Table 2.Baseline demographics of the sample ($N=112$) and by group status.

Variable	Total ($N=112$)	MBRP-A group ($N=57$)	Control group ($N=55$)	p value ¹
Self-reported alcohol and other substance use-related outcomes				
Age, mean (SD)	41.0 (12.2)	40.5 (12.1)	41.9 (11.9)	0.502
Male, n (%)	63 (56.2)	34 (59.7)	29 (52.7)	0.460
Ethnicity, n (%)				
Hispanic or Latino	3 (2.7)	1 (1.8)	2 (3.6)	0.537
Race, n (%)				
White	101 (91.0)	49 (86.0)	52 (96.3)	0.074
Black/African American	5 (4.5)	5 (8.8)	0 (0.0)	
Other	5 (4.5)	3 (5.3)	2 (3.7)	
Education, n (%)				
Less than high school/GED	3 (2.7)	3 (5.3)	0 (0.0)	0.220
High school/GED	15 (13.4)	8 (14.0)	7 (12.7)	
College	82 (73.2)	42 (73.7)	40 (72.7)	
Graduate degree	12 (10.7)	4 (7.0)	8 (14.6)	
Employment (past 90 days), n (%)				
Unemployed	36 (32.1)	22 (38.6)	14 (25.5)	0.036
Employed (part or full time)	62 (55.4)	25 (43.9)	37 (67.3)	
Other ²	14 (12.5)	10 (17.5)	4 (7.3)	
Annual Income (past year), n (%)				
< \$20,000	52 (46.4)	29 (50.9)	23 (41.8)	0.160
\$20,000 to \$34,999	23 (20.5)	9 (15.8)	14 (25.5)	
\$35,000 to \$49,999	13 (11.6)	4 (7.0)	9 (16.4)	
\$50,000	24 (21.4)	15 (26.3)	9 (16.4)	

¹ $p < 0.05$ (Chi square test for categorical, two-sample t-test for continuous variables)² Public assistance, Supplemental Security Income, temporary leave, retired

Table 3.Baseline clinical characteristics of the sample ($N=112$) and by group status.

Variable	Total ($N=112$)	MBRP-A group ($N=57$)	Control group ($N=55$)	p value ^I
Lifetime Addiction Treatment History				
# Detoxification Episodes, <i>mean (SD)</i>	4.8 (18.0)	3.9 (10.8)	5.7 (23.4)	0.597
# Residential Treatment Episodes, <i>mean (SD)</i>	1.0 (1.6)	0.9 (1.5)	1.1 (1.8)	0.604
# Outpatient Treatment Episodes, <i>mean (SD)</i>	2.3 (1.5)	2.3 (1.3)	2.4 (1.7)	0.546
# Mutual Self-Help Meetings, <i>mean (SD)</i>	232.4 (540.0)	175.9 (496.3)	290.9 (580.4)	0.262
Primary and secondary outcome measures				
Alcohol consumption (TLFB): pre-quit period (6 months prior to the alcohol quit date)				
# Drinks per Day, <i>mean (SD)</i>	6.1 (5.0)	5.7 (4.5)	6.4 (5.5)	0.466
% Drinking Days, <i>mean (SD)</i>	59.4 (34.8)	59.0 (35.9)	59.7 (34.1)	0.916
% Heavy Drinking Days, <i>mean (SD)</i>	50.4 (35.5)	48.6 (36.4)	52.4 (34.8)	0.569
Alcohol consumption (TLFB): quit date to enrollment				
# Days (quit-to-enrollment), <i>mean (SD)</i>	39.9 (21.9)	38.2 (20.9)	41.7 (23.0)	0.406
# Drinks per Day, <i>mean (SD)</i>	0.02 (0.06)	0.01 (0.05)	0.02 (0.08)	0.559
% Drinking Days, <i>mean (SD)</i>	0.4 (1.7)	0.4 (1.4)	0.5 (2.0)	0.622
% Heavy Drinking Days, <i>mean (SD)</i>	0.1 (0.7)	0.1 (0.7)	0.2 (0.7)	0.827
Drinking-related consequences (DrInC)				
Lifetime, total score, <i>mean (SD)</i>	34.4 (6.8)	34.2 (7.2)	34.6 (6.4)	0.807
Past 3 months, total score, <i>mean (SD)</i>	49.1 (21.9)	45.2 (21.7)	53.1 (21.6)	0.056

Abbreviations: DrInC: Drinking-Related Consequences; TLFB: Timeline Followback.

