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Effects of Mindful Attentional Regulation on Illicit Opioid Use for Individuals Participating in Medication Assisted Treatment: A Pilot Study

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Walden University

College of Social and Behavioral Sciences

This is to certify that the doctoral dissertation by

Stephen L. Sooter

has been found to be complete and satisfactory in all respects,
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Walden University
2021

Abstract

Effects of Mindful Attentional Regulation On Illicit Opioid Use For Individuals Participating in Medication Assisted Treatment: A Pilot Study

By

Stephen L. Sooter

MS, Psychology, Walden University, 2010

BA, California State University, Hayward, 1988

Proposal Submitted in Partial Fulfillment

Of the Requirements for the Degree of

Doctor of Philosophy,

Clinical Psychology

Walden University

August 2021

Abstract

Illicit opioid use takes thousands of Americans' lives each year, reduces the quality of life for affected individuals, and results in sizable socioeconomic costs. Existing research has supported medication-assisted treatment (MAT) for this condition; however, MAT participants often continue to experience opioid craving and using behaviors. Mindfulness based relapse prevention (MBRP) uses mindfulness meditation and cognitive behavioral therapy to reduce likelihood of substance use relapse. This study used a combination of physical dependence theory, positive incentive theory, and classical conditioning theory to evaluate the impact of MBRP on illicit opioid use and cravings in a quantitative randomized, controlled experimental design. Volunteer participants (n=52) from a California Bay Area MAT program site were randomly assigned to experimental and control groups. Illicit opioid use, opioid cravings, and mindfulness data outcomes were evaluated at pretest, midtest, and posttest intervals for the experimental group receiving MBRP and treatment as usual and a treatment as usual control group. Multiple feasibility confounds including participant dropout interfered with study implementation, resulting in insufficient statistical power for analysis. The findings indicated the importance of anticipating feasibility problems in future similar study designs; however, on an individual level MBRP participants did report positive reactions to treatment. Empirically determining MBRP effectiveness in reducing illicit opioid use and cravings for MAT program participant may foster positive social change by reducing public health, behavioral, social, and legal problems, as well as human suffering associated with illicit opioid use.

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Dedication

This work is dedicated to the memory of Ron Kletter, PhD, clinical psychologist, innovative leader, and staunch patient advocate in the field of medication-assisted treatment (MAT), and to MAT patients everywhere, who courageously face the daily rigors of their opioid use condition as they move toward recovery. It is my hope that this research offers insight into an additional path of healing and wellness for the MAT program patient.

Acknowledgments

This research study required the assistance and support of many individuals. I thank my Doctoral Committee Chairperson, Chet Lesniak, PhD, who mentored and supported me throughout this effort. Second, I offer my thanks to David Yells, PhD, Doctoral Committee Methods member, who provided sound guidance for my study design. I gratefully acknowledge Evan Kletter, PhD, the former Chief Executive Officer of BAART Programs, Inc., and David White, PhD, CEO of BayMark Health Services, both of whom kindly supported this initial research effort through provision of the study site and access to program patient volunteer participants, relevant data, and needed site personnel. Most importantly, I acknowledge the MAT program patients that participated in the study. This writer is grateful for their willingness to support this research effort. It offers hope for integration of effective treatment options for the many other MAT program patients across the U.S.

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Chapter 1: Introduction to the Study

Introduction

This pilot study involved evaluating the effectiveness of Mindfulness-Based Relapse Prevention (MBRP; Bowen, Chawla, & Marlatt, 2011) manualized treatment in reducing illicit opioid use for individuals with opioid use disorder. MBRP was planned for implementation at a medication assisted treatment (MAT) program site located in the California Bay Area, where patients with opioid use disorder receive comprehensive treatment services for their condition. Despite MAT service provision efforts, opioid use relapse remains a serious concern for MAT program participants. Relapse involving illicit opioid use has strong and negative impacts on the physical, psychological, and social wellbeing of MAT program patients. Prior to implementation of this study, the effectiveness of MBRP as a treatment adjunct was not yet evaluated in MAT program settings. This study is an attempt to address this research gap.

This study was intended to foster beneficial social change through increasing awareness within medical, psychological, and treatment fields regarding indications and effectiveness of MBRP applications in the context of MAT programs. Further, if found effective, use of MBRP in the MAT program setting would likely reduce MAT program patient relapse frequency, thus improving the quality of life and MAT program effectiveness for patient participants. In addition, reduced relapse rates arising through MBRP use in the MAT program setting would likely reduce health and safety risks and

costs associated with relapse, as well as related demands and costs in terms of healthcare, law enforcement, legal, and social services systems.

