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Mindfulness-Based Intervention Effects on Substance Use and Relapse Among Women in Residential Treatment: A Randomized Controlled Trial With 8.5-Month Follow-Up Period From the Moment-by-Moment in Women's Recovery Project

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ABSTRACT

Objective: We tested the efficacy of Moment-by-Moment in Women's Recovery (MMWR), a mindfulness training program adapted for ethnoculturally diverse women with complex social and clinical histories in residential treatment for substance use disorder, on substance use and relapse outcomes.

Methods: Participants were randomized to MMWR (n = 100; 60% Hispanic/Latina, 18% non-Hispanic Black) or the attention control condition, Neurobiology of Addiction (n = 100; 56% Hispanic/Latina, 21% non-Hispanic Black). Substance use outcomes (days until first use, days of use, and relapse status: abstained, lapsed, relapsed) were obtained from interviewer-assisted timeline followback for an 8.5-month follow-up period spanning the intervention start through the 6-week intervention period and 7 months after the intervention ended.

Results: An intent-to-treat survival analyses showed that time delay to first marijuana use favored MMWR (hazard ratio = 0.44, 95% confidence interval = 0.20–0.98, p = .049) with a medium-to-large effect size. In negative binomial hurdle models, the MMWR group showed fewer days of marijuana use at 3.5 months (B = −1.71, SE = 0.79, incidence rate ratio = 0.18, p = .030) and a trend at 7 months after the intervention (B = −0.90, standard error = 0.55, incidence rate ratio = 0.41, p = .10). For marijuana, mindfulness practice time during the intervention predicted time delay to first use (B = 0.28, p = .006) and total abstinence days (B = 0.34, p = .002) across the 7 months after MMWR. No other substance use outcomes showed differential response to MMWR relative to controls. Only in MMWR, number of study intervention sessions attended (dose) correlated with a greater length of time to alcohol intoxication (r = .48, p < .001), fewer days of alcohol intoxication (r = −.24, p = .020), and greater improvement in mindfulness skills (r = .61, p < .01).

Conclusions: MMWR added to an ongoing intensive residential treatment program serving vulnerable women is protective against marijuana use but no other substance use outcomes. Mindfulness practice time predicted a delay in time to first marijuana use. MMWR class attendance, an indicator of intervention dose, appears protective of alcohol intoxication at follow-up; thus, extended MMWR exposure might be useful.

Key words: mindfulness, substance use disorder, women, residential treatment, relapse, Hispanic/Latina, NCT02977988.

INTRODUCTION

Prevention of substance use and relapse is a major goal of treatment for people with substance use disorders (SUDs) (1). Sustained abstinence among individuals who enter SUD remains low because 50% to 70% of those treated return to drug use or problem drinking in the first year after treatment (2). The economic, social, and health consequences of continued substance use among individuals with SUD are significant (1,3). Accordingly, developing and testing new relapse prevention interventions, which build upon treatment successes made to date, is a priority in SUD research (1).

Women who enter SUD treatment, including residential treatment, often must overcome significant barriers (e.g., stigma, fear of legal prosecution, family opposition, co-occurring mental health conditions, and parenting responsibilities) (4), making their success in treatment particularly important. Residential treatment is

ITT = intent-to-treat, **MBI** = mindfulness-based intervention, **MBRP** = mindfulness-based relapse prevention, **MBSR** = mindfulness-based stress reduction, **MMWR** = Moment-by-Moment in Women's Recovery, **NA** = Neurobiology of Addiction, **PTSD** = posttraumatic stress disorder, **RCT** = randomized controlled trial, **SUD** = substance use disorder, **TLFB** = timeline followback

SDC Supplemental Digital Content

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an important target for intervention development because it serves individuals who exhibit the most heightened levels of problems as per criteria set forth by the American Society for Addiction Medicine, including SUD severity, social burdens, and health problems (5–7). Moreover, women in residential SUD treatment present with complex interpersonal and clinical profiles. As compared with men receiving SUD treatment, women report higher rates of trauma in the form of physical (70% versus 32%) and sexual abuse (54% versus 15%) (8) and more complex medical comorbidities (9,10). The most vulnerable women are served in sex-specific residential programs. For example, compared with women in mixed-sex programs, those in women-only residential programs are more likely to be homeless, be on probation, and have a longer history of drug use (9,11), and such programs address the unique needs of women (e.g., child care and child services, and trauma informed care) and thereby can facilitate treatment access (4,9,12). These findings highlight the need for developing and testing interventions intended to improve SUD outcomes in residential treatment among women with the health and social burdens that are commonly associated with reduced treatment success and increased relapse risk (4,13,14).

Furthermore, although SUD treatment is delivered in varied settings and modalities, residential and inpatient programs serve a significant portion of individuals who receive SUD treatment. In 2016, among those who received SUD treatment, nearly 1 million Americans (41%) received it in a rehabilitation inpatient/residential program and another 732,000 (33%) received treatment in a specialty hospital inpatient unit (15). Together, these modalities of treatment served more people than specialty rehabilitation outpatient (1.446 million, or 65%) and many more than those who received SUD treatment in physician offices (540,000, or 24%; percentages do not sum to 100% because of multiple SUD treatment services per individual per year).

Mindfulness-based interventions (MBIs), defined as the family of interventions that include mindfulness as their central practice (e.g., mindfulness-based stress reduction [MBSR] and mindfulness-based cognitive therapy) (16), offer a therapeutic approach to support women receiving SUD treatment. Mindfulness is a teachable quality of being that, by definition, involves attending to one's experiences on a moment-to-moment basis with openness and the intention to cultivate nonjudgmental, nonreactive states of awareness (17). Conventional cognitive and behavioral therapies use shared dialogue focused on reducing or eliminating substance-using patterns (e.g., thought stopping or replacement and avoidance of challenging experiences) and replacing them with healthier alternative cognitions and behaviors. Conversely, MBIs use mindfulness meditation to cultivate an open, accepting, and nonreactive awareness of the conscious experience that contain those cognitive and emotional states. Programs such as Mindfulness-Based Relapse Prevention (MBRP) (18) and Mindfulness-Oriented Recovery Enhancement (19) are modeled after the first generation of mindfulness-based therapies like MBSR in terms of their structure and format and are examples of how MBIs can be supportive of conventional approaches to SUD treatment.

