Acceptability of Mindfulness-Based Intervention among Women with Substance Use Disorder

by

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ABSTRACT

Research on acceptability of mindfulness-based interventions (MBIs) for populations with substance use disorders (SUD) is extremely limited. Intervention development and testing guidelines note that acceptability of the intervention by the target population is important for retention, efficacy, and intervention integrity. Yet, MBIs for SUD studies have not measured acceptability or have done so in a cursory manner, therefore, the question remains of whether MBIs are acceptable to populations in SUD treatment. The proposed study seeks to fill this knowledge gap by undertaking a conceptually-grounded empirical approach to assess acceptability of Moment-by-Moment in Women's Recovery (MMWR), which is an MBI for women with SUD. This document is divided into five chapters. Chapter 1 introduces the topic and provides background literature. Chapter 2 systematically reviews MBIs for SUD studies to assess measurement of acceptability. Chapter 3 analyzes the psychometric properties of two acceptability surveys used in MMWR. Chapter 4 examines the associations among the acceptability surveys, personal characteristics of the participants, and application of intervention techniques. And Chapter 5 summarizes the previous chapters and discusses future directions for this line of work. There is a need for a greater understanding of which factors may influence participants' abilities to accept an intervention. The results identify sociodemographic and clinical characteristics that can inform future intervention adaptations, screening, or pre-intervention programs to increase efficiency of SUD intervention delivery and relevance. The long-term goal is to improve fit and efficacy of MBIs for SUD for minority and underrepresented populations.

DEDICATION

I dedicate this dissertation to all the women working through their recovery. May you find the support that fits your needs and empowers you to change the world. Your hard work, dedication, and success is what makes this research worthwhile. I support you as a researcher, a family member, and a friend.

And to all the graduate students managing their imposter syndrome. To the first-generation students struggling to justify your schooling to your family. To the students using Google to learn the fancy words in their textbooks and lectures because you have never heard the words spoken in conversation. It gets easier. Do not give up; do not think you are not capable or worthy. Work harder than your peers, even if it is not fair. Your hard work will pay off.

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CHAPTER 1

INTRODUCTION

Developing efficacious interventions for relapse prevention among individuals with substance use disorder (SUD) is a long-standing research priority for the National Institutes of Health (NIH) National Institute on Drug Abuse (NIDA) (NIDA, 2010). Among individuals who receive SUD treatment, 40%-60% relapse within one-year post-treatment (McLellan, Lewis, O'Brien, & Kleber, 2000; McLellan, McKay, Forman, Cacciola, & Kemp, 2005). Contemporary behavioral approaches to address relapse are based on Marlatt's cognitive behavior model of relapse prevention (Larimer, Palmer, & Marlatt, 1999; Marlatt, 1985; Marlatt & Donovan, 2005), which focuses on self-monitoring, identification and avoidance of high-risk situations; and combining skills-training with cognitive interventions to prevent or limit relapse. There is considerable empirical evidence to support the efficacy of the cognitive behavior model and it is the most widely disseminated approach to SUD treatment (Bien, Miller, & Tonigan, 1993; Carroll, 1996; Carroll, Rounsaville, & Gawin, 1991; Davis & Glaros, 1986; Fals-Stewart, & O'Farrel, 2003; Irvin, Bowers, Dunn, & Wang, 1999; Kadden, 2001; Monti, Rohsenow, Michalec, Martin, & Abrams, 1997; Witkiewitz, Marlatt, & Walker, 2005).

Mindfulness-Based Stress Reduction

Mindfulness-Based Stress Reduction (MBSR) is an 8-week intensive mindfulness training program that teaches the participants how to integrate moment-to-moment awareness into their everyday life. MBSR was developed in 1979 by Jon Kabat-Zinn at the University of Massachusetts Medical Center to help patients learn a coping resource for intense physical symptoms, chronic medical conditions, and difficult emotional

situations (Kabat-Zinn, 1994). Since then, MBSR has been adapted for a wide range of populations including perons with physical and behavioral difficulties.

Mindfulness-Based Interventions

Mindfulness-based interventions (MBIs) are programs, often adapted from MBSR, that address a specific problem using mindfulness as the core therapeutic practice. MBIs for SUD are a part of the third wave of empirically tested behavioral health intervention approaches for SUD. The first wave focused on behavioral therapies and the second wave built upon that and expanded to cognitive behavioral therapies as mentioned previously (Marlatt, & Walker, 2005). MBIs for SUD integrate mindfulness meditation practices with relapse prevention skills to target two major relapse predictors, craving and negative affect (Bowen, Chawla, & Marlatt, 2011). MBIs for SUD emphasizes flexible cognitive processing by non-judgmental, purposeful observation of emotions, thoughts, and body sensations to disrupt automatic substance related cognitive processes and reactions (Bowen, Chawla, Collins, et al., 2009; Witkiewitz & Bowen, 2010). Mindfulness practice encourages awareness of uncomfortable and challenging states and discourages reacting automatically (Witkiewitz, Lustyk, & Bowen, 2013).

Early MBI for SUD studies show promising results. Findings from clinical trials indicate beneficial outcomes with respect to better clinical status at discharge (i.e., more clinical progress during treatment) among those who drop out of treatment (Black & Amaro, 2019), fewer drug use days or abstinence (Biseul, Ickick, Seguin, Bellivier, & Scott, 2017; Witkiewitz, Warner, Sully, et al., 2014) lower relapse rate (Witkiewitz, Warner, Sully, et al., 2014), and lower ratings of cravings (Witkiewitz, Lustyk, & Bowen, 2013; Zemestani & Ottaviani, 2016). Systematic reviews have reported mixed findings. A

meta-analysis by Grant et al (2017) tested the effectiveness of mindfulness-based relapse prevention (MBRP) a specific MBI for SUD developed by Bowen et al. (2009). The meta-analysis concluded that MBRP versus a comparator treatment/intervention yielded no effect for relapse to substance use, frequency of use, quantity of use, treatment dropout, depressive symptoms, anxiety symptoms, and mindfulness. A small effect was found for withdrawal/craving (standardized mean difference [SMD] = - 0.13, 95% CI = -0.19 to - 0.08, I^2 = 0%, low QoE) and negative consequences from substance use (SMD = - 0.23, 95% CI = - 0.39 to - 0.07, I^2 = 0%, low QoE). It is important to note that this meta-analysis only included MBRP and many of the included studies mentioned using an adapted shortened version, including one with as few as 9 contact hours, while the standard MBRP requires 16 contact hours. Another meta-analysis found significant small-to-large effects in reducing frequency and severity substance misuse (d = − 0.33, 95% CI = − 0.88 to − 0.14), craving (d = −0.65, 95% CI = −0.88 to −0.42), and stress intensity (d = −1.12, 95% CI = − 2.24 to −0.01) for MBIs versus the comparative treatment as usual or tradition relapse prevention. This systematic review included a wider range of MBIs not only MBRP (Li et al., 2017).

MBIs for SUD are thought to work through multiple mechanisms of action that show improvements in areas such as 1) stress reactivity, 2) awareness of the emotional salience-monitoring system, and 3) ability to break the automaticity of drug-seeking behaviors (Witkiewitz, Lustyk, & Bowen, 2013). Behavioral and neuroimaging evidence indicates plausible mechanisms through which mindfulness may change neural responses to craving and negative affect, consequently having the potential to reduce the risk of relapse. Mechanisms such as increasing present moment awareness and sitting with

discomfort induce strengthening of the medial prefrontal cortex, nucleus accumbens, and amygdala which helps with controlling cravings and reward circuitry (Witkiewitz, Lustyk, & Bowen, 2013). Other neural mechanisms by which MBIs are hypothesized to work include increasing metacognitive attentional control which enhances the functional connectivity and allows individuals to self-regulate craving, impulses, and rewards (Garland, et al., 2018). One type of MBI for SUD is Moment-by-Moment in Women's Recovery (MMWR), which stems from MBSR.

Moment-by-Moment in Women's Recovery

The MMWR is a 6-week, 12-session MBI for SUD relapse prevention specifically designed to acknowledge the lived experience of, and be relatable to, low-income, ethnoracially diverse women with an attention to literacy level and language. This program was developed with MBSR as a foundation, then underwent multiple iterations based on participant and facilitator feedback (Vallejo & Amaro, 2009). The MMWR program focuses on the role of stress specific to relapse, and help the participant to increase their awareness of craving and observing without reacting in a habitual manner (Vallejo & Amaro, 2009). MMWR was developed to be used in either outpatient or residential SUD programs with special attention to trauma and mental health conditions of the participants.

Traditional relapse prevention interventions focus on changing stimuli that prompt relapse (e.g., thought-stopping, avoidance of negative or challenging experiences and emotions). In contrast, MMWR emphasizes intentional awareness and acceptance of experiences even when they are uncomfortable or unwanted, changing the relationship with stimuli, thereby introducing personal control over triggers (e.g., craving, negative

affect). MMWR does this by targeting emotion regulation and stress reduction as core intervention components which are associated with long-term SUD recovery and decreased risk of relapse (Amaro, et al., 2014). This is an important distinction between traditional relapse prevention and MMWR because suppression, rather than awareness, can lead to an increase in the activation of substance use related thoughts and memories (Breslin, Zack, McMain, 2002; Witkiewitz, Bowen, Harrop, Douglas, Enkema, Sedgwick, 2014).

Each of the twelve sessions follows a similar format, there are five segments: (1) welcome and brief check-in with a discussion of the objectives and a brief mindfulness meditation practice; (2) educational presentation and discussion of lesson content; 3) mindfulness practices related to the session's themes; (4) practice of sitting or walking meditation, body scan, or standing stretching; and (5) selected reading related to session topic, practice assignments for the next class, and closing meditation (Amaro & Black, 2017). Session themes for discussion included topics such as preventing relapse, building inner safety while in treatment, healthy ways of coping with stress, the role of perceptions, anxiety, fear, and panic attacks, shame & guilt, self-talk, mindful communication, working with anger & violence, and painful thoughts. See Appendix C for information about each session including the topic and skills taught.

Through didactic and experiential mindfulness practices (e.g. meditation, body scan, yoga or mindful movement), participants are taught strategies to become aware and respond rather than to react to real-time thoughts, emotions, and sensations, including those that may put them at risk for relapse (Black & Amaro, 2019). Practicing these strategies in a regular and standardized manner (formal practice), builds participants'

skills in these practices, creates habit of practice and enables participants to put these strategies to work in everyday life when confronting internal (e.g., thoughts, emotions and body sensations) and external (e g., from interactions with others) stressors. While formal practice strengthens participants' mindfulness skills, applied mindfulness is the application of these skills in daily life to cope with challenging situations that may lead to relapse.

Acceptability of MMWR

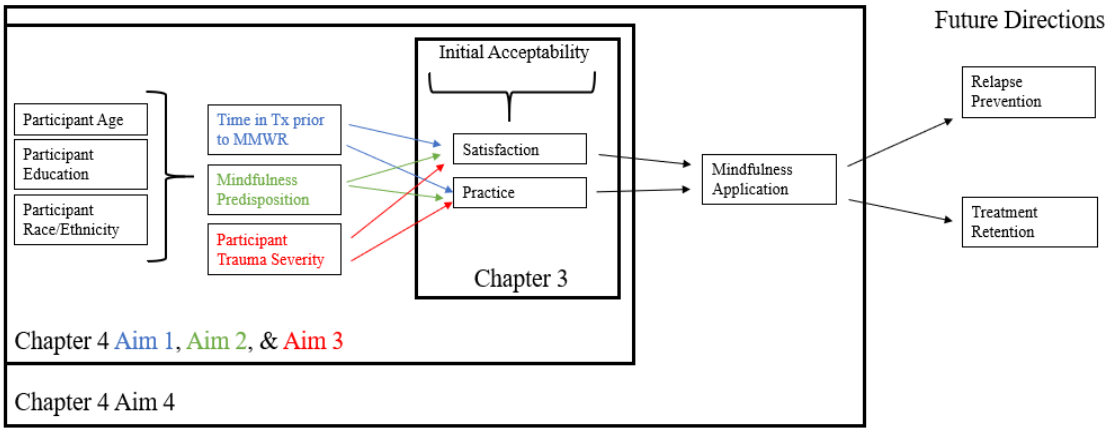
An important yet understudied factor in MBIs for SUD is the acceptability and potential fit of MBIs for SUD populations with specific sociodemographic and clinical features, such as trauma symptomology. Acceptability is a multi-faceted construct that reflects the degree to which participants find the intervention to be appropriate (Sekhon, Cartwright, & Francis, 2017). Acceptability can also be thought of as a measurement of intervention "fit", which refers to the relevance of the intervention to the target population and how well the intervention meets the needs of that population (Castro, Barrera, & Martinez, 2004). When participants perceive an intervention to be relevant to their situation, they may be more likely to take to the teachings and participate in the recommended practices. Research on acceptability of MBIs for SUD is extremely narrow and demonstrates a lack of conceptually-grounded assessment approaches, measurement limitations, as well as an inadequate assessment of variations in acceptability across clinical profiles. While assessment of acceptability is regarded as important for retention, adoption, implementation, and dissemination (Bak, van Dam, & Janssens, 2018; Diepeveen, Ling, Suhrcke, Roland, & Marteau, 2013; Proctor, Silmere, Raghaven, et al., 2011; Stok, de Ridder, de Vet, et al., 2016), studies using MBI for SUD have not

measured acceptability or have done so in a cursory manner. More details on how acceptability has been measured, how many studies report it, and specific limitations of the MBI for SUD studies are discussed in chapter 2.

Outline for the Current Study

The present dissertation study seeks to fill the gap in knowledge related to acceptability by undertaking a conceptually-grounded and empirical approach to assess acceptability of MMWR.

Figure 1: Conceptual Framework for Chapters 3 & 4



Chapter 2

Chapter 2 presents a systematic review of the MBI for SUD literature. The purpose of Chapter 2 was to first examine the tools used for assessment of acceptability and then summarize how, when, and for whom acceptability was reported. Chapter 2 also provides suggestions for measuring acceptability of MBIs for SUD relapse prevention moving forward.

Findings from Chapter 2 suggest that there is limited research to inform the best time (during or after an intervention) to assess acceptability. All the MBI for SUD studies that measured acceptability included in Chapter 2 did so during the last intervention

session or post-intervention (Bautista, James, & Amaro, 2019). This finding informed the analyses used chapters 3 and 4 assessing initial acceptability following the first week of intervention exposure. Measuring initial acceptability, as opposed to ending acceptability, will provide insight into areas of difficulty that occur early in the intervention, which may inform adaptation necessary to increase retention.

Other findings from this systematic review raised some concerns regarding the incongruence between the conceptual and operational definitions of acceptability. For example, using attrition/completion as a measure of acceptability is not precise. There are many reasons a participant may not complete the full intervention that are unrelated to acceptability (e.g., competing family demands, medical or court appointments, illness, moving to a new treatment facility, being arrested or incarcerated). Participants can also complete an intervention without enjoying the intervention, adopting the teachings, or practicing the behaviors. Consequently, measuring completion rate alone does not accurately represent acceptability, especially in residential treatment settings.

Chapter 3

Chapter 3 is a psychometric paper which presents a conceptually-grounded and empirical approach to assessing acceptability of MMWR. Sekhon et al. (2017) published a review of forty-three systematic reviews with the purpose of developing a multi-construct theoretical framework of acceptability of healthcare interventions. Of the forty-three reviews included, none mentioned an acceptability theory.

The review resulted in the development of the Theoretical Framework of Acceptability (TFA), which is a tool to guide the study of intervention acceptability among target audiences (Sekhon, et al., 2017). The TFA includes multiple constructs such as affective

attitude, burden, ethicality, intervention coherence, opportunity costs, perceived efficacy, and self-efficacy. The present study will assess affective attitude, perceived effectiveness, and intervention coherence using a satisfaction survey and will assess burden, opportunity costs, and self-efficacy using a practice survey. These factors provide individual pieces of acceptability that can be used independently or concurrently to measure the overall construct of acceptability. The purpose of Chapter 3 was to empirically identify factors of initial acceptability of MMWR. These factors were created using the items designed to assess participant satisfaction and practice.

Chapter 3 examined two research questions:

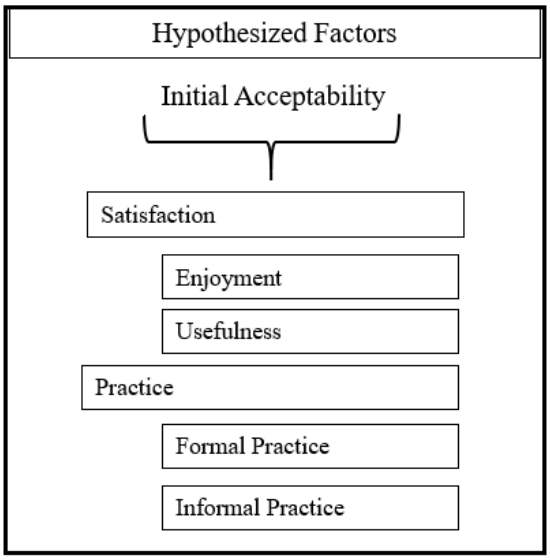
Research Question 1: What are the factors of satisfaction in the 17-item satisfaction survey?

Hypothesis 1: Items that measure satisfaction will yield two factors reflecting the constructs of enjoyment and perceived usefulness.

Research Question 2: What are the factors of practice found within the 16-item practice survey?

Hypothesis 2: Items measuring practice will yield two factors representing the constructs of formal and informal practice.

Figure 2: Hypothesized Factors for Chapter 3



The hypothesized factors for chapter 3 are illustrated above in Figure 2. The satisfaction and practice survey are both considered factors of initial acceptability. The satisfaction survey is hypothesized to break down into two factors: enjoyment and usefulness. The practice survey is hypothesized to break down into two factors: formal and informal practice.

Chapter 4

Chapter 4 used the subscales derived from Chapter 3 to examine the associations of acceptability with participant characteristics at pre-intervention and application of intervention techniques at post intervention. The purpose of chapter 4 was to 1) identify the strongest predictors (days in treatment, mindfulness disposition, and trauma severity) of factors identified as salient to acceptability; and 2) assess the relationship between the factors of acceptability and application of intervention techniques.

There is currently a lack of empirical studies indicating whether more time in treatment prior to introducing MBIs for SUD is associated with greater acceptability. In addition, there is limited evidence related to the best time to introduce an MBI in SUD treatment. Bowen, Chawla, & Marlatt (2011) designed their mindfulness-based relapse prevention (MBRP) intervention as an aftercare program with the rationale that at such time, participants may have greater clarity in their thoughts, emotional reactions, and behavioral patterns following treatment than in early stages of treatment.

Another possible predictor of acceptability is mindfulness predisposition, which is defined as an individual's propensity towards mindfulness in everyday life or their trait mindfulness (Kiken, Garland, Bluth, Palsson, & Gaylord, 2015). This may influence participants' initial response to MMWR because participants who come in with a natural attraction towards a mindful state of being may resonate more with the intervention, find it easier to practice, and perceive greater benefits from their practice. The distributive model of acceptability suggests that participants' prior familiarity, or natural comfort with the material or teachings, could positively influence their acceptability of that treatment (Carter, 2008).