This chapter includes a description of the background for the study, summary of relevant research, gaps in research this study attempted to fill, and need for the study. Chapter 1 continues with the problem statement, relevance and significance to the field, and the identified critical research gap. The study purpose is delineated, including core methodological approaches, intent, and identified variables and potential mediating variables. Next, study research questions and hypotheses are included along with a description of measurement methods. Following this, I describe relevant theoretical and conceptual frameworks and how they relate to the phenomena being evaluated, research questions and hypotheses, and how they inform the study's methodological design. The nature of the study is then discussed including its design rationale, variables and potential mediating variables, and methodology. All known variables and key terms are operationally defined. Assumptions underlying the study are critically examined. The scope and delimitations of the study are discussed, including an examination of internal and external validity. Following this, limitations of the study are described, including relevant internal and external validity threats, potential biases, and measures to address these concerns. The significance of the study for the field is then addressed and social change implications are discussed. Chapter 1 concludes with a summary of the chapter along with a transition to Chapter 2.

Background

Opioid use disorder has emerged as a growing societal problem over the past several decades. The National Institute on Drug Abuse (NIDA, 2020) reported that in 2017, opioid overdose was implicated in the deaths of more than 47,000 Americans. There was a 430% increase in U.S. hospitalizations associated with illicit opioid use between 1999 and 2009 (Substance Abuse & Mental Health Administration (SAMHSA; 2011). The NIDA (2020) reported that as of the end of 2018, opioid overdose was the primary cause of 128 deaths each day in the U.S. The Centers for Disease Control (CDC, 2021) reported that drug overdose deaths have increased by 400% since 1999, including a 6% increase in opioid-related deaths overall and a 15% increase in synthetic opioid associated deaths during 2019. The Office of National Drug Control Policy (ONDCP, 2011) said there was an increase of 402% in prescription opioid use among Americans from 1997 to 2007. The NIDA (2011) reported that of the 7 million individuals in the U.S. in 2010 who used prescription drugs nonmedically, 5.1 million abused opioids. The SAMHSA (2020a) said between 2018 and 2019, there were 10.1 million individuals who misused opioids, and two-thirds of drug overdose deaths were opioid related. Taken together, these reports suggest an increasing frequency of opioid misuse and opioid associated deaths over the past 2 decades.

MAT has been established as a highly effective treatment for opioid use disorder (Batki et al., 2005; Kosten & George, 2002; Parrino et al., 1993; SAMHSA, 2020b, Volkow, 2007b). Despite the demonstrated effectiveness of MAT program participation,

relapse among MAT program participants remains a significant liability (Kreek, 2007). Relapse rates while enrolled in MAT tend to reduce over time, with an average rate of 19.7% measured over a 36-month treatment episode (Clark et al., 2014). Moreover, discontinuance of MAT is associated with a relapse rate of almost 100% (Calsyn et al., 2006), suggesting that whereas relapse while enrolled in MAT is a concern, it is a much greater concern where treatment is discontinued. This suggests the need for effective treatment adjuncts that are likely to reduce this propensity toward relapse within the context of MAT program settings. MBRP, a manualized treatment approach for substance use integrating mindfulness practices with cognitive behavioral therapy techniques, has been found to be highly effective as a treatment for substance use disorders (Bowen et al., 2009; Bowen et al., 2011; Bowen & Enkema, 2014; Bowen & Kurz, 2012; Witkiewitz & Bowen, 2010; Witkiewitz et al., 2013a; 2013b). MBSR has not yet been evaluated as a treatment adjunct for individuals participating in MAT programs.

This pilot study addressed a gap in research by evaluating MBRP for effectiveness as an adjunctive treatment for individuals enrolled in a MAT program. This study will lead to beneficial social change through increased researcher and clinican awareness of effectiveness of MBRP applications in the context of MAT programs. Further, if found effective, use of MBRP in the MAT program setting would likely reduce MAT program patient relapse frequency, thus improving the quality of life and MAT program effectiveness for patient participants. In addition, reduced relapse rates arising through MBRP use in the MAT program setting would reduce health and safety

risks and costs associated with relapse, as well as related use demands and costs in healthcare, law enforcement, legal, and social services systems.