Recent reviews of MBIs for SUD have summarized the emerging efficacy results for substance use and relapse (20–22). The meta-analysis by Grant et al. (21) regarding nine randomized controlled trials (RCTs) published between 2000 and 2016 evaluated MBRP for adults diagnosed with SUD. The authors concluded an overall null effect of MBRP on substance use relapse and frequency of use relative to comparator groups. The meta-analysis by Li et al. (22) analysis included 42 studies using various MBIs for substance use (MBRP and other MBI configurations). Of the 42 studies, only 3 RCTs evaluated number of days of substance use or binge drinking and provided sufficient data to calculate effect sizes. The authors reported that a small posttreatment effect size for days of substance use and binge drinking favored MBIs relative to controls (Cohen $d = -0.28$, 95% confidence interval [CI] = −0.54 to −0.03). Postintervention follow-up periods ranged from 2 weeks to 12 months. Both meta-analyses note major limitations in the current body of evidence, which include small sample size, short follow-up periods, and high rates of attrition among the few studies with longer-term follow-up. Furthermore, most MBI efficacy studies for substance users represent largely non-Hispanic White samples.

The purpose of the current report is to test the efficacy of Moment-by-Moment in Women's Recovery (MMWR) (23,24), an MBI adapted for vulnerable and ethnoculturally diverse women with complex social and clinical histories. MMWR is an adaptation of MBSR (17) and developed to improve intervention acceptability and fit for low-income, racially and ethnically diverse women in SUD treatment. Our adaptation is intended to address issues pertinent to SUDs, relapse prevention, literacy, trauma, and cultural diversity among women. As with existing programs (e.g., MBRP), MMWR uses mindfulness practice to support stress reduction and relapse prevention skill development.

We previously reported on the shorter-term outcome of this trial, residential treatment retention (25). Survival analysis showed that MMWR participants compared with controls were less likely to leave residential treatment without satisfactory progress in the 5 months after the intervention. The effect size was medium to large, suggesting clinical importance for effects on residential SUD retention. We also reported on therapeutic target measures such as mindfulness skills and found that both study groups showed significant increases at immediate postintervention. However, only in the MMWR group did class attendance (dose) have a large-size correlation with improved mindfulness skills ($r = .61$ [$p < .01$] versus $r = .15$ [$p = .14$] for controls). The purpose of this current report is to test the efficacy of MMWR on substance use, our longer-term outcome. We use a parallel-group RCT with a time-matched psychoeducation control to ascertain MMWR effects on substance use and relapse. Substance use outcomes (days until first drug use and alcohol intoxication, total days of use, and relapse status: abstain, lapse, relapse) were all obtained from interviewer-assisted timeline followback (TLFB), and we tested for study group differences in these outcomes for overall drug use, methamphetamines, marijuana, and alcohol to intoxication across an 8.5-month follow-up period.

METHODS

Study Design

This parallel-group RCT (NCT02977988) active from 2016 to 2018 was designed to compare substance use and relapse among women assigned to one of two study groups as adjuncts to their residential SUD treatment. Study groups were MMWR or Neurobiology of Addiction (NA), with NA serving as the psychoeducational control condition (for detailed study protocols, see Refs (24,26)). Baseline interviews occurred before randomization, postintervention

interviews occurred between 1 and 14 days after the last study intervention session, and follow-up interviews were held approximately 7 months after the last study intervention session. All participants received comprehensive SUD treatment services, including relapse prevention, as normally provided by the treatment facility without affecting the level of usual care provided to patients. The study site offered no structured mindfulness training services as usual care during the study. The University of Southern California Institutional Review Board (IRB) approved this study (UP-14-00391).

Study Site Standard Care

The site for the study was a publicly funded residential treatment facility for women diagnosed with SUD in Southern California. It had the capacity to provide on-site housing and comprehensive services for up to 110 women and their children (up to two underage children each, with exceptions for more children considered; children living outside the facility had option to visit weekly and/or stay in contact via telephone). Services as usual including substance use education, relapse prevention, trauma recovery, individual counseling, and random urine screens. The site coordinated services for women with multiple vulnerabilities, including those with mental health issues, trauma (physical and/or sexual abuse) in their past or present, and/or health problems such as HIV/AIDS. Although women could remain in residential treatment for up to 12 months, the average length of stay was 5.5 months. For further details on the study site and services provided, see Ref (24).

Participants and Procedures

Participants were adult women clinically diagnosed with SUD and admitted to the residential SUD treatment program study site. Upon admission, all patients met one-on-one with the site's intake clinician coordinator who conducted an assessment for SUDs, mental health disorders, and suicidality using the *Diagnostic and Statistical Manual of Mental Disorders* (5th Edition) (27) and an in-house psychosocial assessment to inform case management and treatment plan. The site psychiatrist and on-site clinician coordinator discussed diagnostic assessment, determined final diagnoses, and recorded findings in the patient chart. The site intake counselor verified study eligibility and, for those women who were eligible, informed clients about our study. The study interviewer made appointments with prospective participants who agreed to be contacted, conducted the informed consent and Health Insurance Portability and Accountability Act process, and administered the baseline assessment interview. As part of the site's normal postadmission protocol, patients immediately began receiving services as usual including individual and group therapy, psychoeducation groups, relapse prevention, and other services. Therapy groups were scheduled on a 6-week cycle, and so we fit our 12 session intervention to the 6-week cycle.

Inclusion criteria for our RCT were as follows: client at the residential treatment study site, female, adult aged 18 to 65 years, diagnosed with SUD, fluent in English, and agreed to participate in the study. Exclusion criteria were as follows: inability to comprehend or sign the informed consent due to language reasons, cognitive impairment, untreated psychotic disorder untreated severe chronic mental health condition, past 30-day suicidality based on clinical intake assessment, >65 years of age, current prisoner, >6 months pregnant, enrolled in another study, and not willing to sign a Health Insurance Portability and Accountability Act form or be audio recorded during interviews and intervention sessions. As shown in Figure 1, of those who did not meet the study criteria, most were prisoners (23.9%). Others were >6 months pregnant (9.5%), had untreated chronic psychotic disorder–schizophrenic or schizoaffective disorder (4.9%), serious cognitive impairment affecting ability to understand consent (4.9%), spoke no English (2.1%), or were at risk for suicide (1.4%). Eligible women were not enrolled in the RCT if they had left the treatment facility at or before the study intervention start date or missed the first introductory required class session (see Figure 1 for number of women not included in the modified intent-to-treat [ITT] analytic sample).