^I $p < 0.05$ (Chi square test for categorical, two-sample t-test for continuous variables)

Table 4.Outcomes by group status during the 26-week follow-up period [$N=112$].

Variable	MBRP-A group ($N=57$)	Control group ($N=55$)	p value ¹	Cohen's d	p value ² (repeated measures)
Interval Addiction Treatment History					
# Detoxification Episodes, <i>mean (SD)</i>					
8-week follow-up	0.02 (0.1)	0.1 (0.4)	0.089	0.27	-
26-week follow-up	0.1(0.3)	0.06 (0.3)	0.339	-0.13	
# Residential Treatment Episodes, <i>mean (SD)</i>					
8-week follow-up	0.02 (1.3)	0.02 (0.1)	0.990	0.01	-
26-week follow-up	0.02 (0.1)	0.00 (0.00)	0.322	-	
# Outpatient Treatment Episodes, <i>mean (SD)</i>					
8-week follow-up	0.7 (0.5)	1.3 (3.1)	0.167	0.26	-
26-week follow-up	0.7 (1.7)	0.5 (0.5)	0.402	-0.16	
# Mutual Self-Help Meetings, <i>mean (SD)</i>					
8-week follow-up	18.7 (23.6)	25.5 (28.1)	0.173	0.25	-
26-week follow-up	21.2 (26.5)	33.6 (44.9)	0.088	0.34	
Primary and Secondary Outcome Measures					
Alcohol Consumption (TLFB): past 28 days					
Participants reporting any drinking	17 (29.8)	15 (27.3)	0.765	-0.05	0.536
8-week follow-up, # (%)	20 (38.5)	20 (37.7)	0.939	-0.01	
26-week follow-up, # (%)					
Participants reporting any heavy drinking					
8-week follow-up, # (%)	10 (17.5)	10 (18.2)	0.930	0.02	0.585
26-week follow-up, # (%)	14 (26.9)	13 (24.5)	0.779	-0.05	
# Drinks per Day					
8-week follow-up, <i>mean (SD)</i>	0.2 (0.5)	0.2 (0.5)	0.880	0.01	0.609
26-week follow-up, <i>mean (SD)</i>	0.7 (1.7)	0.3 (0.7)	0.199	-0.31	
% Drinking Days					
8-week follow-up, <i>mean (SD)</i>	6.5 (16.9)	3.4 (7.7)	0.220	-0.23	0.084
26-week follow-up, <i>mean (SD)</i>	11.5 (22.5)	5.9 (11.6)	0.106	-0.31	
% Heavy Drinking Days					
8-week follow-up, <i>mean (SD)</i>	2.4 (6.5)	1.5 (4.0)	0.387	-0.17	0.299
26-week follow-up, <i>mean (SD)</i>	4.5 (9.3)	3.2 (8.7)	0.486	-0.14	
Drinking-related consequences (DrInC): past month					

Variable	MBRP-A group (N=57)	Control group (N=55)	<i>p</i> value ¹	Cohen's <i>d</i>	<i>p</i> value ² (repeated measures)
Total Score					
8-week follow-up, <i>mean (SD)</i>	11.2 (16.3)	17.8 (19.3)	0.061	0.37	0.188
26-week follow-up, <i>mean (SD)</i>	11.3 (16.9)	16.5 (17.6)	0.139	0.30	

Abbreviations: DrInC: Drinking-Related Consequences; TLFB: Timeline Followback.

¹ *p* value (Chi square test for categorical, two-sample t-test for continuous variables)

² *p* value resulting from a repeated measures analysis (linear mixed effects model) adjusted for baseline values of the measure, gender, age, race, and employment status