Problem Statement

Opioid use disorder is a current and pervasive problem in the U.S. Over 3.7 million individuals in the U.S. have used heroin (NIDA, 2005a). In 2004, approximately 314,000 individuals used heroin (NIDA, 2005a). This increased by over 47% to 669,000 heroin abusers in 2012 and 745,000 persons in 2019 (NIDA, 2014b). The NIDA (2014a) said 5.1 million individuals used opioid medication illicitly in 2012. The SAMHSA (2020a) said that 10.1 individuals abused opioids in 2019, an increase of almost 50% from 2012. Chronic pain affects 33% of Americans and is a factor strongly implicated in opioid use disorder (Johannes et al., 2010; NIDA, 2014a). The SAMHSA (2020a) said in 2019, 9.7 million individuals abused prescription opioids. Drug Awareness Warning Network (DAWN) data indicated a 183% increase in ER visits associated with illicit opioid use during the period from 2004 to 2011 (SAMHSA, 2013a). The SAMHSA (2020a) reported a 30% increase for the period from July 2016 to September 2017. These data trends strongly suggest that illicit opioid use is continuing to increase at a concerning rate.

Opioid use disorder is characterized as a chronic relapsing condition where post-remission relapse is highly likely (California Society of Addiction Medicine, 2008; Dennis & Scott, 2007; Leshner, 1989; 2001; SAMHSA, 2020b, Volkow, 2007a; 2007b). MAT participants are thus at increased risk for episodic relapse of illicit opioid use and

are likely to benefit from adjunctive treatment interventions (Logan & Marlatt, 2010; Parrino et al., 1993). Relapse into illicit opioid use is strongly associated with increased risk of disease contraction, including hepatitis C (HCV) and human immunodeficiency virus (HIV) and adverse medical complications, and is further associated with elevated risk of oversedation, coma, and death due to central nervous system suppression (California Society of Addiction Medicine, 2008; Parrino et al., 1993; Volkow, 2007a; 2007b). Further associated risks include secondary general medical conditions, symptomatic exacerbation of concomitant psychiatric disorders, criminal behavior in order to sustain illicit opioid use, and social dysfunction leading to marginalization by and alienation from familial and other potential supportive resources (California Society of Addiction Medicine, 2008; Parrino et al., 1993; Volkow, 2007a; 2007b). Any therapeutic adjunct associated with reduced relapse risk is likely to benefit the health and wellbeing of MAT program participants.

Mindfulness-based practices are effective in treatment of several general medical conditions including fibromyalgia, cancer, multiple sclerosis, eating disorders, and impaired immune system response (Chang et al., 2004; Jain et al., 2007; Kabat-Zinn, 2002; 2009; Zeidan et al., 2011). Mindfulness-based practices have been found to be effective as treatments for anxiety, depression, posttraumatic stress disorders, and substance use disorders (Brantley, 2007; Brewer et al., 2010; Davidson, 2010; Farb et al., 2012; Marlatt, 2006; Modinos et al., 2010). A research gap exists in that MBRP has not yet been evaluated as a treatment for opioid use disorder within the population of

individuals being treated at MAT programs. This pilot study was used to address this research gap by examining the effectiveness of MBRP in reducing illicit opioid use for participants currently enrolled in a MAT program in California.

Purpose of the Study

Study Intent

The purpose of this quantitative pilot study design was to evaluate the effectiveness of MBRP as a therapeutic adjunct to MAT program participation. I examined the relationship between mindfulness of MAT program participants and frequency of illicit opioid using and craving behaviors.

Study Variables

I used a concurrent mixed methods design, including quantitative, randomized, and controlled experimental single-site pilot designs using repeated measures. Multivariate analysis of covariance (MANCOVA) was used to evaluate relationships between the dependent and independent variables over time.

The dependent variables (DVs) in the study were based on the outcomes of two standardized measures broadly used in substance abuse treatment and research. The first was the Addiction Severity Index (ASI; McLellan et al., 1985). The ASI is used to evaluate for examinee functioning across multiple domains, asking lifetime problem frequency for a total number of years, where the problem was evidenced at least once during any year, and problem frequency within past 30 days, where the problem was evidenced at least once. Using a Likert scale design the examinee indicates problem

severity and need for treatment. The ASI Alcohol/Drugs subscale data was used in this study. This ASI subscale is scored through weighted summing of individual item results within each subscale. Index composite score ranges from no problem severity (0.00) to very high problem severity (1.00) The ASI Alcohol/Drugs subscale data outcomes were used in this study to measure severity of participant opioid use at three specified testing intervals.