Trained research staff members, blinded to group assignment and study hypotheses, captured participant data during in-person interviews using the Research Electronic Data Capture computer-assisted interview process. The informed consent process ensured women of confidentiality regarding their test results as well as data obtained from them via interviews and surveys and data obtained from clinical records. Research staff members were part of the research team and not part of the clinical team. They were trained in confidentiality protocols as per requirements by the IRB. We protected all data as per all standard and accepted IRB requirements. To ensure data quality control for data not immediately entered into the Research Electronic Data Capture during the participant interview (e.g., alcohol and drug test results, admission and discharge dates, and status), we applied double-data entry to a minimum of 10% of randomly selected data to ensure data correctness. Baseline interviews were conducted at the study site, and subsequent interviews were conducted at the study site for participants who remained in treatment or at a convenient community location for those no longer in treatment at the study site. Baseline and follow-up assessments required approximately 1.5 to 2 hours to complete and postintervention assessments required approximately 1 hour to complete. Participants received compensation for their interview time (baseline and postintervention: $30, follow-up: $40; $5 for a urine sample, $5 for a Breathalyzer test, and $20 for transportation/babysitting for women no longer receiving services at the study site at follow-up interviews). Enrollment in the study was rolling until a cohort was filled. Cohorts began the assigned intervention every 6 weeks, resulting in approximately 10 women per group. Participants were blinded to their study group assignment until they attended the first orientation class session to prevent self-selection bias related to any preintervention expectancies about the intervention.

Group-based intervention sessions were held two times per week during the same time slot but in separate locations at the study site. The average (standard deviation [SD]) time between residential site admission and study intervention start was 37.9 (15.0) days for our sample (75% of our sample started the study intervention within 50 days of residential entry). This time interval varied across study participants because of extenuating circumstances such as the individual was not available or sufficiently stable for baseline interview in time to enter the next cohort.

Randomization

To minimize bias across study groups related to participant characteristics, we applied urn randomization as implemented by the Urn

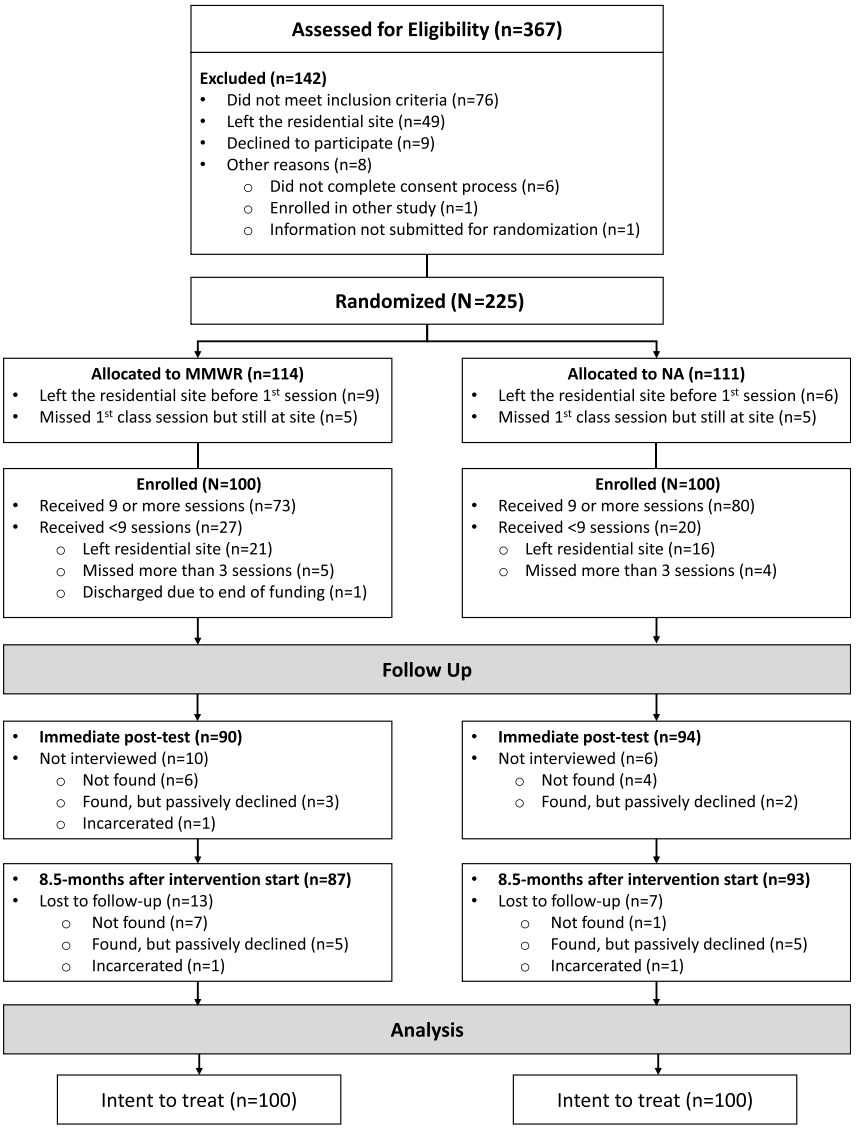

FIGURE 1. Trial CONSORT diagram. Our modified ITT analysis of $N = 200$ did not include the 25 women randomized to a study group who left the residential site before the study intervention date or who never showed up to the first class and were thus excluded from analysis based on receiving no dose of the intervention. ITT = intent to treat; NA = Neurobiology of Addiction psychoeducation; MMWR = Moment-by-Moment in Women's Recovery.

Randomization Program (version 1.01) after a group of 10 to 30 women were deemed eligible. Strata variables included current pregnancy (yes or no) and age (18–31 or 32–65 years) to ensure these characteristics were equivalent across groups at baseline as they can be influential to SUD treatment outcomes. The urn approach is robust against experimental bias in clinical trials because it is a compromise between perfect balance in treatment assignments and complete randomization to eliminate experimental bias (28). No baseline variables differed by study group at the $p < .05$ level.