There is a lack of clinical trials of MBIs that specifically assess acceptability among the participants with SUDs and co-occurring mental health challenges, such as trauma severity. There is a need for further study of the association between co-occurring mental health challenges and acceptability of MBIs for SUD (Kelly, Latta, & Gimmestad, 2012). This is important because of the large proportion of women in SUD treatment that have a co-occurring mental health condition and trauma exposure. In an earlier version of MMWR, participants expressed the difficulty with the body scan when the focus was on

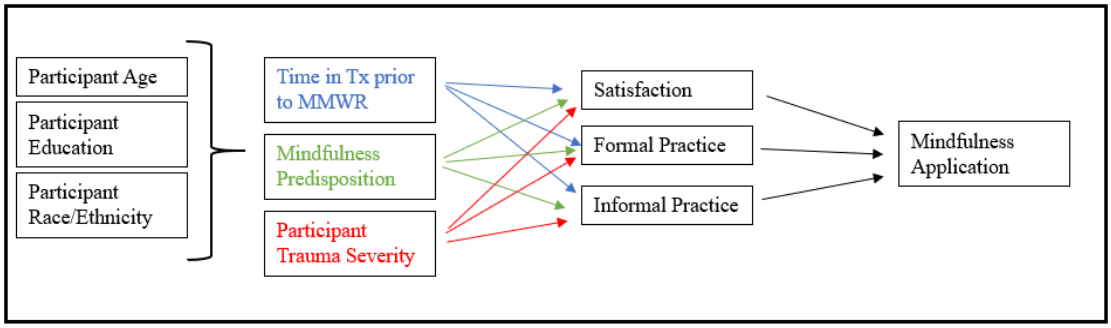
a body part involved in a prior experience of abuse or a body part associated with a former trauma (Vallejo, et al., 2009). Women that participated in an MBSR program reported that they were not prepared to confront the painful memories and strong emotions that arose during meditation. Suggesting they may have needed treatment for the trauma prior to the experience of meditation (Harris, 2015). MMWR has since been adapted to improve the acceptability among women with trauma and mental health conditions that may make it difficult to participate in the intervention. Other clinical trials that have included participants with co-occurring mental health disorders have not examined this group individually or assessed if there is a relationship between trauma severity and acceptability of the intervention.

Because acceptability is often assessed as a preliminary analysis and answered by a simple yes or no result, there are a lack of studies that assess whether acceptability is related to other intervention factors. Acceptability is theoretically associated with greater retention and intervention efficacy (Proctor, et al., 2011), but there is little-to-no data to support this. Chapter 4 will assess if the acceptability factors of satisfaction and practice measured after session 2 and 3, respectively, are related to the application of intervention technique at the end of the twelve sessions. Theoretically, those that accept the intervention early will have more time with the practice and have a higher dose response, therefore it is logical to assume that these factors would influence their progression in the development of mindfulness application by session 12.

Based on the information presented above, chapter 4 proposes the following hypotheses:

1. Days in treatment prior to the start of the intervention is positively associated with acceptability,
2. Mindfulness predisposition at baseline is positively associated with acceptability,
3. Trauma severity at baseline is negatively associated with acceptability, and
4. Acceptability is a predictor of mindfulness application at the end of the intervention.

Figure 3: Conceptual Framework for Chapter 4



Chapter 5

And finally, Chapter 5 presents an integrated discussion of the findings from Chapter 2 – 4; Culminating with future directions for this line of work and what can be done to advance the science of intervention acceptability.

The long-term goal of this line of research is to improve the fit of MMWR by creating evidence-based recommendations for adaptations based on the associations between participant characteristics, initial acceptability, and applied mindfulness. These recommendations would be tailored to fit groups based on their personal characteristics, such as days in treatment prior to their first MMWR session, mindfulness predisposition,

and trauma symptomology. This study can have a positive public health impact by improving SUD outcomes via precision treatment.

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CHAPTER 2

ACCEPTABILITY OF MINDFULNESS-BASED INTERVENTIONS FOR SUBSTANCE USE DISORDER: A SYSTEMATIC REVIEW

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Abstract

Background and Purpose: Mindfulness-based interventions (MBI) for substance use disorders (SUD) have shown promising results. However, acceptability of MBIs in the context of SUD treatment has yet to be systematically assessed across published studies. Our aims were to (a) review the literature for assessments of acceptability; (b) summarize how, when, and for whom acceptability is being measured; and (c) create suggestions for best practices in measuring acceptability of MBIs for SUD.

Methods: Five databases were searched with key terms related to mindfulness, relapse prevention, and SUD.

Results: Results highlight that studies of MBIs for SUD treatment lack acceptability assessment, a consistent definition of acceptability, and standardized measurements of acceptability. Conclusion: The lack of measurement and conceptual consistency make it difficult to conclude acceptability of MBIs for SUD treatment. It is imperative that more efforts be directed toward measurement of intervention acceptability to assess whether such interventions could be taken to scale.

Keywords: Acceptability Framework; Measurement; Mindfulness-Based Interventions; Mindfulness-Based Relapse Prevention; Substance Use Disorder; Treatment Acceptability

1. Introduction

Substance use disorder (SUD) is a significant public health problem affecting more than 20 million Americans [1]. The consequences and costs of SUD are far reaching for individuals, families, communities, and health care systems [2]. The economic impact of SUD is estimated to be more than $400 billion annually in costs related to health care, crime, and loss of work productivity [3]. Although efficacious treatments for SUD exist, many individuals who enter treatment drop out prematurely, contributing to high rates of relapse [4,5]. Accordingly, treatment and relapse prevention are long-standing and growing priorities in the field of SUD research.

In the last 10 years, interest has increased in the potential utility of mindfulness-based interventions (MBIs) as an approach to reduce relapse among individuals in SUD treatment [6]. As part of a third wave of empirically tested behavioral therapies, MBIs were preceded by behavioral therapy and cognitive behavioral therapy [7]. In contrast to the first two waves of these therapies, which focused on modification of cognitive, emotional, and behavioral processes, MBIs focus on "cultivating a non-judgmental awareness of the experience and awareness of the experience of consciousness that encompasses those same cognitive, emotional, and behavioral self-regulation processes" [8]. MBIs are designed to help modulate the stress response through increased awareness and nonjudgmental attention. Mindfulness helps individuals increase awareness of their experience in the moment, learning to respond than react to emotions or situations [9]. Recent literature supports the idea that mindfulness increases emotional regulation and self-control by increasing sensitivity to and awareness of affective cues and may be beneficial in SUD relapse prevention [10-13].

Research on the application of MBIs for SUD treatment is primarily based on adaptations of Jon Kabat-Zinn's mindfulness-based stress reduction (MBSR) intervention [6,14] and Marlatt's relapse prevention intervention [15]. MBIs adapted for relapse prevention are typically multiweek behavioral interventions [10,13] with session duration and frequency varying depending on the treatment setting and population. The foundation of MBIs for SUD treatment is the utilization of mindfulness as a "cultivatable skill" to help individuals learn to self-regulate both their emotions and behaviors in response to stressors that may otherwise prompt relapse [6].

Another important element of MBIs for SUD treatment is the concept of craving. In their 2013 article, Witkiewitz et al. [16] offered both a conceptual and detailed explanation of craving as the catalyst of relapse. The desire to use substances (alcohol and drugs) can be viewed as "an effort to either hold on to or avoid cognitive, affective or physical experiences" [16]. In the context of MBIs adapted for SUD relapse prevention, craving is understood as the urge or desire to experience the effects of the drug or alcohol—and is one of the greatest predictors of relapse [16,17]. MBIs for SUD are, in part, designed to help participants understand the passing or transient nature of the urge or craving that they experience and offer practices to develop strategies that support the attenuation of craving, impulsivity and compulsivity, negative mood, and stress reactivity [6,16]. Mindfulness-based skills may increase emotional regulation in response to stress and self-control in response to craving [12].

The most common type of MBI for SUD is mindfulness-based relapse prevention, which posits that it is a "novel mindfulness-based aftercare approach, [which] integrates core aspects of relapse prevention with practices adapted from MBSR and [mindfulness-

based cognitive therapy] MBCT" [18]. For the purposes of this study, the authors use the abbreviation "MBI for SUD" when discussing any MBI adapted for SUD and the abbreviation MBRP only when referring to the specific program developed by Bowen et al. [16] for individuals in aftercare after completion of SUD treatment.

Although several studies showed promising results of efficacy of MBIs for SUD treatment and relapse prevention [8,11,16,18], a remaining question is whether MBIs for SUD are acceptable to end users—a key factor in broad dissemination and adoption [19,20]. It is important to assess intervention acceptability because successful implementation depends on participant acceptability; even if an intervention is efficacious, there can be issues in implementation and adoption if acceptability is low [21,22]. While there is theoretical support for the associations between acceptability and intervention enrollment, attendance, and long-term adoption of intervention practices [19-22], there remains a lack of empirical support of these associations within MBIs for SUD. This gap in knowledge can be attributed in part to the lack of systematic assessment of acceptability of MBIs for SUD across published studies.

Intervention acceptability is defined as "a multifaceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention" [23]. From a clinical perspective, treatment acceptability is composed of multiple domains, "including perceived cruelty or unfairness, consistency with one's beliefs about how treatment should be and whether the treatment is recommendable to others" [24].

Currently in the field of intervention research, terms are often used interchangeably with acceptability, such as fidelity, adherence, and commitment. To clarify these terms: Treatment fidelity refers to a process of monitoring the program implementation with the goal of enhancing the accuracy and consistency [25]. Participant adherence refers to the active involvement of participating in the prescribed intervention [26]. Commitment may be defined as the participants' intention and willingness to participate in the intervention, which is a factor of acceptability but not a standalone measure [23].

The purpose of this paper is to (a) examine the literature on MBIs for SUD relapse prevention for assessments of acceptability; (b) summarize how, when, and for whom acceptability is being measured; and (c) create suggestions for the best practices of measuring acceptability of MBIs for SUD relapse prevention.

2. Methods

2.1. Data sources and selection

The authors conducted five data searches between June 1, 2018, and June 21, 2018, using the social science databases PsycINFO, PubMed, ERIC, CINHAL, and Academic Search Premiere. The database searches involved the following key terms: "mindfulness-based relapse prevention" and "substance" or "alcohol" or "drug." The search term "substance" was added to reduce the amount of literature related to depression relapse prevention that was present without this search term. The inclusion criteria were scholarly journal articles published in English and involving adult-only populations during the past decade (2008–2018); 65 articles were identified from this search. After reviewing the abstracts, 36 articles were removed for lack of relevance,

leaving 29 articles for full review. Lack of relevance includes articles focused on testing a measure not related to acceptability (psychometric studies), editorials, and studies not using an MBI for SUD. Following a full review of the articles, 11 additional papers were removed. Seventeen articles were included in the data extraction for the present study. The PRISMA flow diagram [27] was used to illustrate the detailed database search and article selection procedures (Figure 1).

2.2. Data extraction

The first and second authors used identical procedures to extract data and then convened to consolidate notes regarding difficult cases. The following information was extracted from the 17 articles that met the inclusion criteria: (a) primary and secondary outcomes of the study, (b) study design, (c) sample, and (d) whether acceptability was measured. This information is displayed in Table 1. Of the 17 studies in Table 1, only four studies measured acceptability. These four studies were used to create Table 2, for which the following acceptability-related information was extracted: (a) acceptability measures utilized, (b) timing of acceptability measurement, (c) sample characteristics, (d) use of acceptability in the outcome analysis, and (e) findings related to acceptability.

3. Results

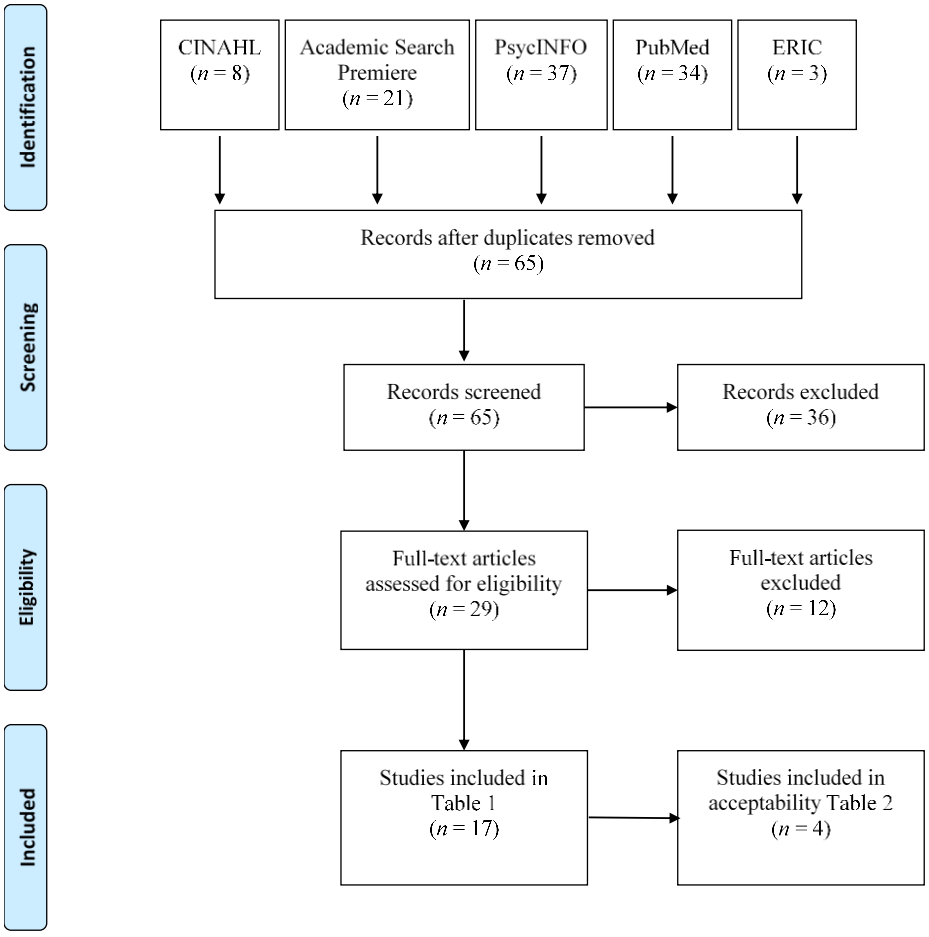

Figure 1: PRISMA Diagram

3.1. Results of data synthesis

[See Table 1 in Appendix D]

3.1.1. Measurements used to assess acceptability

The measures that authors claimed to assess acceptability were (a) satisfaction, assessed by 50% of the studies [8,28]; (b) follow-up rates of the outcome evaluation, assessed by 25% of the studies [29]; (c) evidence of utilization of intervention practices, assessed by 25% of the studies [18]; and (d) intervention session attendance, assessed by 25% of the studies [8]. Only one study [8] used attendance and satisfaction as two

independent measures of acceptability. None of the studies reported the reliability or validity of the acceptability assessment tools, leaving the details of measurement unclear.

3.1.2. Timing of acceptability assessment

The most common time for measuring acceptability was during postintervention follow-up: at the end of the final intervention session [8,28], 15-week follow-up [29], and 4-month follow-up [18]. Two studies also measured acceptability weekly during the intervention [8,18].

3.1.3. Samples

Of the four studies that assessed acceptability, sample sizes ranged from 15 to 318 participants. Two studies involved only women [8,29,30]; of the two mixed-gender studies, one had a 36.3% female sample [18] and the other had a 67% female sample [28]. Only one study [29] compared racial and ethnic groups based on the measure of acceptability, indicating that follow-up rates of the outcome evaluation were higher among racial and ethnic minorities than among non-Hispanic White participants.

[See Table 2 in Appendix E]

3.1.4. Acceptability findings

All four studies that measured acceptability concluded that the intervention was acceptable based on the various assessment used. Amaro et al. [8] reported high satisfaction and modest attendance and completion. Bowen et al. [18] indicated that 86% of the sample reported practicing at postintervention and 54% at the 4-month follow-up assessment. Frequency of use of mindfulness practices at follow-up averaged 4.7 days per week and approximately 30 minutes per practice session [18]. Bowen et al. [28] reported

high satisfaction across multiple items, including perceived importance and likelihood of continuing formal and informal practice.

3.1.5. Comparable measures not used to assess acceptability

Six studies excluded from Table 2 [11,30-34] (due to not specifying acceptability assessment) were identified as using measures of practice, retention, attendance, and follow-rates as a measure of a construct other than acceptability. This is important to mention because the use of the same variables for different constructs creates confusion in defining the variables. For example, practice may be used as a measure of feasibility in Study A, then as a measure of acceptability in Study B. It is not meaningful to conclude that one approach is acceptable based on high practice, then utilize the same measure to assess feasibility in another study. What constitutes feasibility needs to be clearly defined and differentiated from acceptability.

4. Discussion

The overall lack of attention to the measurement and assessment of acceptability and inconsistent types of measures of acceptability in published articles on MBIs for treatment of SUD is concerning. A deficiency in the use of a standard definition may, in part, explain the heterogeneity of acceptability measurements that were reported. Given the significance of SUD and the high rate of relapse, directing efforts to measure program acceptability is warranted. Utilization of a standardized definition and shared conceptual framework may help researchers develop strong measurements that accurately depict and report intervention acceptability.

The lack of acceptability assessment is not exclusive to MBIs for SUD. Zimmermann, Burrell, and Jordan [35] reviewed eight MBI studies (including MBCT,

MBSR, and acceptance and commitment therapy) aimed at improving psychological well-being for adults with advanced cancer. Of the eight included studies, five studies reported acceptability (two studies used a rating of intervention helpfulness as a measure of acceptability, one used qualitative data, and two did not discuss the method used for acceptability measurement) and three studies did not report acceptability.

Although assessment of treatment acceptability related to MBIs for SUD remains underdeveloped, related fields have created and implemented effective means of measurement. The work of Milosevic et al. [24] sought to evolve the field of anxiety research by establishing a valid and reliable measurement of acceptability as it relates to participant experience. The Treatment Acceptability/Adherence Scale (TAAS), a self-report questionnaire, was developed in 2015 to measure the psychometric properties associated with acceptability of and adherence to related interventions or treatments in the context of anxiety disorders. The TAAS was found to be reliable (Cronbach's α ranging from 0.79 to 0.88, depending on the condition). Convergent and divergent validity were confirmed by significant correlations with the following measures: Endorsement and Discomfort Scale ($r = 0.79$, $p < 0.01$); Credibility/Expectancy Questionnaire, Credibility Subscale ($r = 0.76$, $p < 0.01$); Credibility/Expectancy Questionnaire, Expectancy Subscale ($r = 0.66$, $p < 0.01$); and State Anger Expression Inventory-2, State Anger Subscale ($r = -0.55$, $p < 0.01$). A similar model with rigorous testing could help establish a method to assess acceptability of MBIs for SUD treatment.

Sekhon et al. [23] reviewed 43 systematic reviews of health care interventions, none of which mentioned an acceptability theory or model. This led to the development of the theoretical framework of acceptability (TFA), which is "represented by seven component

constructs: affective attitude, burden, perceived effectiveness, intervention coherence, opportunity costs, and self-efficacy" [23].

The TFA provides a good model for the measurement of acceptability as applicable to each intervention stage. It may not be necessary to assess all seven acceptability constructs in every study. For example, if an intervention is in the pilot phase, the researchers may be interested in the anticipated perceived burden among participants and facilitators, which may inform adaptations to improve fit of the intervention prior to delivery. Alternatively, during a randomized controlled trial phase, the researchers may be more interested in the participants' experiences of self-efficacy and perceived effectiveness following exposure to the intervention.

Balance is needed between developing a consistent measure of acceptability that can be applied across studies and limiting acceptability to a single measurement. Of the MBIs for SUD studies reviewed in this paper, self-report acceptability from the participant or patient perspective was the most common. However, Sekhon et al. [23] discussed valuable information to be gained by assessing acceptability from the facilitators' perspectives as well. For example, if an intervention has low facilitator acceptability, the facilitator may be altering the intervention, which could lead to low fidelity and potentially lower efficacy.

After reviewing the acceptability measurements used in the MBI for SUD studies included in this paper, we suggest that the term acceptability only be used when multiple constructs are used together. Otherwise, we suggest simply referring the individual construct being measured. For example, if a researcher is measuring satisfaction, adherence, and practice, those combined measures could be used to infer acceptability. If

the study is only measuring satisfaction, then the researcher should only infer satisfaction, not acceptability.

Inconsistent terminology has also been noted as an issue during intervention implementation [21]. Proctor et al. [21] presented conceptual distinctions among eight implementation outcomes, including acceptability and appropriateness, which are commonly used interchangeably. According to Proctor et al. [21], these two concepts have overlapping features but "acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation, is agreeable, palatable, or satisfactory." And "appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or the problem."