The Opioid Craving Scale (OCS; McHugh et al., 2014) is used to measure severity of cravings for illicit opioids. It consists of three visual analogue scale items measured in 0 (no desire for opioids) to 10 (strong desire for opioids) for item one, and in severity from 0 (no severity) to 10 (extremely strong severity) for the remaining two items. The first scale measures the strength of desire to use opioids during the past 24 hours. The second scale measure how strong desire to use opioids has been during the past week when exposed to an environmental cue associated with opioid use. The third scale requires recollection of the most recent environment and time of day where the examinee used opioids and rates the likelihood of opioid use if the examinee were in that environment at that time today (McHugh et al.). The OCS was used in this study to measure participant opioid craving severity at three specified testing intervals.

The independent variable (IV) levels in the study were the MBRP manualized treatment intervention administered for a proscribed 8-week period as an adjunct to treatment as usual (TAU) in an experimental group of MAT program participants, and

TAU in the control group of MAT program participants during a concurrent 8-week period.

A potential mediating variable (MV) in the study was the effect of MBRP manualized treatment on participant states of mindfulness. This was evaluated by observing variance between pretest, midtest, and posttest outcome scores measured by the Toronto Mindfulness Scale (TMS; Lau et al., 2006). The TMS measures two factors of mindfulness: curiosity and decentering. It consists of 13 questions associated with each factor. The examinee indicates level of agreement with test item statements using a Likert scale response from zero (no agreement) to four (very much agreement). Higher scores indicate increased clinical evidence of mindfulness effects in the test subject.

Statistical covariance data outcomes of TMS scores would likely reveal any significant mediating associations between changes in participant mindfulness and DV outcomes. The MV outcomes were used only for observational purposes, and were not included in the study research questions and hypotheses.

Research Questions and Hypotheses

RQ1: Is exposure to MBRP manualized treatment associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program?

H_01: Exposure to MBRP manualized treatment is not associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

H_a1: Exposure to MBRP manualized treatment is associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

RQ2: Is exposure to MBRP manualized treatment associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program?

$H_0$2: Exposure to MBRP manualized treatment is not associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

H_a2: Exposure to MBRP manualized treatment is associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

Dependent Variables

The DVs were frequency of illicit opioid use as measured by ASI Alcohol/Drugs subscale outcomes and severity of participant opioid cravings as measured by Opioid Craving Scale outcomes.

Independent Variable

The IV for this study consisted of treatment with two distinct levels: the experimental group level wherein the MBRP manualized treatment intervention was provided to participants as a treatment adjunct in addition to their TAU at the MAT

program, and the control group level wherein the participants received only TAU at the MAT program.

Groups were randomly assigned using a random number table. Each experimental group participant was exposed to MBRP manualized treatment. Participants not attending a minimum of six out of eight possible MBRP group sessions while participating in TAU at the MAT program were classified as study dropouts. The control group level experienced TAU as it was practiced within the context of the MAT program and did not receive the MBRP manualized treatment. For the control group condition, participants discontinuing TAU at the MAT program during the eight-week study period were classified as study dropouts. The only between groups variable was administration of the MBRP manualized treatment. This variable was measured by participant completion of the eight weeks required in the MBRP treatment protocol.

Theoretical and Conceptual Framework for the Study

Theoretical Foundation

Mindfulness practices have been found to be effective in terms of treating multiple conditions including stress associated conditions, impaired immune system response, cancer, chronic pain, and substance use disorders (Chang et al., 2004; Jain et al., 2007; Kabat-Zinn, 2002; 2009; Shapiro & Schwartz, 2000; Witkiewitz et al., 2005; Zeidan et al., 2011). Their effectiveness is associated with improved treatment outcomes for multiple psychiatric disorders, including substance use conditions (Brewer et al., 2010; Davidson, 2010; Farb et al., 2012; Kabat-Zinn, 2002; 2009; Marlatt, 2006;

Modinos et al., 2010). The area of the brain known as the prefrontal cortex (PFC) regulates behavior to minimize risk of physical harm and assure optimal chances for survival. The mesolimbic dopaminergic system regulates behaviors associated with rewarding activities such as eating, drinking, sexual activity, and mood-altering substance use. Cognitive deficits in PFC mediation of signals from the mesolimbic dopaminergic system increase the opioid-dependent individual's vulnerability to relapse, and reduce capability to regulate drug craving, seeking, and using behaviors (Childress et al., 2008; Dennis & Scott, 2007; Kosten & George, 2002). States of mindfulness reflect calm, fully aware, and optimally balanced cognitive functioning arising from ongoing practice of nonjudgmental, nonreactive acceptance of experiential phenomena. These mindful states have been associated with more adaptive PFC regulation of limbic system signaling than is consistently found in individuals that do not practice mindfulness (Brewer et al., 2010; Farb et al., 2012; Ostafin & Marlatt, 2008; Modinos et al., 2010). This suggests that increased attentional control over illicit opioid craving, seeking, and using behaviors achieved through mindfulness practice may reduce illicit opioid use. Research suggests opioid use disorder signs and symptoms associated with relapse might be effectively mediated through clinical applications of mindfulness such as MBRP.