Interventions

Moment-by-Moment in Women's Recovery

This intervention was delivered twice weekly for 80 minutes per session, for a total of 12 group-based sessions across 6 weeks. MMWR was guided by an instructional facilitator's manual with standardized lesson plans. The curriculum was developed by H.A (23) based on a previous version they developed over a 3-year period with input and review from focus groups of women and providers in SUD treatment. An experienced teacher trained in both MBSR and MMWR facilitated all sessions along with an on-site masters-level clinician with experience in SUDs who cofacilitated the intervention. Each session had a central theme including the role of stress and craving in SUD and relapse, stress within and outside of SUD residential treatment, explanation of mindfulness, and formal and informal mindfulness practices, using mindfulness practices to identify and manage difficult internal (e.g., difficult emotions, thoughts, and body sensations) and external (e.g., difficult situations and relationships) stimuli and their roles in craving and relapse. Each session was divided into

five segments in the following general order: a) welcome, review of group culture, brief homework practice check-in, objectives, and brief mindfulness meditation or practice; b) didactic psychoeducational presentation and discussion of lesson content; c) experiential meditation and mindfulness practices related to the session's theme; d) practice of sitting or walking meditation, body scan, and/or standing stretching; and e) selected reading related to session topic, assignments for the next class, and closing meditation. Trainees were expected to learn skills to approach experiences and stressors using mindfulness principles. Students learned about the role of automatic reactivity to stressors and its relation to SUDs and relapse; the connections between stress, triggers, and relapse; and how to use mindfulness practices to respond best to related thoughts, emotions, body sensations, and triggers while still avoiding relapse. Teachers instructed on the use of formal practices (audio-guided sitting meditation, sitting meditation without audio, loving kindness meditation, walking meditation, body scan, and mindful stretching) and informal practices (stop light technique, triangle of awareness, mindfulness of breath, mindfulness of emotions, mindfulness of thoughts, mindfulness of body sensations, and mindfulness of cravings). Throughout the course, students were encouraged to bring mindful awareness into their daily life by using informal practices and to engage in formal meditation practices as homework in accordance with practice assignments and guided meditation audio recordings.

NA Psychoeducation Control

This intervention was delivered twice weekly for 80 minutes per session, for a total of 12 group-based sessions across 6 weeks. NA was guided by an instructional facilitator manual with standardized lesson plans. The curriculum was develop by H.A. based on a previous version developed by H.A. over 3 years with input and review from focus groups of women and providers in SUD treatment, and subsequently reviewed by three content experts. A masters-level educator with a background and training in NA facilitated all sessions, and an on-site masters-level clinician with experience in SUDs and training in NA cofacilitated the intervention. Participants received didactic education on the structure and function of the brain and the NA. Although educational and centered on knowledge acquisition, the program has no proven efficacy in altering substance use behavior. It included didactic psychoeducational presentation using PowerPoint, video recordings, exercises, games, and group discussions to reinforce the session content and respond to questions. Sessions did not address behavior change strategies, stress reduction, mindfulness, or relapse-related content. Films, videos, exercises, activities, and discussions were used to explain content and promote participant engagement. Topics included the following: a) definition of addiction linked to brain disease, b) brain structure and function and those related to addiction, c) effects of substances on the brain, d) rewarding effects of substances and how these effects lead to addiction, e) definitions and brain functions related to craving and withdrawal, and f) the role of treatment in the recovery process. Participants were expected to gain knowledge pertaining to basic brain structure and function and the effects of drugs on both.

The NA intervention was designed to match MMWR on time commitment, usefulness, and group and teacher exposure to psychoeducational content. We assessed participant satisfaction via self-report at the end of the 2nd and 11th class sessions using a form that comprises 17 items (response options 1–5, with higher scores indicating more satisfaction with the intervention) developed by the research team that assessed the learning experience, usefulness, enjoyment, and facilitator.

Teacher Training, Certification, and Fidelity

Lead teachers for each intervention had at least 2 years of experience in their respective topics. MMWR lead teachers were experienced mindfulness facilitators; one was in the process of acquiring MBSR instructor certification at project start. MMWR lead teachers received training and ongoing supervision from H.A. and an MBSR-certified senior teacher and trainer and codeveloper of MMWR. NA lead teachers received training and ongoing supervision from H.A. and the codeveloper of NA with masters-level clinical training in SUD treatment and expertise in neurobiology of SUDs. For further details on teacher training and certification processes and fidelity measures and ratings, see previously published articles (23,24) and the Supplemental Digital Content, http://links.lww.com/PSYMED/A711.

Measures

Substance Use and Relapse

To quantify substance use at the three assessment points (baseline, postintervention, and follow-up), our trained study staff used the TLFB measure, which is a comprehensive retrospective calendar-based validated semistructured interview measure of daily substance use (29). From TLFB data, we calculated substance use from study intervention start date through the day of the last intervention session date (6 weeks later) and from intervention end date to 7 months later (8.5-month follow-up period in total). The interview window for postintervention assessment was 1 to 14 days after the intervention end, and for the follow-up assessment, the window was 7–9 months after the intervention end, and this variability was dependent on participant availability. This allowed for the quantification of daily substance use from study intervention start date to study end point. TLFB data allowed us to operationalize three substance use outcomes for any drug use and alcohol to intoxication as well as methamphetamine and cannabis/marijuana, including the following: *time to first use*, quantified as days until first any drug use or alcohol intoxication; *days of use*, quantified as the total number of days in which any drugs were used or alcohol intoxication occurred, and *relapse status*, quantified according to Gossop et al. (30) as a) *abstinent*, did not use during the period after the study intervention; b) *lapse*, used after study intervention but did not revert to regular use on one-third or less of days after first use; and c) *relapse*, used substance after the study intervention and continued to use regularly on more than one-third of days from first use.