Based on the frameworks of Proctor et al. [21] and Sekhon et al. [23] and the intervention specifics related to MBIs for SUD treatment, we encourage the construction of acceptability scales for each intervention stage: development (Stage 1), efficacy (Stages II and III), effectiveness (Stage IV), and implementation (Stage V). The acceptability scales for Stage I should focus on anticipated ethicality (how mindfulness may complement or clash with one's own value system) and affective attitude (feelings associated with initial impression of the MBI) prior to participating in or facilitating the intervention. The acceptability scales for Stages II and III should focus on anticipated burden (effort or time needed for the MBI) and opportunity costs (perceived value of mindfulness). The acceptability scales for Stage IV may want to consider including aspects previously mentioned (if they were not assessed in the previous stage) and assess multiple aspects over time during the intervention, acknowledging that acceptability may

change with exposure to the intervention. The acceptability scales for Stage V should assess the self-efficacy of the participants or facilitators (how confident are they that they can perform the task) and the perceived effectiveness (the extent to which they believe the MBI will help in their SUD recovery and relapse prevention). Across fields, it is imperative to procure validated instruments that accurately measure treatment acceptability and reflect participants' experiences.

4.1. Limitations of the present review

The present study was limited to empirical studies indexed in the following databases: PsycINFO, PubMed, ERIC, CINHAL, and Academic Search Premiere. The reviewed articles were restricted to English language only with adult populations. Varied measurements among the studies may not adequately capture the multiple dimensions of the latent construct of acceptability.

To the authors' knowledge, currently there are no standardized means to assess acceptability of MBIs for SUD treatment, nor is there a way to combine multiple measurements of acceptability into a composite score. This is a promising future avenue of work for researchers in the field of MBIs for SUD.

The National Institutes of Health stage model brings attention to the importance of Stage I (intervention generation and refinement) and mentions that the stages are not linear. Intervention generations and refinement (including acceptability) should also be assessed during and after later stages, such as Stage V (implementation) to ensure acceptability in multiple settings and populations [36]. With MBIs for SUD studies still in their infancy and gaining promising evidence of efficacy, now is an opportune time for assessment of acceptability.

4.2. Future research

Future research should be conducted to advance the field of SUD relapse prevention by systematically measuring acceptability. There is a need to clearly define and differentiate the terms acceptability and feasibility to create measures that adequately capture the importance of each term and their possible influence on intervention efficacy. Assessing if and how acceptability differs by sample characteristics, such as race and ethnicity, treatment stage, and clinical profile (e.g., problem severity, comorbidity), could provide valuable insights to improve intervention retention and completion for disadvantaged individuals struggling with SUD. Further, identifying culturally specific characteristics associated with acceptability could inform appropriate adaptations of existing MBIs for SUD, potentially resulting in increased acceptability, retention, and long-term recovery. Barrera and Castro [37] discussed the importance of adapting an intervention not only to the problem (such as substance use), but also to the culture of the participants. Participant engagement (a factor of acceptability) is related to the social validity of an intervention, and generalizability of an intervention may not be possible if it is not applicable to a subcultural group [38].

4.3. Conclusion

The current review highlighted the dearth of research examining the acceptability of MBIs for SUD. Additional research is needed to develop a rigorous measurement of MBIs for SUD acceptability. There is a need to provide consistent definitions and precise language when inferring acceptability from the results of studies on MBIs for SUD. Our purpose is to bring attention to the inconsistency of acceptability measurement and provide suggestions for future assessment.

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Conflict of Interest

The authors have no conflict of interests to report.

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CHAPTER 3

PSYCHOMETRIC PROPERTIES OF ACCEPTABILITY SURVEYS FOR MOMENT-BY-MOMENT IN WOMEN'S RECOVERY

Abstract

Acceptability is an important construct in intervention implementation and dissemination. There is a dearth of studies that examine instruments used to assess acceptability of mindfulness-based intervention for substance use disorders. Moment-by-moment in women's recovery (MMWR) is a mindfulness-based intervention adapted for ethnically diverse women with substance use disorder and other mental health conditions. The development and testing of acceptability measurement tools are essential for standardizing the assessment of acceptability across interventions. The present study analyzed the validity and reliability of two acceptability surveys, satisfaction and practice, completed by 100 women following the second and third sessions, respectively. Exploratory factor analyses (EFAs) and Cronbach's alphas were conducted for each survey. Content Validity Index was used to assess the validity of the item wording. The Satisfaction survey resulted in a single factor construct with all 17 items retained. The Practice survey resulted in a two-factor construction reflecting formal practice with eight items and informal practice for six items, two items were removed. The content validity assessment recommended both surveys be reduced to ten items each. Results from this study establish a foundation for future studies to assess acceptability of MMWR in a systematic manner.

Keywords: acceptability, mindfulness-based intervention, psychometrics, satisfaction, practice

Introduction

Substance use disorders (SUD) affects over 20 million Americans (SAMHSA, 2011). There are many types of treatment for SUD, the most empirically supported behavioral treatment is cognitive-based relapse prevention (Bien, Miller, & Tonigan, 1993; Carroll, Rounsaville, & Gawin, 1991; Carroll, 1997; Davis & Glaros, 1986; Fals-Stewart, & O'Farrel, 2003; Irvin, Bowers, Dunn, & Wang, 1999; Kadden, 2001; Monti, Rohsenow, Michalec, Martin, & Abrams, 1997; Witkiewitz, Marlatt, & Walker, 2005).

Within the last 15 years, a third wave of SUD intervention development has advanced based on the use of mindfulness with a focus on teaching non-judgmental awareness of cognitive, emotional, and behavioral self-regulation processes (Amaro & Black, 2017; Amaro, Spear, Vallejo, Conron, & Black, 2014).

Moment-by-Moment in Women's Recovery (MMWR) is a mindfulness-based intervention specifically tailored for women in treatment for substance use disorder. In a recent randomized clinical trial, MMWR participants were significantly less likely to leave residential treatment without satisfactory progress as compared to the educational control participants following the intervention period. Results suggest the skills developed by participants in the MMWR intervention improved treatment retention. Other results suggest a dose response relationship between the number of sessions attended and increased mindfulness, increase positive affect, and decreased distress levels (Black & Amaro, 2019).

In addition to the primary outcomes, the study assessed process measures including intervention satisfaction and frequency of practice of intervention techniques. Satisfaction and practice are individual aspects of a larger concept referred to as

acceptability (Bautista, et al., 2019). Acceptability refers to participants perceptions of an intervention's appropriateness and relevance for their situation, and the participants' response during and after the intervention (Bautista, et al., 2019; Sekhon, et al., 2017).

Acceptability is an important concept to measure in all clinical trials, but specifically within MBIs for SUD because these interventions are gaining popularity and it is imperative to understand potential barriers to participant acceptability in the clinical trial phase, prior to large-scale dissemination. Current literature suggests that acceptability is a multidimensional construct (Carter, 2008; Sekhon, et al., 2017) yet it is often measured by a single-dimension measure such as completion rate, attendance, satisfaction, or practice (Bautista, et al., 2019; Harris, 2015; Witkiewitz, 2013). Given the multidimensionality of acceptability, measurement requires assessment of many factors to identify individual associations with participant characteristics.

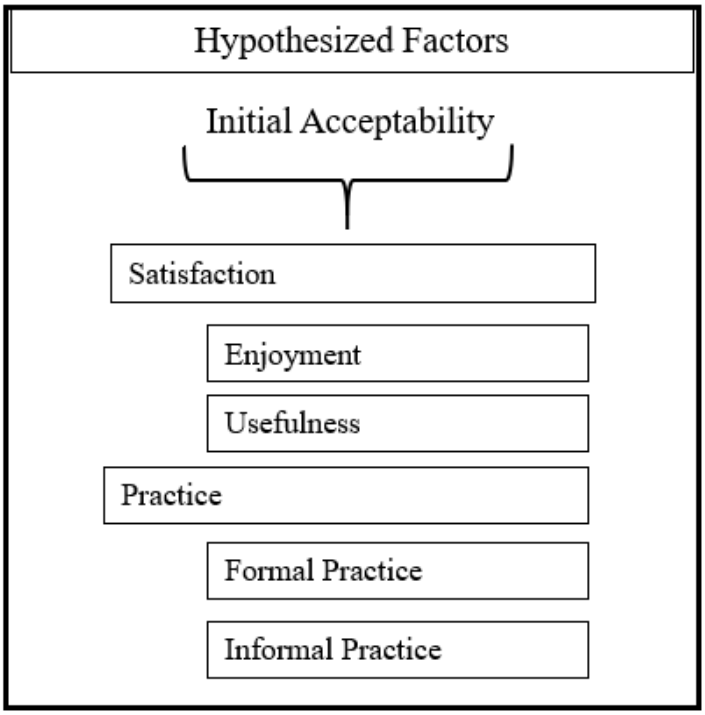
Studies that have reported acceptability of MBIs for SUD studies have blurred the lines between feasibility and acceptability by using the same scales to infer findings for each construct (Bautista, et al., 2019). Clear conceptual and operational definitions of acceptability, will help to distinguish it from related constructs, such as feasibility. Proctor, et al. (2011) also found conceptual and operational challenges for implementation terms with overlapping purposes such as acceptability and appropriateness or having too many terms to explain the same concept without means to differentiate the terms contributions to measurement error in the field.

Devon, et al. (2007) discusses the importance of psychometric testing of new instruments prior to the main research analyses. Results cannot be trusted if the

measurements used to derive the results are not valid and reliable. As noted by Dr. Sue Hegyvary, editor of the Journal of Nursing Scholarship "Validity and reliability are basic requirements for research…" Devon et al., (2007) (pg. 161)

The purpose of this study was to examine validity and reliability while empirically identifying factors of initial acceptability of MMWR using the items designed to assess two facets of acceptability; participant satisfaction and practice. The present study examined the following two hypotheses: Hypothesis 1: Items that measure satisfaction will yield two factors reflecting the constructs of enjoyment and perceived usefulness. Hypothesis 2: Items measuring practice will yield two factors representing the constructs of formal and informal practice.

Figure 1: Hypothesized Factors



2. Methods

Participants

Data used in the present study were collected as part of the parent randomized clinical trial conducted in a publicly funded, women-only, residential treatment center located in Los Angeles County, California (Amaro & Black, 2017; Black & Amaro, 2019). The analytic sample is limited to 100 female participants randomized to receive MMWR, of which, the majority identified as Latina. Attention-control group participants, received an educational intervention unrelated to mindfulness or the outcomes of interest in the parent study. Thus, control group participants are not included in the present analyses because they were not exposed to the intervention and did not complete the MMWR intervention acceptability measures. See **Table 1** for participant characteristics. The only variables used in the analyses of the present study were intervention satisfaction and practice, therefore, table 1 is displayed for more information about the participants, not the variables of interest. For full recruitment, enrollment, and attrition information see consort diagram (Appendix F).

Table 1: Participants Descriptive Information (n=100)

Variable	Mean (SD)	N (%)
Age	32.38(9.82)	
Race/Ethnicity		
Hispanic		60 (60.00%)
Non-Hispanic Black		18 (18.00%)
Non-Hispanic White		20 (20.00%)
Other		2 (2.00%)
Education (years)	11.67 (2.15)	
Craving	2.29 (1.70)	
Distress Tolerance	3.01 (1.21)	
Living Situation (8 months prior to Tx)		
Homeless		25 (25.00%)
Non-stable		7
Institution		16

Own place		17
Someone else's		35
Mandated to Treatment		83
Religious Preference		
Christian		83
Other Religion		2
Other Beliefs		5
Atheist		10
Marital Status		
Married		6
Sep/Divorce/Widow		18
Never married		76
Mental Health Diagnosis (#)		
1		9
2		74
3		14
Trauma Severity		
Range	0 – 46	
Mean	16.23 (11.94)	
Number of Sessions Attended (of 12)	9.49 (3.20)	

Inclusion and exclusion criteria

The inclusion criteria were that the participant must be (1) a new patient at the study site, (2) female, (3) 18-65 years of age, (4) diagnosed with SUD, (5) fluent in English, and (6) agreed to participate. The exclusion criteria were that the participant must not: (1) have an inability to understand or sign the informed consent, (2) have a cognitive impairment, (3) have any untreated psychotic disorder/severe mental health disorder, (4) be imprisoned, (5) have reported suicidality (past 30 days), or (6) be more than six months pregnant. Screening assessments were conducted to determine eligibility prior to consent and in-person interviews.

Procedures

An onsite study coordinator identified female patients who met study eligibility criteria using information from the residential treatment site's intake assessment. The study coordinator confirmed eligibility and obtained permission from eligible patients to be contacted by the study interviewer. The interviewer made appointments with prospective participants, conducted the informed consent, and administered the baseline assessment (Amaro & Black, 2017). Trained research staff collected participant data during in-person interviews using a computer-assisted interview process and stored the data in the online data platform, Research Electronic Data Capture (REDCap).

Further information was abstracted from clinic records and acceptability data were collected via self-administered surveys during intervention sessions. Additional information regarding procedures for the MMWR can be found in an article published by the principal investigators of the parent study (Amaro & Black, 2017). This study received Institution Review Board (IRB) approval from University of Southern California (Appendix B) and from Arizona State University for secondary, de-identified data analyses (Appendix C).

Measurements

Measures used in present study came from sessions two and three of the twelve session intervention. The satisfaction survey was administered at the end of the second intervention session. The practice survey was administered at the third intervention session.

Intervention Satisfaction Survey: 17 items rated on a dimension from "1 = Not at all" to "5 = Very much" (high scores indicate higher satisfaction) were used to assess

various aspects of satisfaction following the second session: session content, skills learned, perceived usefulness, importance for recovery. A sample item is "How much did you enjoy participating?" The items were developed over time through multiple Mindfulness-Based Intervention trials (Amaro & Black, 2017; Black & Amaro, 2019) to capture satisfaction with various aspects of the MMWR intervention. The present study was the first to assess the psychometric properties of this survey. While the participants were only been exposed to two sessions, they were taught the basics of mindfulness and therefore were capable of answering all the questions in the satisfaction survey listed in table 2 in regards to their satisfaction thus far in the intervention.

Table 2: Item Descriptive Statistics

	Item – Satisfaction	Range	Mean (SD)
1	How much did you enjoy participating?	1-5	3.98 (0.97)
2	How much did you learn about stress and relapse?	1-5	3.80 (1.01)
3	How much insight have you gained into personal patterns that put you at risk for relapse or leaving treatment?	1-5	3.59 (1.20)
4	How much have you improved your understanding of stress in residential treatment?	1-5	3.71 (1.08)
5	How much stress reduction skills have you gained?	1-5	3.69 (0.97)
6	How much did you learn about working with difficult emotions?	1-5	3.84 (0.85)
7	How much did you learn about working with body sensations?	1-5	3.99 (0.87)
8	How much did you learn about working with difficult thoughts?	1-5	3.80 (0.93)
9	How much of what you learned helped you understand yourself?	1-5	3.77 (0.97)
10	How much did you learn about skills to help you reduce feeling of stress?	1-5	3.94 (0.83)
11	How much did you learn skills to help you live in the present moment?	1-5	4.01 (0.89)

12	How much did the facilitator encourage discussion?	1-5	3.99 (1.10)
13	How useful was the information presented to you?	1-5	4.13 (0.88)
14	How important is this group in your recovery?	1-5	4.25 (1.01)
15	Would you recommend this group to other women in recovery?	1-5	4.38 (0.99)
16	Please rate the group facilitator's knowledge	3-5	4.57 (.71)
17	Overall, how would you rate today's group?	1-5	4.28 (.99)

Full description of response categories: 1 = Not at all, 2 = Not much, 3 = it was OK, 4 = A lot, 5 = Very Much

Intervention Practice Survey: The survey containsn16 items, rated on a dimension from "0 = Never" to "5 = 4 or more times a day" which assessed frequency of use of specific types of mindfulness practices since the previous class session (e. g., STOP Light Technique, Triangle of Awareness, sitting and walking meditation, mindful stretching) following the third session. A sample item is "How often did you practice or use Mindfulness in noticing your breath?" Like the satisfaction survey, the practice survey items were also developed over time through multiple studies, and the current version of the was designed to match the MMWR curriculum (Amaro & Black, 2017; Black & Amaro, 2019). The present study was the first to assess the psychometric properties of this survey. **The bold items in table 3 are the practices that were reviewed during the first three sessions.** The non-bold items were not introduced during a class session prior to data collection at the end of session 3. It is possible that the participants could still practice these items without an in-class introduction. For example, item nine (non-bolded) asks participants how often they use mindfulness to notice their breath, which is a foundation for most mindfulness practices, including sitting meditation (bolded) and therefore may be a skill learned through the MMWR classes when the bolded skills were taught, even if not explicitly stated.

Table 3: Item Descriptive Statistics			
	Item – Practice	Range	Mean (SD)
1	**How often did you practice or use sitting meditation with the audio?**	0-5	1.77 (1.29)
2	**How often did you practice or use sitting meditation without the audio?**	0-5	1.96 (1.54)
3	**How often did you practice *Love and Kindness* meditation?**	0-5	2.16 (1.56
4	**How often did you practice walking meditation?**	0-5	2.02 (1.53)
5	**How often did you practice or use the body scan?**	0-5	1.33 (1.36)
6	**How often did you practice or use Mindful stretching?**	0-5	1.85 (1.23)
7	**How often did you practice or use the *Stop Light Technique*?**	0-5	1.73 (1.48)
8	**How often did you practice the *Triangle of Awareness*?**	0-5	1.79 (1.44)
9	How often did you practice or use Mindfulness in noticing your breath?	0-5	2.46 (1.53)
10	How often did you practice or use Mindfulness to be aware of your emotions?	0-5	1.66 (1.49)
11	How often did you practice or use Mindfulness to be aware of your thoughts?	0-5	2.74 (1.59)
12	How often did you practice or use Mindfulness to be aware of your body sensations like your heartbeat, sweaty hands, pain, other?	0-5	2.40 (1.64)
13	When I have cravings, I used mindfulness to notice my cravings without judgment	0-5	2.03 (1.64)
14	When I have cravings, I used mindfulness to experience cravings without reacting	0-5	1.97 (1.64)
15	When I have cravings, I used mindfulness to notice that cravings are not permanent, they come and go	0-5	1.99 (1.62)
16	How often did you practice or use Mindfulness or anything else you learned in class for something else in your life?	0-5	2.70 (1.48)

Full description of response categories: 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.

Data Analysis Plan

Validity

Validity of the satisfaction and practice acceptability surveys was assessed using methods for face validity and content validity. Face validity was assessed based on the content of each item included in the surveys. While face validity is not the strongest form of validity testing, it is necessary for new surveys to be thoroughly reviewed word-by-word to confirm the items match the overall measurement goal of the construct (Devon, et al., 2007). The principal investigator (H. Amaro) noted the benefits and disadvantages of listing specific types of practices in both the satisfaction and practice surveys when collected at early sessions prior to the type of practice being introduced. The benefit being of this approach is that the survey can stay consistent across measurement points in sessions three, six, nine, and twelve for practice and sessions two and eleven for satisfaction. The disadvantage is that the participants have not been exposed to the type of practice at the time we were measuring their satisfaction of it and their frequency of practicing it.

Content validity was assessed for the purposes of the present study following the completion of the parent study. Data related to the content validity was not collected by the parent study principal investigators. The content validity assessment was based how well the items of each scale assessed the complete range of the construct (Devon, et al., 2007). Five independent raters assessed each item for relevance using the Content Validity Index (CVI) method (Lawshe, 1975). Items were rated on a scale ranging from 0 (not necessary), 1 (useful), and 2 (essential). The 0 rating indicates that it is not necessary to ask that item in order to assess the construct. The rating of 1 indicates that the

information collected for that item could be useful in measuring the construct and the rating of 2 indicated that the information collected using that item is essential for assessing the construct. Item receiving ratings of 1 or 2 by the majority of raters should be retained for further analyses.