Conceptual Framework

Ostafin and Marlatt (2008) observed that implicit processes regulated in the limbic system of the brain are strongly associated with substance use disorders. These findings suggest that mindfulness practices may enhance control of opioid use cravings

and seeking behaviors, thereby reducing illicit opioid use and resultant health risk behaviors and offering symptomatic relief and improved quality of life for participants. Wenk-Sormaz (2005) noted that meditation facilitated cognitive and affective responsivity. This suggests that engagement in mindfulness-based practices may increase individual capability for regulating emergence of autonomic substance use cravings via enhanced PFC functioning.

Continued mindful experiencing of substance use cravings deconditions associations between substance use behavior and cravings, thereby decreasing vulnerability to relapse (Marlatt & Chawla, 2007; Ostafin & Marlatt, 2008). Marlatt and Chawla (2007) said this therapy ultimately reduces substance cravings and counteracts substance addiction through facilitating awareness and acceptance of present moment experiences, thereby reducing individual propensities toward using substances to cope with aversive existential realities.

Mindfulness-based treatment interventions have been found effective in terms of treating substance use disorders and associated craving, seeking, and using behaviors (Bowen et al,, 2011; Bowen et al., 2005; Bowen et al., 2006; Bowen et al., 2009; Witkiewitz et al., 2005). Whereas MBRP has been found effective in reducing illicit opioid, stimulant, and alcohol relapse frequency in several distinct populations, it has not been conclusively evaluated for its effectiveness as a treatment adjunct for individuals participating in a MAT program. The increasing severity and prevalence of national

opioid use and the chronic relapsing nature of OUD for MAT program participants suggests a need to evaluate the effectiveness of MBRP as a treatment adjunct.

This study was an attempt to fill identified research gaps through determining the efficacy of the MBRP protocol as a treatment adjunct for use by MAT programs, clinicians, and patients. If established as effective in terms of reducing MAT patients' risk of relapse, MBRP protocol would thus represent an inexpensive, efficient, and cost-effective means of reducing potential harms posed to MAT program participants due to illicit opioid use relapse.

Mindfulness-based treatment interventions that are effective in terms of regulating illicit opioid use, craving, seeking, and using behaviors in MAT participants merit further empirical investigation. MAT program treatment effectiveness and quality of life for MAT participants would likely be enhanced through integration of mindfulness-based interventions that support them in reducing illicit opioid cravings and use. Aversive effects involving cooccurring psychiatric conditions, crime, health care overuse and costs, social alienation, and stigma would be reduced through implementation of treatment adjuncts that reduce illicit opioid relapse frequency, duration, and severity. MBRP is a group treatment model, thus reducing staff/patient ratios and associated costs while still offering enhanced treatment effectiveness. Enhanced MAT outcomes and reducing associated costs likely would improve public perception of MAT effectiveness and the need for enhanced treatments for opioid dependence, thereby reducing social stigma and its negative effects on opioid-dependent persons and others with substance

use disorders, further facilitating support for and increased participant enrollment in MAT programs. A more in-depth review follows in Chapter 2.

Nature of the Study

Design Rationale

This study was intended to determine if participant exposure to MBRP manualized treatment is associated with reductions in frequency of illicit opioid use and opioid use cravings for individuals concurrently participating in MAT programs for their opioid use disorder. I addressed the research questions through measurements of DV frequency outcomes associated with reported opioid use and cravings throughout the 8-week study period. A gap in the research addressed by this study is that no research evaluated the effects of MBRP manualized treatment on illicit opioid use of MAT program participants.

Key Variables

The two DVs in this study were frequency of participant illicit opioid use as measured by ASI Alcohol/Drugs subscale (McLellan et al., 1985) and severity of participant opioid cravings as measured by the Opioid Craving Scale (McHugh et al., 2014).

The IV for this study consisted of two levels: the experimental group exposed to MBRP manualized treatment in addition to TAU at the MAT program, and the TAU-only control group. This IV was considered valid if participants assigned to the experimental group attends at least six of the eight weekly MBRP group sessions, and if control group

participants remain in TAU for the concurrent eight-week period of their experimental group counterparts.

Potential MVs included observed changes in participant mindfulness as measured by participant TMS outcome scores. Attempts were made to identify mediating variables and describe their potential effects on the study outcomes.