Alcohol and Drug Use Confirmation Tests

Breathalyzer (for alcohol) and urine (for drug) samples were collected at postintervention and follow-up. We calculated agreement rates for any and each drug (excluding alcohol) against TLFB self-report. Only two participants had a positive Breathalyzer result. For urinalysis, we compared TLFB drug use reports for 3 days before the urinalysis date against the urinalysis result. For both

TABLE 1. Baseline Characteristics for the Total Sample and by Study Group

Variable	NA (n = 100)	MMWR (n = 100)	Total (N = 200)
Age, M (SD), y	32.6 (8.4)	32.4 (9.8)	32.5 (9.1)
Race/ethnicity			
Hispanic or Latina	56	60	116 (58.0)
Non-Hispanic Black	21	18	39 (19.5)
Non-Hispanic White	22	20	42 (21.0)
Other	1	2	3 (1.5)
Currently pregnancy	7	5	12 (6.0)
Education level			
Less than high school	46	47	93 (46.5)
Completed high school	28	31	59 (29.5)
Some education after high school	26	22	48 (24.0)
Homeless before residential entry	23	24	47 (23.6)
Incarcerated any time in 8 mo before residential entry	65	59	124 (62.0)
Restricted environment in 8 mo before residential entry	100	99	199 (99.5)
Mandated to residential	82	83	165 (82.5)
Criminal Justice System	51	46	97 (48.5)
Department of Children and Family Services	31	37	68 (34.0)
Not mandated	18	17	35 (17.5)
Used substance during 8 mo before residential entry			
Meth/amphetamine	79	73	152 (76.0)
Cannabis	55	50	105 (52.5)
Alcohol to intoxication (≥5 drinks in one sitting)	49	51	100 (50.0)
Cocaine and/or crack	12	14	26 (13.0)
Other sedatives/hypnotics/ tranquilizers	10	7	17 (8.5)
Hallucinogens	7	6	13 (6.5)
Heroin	8	5	13 (6.5)
Opiates/analgesics	6	7	13 (6.5)
Methadone, nonprescription	1	2	3 (1.5)
SUD diagnosis at residential entry			
Alcohol use disorder	10	9	19 (9.5)
Drug use disorder	71	74	145 (72.5)
Both disorders	18	14	32 (16.0)
Mental health diagnosis other than SUD[a]			
None	30	37	67 (33.5)
1	45	49	94 (47.0)
≥2	24	11	35 (17.5)
Mental health diagnosis[b]			
PTSD[a]	40	21	61 (30.5)
Depressive disorder	18	21	39 (19.5)
Trauma history, LSC-R			
Childhood trauma	84	86	170 (85.0)
Adulthood trauma[a]	83	74	157 (78.5)
Sexual trauma	69	71	140 (70.0)
Physical trauma	71	72	143 (71.5)
PSS-SR total[a], M (SD)	18.6 (13.1)	16.2 (11.9)	17.4 (12.5)
Days in residential before study intervention start, M (SD)	37.4 (14.1)	38.4 (15.9)	37.9 (15.0)

Values are presented as mean (SD) or n (%). The denominator of 100 in each study group makes n equal to the percent, and so percentages are not shown. No baseline variables differed by study group at the $p < .05$ level. Mental health disorder was diagnosed using the *Diagnostic and Statistical Manual of Mental Disorders* (5th Edition).

NA = Neurobiology of Addiction psychoeducation; MMWR = Moment-by-Moment in Women's Recovery; M (SD) = mean (standard deviation); SUD = substance use disorder; PTSD = posttraumatic stress disorder; LSC-R = Life Stressor Checklist Revised; PSS-SR = PTSD Symptom Scale Self Report.

[a] Used as mental health covariates in adjusted models because of a priori conceptual relevance to the effect of study intervention on recovery.

[b] Diagnoses present in <10% of total sample not reported because of space limitations.

postintervention and follow-up, cross-measure agreement was >80% for all drug categories (range, 80% for any drug to 99% for methamphetamine; n range, 158–184). Agreement did not differ by study group at either assessment, suggesting the validity of using TLFB data as our outcome measure. False-positives (substance use denied with positive urinalysis) ranged from 1% for methamphetamine to 19% for any drug at postintervention and 7% for methamphetamine and 22% for any drug at follow-up.

Person Characteristics and Covariates

Age, race/ethnicity, education, homelessness, pregnancy status, and 8-month preadmission history including living in a restricted environment, and substance use were reported at study baseline interview. Other self-report measures at study baseline included validated psychometric scales of adulthood trauma exposure (Life Stressor Checklist Revised) (31) and posttraumatic stress disorder (PTSD) symptoms (PTSD symptom Scale Self Report) (32). From site clinical records, we obtained data on mandated residential treatment and mandating agency, substance use diagnoses at treatment entry, mental health diagnoses, and days in residential treatment before study intervention start date. Mindfulness skills were assessed with the 24-item version of the Five Factor Mindfulness Questionnaire (FFMQ) (33), a measure validated among samples with SUD (34). In our sample, the Cronbach α was .83 for the total FFMQ scale. In the MMWR group, mindfulness practice frequency data were collected in questionnaire format at the end of study class sessions 3, 6, 9, and 12. Inquired on how often specific practices were used (outside of class sessions) in the past 7 days such as sitting and walking meditation, friendly kindness meditation, light mindful stretching poses, and awareness of emotions, thoughts, and physical sensations in the body. Response options were 0 (never), 1 (less than once a day), 2 (once a day), 3 (two times a day), 4 (three times a day), 5 (four or more times a day), and 6 (daily). Cronbach α in our sample was .92 for the total scale.

Data Analysis

Our analytic sample size of 200 was powered to detect a medium-sized effect (Cox regression hazard ratio [HR] = 0.51) for days until first drug use with a two-sided $p < .05$ significance level, 80% power,

and a 35% probability of substance use in the control group. Our ITT analysis of $N = 200$ did not include the 25 women randomized to a study group who never showed up to the first class and were thus excluded from analysis based on receiving no dose of the intervention. Prediction models included clinical covariates identified a priori as having conceptual relevance for their impact on the effect of study intervention on recovery (i.e., number of mental health diagnoses coded as SUD only, one co-morbid mental health diagnosis, two or more comorbid mental health diagnoses, adulthood trauma exposure [summed domain score from Life Stressor Checklist Revised], PTSD diagnosis via the *Diagnostic and Statistical Manual of Mental Disorders* [5th Edition], and PTSD symptom score [PTSD symptom Scale Self Report]). These models also adjust for an inherent study design variable (i.e., days in residential treatment before study intervention start date). Unadjusted models as effect size confirmation is located in the online supplement. We use the piecewise Cox regression PHREG procedure in SAS version 9.4 (SAS Institute) to model time periods during and after the study intervention (i.e., piece 1 predicting outcome events during the intervention period and piece 2 predicting outcome events after the intervention). Resulting HR effect sizes are interpreted as small (0.77), medium (0.53), and large (0.36) (35). Next, because of the zero-inflated distribution of days of substance use, we use negative binomial hurdle models to estimate *any use* (versus abstinence) and *days of use among users* simultaneously (36). Finally, we compute unadjusted and adjusted proportional estimates for group differences in relapse status (i.e., abstinent, lapse, relapse), and effect size is expressed as odds ratios (ORs). Unadjusted models for all outcome measures are presented in Tables S1 and S2 (Supplemental Digital Content, http://links.lww.com/PSYMED/A711).