The purpose of these ratings was to identify which items were best for gathering the necessary or useful information and which items were not necessary to use when measuring the constructs. Five experts provided ratings of each item to develop the most conceptually sound scale possible. Each expert reviewed the study protocol article and the satisfaction and practice surveys as it was presented to the participants. They reviewed each item and rated whether the information collected from that item was essential, useful, or not necessary for assessing the construct of satisfaction or practice, respectively.

The raters of this assessment were individuals trained in mindfulness-based intervention delivery, psychometrics testing, and/or SUD treatment programs. Individuals involved in the survey development, intervention delivery, or data analyses were excluded as raters to minimize bias. The content validity ratio (CVR) was then computed for each item based on the number of raters who rated that item as essential and the number of raters. Items with a low CVR, (<.50) were removed and the CVI is the mean for the retained items. This value was chosen as a conservative estimate with only five raters in order to produce a list of the most essential items. To obtain a value over .50, at least four of the five raters must rate the item as essential.

Factor Analyses

For the factor analyses, the full scale was used in order to create two separate results using all the items and compare the results from the CVI and the factor analyses. Two separate exploratory factor analyses (EFAs) were conducted to examine the construct validity of the two measures of acceptability. The first EFA examined the factor structure of the 17-item Satisfaction Survey that was administered at session two. The second EFA examined the factor structure of the 16-item Practice Survey that was administered at session three. Eigenvalues, scree plots of these values, parallel analysis, patterns of factor loadings, and inter-factor correlations were used to generate plausible factor models for the constructs underlying the measures. For each of these two factor analyses, the name of each emergent major factor was based on the identity of its highest loading items. Within each factor, the items that loaded at .50 or higher were retained to create a sub-scale that identified distinctly different facets of acceptability.

Parallel analysis is an empirical method for factor retention (Pallant, 2007; Patil, Singh, Mishra, & Donavan, 2007; Hayton, Allen, & Scarpello, 2004). Using the parallel analysis engine by Gonzaga University, eigenvalues from randomly generated correlation matrices that corresponded with the sample data parameters were calculated. These randomly generated correlation matrices were then compared with eigenvalues extracted from the sample data. The number of factors retained equaled the number of eigenvalues (generated from the sample data) that were larger than the corresponding random eigenvalues (Horn, 1965).

Reliability

Reliability was assessed using Cronbach's alpha coefficient to calculate the internal consistency of each total scale and subscales.

3. Results

Satisfaction Survey

Content Validity

Using the Content Validity Index (CVI) by Lawshe (1975), each item from the practice survey was rated by five content experts on a scale of "0= not necessary" "1= useful" and "3=essential." The following formula was used to assess the CVR for each of the 16 practice items:

$$\mathrm{CVR} = \frac{\mathrm{n_e} - \mathrm{N}/2}{\mathrm{N}/2}$$

In this formula the n_e is the number of experts who rated the item as "2 = essential" for assessing the measured construct, N is the total number of experts that provided ratings for the item. For example, the first item is "How much did you enjoy participating?" A total of 2 out of 5 experts rated the item as essential, which equals a CRV of (2 - 5/2)/5/2 = -0.20. For a full list of CVR for each item see Table 4. Items with a CRV over .50 were retained. The mean CVR for 10 retained items was .83.

Table 4: Content Validity Ratio for the Satisfaction Survey by Rater

	Item – Satisfaction	R1	R2	R3	R4	R5	Total Essential Ratings	CVR
1	How much did you enjoy participating?	1	1	1	2	2	2	-0.2
2	How much did you learn about stress and relapse?	2	1	1	2	2	3	0.2

3	How much insight have you gained into personal patterns that put you at risk for relapse or leaving treatment?	2	2	2	2	2	5	1
4	How much have you improved your understanding of stress in residential treatment?	1	1	1	1	2	1	-0.6
5	How much stress reduction skills have you gained?	2	2	2	2	0	4	0.6
6	How much did you learn about working with difficult emotions?	2	2	2	2	2	5	1
7	How much did you learn about working with body sensations?	2	2	2	2	2	5	1
8	How much did you learn about working with difficult thoughts?	2	2	2	2	2	5	1
9	How much of what you learned helped you understand yourself?	1	2	2	2	2	4	0.6
10	How much did you learn about skills to help you reduce feeling of stress?	2	1	1	2	2	3	0.2
11	How much did you learn skills to help you live in the present moment?	2	2	2	2	1	4	0.6
12	How much did the facilitator encourage discussion?	2	1	1	1	1	1	-0.6
13	How useful was the information presented to you?	2	1	2	2	2	4	0.6
14	How important is this group in your recovery?	2	2	2	2	2	5	1
15	Would you recommend this group to other women in recovery?	2	2	1	2	2	4	0.6
16	Please rate the group facilitator's knowledge	2	1	1	1	2	2	-0.2
17	Overall, how would you rate today's group?	2	1	1	2	2	3	0.2

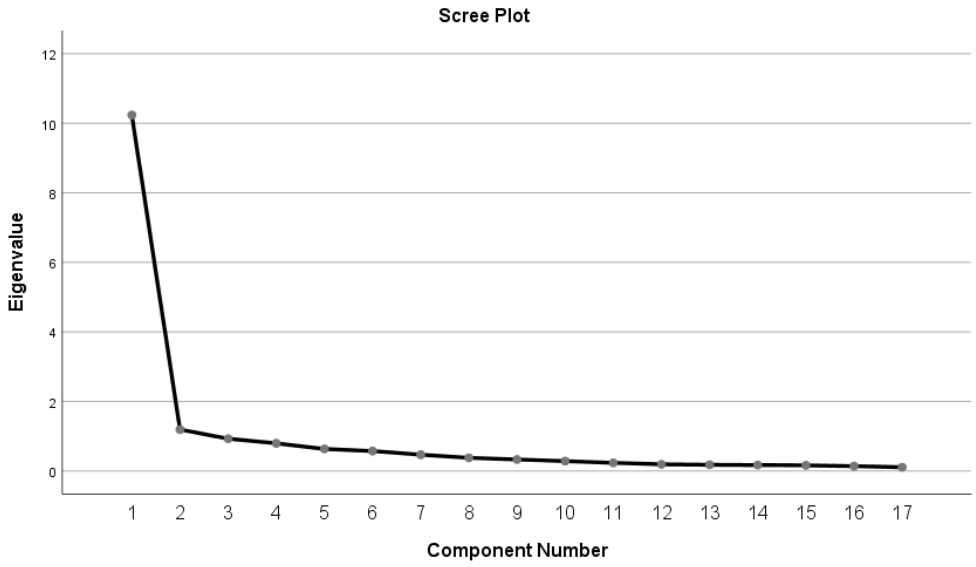
Data Screening

Suitability of data for factor analysis was assessed by examination of the correlation matrix, which revealed most coefficients between .3 and .8, suggesting the items are correlated without the presence of multicollinearity or redundancy. The Kaiser-Meyer-Olkin (KMO) measure of sampling was .94, exceeding the recommended value of .6 (Kaiser, 1974), and Bartlett's Test of Sphericity (Bartlett, 1954) was significant ($\chi 2$ = 1064.70, df = 136, $p < .001$) which further supports the suitability of the data indicated by the correlation matrix.

Factor Analysis

The items that were recommended to be removed based on the results from the CVI were included in the factor analyses in order to compare the results from the two separate tests. The unrestricted exploratory factor analysis (EFA) produced a 2-factor solution with eigenvalues greater than one and recovered 67.22% of the sample variance. Scree test suggested a gap between factor 1 (eigenvalue = 10.24) and factor 2 (eigenvalue = 1.19). The parallel analysis suggested that 1 factor be retained. Based on the scree plot and the parallel analysis, one-factor was retained rather than the two-factor solution suggested by the eigenvalue. Factor rotations were not performed, due to the evidence supporting a 1-factor solution.

Figure 2: Scree Plot for the 17-item Satisfaction Survey



One-Factor Solution

Using the component matrix for interpretation, one factor aligned with 60.22% of the overall variance. All 17 items loaded onto factor 1 (values ranged from .50 to .90; α = .95). The items generally reflected the construct of *satisfaction*, without clearly distinguishing between items relating to enjoyment, facilitator, or perceived usefulness (Table 5).

Table 5: Item factor loadings and communalities for 17-item Satisfaction

	Item – Satisfaction	Factor 1 Loading	Communality
1	How much did you enjoy participating?	.74	.55
2	How much did you learn about stress and relapse?	.71	.51
3	How much insight have you gained into personal patterns that put you at risk for relapse or leaving treatment?	.50	.25
4	How much have you improved your understanding of stress in residential treatment?	.73	.53
5	How much stress reduction skills have you gained?	.79	.63

6	How much did you learn about working with difficult emotions?	.84	.71
7	How much did you learn about working with body sensations?	.78	.60
8	How much did you learn about working with difficult thoughts?	.82	.67
9	How much of what you learned helped you understand yourself?	.82	.68
10	How much did you learn about skills to help you reduce feeling of stress?	.90	.81
11	How much did you learn skills to help you live in the present moment?	.87	.76
12	How much did the facilitator encourage discussion?	.66	.44
13	How useful was the information presented to you?	.89	.80
14	How important is this group in your recovery?	.81	.66
15	Would you recommend this group to other women in recovery?	.85	.72
16	Please rate the group facilitator's knowledge	.58	.33
17	Overall, how would you rate today's group?	.77	.59

Practice Survey

Content Validity

Content validity for the practice survey was assessed using the same formula as the satisfaction survey explained above. For example, the first item is “How often did you practice or use sitting meditation with the audio?” A total of 5 out of 5 raters scored the item as essential, which equals a CVR of (5 - 5/2) / (5/2) = 1.00, but for the eighth item: “How often did you practice the Triangle of Awareness?” only 2 out of 5 raters scored the item as essential, therefore the CVR equaled -0.20. For a full list of CVR for each item see Table 6. All items with a CVR over 0.50 were recommended to be retained. The mean CVR for the recommended retained nine items was .73.

Table 6: Content Validity Ratio for the Practice Survey by Rater								
	Item – Practice	R1	R2	R3	R4	R5	Total Essential Ratings	CVR
1	How often did you practice or use sitting meditation with the audio?	2	2	2	2	2	5	1
2	How often did you practice or use sitting meditation without the audio?	2	2	2	2	2	5	1
3	How often did you practice *Love and Kindness* meditation?	2	2	1	2	2	4	0.6
4	How often did you practice walking meditation?	2	2	1	2	2	4	0.6
5	How often did you practice or use the body scan?	2	2	1	2	2	4	0.6
6	How often did you practice or use Mindful stretching?	2	0	1	2	2	3	0.2
7	How often did you practice or use the *Stop Light Technique*?	2	1	1	2	2	3	0.2
8	How often did you practice the *Triangle of Awareness*?	2	1	1	2	0	2	-0.2
9	How often did you practice or use Mindfulness in noticing your breath?	2	2	1	2	1	3	0.2
10	How often did you practice or use Mindfulness to be aware of your emotions?	2	2	2	2	1	4	0.6
11	How often did you practice or use Mindfulness to be aware of your thoughts?	2	2	2	2	1	4	0.6
12	How often did you practice or use Mindfulness to be aware of your body sensations like your heartbeat, sweaty hands, pain, other?	2	2	2	2	1	4	0.6
13	When I have cravings, I used mindfulness to notice my cravings without judgment	1	1	2	2	2	3	0.2
14	When I have cravings, I used mindfulness to experience cravings without reacting	2	1	0	2	2	3	0.2
15	When I have cravings, I used mindfulness to notice that	2	2	2	2	2	5	1

	cravings are not permanent, they come and go							
16	How often did you practice or use Mindfulness or anything else you learned in class for something else in your life?	1	2	2	1	1	2	-0.2

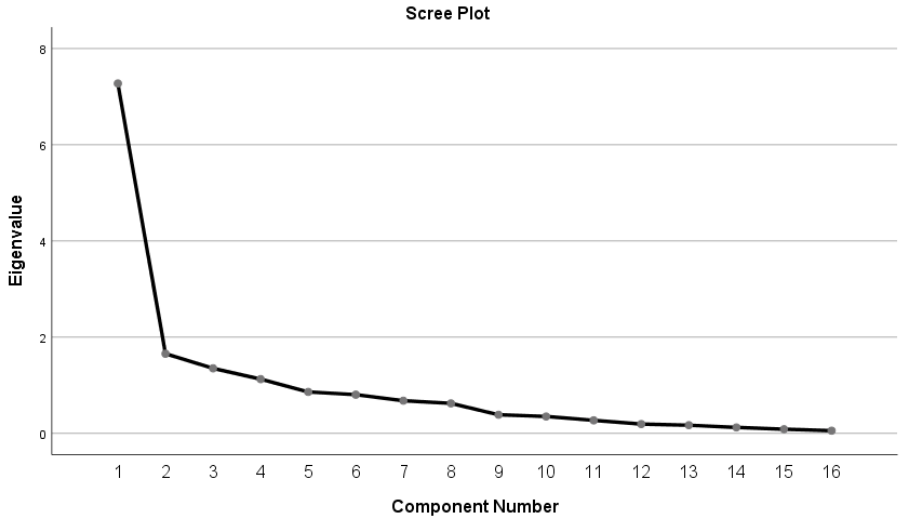
Data Screening

Suitability of data for factor analysis was assessed by examination of the correlation matrix, which revealed most of the coefficients were between .3 and .8, suggesting the items are correlated without the presence of multicollinearity or redundancy. The Kaiser-Meyer-Olkin (KMO) measure of sampling was .83, exceeding the recommended value of .6 (Kaiser, 1974), and Bartlett's Test of Sphericity (Bartlett, 1954) was significant ($\chi^2 = 749.65$, df = 120, $p < .001$) which further supports the suitability of the data indicated by the correlation matrix.

Factor Analyses

The unrestricted EFA produced a four-factor solution with eigenvalues greater than one, and recovered 71.29% of the sample variance. Scree test indicated a gap between factor #1 (eigenvalue = 7.27) and factor #2 (eigenvalue = 1.66), which suggests retaining one-factor. The parallel analysis suggested that two factors be retained. Based on these results, two factors were retained.

Figure 3: Scree Plot for the 16-item practice survey



Direct Obliman (oblique) and Varimax (orthogonal) rotations were performed across the series of analyses. First the oblique rotation was used based on the assumption that the underlying constructs would be correlated. For factors to be considered oblique there should be a correlation greater than that of the average factor loadings (Samuel, 2016). The two-factor solution in the present study was correlated at .48. Despite the correlation being slightly under the average factor loading, the theoretical support combined with the .48 statistical support suggests the oblique rotation would provide the most accurate representation of the data.

Two-Factor Solution

Using the pattern matrix for interpretation, two factors aligned with 55.80% of the overall variance (see Table 7 for full pattern matrix). Eight items loaded onto factor 1 (values ranged from .41 to .95; $\alpha = .92$) and aligned with 45.46% of the variance. The items generally reflected the construct of *informal mindfulness practice*, with items such as “When I have cravings, I use mindfulness to notice that cravings are

not permanent, they come and go" and "How often did you practice or use mindfulness to be aware of your emotions?" rated from "never" to "4 or more times a day." Six items loaded onto factor 2 (values ranged from .43 to .85; $\alpha = .80$) and aligned with 10.35% of the variance. These items generally reflected the construct of *formal mindfulness practice*, with items such as "How often did you practice or use the body scan?" and "How often did you practice walking meditation?" rated from "never" to "4 or more times a day." One item ("How often do you practice the Triangle of Awareness?") cross-loaded onto two factors (factor 1 = .41 and factor 2 = .41) and one item ("How often did you practice or use sitting meditation with the audio?") did not load within the solution. These two items were excluded for both subscales for lack of specificity and relatedness, respectively.

Table 7: Item factor loadings and communalities for 16-item Practice Survey

	Item – Practice	Factor 1 Loading	Factor 2 Loading	Communality
1	How often did you practice or use sitting meditation with the audio?	-	-	.17
2	How often did you practice or use sitting meditation without the audio?		.85	.64
3	How often did you practice *Love and Kindness* meditation?		.64	.37
4	How often did you practice walking meditation?		.61	.40
5	How often did you practice or use the body scan?		.43	.26
6	How often did you practice or use Mindful stretching?		.76	.54
7	How often did you practice or use the *Stop Light Technique*?	.41		.42
8	How often did you practice the *Triangle of Awareness*?	.41	.41	.50
9	How often did you practice or use Mindfulness in noticing your breath?		.58	.64

10	How often did you practice or use Mindfulness to be aware of your emotions?	.69		.69
11	How often did you practice or use Mindfulness to be aware of your thoughts?	.74		.79
12	How often did you practice or use Mindfulness to be aware of your body sensations like your heartbeat, sweaty hands, pain, other?	.67		.71
13	When I have cravings, I used mindfulness to notice my cravings without judgment	.91		.77
14	When I have cravings, I used mindfulness to experience cravings without reacting	.94		.79
15	When I have cravings, I used mindfulness to notice that cravings are not permanent, they come and go	.95		.75
16	How often did you practice or use Mindfulness or anything else you learned in class for something else in your life?	.47		.50

Discussion

Summary of findings

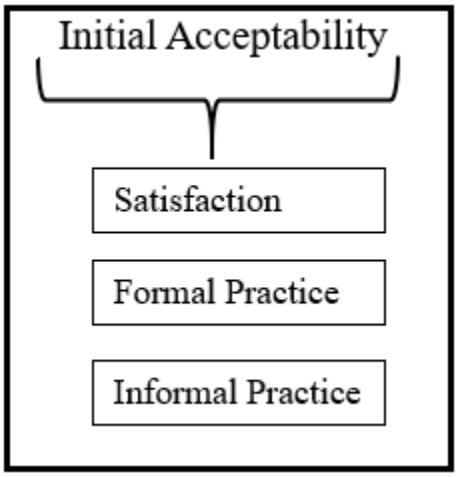
The present study used a collection of rigorous tests to identify the strongest possible combination of items to assess acceptability of MMWR. The findings from the content validity test suggest the surveys had good validity for measuring the concepts of satisfaction and practice, but some items may not be essential for assessing each concept. None of the satisfaction items received a zero rating (not necessary) from any of the raters. Only three items from the practice survey received a zero rating, none of which were rated with a zero by more than one rater.

The satisfaction survey factor analysis resulted in a one-factor solution with all 17 items grouping together. This suggests that the items are similar enough to be used as one survey without removing any items. The practice survey factor analysis resulted in two distinct subscales that measure formal and informal practice of mindfulness techniques. One of the sixteen items did not load on either factor and one item loaded evenly on both factors, suggesting that these items could be excluded in the next version of the survey. Interestingly, the item that did not load onto either factor (How often did you practice or use sitting meditation with the audio?) was an important item for assessing overall practice. This item not loading onto either factor suggests that the participants responses to this question were inconsistent with their answers to the rest of the questions. The item mean and standard deviation seem normal as compared to the other items, while the mean is low (1.77), it is similar to the means for the other items. We would like to see the mean for this item be higher considering the extra effort costs that were invested to make sure each participant had an MP3 player with the meditation recordings on them.

The low to moderate correlation between the formal and informal practice factors suggest that these subscales could be used independently or together in future analyses. Using these subscales independently could be useful for assessing patterns in the development of mindfulness practice over time. For example, a future study may see which practice (formal or informal) is adopted first by participants and if there is higher satisfaction associated with practicing one or the other. We can also assess personal characteristics that may be associated with formal or informal practice separately, therefore providing information about the profile of the participants most and least likely to engage in either practice. Future analyses should be careful not to introduce

multicollinearity into the model when using both scales due to the moderate relationship between factors.

Figure 4: Resulting factors from the Exploratory Factor Analyses



Based on the findings from the reliability tests each of the three surveys are reliable with the items resulting from the factor analyses. All Cronbach's alphas were over .80, which is the considered a good value for internal consistency, as defined by George and Mallery (2003) " ≥ .9 is considered excellent, ≥ .8 is considered good, ≥ .7 is considered acceptable, ≥ .6 is considered questionable, ≥ .5 is considered poor, and anything ≤ .5 is considered unacceptable" (p. 231).