Methodology

The research design was a quantitative randomized controlled single-site pilot study design using repeated measures. This is a mixed within-between subjects design with time as the within-subjects factor and groups as the between-subjects factor. MANCOVA was used to statistically evaluate relationships between dependent, independent, and any identified MVs over time..

The study duration was 8 weeks, consistent with established requirements of MBRP manualized treatment. Data collection occurred during MBRP manualized treatment administration.

Definitions

Cue Reactivity: A condition where nonvolitional neurobiological responses to environmental conditions serve as stimuli for opioid craving, seeking, and using behaviors (Childress et al., 2008; Dennis & Scott, 2007).

Medication Assisted Treatment (MAT) Program: A comprehensive treatment approach for individuals with opioid use disorder that includes supervised opioid

pharmacotherapy, counseling and medical and social support services (Parrino et al., 1993).

Meditation: The contemplative state wherein the individual reflects on experiential phenomena as they arise into conscious awareness (APA, 2007).

Methadone: A synthetic opioid analgesic medication used to treat opioid dependence and chronic pain (Parrino et al., 1993).

Mindfulness: A condition wherein an individual's awareness is focused on unfolding experience (APA, 2007).

Mindfulness-Based Relapse Prevention: A therapeutic approach to treatment of substance use disorders involving mindfulness meditation and cognitive behavioral therapy interventions (Marlatt & Chawla, 2007).

Mindfulness-Based Stress Reduction: A therapeutic approach involving mindfulness practices to reduce maladaptive stress reactivity and improve quality of life (Kabat-Zinn, 1982, 2002).

Mindfulness Meditation: A specific contemplative approach in which thoughts, feelings, and sensations are intentionally and nonjudgmentally experienced as they arise into conscious awareness (APA, 2007).

Opioids: Drugs with pain relieving and euphoric effects (APA, 2007).

Opioid Dependence: The condition where continued exposure to opioid drugs results in neurobiological adaptation to opioids (APA, 2013).

Opioid Relapse: The phenomenon where an individual returns to illicit opioid use after a sustained period of abstinence (Parrino et al., 1993).

Opioid Tolerance: Condition where increasing amounts of opioids are needed to experience drug effects (APA, 2013).

Opioid Use Disorder: A persistent maladaptive pattern of illicit opioid use despite attempts to reduce or eliminate such use, continuing over a sustained period of time, and presenting with adverse symptoms.

Opioid Withdrawal: The condition where, once dependence has occurred, discontinuance of the exogenous opioid results in the onset of multiple adverse physical symptoms (APA, 2013).

Vipassana: A mindfulness meditation practice where intentional focus on breathing is used to regulate attention and enhance experiential awareness (Fenner, 2002).

Assumptions

DVs for this study were frequency of participant-reported illicit opioid use and opioid craving. Illicit opioid use was measured using the ASI Alcohol/Drugs subscale (McLellan et al., 1985), and opioid craving was measured through the OCS (McHugh et al., 2014). These scales were assumed to be reliable and accurate means of evaluating frequency of participant illicit opioid use and craving.

This DV was assumed to have normal distribution and homogeneity of variance between and within the study experimental and control group levels. Both groups were

randomly assigned from the larger MAT program patient population where the study was conducted.

It was also assumed that statistical covariance analysis would reveal any significant mediating associations between changes in participant mindfulness and DV outcomes.

Scope and Delimitations

Internal Validity

This pilot study involved examining the effects of MBRP group participation on illicit opioid use and opioid cravings experienced by opioid-dependent individuals enrolled in MAT programs. Whereas mindfulness practices have been evaluated for their effectiveness in terms of reducing illicit substance use of participants in multiple program settings, including substance use treatment facilities, no research has specifically addressed the use of MBRP manualized treatment in a MAT program setting. By targeting MBRP in MAT programs, I isolated a narrow segment of individuals with substance use disorders who were MAT program participants, and further narrowed the evaluative focus through limiting the approach to MBRP.

External Validity

This study only included participants who were concurrently enrolled in a MAT program. Thus, individuals experiencing opioid use disorder who were not participating in the MAT program selected for the study were not eligible for participation. Similarly, individuals without a primary diagnosis of opioid use disorder were unsuitable for study

participation. Since the MAT program normally does not admit individuals who are less than 18 years of age, such individuals were not considered eligible for study participation. No other study participation restrictions were planned.