TABLE 2. Adjusted Cox Hazards Regression Piecewise Model (During and After the Study Intervention Period) for Time to First Drug Use and Alcohol Intoxication

Substance Use Outcomes (Reference: NA Group)	*B* (SE)	HR (95% CI for Hazard Odds)	*p*
Any drug use			
During	0.17 (0.44)	1.10 (0.50–2.82)	.70
After	−0.32 (0.31)	0.73 (0.40–1.33)	.30
Meth/amphetamine			
During	0.06 (0.47)	1.06 (0.42–2.69)	.90
After	−0.27 (0.34)	0.77 (0.39–1.50)	.44
Marijuana			
During	0.23 (0.67)	1.26 (0.34–4.73)	.73
After	**−0.82 (0.41)**	**0.44 (0.20–0.98)**	**.049**
Alcohol intoxication			
During	−0.04 (0.56)	0.97 (0.30–2.90)	.95
After	−0.32 (0.46)	0.72 (0.29–1.79)	.49

Substance use data obtained from blinded interviewer-assisted timeline followback calendar. Model covariates include posttraumatic stress disorder diagnosis, Life Stressor Checklist Revised adulthood trauma score, PTSD Symptom Scale Self Report total score, number of mental health diagnoses, and days in residential before intervention start.

Bolded values = $p < .05$.

NA = Neurobiology of Addiction psychoeducation; SE = standard error; HR = hazard ratio; CI = confidence interval; Any drug use = meth/amphetamine, cannabis, cocaine and/or crack, other sedatives/hypnotics/tranquilizers, hallucinogens, heroin, opiates/analgesics, and nonprescription methadone.

TABLE 3. Frequencies for Any Substance Use and Average Days of Use by Group From Study Intervention End Date to Follow-Up

Variable	MMWR ($n = 88$)	NA ($n = 93$)	*p*
Any use, no (%)			
Any drug	32 (36.4)	35 (37.6)	.86
Meth/amphetamine	24 (27.3)	28 (30.1)	.67
Marijuana	14 (15.9)	24 (25.8)	.10
Alcohol intoxication	13 (14.8)	20 (21.5)	.24
Use days among users, M (SD)			
Any drug	16.92 (32.81)	24.97 (51.65)	.21
Meth/amphetamine	10.61 (27.37)	14.74 (35.81)	.39
Marijuana	**5.98 (20.20)**	**16.78 (43.59)**	**.030**
Alcohol intoxication	2.76 (9.53)	2.63 (10.54)	.93

Substance use data obtained from blinded interviewer-assisted timeline followback calendar.

Bolded values = $p < .05$.

MMWR = Moment-by-Moment in Women's Recovery; NA = Neurobiology of Addiction psychoeducation; Any drug use = meth/amphetamine, cannabis, cocaine and/or crack, other sedatives/hypnotics/tranquilizers, hallucinogens, heroin, opiates/analgesics, and nonprescription methadone; M (SD) = mean (standard deviation).

RESULTS

Of 367 site residents screened for our study, 225 were eligible and randomized to a study group (see Figure 1 for CONSORT diagram). Of the eligible, $n = 25$ became ineligible after randomization but before the intervention start. Of those who became ineligible, 15 (9 MMWR, 6 NA) were no longer in SUD treatment at the facility at intervention start, which is one of the eligibility criteria for being in the trial. Ten of the participants (five MMWR, five NA) were not enrolled because they did not receive the required initial intervention orientation session, yet remained at the site. The reason for nonattendance at the first class session in this group was acute scheduling conflict at the site or acute family/court event (e.g., prearranged and nonflexible appointment with child/family court or criminal court, or medical appointment) not related to the study intervention. According to standard guidelines for clinical trials (37), these are acceptable reasons for not including all units randomized in an ITT sample, namely, "failure to take at least one dose of trial medication [intervention]" and "failure to satisfy entry criteria."

Average (SD) time at the residential site before study intervention start for the final sample ($N = 200$) was 37.9 (15.0) days. Lost to study final follow-up assessment was low at 9.5% and did not differ by group ($\chi^2 = 1.45$, $p = .23$). Table 1 provides descriptives for the total sample and by group. Mean age of the sample was 32.5 years, with the majority being Hispanic/Latino (58%), diagnosed with one or more mental health disorders (64.5%), and incarcerated in the 8 months before residential treatment (62%), and nearly half having less than a high school education (46.5%). Substance use in the 8 months before residential entry was mainly meth/amphetamine (76%) followed by cannabis/marijuana (52.5%)

and alcohol intoxication (50%). There were no $p < .05$ group differences at baseline on any measure. Mean scores for participant self-reported satisfaction with the study interventions were high and did not differ by group (MMWR: mean [SD] = 4.13 (0.61) out of 5; control: mean [SD] = 4.13 (0.67) out of 5, $p = .93$).

Time to First Drug Use and Alcohol Intoxication by Study Group

Table 2 shows the adjusted piecewise Cox proportional hazard model results. Time to first any drug use (HR = 0.73, 95% CI = 0.40–1.33 $p = .30$), time to first meth/amphetamine use (HR = 0.77, 95% CI = 0.39–1.50 $p = .44$), and time to first alcohol intoxication (HR = 0.72, 95% CI = 0.29–1.79, $p = .49$) all favored the MMWR group but did not reach statistical significance. Time to first marijuana use after study intervention significantly favored MMWR (HR = 0.44, 95% CI = 0.20–0.98, $p = .049$) with a medium-to-large size of effect.