Limitations

Despite the small sample size, the data produced acceptable KMO values. While power may be considered a limitation, there is not an official power analysis used for factor analyses. Nevertheless, small sample sizes can produce inconsistent results that may not be generalizable to the larger population. While some surveys can be validated using large representative national samples, the data collected with these surveys is limited to only individuals in the MMWR program, therefore gathering data to create a

large sample size would take a multitude of cohorts over the course of many years. It is also important to note that this sample was all female and currently living in a residential treatment facility for substance use disorder. The surveys were specifically tailored to fit the MMWR intervention and may not be applicable or appropriate for use in another intervention.

The content validity findings could be improved by collecting feedback from raters with specific expertise in MBIs for SUD. Additionally, having five raters review each item is adequate, but the CVI findings may be less biased with ten or more raters. Future assessments should include at least ten raters with training in MBIs for SUD and at least one formal introduction and overview of MMWR.

Lastly, while some of the items are specific to MMWR and designed for the women in this study, many of the items are applicable to other MBIs for SUD and could be useful for other clinical trials to include in the assessment of their intervention.

Future directions

The present study is the first of its kind to present an empirical analysis of acceptability measures. These findings play a crucial role in the development of acceptability as a stand-alone-assessment in clinical trials. We can now use these valid and reliable surveys for future assessment of the role of acceptability in MMWR across participant characteristics. The authors are currently using the results of this study to assess the association between these factors and participant characteristics. Future studies may assess the possibility of creating a composite score or a mechanism to combine multiple acceptability facets into one scale.

The present study assessed the validity and reliability of the initial measurements of satisfaction and practice of MMWR. Satisfaction was assessed additionally at session eleven and practice was assessed additionally at sessions six, nine, and twelve. Future analyses should assess the validity and reliability along with the factor constructs of the other timepoints. Depending on which timepoint is the focus, future analyses may consider only assessing practice items that have been discussed in a class session prior to the assessment. There are more sophisticated methods for testing the validity and reliability of these surveys, future studies may consider a structural equation model to assess how these constructs relate to each other and other intervention factors.

Conclusions

In conclusion, the satisfaction and practice surveys presented in the study were deemed valid for measuring each concept, respectively. There were some items that could be removed to improve the reliability of the survey and lessen the fatigue of participants. Future studies may benefit from using valid and reliable measures of acceptability and/or conducting their own psychometric tests to ensure sound measures for the constructs before examining the role of acceptability in the intervention and making any conclusion as to the acceptability of the intervention.

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CHAPTER 4

ASSOCIATIONS BETWEEN ACCEPTABILITY, PARTICIPANT CHARACTERISTICS AND APPLICATION OF INTERVENTION TECHNIQUES

Abstract

The aim of this study was to assess the predictors of participant acceptability of a 12-session mindfulness-based intervention (Moment-by-Moment in Women's Recovery, MMWR) designed for ethnoculturally diverse women in substance use disorder (SUD) treatment. The current analyses employ data from a phase II parallel-group randomized clinical trial parent study implemented in a large residential women's treatment program in greater Los Angeles. Data from 100 women randomly assigned to the MMWR intervention are the focus of analyses. There was a significant correlation between mindfulness predisposition and informal practice, r=.22, p=.045, and significant correlations of applied mindfulness with informal practice r= .26, p= .04 and with satisfaction, r=.26, p=.04. Women with higher mindfulness predisposition at baseline subsequently reported higher frequency of informal practice following the third of twelve sessions. Women with higher satisfaction and high frequency of informal practice early in the intervention subsequently reported higher application of intervention techniques after the final session. These findings provide support for the potential role of early acceptance of the intervention for later uptake of the practices in daily life.

Keywords: acceptability, mindfulness-based intervention, substance use disorders, women, trauma

Findings from Mindfulness-based interventions (MBI) for substance use disorders research are promising despite still being in early stages. Behavioral and neuroimaging evidence indicates plausible mechanisms through which mindfulness may change neural responses to craving and negative affect, consequently having the potential to reduce the risk of relapse. Mechanisms such as increasing present moment awareness and sitting with discomfort is associated with strengthening the medial prefrontal cortex, nucleus accumbens, and amygdala to assist with controlling cravings and reward circuitry (Witkiewitz, Lustyk, & Bowen, 2013).

Moment-by-Moment in Women's Recovery (MMWR) program is an MBI for SUD relapse prevention specifically designed for low-income ethnoracially diverse women. This program was developed with Mindfulness-Based Stress Reduction (MBSR) as a foundation, then underwent multiple iterations based on participant and facilitator feedback (Vallejo & Amaro, 2009). The MMWR program focuses on the role of stress specific to relapse, and helps participants increase their awareness of craving and observing without reacting in a habitual manner (Vallejo & Amaro, 2009). MMWR was developed to be used in either outpatient or residential SUD programs with special attention to trauma and mental health conditions of the participants.

An important yet understudied factor in MBIs for SUD is the acceptability and potential fit of MBIs for SUD populations with specific clinical features, such as trauma symptomology. Acceptability is a multi-faceted construct that reflects the degree to which participants find the intervention to be appropriate (Sekhon, Cartwright, & Francis, 2017). Research on acceptability of MBIs for SUD is extremely narrow and demonstrates an inadequate assessment of variations in acceptability across participant profiles. While

assessment of acceptability is regarded as important for retention, adoption, implementation, and dissemination (Bak, van Dam, & Janssens, 2018; Diepeveen, Ling, Suhrcke, Roland, & Marteau, 2013; Proctor, Silmere, Raghaven, et al., 2011; Stok, de Ridder, de Vet, et al., 2016), studies using MBI for SUD have not measured acceptability or have done so in a cursory manner.

Intervention and participant characteristics that may be associated with acceptability are 1) time in treatment prior to starting the intervention, 2) mindfulness predisposition, and 3) trauma severity. Time in treatment prior to starting the intervention is an intervention-specific factor, that could significantly influence acceptability in future interventions. Mindfulness predisposition and trauma severity are participant-specific factors and if these significantly influence acceptability, the intervention may need to be adapted to meet participants where they are or in extreme cases, participants may not be well-suited for the intervention.

There is currently a lack of empirical studies indicating whether more time in treatment prior to introducing MBIs for SUD is associated with greater acceptability. In addition, there is limited evidence related to the best time to introduce an MBI for SUD intervention. Bowen, Chawla, & Marlatt (2011) designed their mindfulness-based relapse prevention (MBRP) intervention as an aftercare program so that participants may have greater clarity in their thoughts, emotional reactions, and behavioral patterns following treatment than in early stages of treatment. Harris (2015) provided qualitative narratives from MBRP participants who completed the intervention as residents in a treatment community. Many participants noted that during their early recovery process the MBRP sessions were challenging and they found it difficult to confront their

emotions and cravings. However, other participants in the same study mentioned how beneficial MBRP was, as early as the detoxification stage of treatment and credited MBRP for their ability to stay in treatment and complete the program. If MBIs for SUD, such as MMWR, can be offered as an adjunct class during treatment, rather than an aftercare program, the skills developed could help with treatment retention and could reach a greater number of women, since the great majority do not complete treatment. Aftercare patients represent a very small percent of those in SUD treatment – the ones that have already demonstrated success in treatment completion and clinical progress towards recovery, this percent is even smaller among Latino and African American patients (Guerrero, Marsh, Duan, Oh, Perron, & Lee, 2013). Therefore, testing if there is an association between time in treatment and intervention acceptability is important when using MMWR during treatment rather than after treatment. A typical process, although many treatment facilities have individual procedures, begins with a patient intake and focus on the prevention of complications related to detoxification and withdrawal from substances, then there is a transition into the abstinence phase before connecting the individual or bringing treatment services (Blondell, Frydrych, Jaanimägi, Ashrafioun, Homish, Foschio, & Bashaw, 2011). Therefore, the majority of SUD treatments do start the first few days the patient is in a new treatment facility if they have not completed the withdrawal processes yet.

Another possible predictor of acceptability is mindfulness predisposition, which is defined as the natural tendency toward mindfulness attitudes. This may influence participants' initial response to MMWR because participants who come in with a natural attraction towards a mindful state of being may find it easier to practice and may perceive

greater benefits from their practice. The distributive model of acceptability suggests that participants' prior knowledge about the intervention will influence their acceptability of that intervention (Carter, 2008).

There is a lack of clinical trials of MBIs that specifically assess acceptability among the participants with SUDs and high trauma severity. There is a need for further study of the association between co-occurring mental health challenges and acceptability of MBIs for SUD (Kelly, Latta, & Gimmestad, 2012). This is important because of the large proportion of women in SUD treatment that have co-occurring conditions such as depression, anxiety, or posttraumatic stress disorder (PTSD) (Amaro et al., 2005). Other forms of trauma include exposure to traumatic events or interpersonal trauma, trauma symptomology, and trauma severity. PTSD can be defined as a disorder with two essential components: 1) a precipitating traumatic event and 2) a resultant constellation of symptoms, including re-experiencing, avoidance or numbing, and hyperarousal (American Psychiatric Association, 2000). There are MBIs specifically designed for individuals with trauma and evidence to suggest that MBIs are not only safe for individuals with trauma, but mindfulness practices may be helpful in treating trauma (Kelly, 2015; Kelly, & Garland, 2016). There are many overlapping mechanisms of action through which mindfulness may be effective in aiding the recovery process for both SUD and trauma. Skills such as the capacity to regulate attention and traumatic thoughts could improve control over arousal, and therefore enable a new way to process traumatic memories with metacognitive awareness (Kelly, & Garland, 2016).

For the present study we will be assessing participant trauma symptomology severity, defined as the frequency in which the participant is bothered by re-experiencing,

avoidance, and hyperarousal in the past 30 days related to a traumatic event (Foa, Cashman, Javcox, & Perry, 1997). MMWR was developed to integrate issues of trauma and mental health problems into the curriculum and delivery methods, many sessions topics center around trauma allow for ample opportunity to address how trauma plays a role in recovery and relapse prevention. These additional steps to ensure participant safety and comfort were taken because of the literature and science expressing the importance of trauma-informed care (Muskett, 2014; Raja, Hasnain, Hoersch, Gove-Yin, & Rajagopalan, 2015; Rosenberg, 2011). The present study aims to examine if trauma severity influences acceptability of MMWR despite the adaptations designed to make the intervention acceptability for this population.

Because acceptability is often assessed as a preliminary analysis and answered by a simple yes or no result, there is a lack of studies that assess whether acceptability is related to other intervention factors. Acceptability is theoretically associated with great retention and intervention efficacy (Proctor, et al., 2011; Sekhon, et al., 2017), but there is little-to-no data testing these theories. The present study will assess if the initial acceptability of the intervention is statistically associated with the application of mindfulness techniques during everyday life and stressful events at the end of the last session of the intervention.

While there is research to support the influence acceptability may have on intervention outcomes, there is dearth of information related to possible factors that may influence acceptability. By assessing the association between factors of acceptability and both intervention and participant characteristics, specific aspects of acceptability that are more challenging can be identified. These findings could lead to recommendations for

screening eligible participants and creating pre-treatment modules for clinical populations prior to starting interventions.

The present study is assessing initial acceptability, which was measured using the satisfaction survey collected following the second session and the formal and informal practice survey collected following the third session. Initial acceptability is important to assess because the participants first impression of the intervention may influence their ability to invest in the intervention and adapt the teachings. Research in the area of first impressions suggest that it is difficult for individuals to reevaluate initial impressions from negative to positive (Cone & Ferguson, 2015). This research is referring to first impressions of people due to the lack of research assessing first impression of an intervention, but first impression theories in general support this notion and may be translatable to intervention science. Therefore, it is important to establish a positive first impression of the intervention.

The aim of this study was to assess the predictors of acceptability of a 12-session mindfulness-based intervention (Moment-by-Moment in Women's Recovery, MMWR) designed for ethnoculturally diverse women in residential substance use disorder (SUD) treatment. Based on the theoretical framework of acceptability (Sekhon, et al., 2017) which discusses possible factors that may influence participant acceptability, we hypothesized that 1) time in treatment prior to the start of the intervention would be positively associated with acceptability (i.e., satisfaction, informal practice and formal practice), 2) trauma severity at baseline would be negatively associated with acceptability (i.e., satisfaction, informal practice and formal practice), 3) mindfulness predisposition at baseline would be positively associated with acceptability (i.e., satisfaction, informal

practice and formal practice), and 4) acceptability (i.e., satisfaction, informal practice and formal practice) would predict application of mindfulness techniques in daily life at the end of the intervention.

Methods

Participants

All participants were adult women admitted to the residential SUD treatment program study site and clinically diagnosed with SUD. The present study includes only participants randomized to the MMWR intervention condition. One hundred and fourteen women were allocated to the MMWR intervention, fourteen women were excluded for missing the first session. For the full consort diagram see Appendix G. Table 1 provides participant characteristic information. Not all variables in table 1 are used in the main analyses for the present study.

Table 1: Participants Descriptive Information (n=100)

Variable	Mean (SD)	N (%)
Age	32.38 (9.82)	
Race/Ethnicity		
Hispanic		60 (60.00%)
Non-Hispanic Black		18 (18.00%)
Non-Hispanic White		20 (20.00%)
Other		2 (2.00%)
Education (years)	11.67 (2.15)	
Living Situation (8 months prior to Tx)		
Homeless		25 (25.00%)
Non-stable		7
Institution		16
Own place		17
Someone else's		35
Mandated to Treatment		83
Religious Preference		
Christian		83
Other Religion		2
Other Beliefs		5
Atheist		10

Marital Status		
Married		6
Sep/Divorce/Widow		18
Never married		76
Craving	2.29 (1.70)	
Distress Tolerance	3.01 (1.21)	
Mental Health Diagnosis (#)		
1		9
2		74
3		14
Days from Tx entry to MMWR start	37.35 (15.86)	
Mindfulness Predisposition	76.96 (12.74)	
Trauma Severity		
Range	0 – 46	
Mean	16.23 (11.94)	
Number of Sessions Attended (of 12)	9.49 (3.20)	
Satisfaction	3.98 (0.72)	
Formal Practice	1.97 (1.06)	
Informal Practice	2.34 (1.24)	
Applied Mindfulness	43.66 (11.06)	

Recruitment, inclusion, exclusion criteria

The Inclusion Criteria were that the participant must be 1) a new patient at the study site, 2) female, 3) 18-65 years of age, 4) diagnosed with SUD, 5) fluent in English, and 6) agree to participate. The Exclusion Criteria were that the participant must not: 1) have an inability to understand or sign the informed consent, 2) have a cognitive impairment, 3) have any untreated psychotic disorder/severe mental health disorder, 4) be imprisoned, 5) have reported suicidality (past 30 days), or 6) be more than six months

pregnant. Screening assessments were conducted to determine eligibility prior to consent and in-person interviews. Further information was abstracted from clinic records and acceptability data were collected via self-administered surveys during intervention sessions. The parent study is a phase II parallel group Randomized Controlled Trial (2016 – 2019) (Amaro & Black, 2017; Black & Amaro, 2019).

Procedures

An onsite study coordinator identified female patients who meet study eligibility criteria using information from the residential treatment site's intake assessment. The study coordinator then confirmed eligibility and obtained permission from eligible patients to be contacted by the study interviewer, who made appointments with prospective participants, conducted the informed consent, and administered the baseline assessment (Amaro & Black, 2017). Participation in the study was completely voluntary.

Trained research staff members collected participant data during in-person interviews using a computer-assisted interview process and stored the date in Research Electronic Data Capture (REDCap). Additional information regarding procedures can be found in an article published by the principal investigators of the parent study, Amaro & Black, 2017. This study received Institution Review Board (IRB) approval from Arizona State University for secondary, de-identified data analyses (Appendix A).

Satisfaction data were collected at the end of session 2 and session 11 of 12 total sessions. Data from the session 2 timepoint were utilized for the present study analyses to assess initial satisfaction, which may differ from ending satisfaction due to the selection bias of only having data from those that made it to session 11. Formal and informal practice data were collected at the end of sessions 3, 6, 9, and 12 of 12 total sessions.

Data from the session 3 timepoint were utilized for the present study analyses to assess initial acceptability after early exposure to intervention techniques. This timepoint is of interest because individuals that adopt the teachings earlier may have more time during the intervention to practice and develop the skills. Mindfulness application data were collected at the end of sessions 3, 6, 9, and 12 of 12 total sessions. Data from the session 12 timepoint were utilized for the present study analyses to assess mindfulness application after MMWR completion.

Measurements

Some variables were included in Table 1, but were not included in the analyses. There variables are living situation eight months prior to entering treatment collected during the baseline interview, whether or not they were mandated to treatment which was collected during treatment intake and abstracted from clinical records, religious preference collected during baseline interview, marital status collected during baseline interview, craving collected during baseline interview and explained in greater detail below, distress tolerance collected during baseline interview and explained in great detail below, the number of mental health diagnosis collected during treatment intake and abstracted from clinical recorders including SUD which was an inclusion criteria, and the total number of sessions of MMWR they attended.

Craving: The Penn Alcohol Craving Scale (PACS; Flannery, Volpicelli, & Pettinati, 1999) is a five-item instrument collected at baseline to assess craving. Frequency, intensity, and duration of thoughts about drinking and other drugs are assessed along with ability to resist drinking and other drugs. The final item asks the responder to provide an average rating of his/her craving over the course of the past

week. The questions on the PACS use descriptors coupled with numerical ratings ranging from "0 = Never" to "6 = Nearly all of the time." The reliability and validity of this scale has been supported through prior studies (Flannery, Allen, Pettinati, Rohsenow, Cisler, & Litten, 2002; Flannery, Roberts, Cooney, Swift, Anton, & Rohsenow, 2001; Flannery, Volpicelli, & Pettinati, 1999; Monterosso, Flannery, Pettinati, Oslin, Rukstalis, O'Brien, & Volpicelli, 2001).

Distress Tolerance: The Distress Tolerance Scale (DTS; Simons & Gaher, 2005) is a 16-item scale, collected at baseline to assess general emotional distress tolerance. The scale has four subscales (tolerance, absorption, appraisal, and regulation) rated on a scale from "1= strongly agree" to "5 = strongly disagree," with higher scores indicating greater distress tolerance. This scale has demonstrated validity and reliability in previous samples (Simons & Gaher, 2005). The value in table one represents the average score among this sample.

For more information regarding the variables tested in the analyses, see the measurement concept table (Appendix H). The following variables were included in the analyses for the present study.

Demographics: The demographic information of age, race/ethnicity, and education were collected at the baseline interview and presented in table 1. Age was measured continuously as the number of years old the participant was at the time of the baseline interview. Race/Ethnicity was categorized as 1) Non-Hispanic White, 2) Non-Hispanic Black, 3) Hispanic, or 4) other. Education was measured continuously at the number of years of formal education, 12 representing high school diploma or GED.

Time in Treatment Prior to Intervention: This score was calculated by counting the number of days between when the participant entered the residential program and when they started the MMWR. This is a one-item score. Values range from 5 – 74 days, with a mean of 37.35. Approximately 80% of the sample had been in treatment at least 3 weeks prior to starting MMWR.

Mindfulness Predisposition: The Five Factor Mindfulness Questionnaire (FFMQ) was collected at baseline to assess five mindfulness facets (observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience) and has demonstrated validity (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006). Internal consistency with individuals' transitioning out of intensive SUD treatment is .91, with subscale alphas ranging from .80 to .87 (Bowen, Chawla, Collins, et al., 2009).

Trauma Severity: The PTSD Symptom Scale – Self Report (PSS-SR) was collected at baseline to assess PTSD symptoms according to DSM-IV. Reliability and validity have been shown for assessing PTSD symptoms experienced by the participant within the last two weeks and one month (Foa, Hembree, Cahill, et al., 2005). There are 17 items, rated on a dimension ranging from 0 (Not at all) to 3 (Almost always). This scale measures frequency of reexperiencing, avoidance, and arousal symptoms related to trauma exposure in the past 30 days. Four symptom cluster ratings can be established a) Re-experiencing (questions 1-5), b) Avoidance (questions 6-12), c) Arousal (questions 13-17), and d) Total PTSD severity (questions 1-17).