The study was not intended to evaluate for other general medical or psychiatric conditions. The study was not intended to evaluate for psychological practices that inform psychotherapeutic interventions for MAT program patients, including therapeutic approaches such as active listening, motivational interviewing, cognitive behavioral therapy, trauma therapies such as seeking safety, or general addictions counseling approaches. The study was not intended to evaluate for neurobiological functioning associated with opioid use disorder.

Potential Generalizability

Generalizability of this study's outcomes was limited in that it was a pilot study with a limited number of participants ($n = 60$). Reduced numbers of participants are associated with reduced statistical power, which in turn suggests reduced generalizability. Further, although participants were randomly assigned to either experimental or control group, the study depended on volunteer participants. It is possible, especially given the limited number of participants, that those selected did not fully represent normative characteristics typically present within the larger MAT program participant population.

This study was intended to evaluate MSRP manualized treatment effectiveness in terms of reducing illicit opioid use within the specific population of MAT program participants. Given an outcome that suggested effectiveness of MBRP, even limited

generalizability could be used as a basis for development of studies with larger populations, greater statistical power, and greater generalizability for the general population of MAT program patients.

Limitations

A potential limitation of this study was that a sufficient number of participants did not complete the entire study period. Such dropout cases were noted with reasons for early discontinuance and addressed in my discussion of data analysis. Additional possible limitations may have included potential extraneous variable effects such as variance in participant age, gender, psychiatric status, general medical conditions, and practical factors limiting participation including scheduling and transportation constraints. The effects of these potential extraneous variables were not measured and remain unknown. A further potential limitation was that only one MAT program site was used for study purposes. It is possible that this site had unique or unknown effects on study participants that may have resulted in skewing data or otherwise limited generalizability.

At the time of study implementation, I had several years of experience practicing mindfulness meditation, and thus could be influenced in terms of confirmation bias involving research outcomes that favored beneficial effects of mindfulness practices on MAT program patients. To guard against this, the study was structured such that MBRP group services were not provided at a MAT program location where I worked, and study participants were not known to me. Statistical analyses were used to address variables.

Significance

While MAT programs are as a highly effective treatment model for individuals with opioid use disorder, the potential for relapse among MAT program participants remains significant. Kreek (2007) said 20% of MAT program patients may relapse at any given time. Given this, MAT participants, despite the known effectiveness of MAT, remain at risk for episodic relapse and are likely to benefit from adjunctive treatment interventions that reduce such risk (Logan & Marlatt, 2010; Parrino et al., 1993).

Mindfulness-based treatment interventions have been demonstrated to be effective at reducing relapse rates among populations with substance use disorders, specifically in MAT program populations (Stotts et al., 2009). This study was built to address existing research gaps by evaluating the effects of MBSR as a treatment adjunct for MAT program patients. This application of MBSR could be broadly used in MAT programs throughout the U.S., thereby fostering positive social change through reducing illicit opioid use relapse rates and its harmful concomitants among thousands of individuals benefiting from MAT program participation.

Summary

This chapter includes the rationale for and scope of this pilot study. This discussion includes the study background, problem statement, purpose, research questions and hypotheses, theoretical and conceptual frameworks, and research methods along with assumptions and limitations of the study. This pilot study was intended to evaluate effectiveness of MBRP manualized treatment when used as a treatment adjunct

for MAT program patients and determine if MBRP is effective in terms of relapse prevention as evidenced by reduced frequency of illicit opioid use and reduced opioid craving severity among those participating in the MBRP protocol.

A quantitative experimental design was proposed, comparing two groups: the experimental group exposed to weekly MBRP procedures, and the TAU group used as a control. Both groups were composed of randomly selected participants concurrently participating in a MAT program located in the Bay Area of California. This study involved testing the hypothesis that use of MBRP as a treatment adjunct within the context of a MAT program would result in changes in frequency of participant illicit opioid use as measured by the ASI Alcohol/Drugs subscale (McLellan et al., 1985) and changes in severity of participant opioid craving as measured by the OCS (McHugh et al., 2014).

Chapter 2 includes a literature review with information regarding historical and current social problems associated with opioid use disorders. It continues with explanations of historical and current treatment approaches used to address opioid use disorder, the role of MAT programs in treatment for this condition, theoretical concepts relevant to opioid use disorders, diagnostic formulation, evaluation, and treatment approaches, and examination of neurobiological substrates of opioid use disorders and their relevant implications. This chapter continues with an exploration of the historical antecedents of mindfulness practices, transitioning into contemporary clinical applications of these practices and examination of research evaluating their effectiveness.