Any Use and Days of Use by Study Group

Table 3 shows the unadjusted frequencies of any use and average days of use by study group from study intervention end date to follow-up. Women in MMWR reported fewer days of marijuana use in the 3.5 months after the study intervention ($B = -1.71$, standard error = 0.79, incidence rate ratio [IRR] = 0.18, $p = .030$). Although in similar direction of effect, this contrast became marginal when extended to follow-up ($B = -0.90$, standard error = 0.55, IRR = 0.41, $p = .10$). Among marijuana users, the average number of days of marijuana use was lower in MMWR (5.98 days) compared with NA (16.78 days; mean difference of 10.80 days, $t(179) = 2.34$, $p = .020$). Table 4 shows results from the adjusted negative binomial hurdle model for any use and days of use, and Supplemental Table S2, http://links.lww.com/PSYMED/A711 shows the similar unadjusted model results.

Substance Use Relapse Status (Abstain, Lapse, Relapse) by Study Group

For any drug use, a majority of participants in both study groups reported either abstinence (MMWR, 63.6%; NA, 62.4%) or lapse behavior (MMWR, 28.4%; NA, 23.7%). Fewer women showed drug use relapse in MMWR (8.0%) compared with NA (14.0%), but the group difference in these proportions did not reach statistical significance ($\chi^2 = 1.89$, $p = .39$). For meth/amphetamine use, a majority of participants in both study groups reported either abstinence (MMWR, 72.7%; NA, 69.9%) or lapse behavior (MMWR, 21.6%; NA, 23.7%), and fewer women relapsed in MMWR (5.7%) compared with NA (6.5%), but the group difference in these proportions did not reach statistical significance ($\chi^2 = 0.18$, $p = .91$). For marijuana use, a majority in both study groups reported either abstinence (MMWR, 84.1%; NA, 74.2%) or lapse behavior (MMWR, 12.5%; NA, 15.1%), and fewer women relapsed in MMWR (3.4%) compared with NA (10.8%), but the group difference in these proportions did not reach statistical significance ($\chi^2 = 4.17$, $p = .12$). For alcohol intoxication, a majority of participants in both study groups reported either abstinence (MMWR, 85.2%; NA, 78.5%) or lapse behavior (MMWR, 14.8%; NA, 20.4%), and fewer women relapsed in MMWR (0.0%) compared with NA (1.1%), but the group difference in these proportions did not reach statistical significance ($\chi^2 = 2.02$, $p = .37$). The adjusted multinomial logistic regression models testing for study group differences on abstinence versus relapse, abstinence versus relapse/lapse, and lapse versus relapse for any drug, meth/amphetamines, marijuana, and alcohol intoxication did not reach statistical significance (all p values > .10). Negative urine test for any drug favored MMWR at postintervention (OR = 1.12, 95% CI =0.54–2.33, $p = .20$) and follow-up (OR = 1.55, 95% CI =0.79–3.02, $p = .20$), but group contrasts did not reach statistical significance.

Class Attendance (Dose) and Practice Time Correlations With Substance Use Outcomes

Average (SD) study intervention class attendance was 9.5 (3.2) days in MMWR and 9.9 (2.9) days in NA out of 12 total sessions. Attendance did not differ by group ($p = .33$). In MMWR, number of classes attended correlated with longer length of time to first drug use ($r = .49$, $p < .001$), longer length of time to alcohol intoxication ($r = .48$, $p < .001$), fewer days of any drug use ($r = -.30$, $p = .009$), and fewer days of alcohol intoxication ($r = -.24$, $p = .020$). In NA, number of classes attended also correlated with longer length of time to first drug use ($r = .40$, $p < .001$) and fewer days of any drug use ($r = .25$, $p = .021$), but was not correlated with length of time to alcohol intoxication ($r = .13$, $p = .23$) or days of alcohol intoxication ($r = .10$, $p = .34$). Total session attendance was correlated with pre-to-post intervention change in FFMQ scores ($r = .61$, $p < .01$) in the MMWR but not in the control group ($r = .15$, $p = .14$). For marijuana only, total mindfulness practice time averaged across the four assessments made across the MMWR intervention predicted time delay to first use ($B = 0.28$, $p = .006$) and total abstinence days ($B = 0.34$, $p = .002$), across the 7 months after the intervention.

DISCUSSION

In this RCT with an 8.5-month follow-up period, we tested MMWR against an active control group to determine its efficacy at improving recovery from SUD by reducing substance use and relapse when applied as an add-on intervention to an all-women residential treatment site. Using an ITT analysis, we find that MMWR showed efficacy for increasing time to first marijuana use as well as reducing days of marijuana use at 3.5 months after the intervention end. The effect on days of marijuana use was marginal at 7-month postintervention follow-up. For marijuana, total mindfulness practice time during the MMWR intervention predicted time delay to first use and total abstinence days across the 7 months after the intervention. Only in the MMWR group, number of study intervention sessions attended (i.e., dose) significantly negatively correlated with length of time to first alcohol intoxication and total days of alcohol intoxication. The positive treatment effects observed for marijuana abstinence were of medium-to-large size and are of clinical importance, considering effects were detected above and beyond a psychoeducation control focused on the brain effects of substance use as well as a multitude of psychotherapies already provided to clients at the inpatient treatment site. The MMWR intervention had null effects on all other substance use outcomes (i.e., any drug use, alcohol to intoxication, and methamphetamine use), and so we interpret these findings as MMWR to not exert additive effect on substance use outcomes other than marijuana in the context of residential treatment.

TABLE 4. Adjusted Negative Binomial Hurdle Model Estimating Any Use and Days of Use by Study Group

	Days of Use (Linear Component of Model)			Abstinence and Nonintoxication (Logistic Component of Model)		
Group Contrast (Reference: NA)	*B* (SE)	IRR (CI)	*p*	*B* (SE)	OR (CI)	*p*
3.5 mo postintervention						
Any drug use	−0.39 (0.43)	0.68 (0.29–1.59)	.37	0.27 (0.42)	1.31 (0.55–2.97)	.52
Meth/amphetamine	−0.51 (0.49)	0.60 (0.23–1.58)	.30	−0.20 (0.44)	0.82 (0.34–1.91)	.64
Marijuana	**−1.71 (0.79)**	**0.18 (0.04–.84)**	**.030**	0.29 (0.57)	1.34 (0.44–4.10)	.61
Alcohol intoxication	1.12 (1.15)	3.06 (0.32–28.93)	.33	0.46 (0.91)	1.58 (0.26–9.52)	.61
7 mo postintervention						
Any drug use	−0.28 (0.34)	0.76 (0.39–1.46)	.41	0.13 (0.36)	1.14 (0.56–2.32)	.72
Meth/amphetamine	−0.16 (0.42)	0.85 (0.37–1.94)	.70	0.20 (0.38)	1.22 (0.57–2.64)	.60
Marijuana	−0.90 (0.55)	0.41 (0.14–1.19)	.10	0.70 (0.44)	2.01 (0.84–4.76)	.11
Alcohol intoxication	0.69 (0.84)	1.99 (0.38–10.44)	.41	0.84 (0.80)	2.32 (0.48–11.13)	.29

Substance use data obtained from blinded interviewer-assisted timeline followback calendar. Model covariates same as Table 2 notes.