Satisfaction Survey: The satisfaction survey consisted of 17-items rated from "1 = Not at all" to "5 = Very much" (high scores indicate higher satisfaction) were used to

assess various aspects of satisfaction: session content, skills learned, perceived usefulness, and importance for recovery. This survey was developed over time through multiple MBI trials by Hortensia Amaro, the current version of the participant satisfaction survey was designed to match the MMWR curriculum. Chapter 3 is the first study to assess the psychometric properties of this survey. For the current sample the Cronbach's alpha was $\alpha = .95$.

Formal Practice Survey: The formal practice survey consisted of 6 items, rated on a dimension from "0 = Never" to "5 = 4 or more times a day" which assesses frequency of use of specific types of formal mindfulness practices (e. g., sitting and walking meditation, love and kindness mediation, and mindful stretching) since the previous class session. This survey was developed over time through multiple MBI trials by Hortensia Amaro, the current version of the practice survey was designed to match the MMWR curriculum. Chapter 3 is the first study to assess the psychometric properties of this survey. For the current sample the Cronbach's alpha was $\alpha = .80$.

Informal Practice Survey: The informal practice survey consisted of 8 items, rated on a dimension from "0 = Never" to "5 = 4 or more times a day", assesses frequency of use of specific types of informal mindfulness practices (e. g., awareness of emotions, thoughts, body sensations, and cravings) since the previous class session. This survey was developed over time through multiple MBI trials by Hortensia Amaro, the current version of the practice survey was designed to match the MMWR curriculum. Chapter 3 is the first study to assess the psychometric properties of this survey. For the current sample the Cronbach's alpha was $\alpha = .92$.

Mindfulness Application: Applied Mindfulness Practice Scale (AMPS) has 15 items, ranging from "0 = never" to "4 = almost always" that assess the application of mindfulness and processes of change in the context of MBIs and general application of mindfulness practice in the last 7 days when facing challenges in daily life (e g., *I used mindfulness practice to stop reacting to my negative impulses*). AMPS has been validated for use with adults undertaking mindfulness-based interventions (Li, Black & Garland, 2016). For the current sample the Cronbach's alpha was $\alpha = .97$.

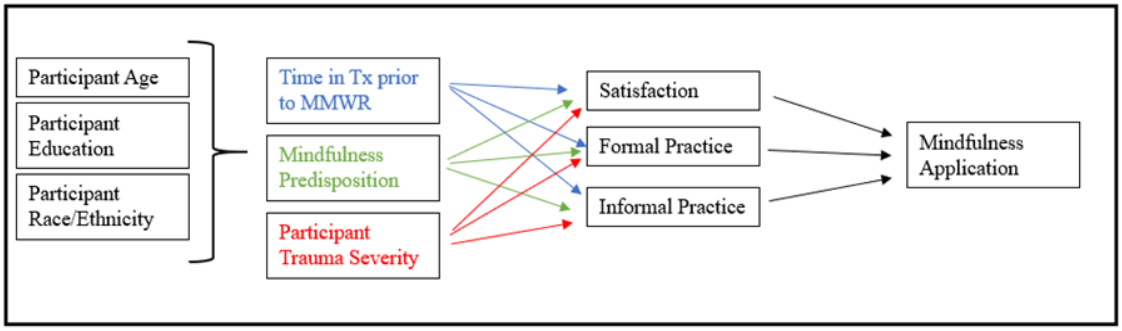
Moment-by-Moment: In Women's Recovery (MMWR)

MMWR was delivered twice weekly for 80 minutes each session for a total of 12 group sessions over six weeks. The intervention took place during the participants residential treatment. The MMWR teachers who were trained in both MBSR and MMWR facilitated the session with an on-site master's-level clinician with experience in SUDs. The teachers were guided by an instructional manual with standardized lesson plans (Amaro & Black, 2017; Black & Amaro, 2019).

Each class session was divided into five segments: 1) welcome, review of group culture, brief homework practice check-in, objectives, brief mindfulness meditation or practice; 2) didactic psychoeducational presentation and discussion of lesson content; 3) experiential meditation and mindfulness practices related to the session's themes; 4) practice of sitting or walking meditation, body scan, or standing stretching; and 5) selected reading related to session topic, assignments for the next class, and closing meditation. Details about each session can be found in Appendix C. Participants were given MP3 players with the guided meditation pre-loaded onto the devise, they were asked to practice the meditations between sessions.

MMWR teaches skills that prepares the participants to approach experiences and stressors using mindfulness principles. The participants learned about the role of automatic reactivity to stressors and its relation to addiction and relapse. The teachers discuss the connections between stress, triggers, and relapse; and how to use mindfulness practices to respond best to related thoughts, emotions, body sensations including those related to stress in a residential treatment setting and experiencing triggers while still avoiding relapse (Amaro & Black, 2017).

Figure 1: Hypothesized Model of relationships between variables



Data Analysis Plan

A series of multivariate linear regression models were conducted to test hypothesis 1 – 3 to estimate the predictive validity of days in treatment prior to the start of MMWR, baseline mindfulness predisposition, and baseline trauma severity on the dependent variables of early intervention satisfaction, early uptake of formal practice and informal practice, respectively. Additionally, a separate regression model was used to assess indicators of acceptability early in the intervention sessions (i.e., satisfaction, formal practice, and informal practice) as predictors of subsequent mindfulness application after completion of the last intervention session. The Model R^2, predictor-specific variance inflation factor (VIF) values, and variable coefficients were examined in

each model. The available complete-case sample size after case wise deletion for missing data afforded for power > .80 to detect moderate effect sizes for change in R^2 ($f^2 = .13$) and for regression coefficients.

An unexpected suppressor effect was found in the regression models with formal and informal practice as dependent variables. To further investigate this suppressor effect, additional correlation and regression analyses were conducted with the subscales related to mindfulness predisposition and trauma severity.

Results

Correlation

Table 2 Pearson correlation between personal characteristics and measures of acceptability

Measurement	1	2	3	4	5	6	7	8	Mean	SD
1. Age	—								32.38	9.82
2. Education	-.00	—							11.67	2.15
3. Days pre Int	.03	.10	—						37.35	15.90
4. MF Predisp	-.02	.13	.16	—					79.96	12.74
5. PTS	-.02	.01	-.19	**-.31****	—				16.23	11.94
6. Satisfaction	.06	-.09	.18	.05	-.17	—			3.98	0.72
7. F. Practice	**.25***	.14	.13	.12	.14	**.25***	—		1.97	1.06
8. I. Practice	.05	**.22***	.17	**.22***	.12	**.23***	**.68*****	—	2.34	1.24
9. Applied MF	.04	-.01	.03	**.25***	-.13	**.26***	.22	**.26***	43.66	11.06

* $p \leq .05$ (2-tailed) ** $p < .01$ (2-tailed) *** $p < .001$ (2-tailed)

Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity, the data were within range and the planned analyses were robust enough for data analysis. The bivariate relationships between 1) age (at the time of baseline assessment), 2) education (as measured by the number of years of education completed), 3) days in treatment prior to the start of the intervention (as measured by the number of days between treatment entry and intervention start), 4) mindfulness predisposition (as measured by the FFMQ), 5) post-traumatic stress (as measured by the PSS-SR), 6) formal practice (as measured by formal practice subscale of

the practice survey), 7) informal practice (as measured by informal practice subscale of the practice survey), 8) satisfaction (as measured by the satisfaction survey), and 9) application of intervention technique (as measured by the AMPS) were investigated using Pearson product-moment correlation.

Worth noting, there was a significant moderate, positive correlation between age and formal practice, $r = .25$, $n = 82$, $p = .02$, the older the woman was, the more formal practice she reported. This suggests that age should be included as a covariate in the regression model with formal practice as the dependent variable. The significant small positive correlation between education and informal practice, $r = .22$, $n= 82$, $p = .05$ indicates that women with more years of education reported more informal practice, suggesting education should be included as a covariate in the regression model with informal practice as the dependent variable.

The significant moderate, negative correlation between mindfulness predisposition and trauma severity, $r = –.31$, $n = 100$, $p = .002$, suggests that participants with high levels of mindfulness predisposition reported lower levels of trauma severity at the baseline data collection. The significant small, positive correlation between mindfulness predisposition and informal practice, $r = .22$, $n = 82$, $p = .045$ supports the hypothesis that women with higher mindfulness predisposition prior to starting the intervention would report high frequency of use of mindfulness practices. Hypothesis 4 was partially supported by the significant small-to-moderate positive correlations between informal practice and applied practice, $r = .26$, $n = 61$, $p = .04$, and between satisfaction and applied practice, $r = .26$, $n = 64$, $p = .04$. Formal practice and applied mindfulness were not significantly correlated, $r = .22$, $n = 61$, $p = .09$.

ANOVA for Race/Ethnic difference

Table 3: Descriptive statistics by Race/Ethnicity

						95% CI for Mean			
	Race/Ethnicity	**N**	**Mean**	**Std Dev**	**Std Error**	**Lower**	**Upper**	**Min**	**Max**
Satisfaction									
	Non-Hispanic White	19	3.75	0.81	0.19	3.35	4.14	1.82	4.76
	Non-Hispanic Black	16	4.34	0.47	0.12	4.09	4.59	3.12	5.00
	Hispanic	53	3.95	0.73	0.10	3.75	4.15	2.06	5.00
	Other	2	4.32	0.37	0.26	0.96	7.69	4.06	4.59
	Total	90	3.98	0.72	0.08	3.83	4.14	1.82	5.00
Formal Practice									
	Non-Hispanic White	16	1.90	0.82	0.20	1.47	2.34	0.83	3.60
	Non-Hispanic Black	14	2.46	1.17	0.31	1.79	3.14	0.17	4.50
	Hispanic	50	1.86	1.09	0.15	1.55	2.17	0.00	4.83
	Other	2	1.75	0.82	0.58	-5.66	9.16	1.17	2.33
	Total	82	1.97	1.06	0.12	1.74	2.20	0.00	4.83
Informal Practice									
	Non-Hispanic White	16	2.46	1.14	0.28	1.86	3.07	0.43	4.57
	Non-Hispanic Black	14	2.68	1.33	0.36	1.92	3.45	0.00	4.43
	Hispanic	50	2.18	1.26	0.18	1.82	2.54	0.00	5.00
	Other	2	3.07	0.71	0.50	-3.28	9.43	2.57	3.57
	Total	82	2.34	1.24	0.14	2.07	2.62	0.00	5.00
Mindfulness Application									
	Non-Hispanic White	16	41.44	9.04	2.26	36.62	46.25	15.00	57.00
	Non-Hispanic Black	10	40.80	12.90	4.08	31.57	50.03	26.00	60.00
	Hispanic	42	45.21	11.53	1.78	41.62	48.81	7.00	60.00
	Other	2	43.00	1.41	1.00	30.29	55.71	42.00	44.00
	Total	70	43.66	11.06	1.32	41.02	46.29	7.00	60.00

Table 3 shows the mean estimates for each outcome variable by race/ethnic group with the standard deviations and standard errors. A preliminary review of these values shows similar estimates across race/ethnic groups. To assess whether the differences are statistically significant, a one-way analysis of variance was performed.

One-way Analysis of Variance (ANOVA)

Table 4: ANOVA for differences between groups

		Sum of Squares	df	Mean Squares	F	Sig.
Satisfaction						
	Between Within Total	3.39 43.11 46.50	3 86 89	1.13 0.50	2.26	.09
Formal Practice						
	Between Within Total	4.18 88.68 90.86	3 78 81	1.40 1.11	1.26	.30
Informal Practice						
	Between Within Total	4.26 120.99 125.25	3 78 81	1.42 1.55	0.92	.44
Mindfulness Application						
	Between Within Total	263.16 8176.61 8439.77	3 66 69	87.72 123.89	0.71	.55

A one-way between-groups analysis of variance was conducted to explore the impact of race/ethnicity on levels of each acceptability variable. Participants were divided into four groups according to their race/ethnicity (Group 1: Non-Hispanic White; Group 2: Non-Hispanic Black; Group 3: Hispanic; Group 4: Other). There were no statistically significant differences at the $p < .05$ level in satisfaction scores for the four race/ethnic groups: $F (3, 86) = 2.26$, $p = .09$. There were no statistically significant differences at the $p < .05$ level in formal practice scores for the four race/ethnic groups: $F (3, 78) = 1.26$, $p = .30$. There were no statistically significant differences at the $p < .05$ level in informal practice scores for the four race/ethnic groups: $F (3, 78) = 0.92$, $p = .44$.

There were no statistically significant differences at the $p < .05$ level in mindfulness application scores for the four race/ethnic groups: $F (3, 66) = 0.71$, $p = .55$.

Due to the race/ethnic differences by satisfaction scores approaching significance at $p = .09$, Post-hoc comparisons using the Bonferroni test were conducted to future explore the possibility of group differences. Results of the post-hoc comparisons indicated that the greatest mean difference was between group 1 and group 2 (mean difference = 0.59, std error = .24), but the mean score for Group 1 ($M = 3.75$, $SD = 0.81$) was not significantly different from Group 2 ($M = 4.34$, $SD = 0.47$). There were no statistically significant differences between any combination of the groups. Therefore, the race/ethnicity variable was not included as a covariate in the regression models.

Regression

Table 5: Simultaneous regression analysis for predictors of Satisfaction at Session 2

Predictor	**R^2**	**F**	**DF**	**β**	**t**	***p***	**95% CI**
Model summary	.05	1.46	(3, 86)			.23	
Days in treatment prior to intervention start				.15	1.38	.17	-.00, .02
Mindfulness Predisposition				-.03	-.23	.82	-.01, .01
Trauma Severity				-.14	-1.23	.22	-.02, 01

To further test the associations between variables of interest, four regression models were conducted. There were no issues with multicollinearity, all variance inflation factors (VIF) were under two. The first regression model included mindfulness predisposition, days in treatment prior to the start of the intervention, and trauma severity as independent variables. This model explained 5% of the variance in satisfaction at session 2, but was not significant overall, $R^2 = .05$, $F (3, 86) = 1.46$, $p = .23$. None of the three independent variables provided significant unique contribution.

Table 6: Simultaneous regression analysis for predictors of Formal Practice at Session 3

Predictor	R^2	F	DF	β	t	*p*	95% CI
Model summary	**.14**	**3.05**	**(4, 77)**			**.02**	
Age at baseline				**.27**	**2.45**	**.02**	.01, .05
Days in treatment prior to intervention start				.11	.98	.33	-.01, .02
Mindfulness Predisposition				.18	1.55	.13	-.01, .03
Trauma Severity				**.25**	**2.15**	**.03**	.00, .04

The second model, which included age, days in treatment prior to the start of the intervention, mindfulness predisposition, and trauma severity explained 14% of the variance in formal practice at session 3, $R^2 = .14$, $F(4, 77) = 3.05$, $p = .02$. Of the covariate and the three independent variables, age ($\beta = .27$, $p = .02$) and trauma severity were both statistically significant ($\beta = .25$, $p = .03$). The beta coefficient is interpreted by the following formula: for everyone one standard unit increase in age, formal practice increases by .27 standard units. For every one standard unit increase in trauma severity, formal practice increased by .25 standard units.

Table 7: Simultaneous regression analysis for predictors of Informal Practice at Session 3

Predictor	R^2	F	DF	β	t	*p*	95% CI
Model summary	**.14**	**3.12**	**(4, 77)**			**.02**	
Years of Education				.16	1.52	.13	-.03, .21
Days in treatment prior to intervention start				.14	1.23	.22	-.01, .03
Mindfulness Predisposition				**.24**	**2.08**	**.04**	.00, .04
Trauma Severity				**.23**	**1.99**	**.05**	.00, .05

The third model included education as a covariate and days in treatment prior to the start of the intervention, mindfulness predisposition, and trauma severity as independent variables. This model explained 14% of the variance in informal practice at

session 3, R^2 = 14, F (4, 77) = 3.12, *p* = .02. Of the covariate and the three independent variables, mindfulness predisposition (β = .24, p = .04) and trauma severity (β = .23, p = .05) both were statistically significant. For everyone one standard unit increase in mindfulness predisposition, informal practice increases by .24 standard units. For every one standard unit increase in trauma severity, informal practice increased by .23 standard units.

Table 8: Simultaneous regression analysis for predictors of Mindfulness Application at Session 12

Predictor	**R^2**	**F**	**DF**	**β**	**t**	***p***	**95% CI**
Model summary	**.20**	**2.24**	**(6, 53)**			**.05**	
Days in treatment prior to intervention start				-.02	-.13	.90	-.18, .16
Mindfulness Predisposition				.21	1.52	.14	-.05, .36
Trauma Severity				.02	.10	.92	-.23, .26
Satisfaction				**.33**	**2.36**	**.02**	.76, 9.41
Formal Practice				.00	.02	.98	-3.28, 3.36
Informal Practice				.21	1.26	.21	-1.11, 4.86

The last model included days in treatment prior to the start of the intervention, mindfulness predisposition, and trauma severity as independent variables the same as the previous models, additionally included were the three acceptability variables; satisfaction, formal practice, and informal practice. This model explained 20% of the variance in mindfulness application at session 12, R^2 = .20, F (6, 53) = 2.24, p = .05. Satisfaction (β = .33, *p* = .02) was statistically significant.

Suppressor effect additional analyses

Trauma severity was identified as a possible suppressor variable in the models with formal practice and informal practice as dependent variables, not in the model with satisfaction or applied mindfulness as dependent variables. The models show a classical

suppression in which the suppressor (trauma severity) is uncorrelated to the criterion (formal and informal practice), but is positively related to another predictor (mindfulness predisposition), and the inclusion of both predictors (trauma severity and mindfulness predisposition) in the model increased the predictive power of both predictors (Cohen & Cohen, 1975; Watson, Clark, Chmielewski & Kotov, 2013). First, to test this, additional regression models were conducted with each predictor independently. As seen in table 9, when trauma severity is not a predictor, mindfulness predisposition is not significant and table 10 shows that when mindfulness predisposition is not in the model, trauma severity is not significant.

Table 9: Simultaneous regression analysis for predictors of Informal Practice at Session 3 without trauma severity

Predictor	**R^2**	**F**	**DF**	**β**	**t**	***p***	**95% CI**
Model summary	**.31**	**2.73**	**(3, 78)**			**.05**	
Years of Education				.18	1.67	.10	-.02, .22
Days in treatment prior to intervention start				.10	.88	.38	-.01, .03
Mindfulness Predisposition				**.**17	1.55	**.**13	-.01, .04

Table 10: Simultaneous regression analysis for predictors of Informal Practice at Session 3 without mindfulness predisposition

Predictor	**R^2**	**F**	**DF**	**β**	**t**	***p***	**95% CI**
Model summary	.30	2.60	(3, 78)			.06	
Years of Education				.19	1.71	.09	-.02, .23
Days in treatment prior to intervention start				.18	1.63	.11	-.00, .03
Trauma Severity				.16	1.43	.16	-.01, .04

To further test if trauma severity was a suppressor variable, the subscales of the mindfulness predisposition scale and the trauma severity scale were assessed individually for correlated with the dependent variables. If trauma severity was a suppressor all of the

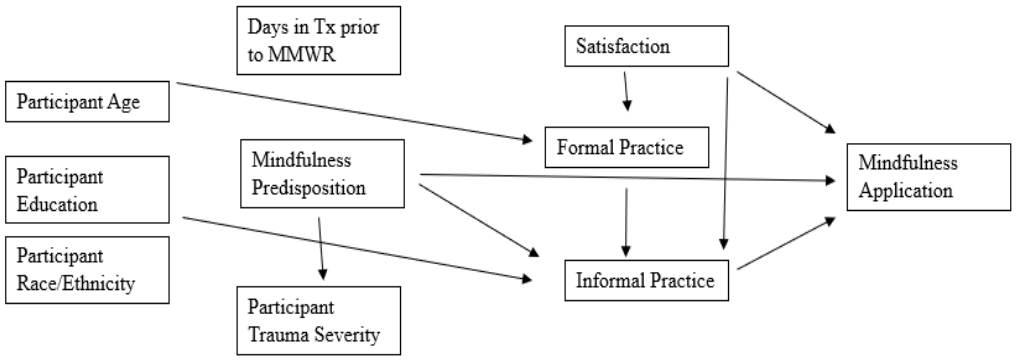
subscales would also be uncorrelated with the dependent variables, but the re-experiencing subscale was significantly positively correlated with formal practice (r =. 22, p =.05) and informal practice (r =.20, p =.07). Therefore, it can be concluded that trauma severity is not a suppressor effect, but there is a third-variable interaction between trauma severity, mindfulness predisposition and formal and informal practice. That is, higher re-experiencing scores were positively correlated with more formal and informal practice. This relationship may suggest that women with high re-experiencing scores at baseline could be using formal and informal practices to manage the re-experiencing symptoms following the third session.