Bolded values = $p < .05$.

NA = Neurobiology of Addiction psychoeducation; SE = standard error; IRR = incidence rate ratio (interpreted as the percentage increase [>1.0] or decrease [<1.0] in drug use or alcohol intoxication days for a 1-unit increase in the predictor); OR = odds ratio (interpreted as the increase [>1.0] or decrease [<1.0] in the odds of abstinence from drug use or alcohol intoxication); CI = confidence interval; Any drug use = meth/amphetamine, cannabis, cocaine and/or crack, other sedatives/hypnotics/tranquilizers, hallucinogens, heroin, opiates/analgesics, and nonprescription methadone.

We compare our mixed findings on substance use to Witkiewitz et al. (38), which is most similar to our RCT with regard to MBI type (i.e., both being adaptations of MBSR with relapse prevention content), intervention format (delivered two times per week for 6–8 weeks), sample type (e.g., women, many mandated to treatment, and many exhibiting mental health symptoms and trauma histories), treatment setting (i.e., SUD residential), and follow-up period (i.e., postintervention and 3.5 months after the intervention end). Although their results did not include use of alcohol or specific drugs such as marijuana, they found that at 3.5 months, MBRP compared with Relapse Prevention showed null effects on drug use abstinence, yet MBRP participants showed fewer drug use days (IRR = 0.04, 96% CI = 0.00–0.12, $p < .001$). At 3.5 months, we show that our MMWR group reported fewer days of marijuana use with a medium-to-large effect size. A trend for fewer days of marijuana use remained at our study end point. Diminished effects as such seem consistent with most longer-term follow-up studies testing MBIs (22) and with diminishing effects of inpatient and outpatient SUD treatments in general. Effects beyond 3.5 months were not available in Witkiewitz et al. to make a comparison to our follow-up results. Other existing MBI trials with all-female samples are not readily comparable to our study because they did not sample from an SUD treatment population, had very small sample sizes, did not assess substance use or frequency of use days, and/or did not assess longer-term follow-up ((39)).

Other studies of MBIs for substance use treatment most similar to MMWR (i.e., MBRP) have focused on either men or mixed-sex samples and have not reported on sex differences (40); thus, comparisons to our study are limited. The largest RCT of MBRP included <29% women and enrolled SUD *aftercare* patients who had completed approximately 4 months of intensive residential or day treatment (18). In their study, MBRP compared with Relapse Prevention showed null effects on any drug use abstinence and days of use at 3 and 6 months after the intervention; however, a significant effect favored MBRP at 12-month follow-up for days of drug use (IRR = 0.69). Our trial also shows null effects on any drug use and alcohol to intoxication across an 8.5-month study follow-up period. It is important to note that the SUD aftercare sample in their MBRP study differs from our intensive residential treatment sample given each sample's relative position on the treatment and recovery spectrum.

Other than MMWR being ineffective for drug use outside of marijuana, an additional interpretation may involve the low overall relapse rates in both of our study groups compared with other reports of 50% or higher relapse within 1 year of entry to SUD treatment (41,42). Our low rates of drug use relapse (i.e., 8% MMWR, 14% NA) are consistent with low rates of relapse across follow-up periods identified in other MBI studies (38,43), and this creates a challenge for detecting effects on relapse status outcomes in particular. Such low rates of relapse may be due to the high proportion (82.5%) of our total sample being mandated to treatment, and so we assume individuals had high social motivation to refrain to use given the legal repercussions of use. Being mandated to treatment has been positively associated with lower relapse in some (44) but not all studies (45). Placing our null findings, other than for marijuana use, in the larger context of the most commonly used MBI for SUD, MBRP, results from two meta-analyses show either an overall null effect (21) or small effects (22) for substance use, and that finding is supported by our study results.

As a study limitation, we selected for psychoeducation rather than an MBI sham control. Our decision to avoid sham is to limit possible negative effects of inaccurate meditation training for this vulnerable population that exhibits co-occurring mental health disorders. Our study was originally powered to detect differences in substance use in a survival analysis. Our sample showed a low count of relapse events as defined by Gossop et al. (30) (i.e., 7 in MMWR and 13 in NA) during the follow-up period, and so our analysis of relapse status was likely underpowered to detect this proportional group difference. Given the behavioral nature of the intervention, it is likely that participants figure out the treatment

type after the treatment begins. We masked assignment information from participants until the first day of the study intervention to guard against this threat. We also blinded outcome interviewers to group assignment. Cross-contamination is possible because all classes were delivered at the same residential site. We used separate class locations at the facility and also found no evidence for contamination based on our assessment of treatment fidelity. The majority of our sample was mandated to SUD treatment, and so our results may not generalize to more autonomous samples not facing legal repercussions of use; however, poor treatment outcomes such as dropout rates can be as high as 50% across mandated and nonmandated samples as well as across various treatment settings (i.e., detoxification, outpatient, inpatient, and substitution treatments) (46). Finally, the generalizability of our findings is limited to similar populations of women in residential SUD settings and those not diagnosed with *untreated* psychotic disorder. However, our sample is characterized by race and ethnic diversity with significant economic vulnerabilities and co-occurring mental health disorders, which we deem to be study strengths.

In summary, MMWR added to an ongoing intensive residential treatment program serving vulnerable women is protective against marijuana use. We found no other direct evidence supporting MMWR for other types of drug use and alcohol intoxication. However, MMWR class attendance and mindfulness practice time, both being proxies of intervention dose, seem protective of multiple types of substance use. Researchers of future studies might consider increased program exposure (i.e., extended beyond 6 weeks or three to four times per week in briefer sessions), increased sample size and study design approaches to power tests of relapse status, and booster sessions after the main intervention period as individuals culminate from inpatient treatment.

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