Discussion

Summary of findings

There were many significant bivariate correlations found between the variables of interests, as shown in figure 2. This diagram depicts individual relationships and was not tested as a cohesive path model control for all other variables. There may be indirect relationships that were not tested through the correlation and regression models alone. For example, there may be an indirect relationship from education to mindfulness application through informal practice, but we are only able to test these relationships individually.

Figure 2: Diagram of significant correlations between variables



Personal characteristics such as trauma severity, mindfulness predisposition, and days in treatment prior to starting MMWR did not significantly predict participant satisfaction with the intervention. Trauma severity and mindfulness predisposition significantly predicted informal practice while trauma severity and age predicted formal practice. Satisfaction was the only significant predictor of application of intervention techniques. While some of the variables did not reach statistical significance, the relationships were trending in the hypothesized direction and may represent a small effect undetectable with the available data and sample size, but may warrant further investigation.

It was hypothesized that days in treatment prior to starting the intervention would be positively associated with formal practice, informal practice, and satisfaction. The findings showed that days in treatment prior to starting the intervention was not a significant predictor in any of the regression models. This may be something to consider with a larger sample size and more refined measurement. It is important to note that the variable of time in treatment prior to starting MMWR ranged from five days to seventy-four days, with the average being a little over a one month (37.35 days). Only 21% of the

sample had been in treatment for three weeks or less. Therefore, the majority of the sample was likely already adjusted to the treatment facility when starting the MMWR program and do not represent the full range of patients in the facility. It may be possible that there is no relationship between these variables, which would suggest that the MMWR intervention could be delivered in the early stages of treatment without reducing the acceptability of the intervention, notwithstanding the other reasons for timing the delivery of the intervention.

The second hypothesis focused on the relationship between mindfulness predisposition and formal practice, informal practice, and satisfaction. There was a positive significant relationship between mindfulness predisposition and informal practice, partially supporting the hypothesis. This suggests that individuals with more mindfulness predisposition at the baseline had greater uptake of informal mindfulness practice by the end of session three. While mindfulness predisposition is sometimes thought of as a steady trait, it can also be thought of as malleable with greater exposure (Kiken, Garland, Bluth, Palsson, & Gaylord, 2015). When thought of as the latter, our results may suggest creating a pre-intervention exposure to mindfulness which could help increase the familiarity and possibly the uptake of informal practice. MBSR has an orientation session prior the start of the intervention which includes:

> *"Familiarizing potential participants with what MBSR is and is not, providing participants with an experience of mindfulness in an atmosphere of trust and non-judgmental awareness and exchange, educating participants about program procedures, assessing how participants interact in the group setting to determine whether the program is a good match, meeting with each*

participant individually for a brief screening interview, eliciting a commitment from participants to engage in active participation in the program, which includes weekly class attendance and a minimum of 45 minutes to one hour of formal home practice as well as informal practice throughout the day." (Santorelli, Kabat-Zinn, Blacker, Meleo-Meyer, & Koerbel, 2017).

Another suggestion could be to extend the intervention for individuals with low mindfulness predisposition either by adding more sessions at the start or at the end of the 12-session intervention.

Hypothesis 3 examined the associations between trauma severity and satisfaction formal practice, and informal practice. Trauma severity was not a significant predictor of satisfaction, but it was a significant predictor for formal and informal practice. Despite not having a significant correlation with the outcome variables, trauma was still a significant predictor in the regression models. This may be due to an interaction with mindfulness predisposition. Trauma severity was a positive predictor indicating that those with higher trauma severity reported more frequent practice. It is also important to note that this finding is specific to MMWR and likely due to the intervention design specifically adapted to address the role of trauma in the recovery process. This finding may not be generalizable to other MBIs for SUD if they are not adapted to be trauma-informed.

The final hypothesis examined the relationship between all the aforementioned variables with applied mindfulness at the end of the intervention. There were multiple significant positive correlations, including mindfulness predisposition, informal practice, and satisfaction with a marginally significant relationship with formal practice. The only

significant variable in the regression model was satisfaction, which indicates that satisfaction is the greatest predictor of applied mindfulness. The best way to increase application, would be to increase satisfaction.

Strengths and Limitations

MMWR was designed for ethnoculturally diverse women and the analyses found no significant differences between racial/ethnic groups on any of the variables of interest, which supports the design. Although, the uneven group sizes and large (60%) proportion of Hispanic/Latina (20% non-Hispanic White and 18% non-Hispanic Black) in the sample makes it difficult to fully assess the possibility of race/ethnic group differences. A previous study examined how racial/ethnic group composition for an MBI for SUD influenced relapse. When the participant race/ethnicity status matched that of the majority of the group, the mindfulness-based treatment condition resulted in fewer relapse days than the traditional relapse prevention (without mindfulness) treatment condition (Greenfield, Roos, Hagler, Stein, Bowen, & Witkiewitz, 2018). It is possible that this effect may be explained by higher acceptability among those who feel more comfortable in an intervention with individuals they identify with as a race/ethnic group. Future studies may assess the role of acceptability among race/ethnic majority and minorities within group setting interventions. Another limitation may be the measurement point for satisfaction at session 2 and practice at session 3. While this may create the limitation of lack of exposure to full intervention, it was intentional to assess initial acceptability due to the lack of prior studies that include an early measure of acceptability and first impressions of the intervention.

As mentioned previously, there may be third-variable interaction effects present, and with a larger sample size we could test for those effects. It may be possible the women with higher trauma reported greater frequency of practice, but that relationship depends on their mindfulness predisposition. In other words, mindfulness predisposition strengthened the relationship between trauma severity, specially re-experiencing severity, and practice frequency. This model could be tested in future studies, if the moderation effect exists in the present data, it is too small to detect with the sample size. This result may indicate that although mindfulness may be difficult for those re-experiencing trauma, it may also be useful for managing or coping with these symptoms.

Implications and Future Directions

Prior research has supported the notion of tailoring interventions to fit specific populations (Bernal, Jimenez-Chafey, & Domenech-Rodriguez, 2009; Castro, Barrera,& Martinez, 2004). The present study identifies specific factors that may influence initial participant satisfaction and uptake of intervention practice within the first three (of twelve) intervention sessions, which are key elements for intervention efficacy (Proctor, 2011). Future studies should seek to find better predictors of satisfaction as it was the greatest predictor of participant application of intervention techniques.

Although not specifically assessed in prior research studies, it is possible that other factors may influence early acceptability. Factors such as optimism towards recovery and intervention efficacy, craving for substances, depression or other mental distress, and spirituality have previously been assessed as outcome measures within MBIs for SUD (Li, Howard, Garland, McGovern, & Lazar, 2017), but these variables may also influence early acceptability of the intervention or acceptability may be a mediating

variable to help explain the increase from pre to post among some of these variables. In addition to the variables of satisfaction and frequency of practice, intervention engagement and quality of mindfulness practice may be factors of acceptability worth exploring in future studies.

Conclusions

Some participant characteristics may influence a participant's ability to accept and adopt intervention teachings and practices early in the intervention delivery. Identifying those characteristics and adapting the intervention to respond to them could improve early intervention acceptability with the long-term goal of improving intervention acceptability for vulnerable populations at high risk for treatment dropout.

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CHAPTER 5

DISCUSSION

Summary of findings

This dissertation assessed acceptability of MMWR, a mindfulness-based intervention (MBI) for women in recovery for substance use disorder (SUD). Chapter 2 reviewed how acceptability has been measured previously across MBI for SUD studies. The findings from chapter 2 highlighted the current lack of consistency in acceptability theoretical, conceptual, and operational definitions which creates an obstacle for systematically reviewing acceptability across studies. Chapter 2 concluded with the suggestion of creating standardized assessments of acceptability of MBIs for SUD.

Since chapter 2 was published in early 2019, additional MBI for SUD studies have been published. Studies such as Roos et al. (2019) concluded acceptability of an MBRP called Rolling MBRP based on the mean score of an item that assessed participant perceived helpfulness and frequency of mindfulness practice. Garland et al. (2019) did not mention acceptability of the mindfulness-oriented recovery enhancement (MORE) intervention. It would be helpful for authors to reference their previous articles where the intervention acceptability data is reported.

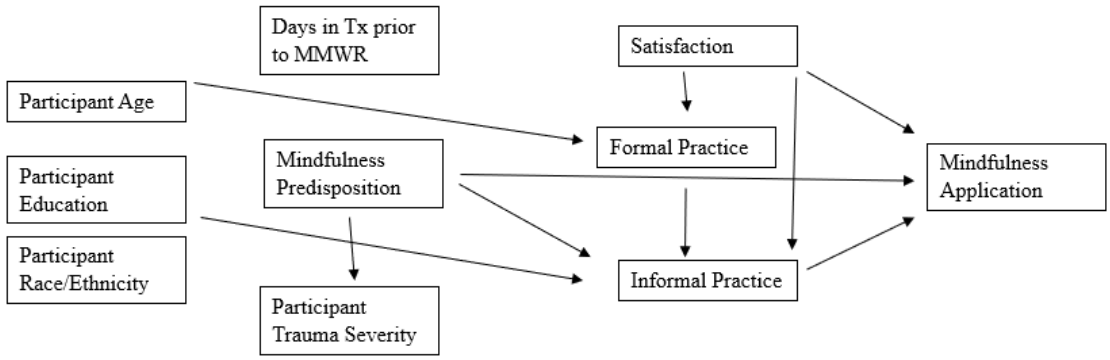
An article that was left out of chapter 2, but warrants mention is Garland et al. (2012). This study examined acceptability of mindfulness-oriented recovery enhancement (MORE) for socioeconomically disadvantaged individuals and found that participants enjoyed the intervention, were engaged, and perceived benefits from their participation. The present study found similar findings among a comparable sample of low-income, low-literacy, racial diverse women. The satisfaction survey used in the present study also

assessed enjoyment and perceived benefits, while the practice survey assessed engagement with the intervention.

Chapter 3 assessed the psychometric properties of two acceptability surveys; the practice survey and the satisfaction survey. These two surveys were used to collect information from 100 participants in the MMWR intervention. The findings suggest alterations of some of the items and retesting the instruments for an optimal balance between comprehensive assessment of acceptability and reduction in possible participant fatigue. The results from the content validity test identified seven items that could be removed from the satisfaction survey and seven items from the practice survey without losing any necessary information. The results of the factor analyses suggested that the practice survey should be divided into two subscales; formal and informal practice. The factor analysis identified two items that could be removed, due to not fitting within the construct or formal or informal practice based on the patterns of participant responses. The factor analysis for the satisfaction survey found a 1-factor construct with all 17 items group together as a cohesive assessment of the construct.

Future research should assess the possibility of creating a composite acceptability score to combine the practice and satisfaction assessments in a logical and meaningful way to improve interpretation of the full acceptability construct.

Figure 1: Resulting model



Chapter 4 used the surveys tested in chapter 3 to look at associations between the participant characteristics of trauma severity, time in treatment prior to starting the intervention, and mindfulness predisposition. The results from the correlation analyses can be seen as depicted in Figure 1. As noted previously, these results do not reflect indirect relationships and may be more accurately assessed using a path model analysis with a larger sample size. Findings indicated multiple relationships between variables of interest, including a relationship between age and formal practice, suggesting that the older a woman was the more formal practice she engaged in after the third session. Days in treatment prior to starting the intervention was only marginally related to satisfaction with a non-significant p-value, which may indicate that MMWR could be introduced earlier into the treatment process without detrimental effects to the participant acceptability. An interesting finding, not previously hypothesized, was that mindfulness predisposition had a significant moderate negative relationship with trauma severity, suggesting that at baseline, women with higher mindfulness predisposition had lower trauma severity. This fits with the literature that having a mindfulness outlook can help individuals cope with their trauma (Follette, Palm, & Pearson, 2006). Counter to prior

literature and our hypothesis, trauma severity was a positive predictor of formal and informal practice, suggesting that those with higher trauma severity at the baseline assessment reported greater practice by the end of session three. This supports the intervention design of being trauma-informed and adapted specifically to accommodate women with a history of trauma.

Support from prior theory

The findings from the previous study build upon the work of Sekhon, et al. (2017) which developed the theoretical framework of acceptability (TFA) and Proctor, et al. (2011) which established a heuristic working taxonomy to distinguish acceptability from other implementation terms such as feasibility and fidelity. Our finding of mindfulness predisposition positively influencing informal practice is consistent with TFA which theorized that intervention coherence, defined as "the extent to which the participant understands the intervention, and how the intervention works" (Sekhon et al, 2017, pg. 9), is a critical antecedent to acceptability of an intervention. Combining these pieces of support we can recommend that MBIs for SUD hold a pre-intervention introductory session to explain how mindfulness works to improve SUD recovery and relapse prevention. Chapter 2 (Manuscript 1) provided future support for the work of Proctor and colleagues (2011) and the need to operationally differentiate acceptability and feasibility.

Relationship between chapters

The common link between chapters 2, 3, and 4 is the tie to intervention acceptability. Chapter 2 identified the gap in current literature, chapter 3 testing the acceptability instruments, and chapter 4 used the instruments to produce in-depth information related to the acceptability of MMWR for the participants. These three

chapters together present a complete picture of the importance of acceptability assessment and the rigor of that assessment.

Strengths and Limitations

This is the first study to assess acceptability of an MBI for SUD at an in-depth level. There is well-established gap in the literature regarding systematic assessment of valid and reliable measures for acceptability across not only MBI for SUD studies but all health behavioral interventions (Bautista, et al., 2019; Sekhon, et al. 2017).

Implications

SUD is an issue that affects over 20 million Americans (SAMHSA, 2014). Less that 1% of those with a SUD received treatment and only a small portion of those that receive treatment complete treatment with satisfactory progress towards recovery (SAMHSA, 2014). Even among those that complete treatment, 40-60% relapse within one-year post-treatment (McLellan, Lewis, O'Brien, & Kleber, 2000; McLellan, McKay, Forman, Cacciola, & Kemp, 2005). Therefore, it is critical that we have efficacious relapse prevention programs that are acceptable to those that participate. Small adaptations can be made to MBIs for SUD that could improve participant satisfaction with the intervention, which could then increase the participants' retention and adaption of relapse prevention knowledge and skills.

As the field ventures into the third wave of cognitive behavioral therapies for substance use disorder, it is important to acknowledge how acceptability plays a role in the adoption and implementation of efficacious interventions. The present study provides a road map for other MBIs for SUD to test acceptability of their interventions, including a

detailed assessment of their measurement tools and what factors are influencing acceptability among the participants.

Findings from this line of research have the potential to influence evidence-based adaptation to MBI for SUD interventions. Evidence-based interventions are not one-size-fits all, and it can be difficult to personalize interventions to fit everyone. Identifying participant characteristics that influence initial acceptability of the intervention can inform precise adaptation designed for specific subgroups. There is currently a plethora of literature to discuss cultural adaptations based on theoretical understandings of cultural influence and fit (Castro et al., 2004), yet there is very little empirical data to support evidence-based adaptations based on other participant characteristics.

Future Directions

Future research should examine the beneficial information that may be collected via qualitative interviews with participants and facilitators. Garland et al. (2012) provides a great example of how qualitative data can build upon the existing quantitative evidence to provide a more nuanced explanation of the process by which participants adopt the intervention techniques and apply them to their everyday life throughout treatment and recovery. Qualitative data could also be collected from the content validity raters for suggestions to edit the items to improve the data collection of acceptability information.

While self-report acceptability from the participant perspective is the most common, Sekhon et al. (2017) recommends collecting information on acceptability from the facilitators' perspectives. If an intervention has low facilitator acceptability, the facilitator may be altering the intervention, which could lead to low fidelity and potentially lower efficacy. Another area for future research is to examine acceptability

longitudinally throughout the intervention, from perceived acceptability prior to the intervention to during the intervention and following up after the intervention is over to assess long-term adaption of the intervention teachings. The present study assessed initial acceptability, while most study assess post-intervention acceptability. A combination of both may provide additional benefits.

Additionally, the field would benefit from standardized measures of acceptability with built-in adaptation suggestions to make the measures specific to the intervention and participants. For studies that use an active control, there is benefit to assessing the acceptability of the active control condition in addition to the intervention group. MMWR active educational control condition assessed the participants' satisfaction which could be compared to the MMWR satisfaction, but the educational control group did not receive practice assignments and therefore lacked similar intervention components for comparison. There is a need for the development of a framework to identify the essential categories of acceptability that would constitute a complete measure. As mentioned in Chapter 2, there is inconsistency in the operational definition of acceptability. Some studies conclude acceptability based on completion rates of the intervention, while others use same term (acceptability) to describe participant satisfaction and/or intervention technique uptake. While all these measures may be types of acceptability, there needs to be clarification in what is an accurate measure of the complete construct and what is a subscale assessment. Finally, the present study could be expanded to include additional factors that may influence acceptability, such as group racial/ethnic composition and response to the facilitator.

Conclusion

This dissertation presented a comprehensive assessment of acceptability of MBIs for SUD with an in-depth assessment of the surveys for MMWR, a specific type of MBI for SUD. Findings from the three manuscripts presented collectively suggest that if acceptability is assessed in a valid and reliable manner, valuable information related to intervention adaptation is derived that will improve intervention and treatment fit for subgroups and ultimately the success of the intervention tested.

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APPENDIX A

PERMISSION FROM CO-AUTHORS FOR THE USE OF CHAPTER 2

I, Tara Bautista, confirm that I have received approval from my co-authors to use the information here as chapters for this dissertation.

APPENDIX B

USC IRB APPROVAL

University of Southern California University Park Institutional Review Board
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Date:	Feb 14, 2017, 08:46am
Action Taken:	
Principal Investigator:	Hortensia Amaro SCHOOL OF SOCIAL WORK
Faculty Advisor:	
Co-Investigator(s):	David Black, Ph.D., M.P.H. HEALTH BEHAVIOR RESEARCH (IPR)
Project Title:	Continuing Review-March 2017
Continuing Review ID:	**UP-14-00391-CR003**
Funding:	**Funding Agency: National Institutes of Health, National Institute on Drug Abuse** **Contract or Grant Number: R01DA038648** **PI of Project: Hortensia Amaro** **SCHOOL OF SOCIAL WORK** **Title of Project: Efficacy of a mindfulness-based intervention for women in early recovery** **PI of Main Grant: Hortensia Amaro** **Title of Main Grant: Efficacy of a Mindfulness-Based Intervention for Women in Early Recovery**

APPENDIX C

ASU IRB APPROVAL

ASU Knowledge Enterprise Development

APPROVAL: MODIFICATION

Dear Karen Marek:

On 2/7/2019 the ASU IRB reviewed the following protocol:

Type of Review:	Modification
Title:	Acceptability of Mindfulness-based relapse prevention for women with substance use disorder
Investigator:	Karen Marek
IRB ID:	STUDY00006379
Funding:	None

The IRB approved the modification to change PIs.

When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Tara Bautista

APPENDIX D

CHAPTER 1 TABLE 1: MMWR SESSION CONTENT

Session	Discussion Topic	Mindfulness Skill Taught
1	Preventing relapse through mindfulness; Building inner safety while in treatment	Sitting meditation
2	Creative responding and healthy coping mechanisms; Bringing awareness to thoughts, emotions, body sensations, and actions	Sitting meditation, Loving Kindness/Forgiveness, eating meditation, Triangle of Awareness, and STOP light
3	The role of perceptions; How perceptions could compromise treatment and lead to relapse: Part 1	Standing Body Scan and Stretching, Sitting meditation, and Walking meditation
4	The role of perceptions; How perceptions could compromise treatment and lead to relapse: Part 2	Standing Body Scan, Awareness of Breath, Loving Kindness/Forgiveness, and Floor Stretching
5	Using mindfulness skills in recovery to relate differently to anxiety, panic attacks, and fear: Part 1	Walking meditation, Standing Stretches, STOP light, Awareness of Breath, Sitting meditation, and Mindful listening/speaking
6	Using mindfulness skills in recovery to relate differently to anxiety, panic attacks, and fear: Part 2	Standing Stretches, RAIN, Sitting meditation, and Loving Kindness/Forgiveness
7	Using mindfulness skills in recovery to understand thoughts about shame and guilt: Learning to relate differently to painful thoughts	Sitting Body Scan, Labeling Thoughts, Journaling, and Standing Stretches
8	Using mindfulness skills to improve communication with others; Brining awareness to how you talk to yourself	Walking meditation, Body Scan, Mindful Communication, Journaling, sitting meditation, Loving Kindness/Forgiveness, and Standing Stretches
9	Silent Practice Retreat	Awareness of Breath, Loving Kindness/Forgiveness, Standing Stretches, Floor stretching, and Walking meditation
10	Using mindfulness skills to work with anger, self-violence and violence toward and from others	Standing Stretches, sitting meditation, and Loving Kindness/Forgiveness
11	Stress cycle and using mindfulness skills to work with anger, self-violence and violence toward and from others	Loving Kindness/Forgiveness

12	Review and graduation	Triangle of Awareness, STOP light, Sitting meditation, Loving Kindness/Forgiveness, and Walking meditation

APPENDIX E

CHAPTER 2 TABLE 1: INCLUDED STUDIES OF MBIS FOR SUD

Table 1: Included studies of MBIs for SUD				
Citation	Primary and Secondary Outcomes	Design	Sample	Acceptability Measured
Amaro et al. [8]	Feasibility, acceptability, substance use, perceived stress, and trauma symptomology	MBRP-W nine-session (1.5–2 h per session weekly), 1-2 trained facilitators per groups of 8 to 15 women, adjunct to SUD treatment; Class 7 is a 4-h silent retreat; meditation techniques, yoga, self-regulation strategies	*N* = 318; 45.3% Hispanic, 34.6% non-Hispanic Black, 20.1% non-Hispanic White and other; M_{age} = 33.9	Yes
Bowen & Kurz [31]	Changes in levels of mindfulness following MBRP	Weekly 2-h sessions with 6–10 participants	*N* = 93; 63% Caucasian; M_{age} = 40.84; 36% female; adults attending SUD inpatient treatment	No
Bowen et al. [18]	Feasibility and initial efficacy substance use outcomes, craving, mindfulness, and acceptance	MBRP intervention with weekly 2-h sessions with 6–10 participants; TAU: 1–2 times weekly for 1.5 h	*N* = 168; M_{age} = 40.5; 36.3% female; adults attending SUD inpatient treatment	Yes
Bowen et al. [28]	Satisfaction, depression, anxiety, craving, symptoms of posttraumatic stress, and experiential avoidance	Adapted MBRP curriculum, 1x week for 6 weeks, 2 h per session; mixed-methods study (focus groups and questionnaires, surveys)	*N* = 15; adults from methadone clinic; M_{age}= 43.8; 67% female; 93% Caucasian	Yes
Bowen et al. [15]	Substance use relapse	MBRP and CBRP matched for dosage (8 weekly 2 h sessions), size (6–10 participants), location, and scope of homework; TAU not matched (1-2 weekly for 1.5 h); MBRP: formal MBSR, MBCT practices with integration of evidence-based practices to decrease relapse for people with SUD	*N* = 286; M_{age} = 39 for MBRP and RP, 37 for TAU; 26% 36%, and 27% female adults attending inpatient care for SUD, respectively	No
Enkema & Bowen [32]	Relationship between craving and substance use, moderated by practice	MBRP (8 weekly 2 h sessions, 6–10 participants), location, and scope of homework (1-2 weekly for 1.5 h)	*N* = 57; M_{age} = 38; 77.2% male; 63.16% White	No
Glasner et al. [11]	Stimulant use, negative affect, psychiatric severity	MBRP (*n* = 31) or HE (*n* = 32)	*N* = 63; M_{age} = 45.3; 71.4% male	No

		concurrent with CM following a 4-week CM-only phase		
Glasner-Edwards et al. [33]	Stimulant use, depression, anxiety, psychiatric severity	Pilot RCT, 12-week contingency management intervention; at Week 4: randomized to MBRP or HE, measurements during intervention and 1-month posttreatment	*N* = 63 (MBRP = 31, HE = 32); M_{age} = 45.3; 71.4% male; 44.4% African American; all participants stimulant dependent	No
Greenfield et al. [39]	Days of drug use and heavy drinking	MBRP (8 weekly 2 h sessions, 6–10 participants), location, and scope of homework (1-2 weekly for 1.5 h)	*N* = 191; M_{age} = 39.04; 71% male; 22 therapy groups	No
Grow et al. [40]	Development of mindfulness meditation home practice during and after MBRP in relation to drug use and craving	Secondary analysis from larger MBRP RCT (8 weekly 2 h sessions, 6–10 participants); TAU: 1-2 weekly for 1.5 h	*N* = 93; M_{age} = 40.84; 64.5% male; 63.4% White	No
Lee et al. [41]	Effectiveness of MBRP psychosocial outcomes drug use, drug avoidance, depression	RCT with 2 (baseline vs postsession) × 2 (MBRP vs. TAU) mixed design; TAU: substance use education; 10-wk MBRP, weekly meetings 1.5 h	*N* = 24; all male; M_{age} = 40.70; MBRP (*n* = 10); TAU (*n* = 14); all Taiwanese	No
Roos et al. [13]	Baseline SUD symptom severity patterns, depression, anxiety as moderated by MBRP, or comparison group	Latent class moderation using data from Bowen's RCTs [15,18]	2014: MBRP vs. TAU (*N* = 286; 71.8% male; M_{age} = 38.44); 2009: MBRP vs. TAU (*N* = 168; 63.7% female; M_{age} = 40.45)	No
Witkiewitz & Bowen [34]	Depressive symptoms, craving at 2-months posttest, and days of substance use	MBRP (8 weekly 2 h sessions, 6–10 participants); TAU: 1-2 weekly for 1.5 h; MBRP (adapted from MBSR) has themes of meditation practices and related RP discussions and exercises	*N* = 168; M_{age} = 40.5; 36.3% female adults attending SUD inpatient treatment	No
Witkiewitz et al. [16]	Mechanisms associated with MBRP that may reduce craving	MBRP RCT; Bowen [18]	*N* = 168; 63.7% male; M_{age} = 40.5; 51.8% Caucasian	No
Witkiewitz et al. [29]	Drug use and addiction severity	RCT of MBRP and RP for SUD; 50-minute sessions 2x weekly for 8 weeks	*N* = 70; all adult women in residential treatment for criminal offenders	Yes

Witkiewitz et al. [30]	Primary: days of substance use and substance use outcomes; secondary: family and social problems, medical problems, legal problems, psychiatric symptoms	RCT of MBRP and RP for SUD; 50-minute sessions 2x weekly for 8 weeks	*N* = 105; adult female population in residential treatment for criminal offenders	No
Zemestani & Ottaviani [42]	Cravings, depressive symptoms, anxious symptoms	MBRP and TAU matched for dose; 8 weekly, 2 h sessions	*N* = 74; M_{age} = 30.1; 79.7% male; Iranian	No

CBRP = cognitive-based relapse prevention; HE = health education; M_{age} = mean age; MBIs = mindfulness-based intervention; MBRP = mindfulness-based relapse prevention; MBRP-W = mindfulness-based relapse prevention for women; N = number of participants; RCT = randomized controlled trial; RP = relapse prevention; SD = standard deviation; SUD = substance use disorder; TAU = treatment as usual.

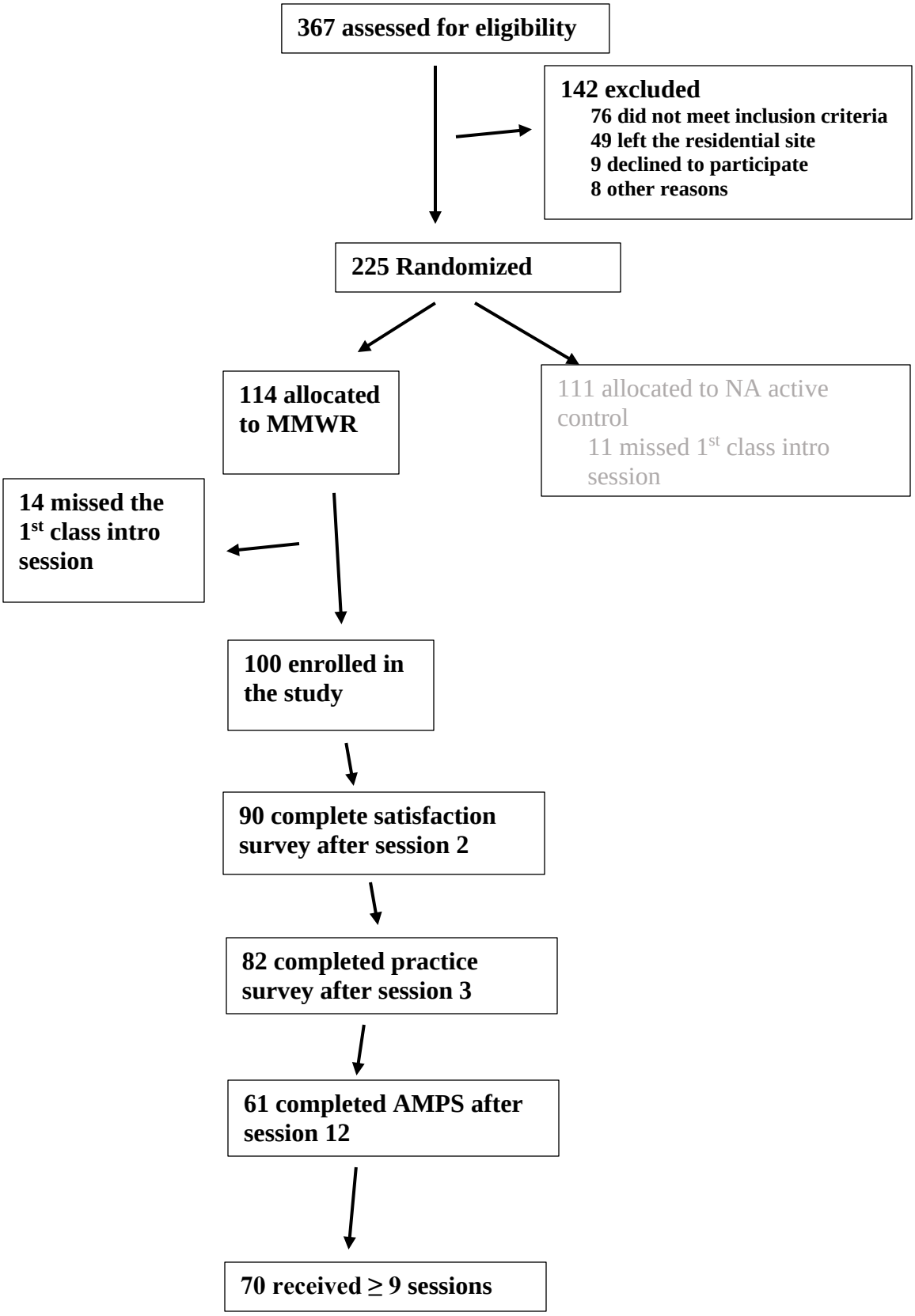
APPENDIX F

CHAPTER 2 TABLE 2: MBIS FOR SUD STUDIES THAT ASSESSED ACCEPTABILITY

Table 2: MBIs for SUD studies that assessed acceptability				
Citation	Evaluation Instrument	Time of Acceptability Measurement	Sample	Acceptability Findings
Amaro et al. [8]	Participation (attendance) and satisfaction questionnaire	Participation: each session; satisfaction: last session	N = 318; M_{age} = 33.9; all female; 45.3% Hispanic, 34.6% non-Hispanic Black, 20.1% non-Hispanic White and other	19.8% attended 1–4 sessions, 35.8% attended 5–9 sessions, 44.3% did not attend any groups; participant satisfaction was high (M = 3.4, SD = 0.3), but completion was modest (36%)
Bowen et al. [18]	Practice	Weekly and 4 months postintervention	N = 168; M_{age} = 40.5; 36.3% female adults; 51.8% Caucasian, 28.6% African American, 15.3% multiracial, 7.7% Native American	Practice reported by 86% at postintervention and 54% at 4-month follow-up; practice at 4-month follow-up: M = 4.7 days, M = 29.9 minutes per session
Bowen et al. [28]	Satisfaction	Immediately following last session	N = 15; adults from methadone clinic; M_{age} = 43.8; 67% female; 93% Caucasian	High perceived importance of course (M = 8.7, SD = 1.11); high stated likelihood of continuing formal (M = 9.0, SD = 1.2) and informal (M = 9.4, SD = 0.8) mindfulness practice; deemed feasible and acceptable, but acknowledged low attendance and retention rates
Witkiewitz et al. [29]	15-week follow-up rates	15-weeks postintervention	N = 70; adult females in residential treatment for criminal offenders; 63.8% non-Hispanic White, 17.4% African American, 13% Native American, 4.3% Asian, 1.4% Hispanic	Significantly better follow-up rates in racial and ethnic minority versus non-Hispanic White participants assigned to MBRP (85.7% vs. 52.6%); suggested MBRP may be more acceptable to minority clients
M = Mean; M_{age} = mean age; MBIs = mindfulness-based intervention; MBRP = mindfulness-based relapse prevention; N = number of participants; SD = standard deviation; SUD = substance use disorder.				

APPENDIX G

CONSORT DIAGRAM


367 assessed for eligibility
142 excluded
76 did not meet inclusion criteria
49 left the residential site
9 declined to participate
8 other reasons
225 Randomized
114 allocated to MMWR
111 allocated to NA active control
11 missed 1st class intro session
14 missed the 1st class intro session
100 enrolled in the study
90 complete satisfaction survey after session 2
82 completed practice survey after session 3
61 completed AMPS after session 12
70 received ≥ 9 sessions

APPENDIX H

CONSTRUCT MEASURMENT TABLE

Domains, Measures, and Measurement Time and Method		
Concept	**Tool**	**Description**
Acceptability	Satisfaction Survey	17 items rated on a 1 to 5 dimension (high scores indicate higher satisfaction) to assess various aspects of satisfaction: session content, skills learned, perceived usefulness, importance for recovery. Total item scores are divided by the number of items to standardize the scores.
Acceptability	Practice Survey	16 items, rated on a 0 to 5 dimension, assesses frequency of use of specific types of mindfulness practices (e. g., STOP Light Technique, Triangle of Awareness, sitting and walking meditation, mindful stretching) since the previous class session. Total scores are standardized to the rated dimension.
Mindfulness Application	Applied Mindfulness Practice Scale (AMPS)	15 items, ranging from 0-4 that assess the application of mindfulness and processes of change in the context of MBIs and general application of mindfulness practice in the last 7 days when facing challenges in daily life (e g., *I used mindfulness practice to stop reacting to my negative impulses*). Total scores are standardized to the rated dimension.
Trauma Severity	PSS-SR	17 items rated on a dimension ranging from 1 (Not at all) to 4 (Almost always). This scale measures frequency of re-experiencing, avoidance, and arousal symptoms related to trauma exposure in the past 30 days. Total scores are standardized.
Mindfulness Predisposition	Five Factor Mindfulness Questionnaire (FFMQ)	Assesses five mindfulness facets (observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience) and has demonstrated validity. Internal consistency with individuals transitioning out of intensive SUD treatment is .91, with subscale alphas ranging from .80 to .87.

Time in Treatment prior to intervention	1-item, author calculated	Time measured by the number of days between baseline assessment and the start of the MMWR cohort.
Covariates Demographics	Self-report demographics questionnaire	age, race/ethnicity, and education

APPENDIX I

SATISFACTION SURVEY

Please tell us about today's session. For each question, check ONE answer below.

		Not at all	Not much	It was OK	A lot	Very much
1.	How much did you enjoy participating?	○	○	○	○	○
2.	How much did you learn about stress and relapse?	○	○	○	○	○
3.	How much insight have you gained into personal patterns that put you at risk for relapse or leaving treatment?	○	○	○	○	○
4.	How much have you improved your understanding of stress in residential treatment?	○	○	○	○	○
5.	How much stress reduction skills have you gained?	○	○	○	○	○
6.	How much did you learn about working with difficult emotions?	○	○	○	○	○
7.	How much did you learn about working with body sensations?	○	○	○	○	○
8.	How much did you learn about working with difficult thoughts?	○	○	○	○	○
9.	How much of what you learned helped you understand yourself?	○	○	○	○	○
10.	How much did you learn about skills to	○	○	○	○	○

	help you reduce feeling of stress?					
11.	How much did you learn skills to help you live in the present moment?	○	○	○	○	○
12.	How much did the facilitator encourage discussion?	○	○	○	○	○
13.	How useful was the information presented to you?	○	○	○	○	○
14.	How important is this group in your recovery?	○	○	○	○	○
15.	Would you recommend this group to other women in recovery?	○	○	○	○	○

Please tell us about today's session. For each question, check ONE answer below.

	Poor	Fair	OK	Very Good	Excellent
16. Please rate the group facilitator's knowledge	○	○	○	○	○
17. Overall, how would you rate today's group?	○	○	○	○	○

APPENDIX J

PRACTICE SURVEY

	In the last seven days...	Never	Less than once a day	Once a day	2 times a day	3 times a day	4 or more times a day
1.	How often did you practice or use sitting meditation with the audio?	○	○	○	○	○	○
2.	How often did you practice or use sitting meditation without the audio?	○	○	○	○	○	○
3.	How often did you practice *Love and Kindness* meditation?	○	○	○	○	○	○
4.	How often did you practice walking meditation?	○	○	○	○	○	○
5.	How often did you practice or use the body scan?	○	○	○	○	○	○
6.	How often did you practice or use Mindful stretching?	○	○	○	○	○	○
7.	How often did you practice or use the *Stop Light Technique*?	○	○	○	○	○	○
8.	How often did you practice the *Triangle of Awareness*?	○	○	○	○	○	○
9.	How often did you practice or use Mindfulness in noticing your breath?	○	○	○	○	○	○
10.	How often did you practice or use Mindfulness to be aware of your emotions?	○	○	○	○	○	○
11.	How often did you practice or use Mindfulness to be	○	○	○	○	○	○

	In the last seven days...	Never	Less than once a day	Once a day	2 times a day	3 times a day	4 or more times a day
	aware of your thoughts?						
12.	How often did you practice or use Mindfulness to be aware of your body sensations like your heartbeat, sweaty hands, pain, other?	○	○	○	○	○	○
13.	When I have cravings I used mindfulness to notice my cravings without judgment	○	○	○	○	○	○
14.	When I have craving I used mindfulness to experience cravings without reacting	○	○	○	○	○	○
15.	When I have cravings I used mindfulness to notice that cravings are not permanent, they come and go	○	○	○	○	○	○
16.	How often did you practice or use Mindfulness or anything else you learned in class for something else in your life?	○	○	○	○	○	○