Neurobiological research evaluating substrates associated with mindfulness practices are explicated, as well as potential relevance to the neurobiology of opioid use disorders. Multiple mindfulness-based treatment approaches are discussed, and research evaluating their effectiveness is critically examined. This leads to an in-depth evaluation of MBSR and a rationale for its potential use as a treatment adjunct for MAT program patients. Chapter 3 includes the research design and methodology for the proposed study. Chapter 4 includes study outcomes, including data and statistical analyses, and Chapter 5 includes a conclusion, summary of relevant results, findings, and recommendations for future research.

Chapter 2: Literature Review

Introduction

Opioid use disorder with physiological dependence is characterized as a chronic relapsing condition where post-remission relapse is highly likely. MAT has been firmly established as a highly effective treatment for opioid use disorder. Despite comprehensive pharmacological, psychological, and medical information offered in MAT programs, participants remain at risk for episodic relapse of illicit opioid use, and are thus likely to benefit from adjunctive treatment interventions that reduce the likelihood of relapse (Logan & Marlatt, 2010; Parrino et al., 1993, SAMHSA, 2020b).

Relapse involving illicit opioid use is strongly associated with increased risk of disease contraction, including HCV and HIV and adverse medical complications, and is further associated with elevated risk of oversedation, coma, and death due to central nervous system suppression (Parrino et al., 1993; Volkow, 2007a; 2007b). Further relapse-associated risks include onset of secondary general medical conditions, symptomatic exacerbation of cooccurring psychiatric disorders, criminality due to sustained illicit opioid use, and social dysfunction leading to marginalization by and alienation from familial and other potential supportive resources (Parrino et al., 1993; Volkow, 2007a; 2007b). Any therapeutic adjunct reducing relapse risk is likely to benefit the health and wellbeing of MAT program participants.

The purpose of this pilot study was to evaluate the effectiveness of MBRP manualized treatment used as a therapeutic adjunct to MAT program participation. This

pilot study also considered the potential mediating effect of changes in participant mindfulness as measured by TMS scores associated with concurrent participation in the manualized MBRP treatment adjunct. In addition, correspondent changes in terms of participant frequency of illicit opioid use were evaluated.

Examining the effects of MBRP on individuals participating in MAT programs for opioid dependence necessitates evaluation of the nature of opioid use disorder, including its neurobiological, psychological, and social concomitants, as well as potential relationships with mindfulness. This chapter involves investigating etiology, theoretical perspectives, and empirically-supported treatment options for substance and opioid use disorders in terms of physiological dependence, including how the condition is evaluated and treated within the context of MAT programs. The chapter continues with examinations of individual and social problems associated with illicit opioid use. Neurobiological structure and functioning of opioid use disorders are explicated. The chapter includes a brief description of the history and development of MAT programs, including a synopsis of the current MAT program philosophy and approach to opioid use disorder treatment.

This chapter continues with an explanation of the historical antecedents of mindfulness practices. The nature of mindfulness and relevant aspects of mindfulness practice are discussed, as well as relationships between states of mindfulness and attentional processes. Neurobiological structure and functioning of the central and peripheral nervous systems relevant to states of mindful attention are evaluated, and

implications of these findings in terms of MBRP as an adjunctive treatment for opioid use disorder are explored. Relevant aspects of contemporary psychological treatment approaches incorporating mindfulness practices are described.

Literature Search Strategy

The Walden University online library was used to access EBSCOHost in order to find research related to mindfulness and substance use disorder treatment applications. Databases used included Academic Search Premiere, PsycArticles, PsycInfo, SocINDEX, Thoreau, Mental Measurements Yearbook, CALDATA, National Institutes of Health, American Psychiatric Association, American Psychological Association, American Medical Association, Substance Abuse and Mental Health Services Administration, Centers for Substance Abuse Treatment, National Institute on Drug Abuse, Food and Drug Administration, PubMed, and National Library of Medicine. Google and Google Scholar were also used.

Key search terms were *substance use*, *substance use disorder*, *opioid use disorder*, *mindfulness*, *neurobiology*, *neurobiology of mindfulness*, *neurobiology of attention*, *mindfulness and attention*, *attentional regulation*, *attentional dysregulation*, *attention regulation*, *opioid use disorder*, *neurobiology of opioid use disorder*, *neurobiological substrates of opioid use disorder*, *neurobiological substrates of attention regulation*, *neurobiological substrates of mindfulness*, *mindfulness based stress reduction*, *MBSR*, *mindfulness based cognitive therapy*, *MBCT*, *mindfulness and rational emotive behavior therapy*, *MBREBT*, *rational emotive behavior therapy*, *REBT*, *cognitive*

behavioral therapy, CBT, *cognitive therapy*, *CT*, *mindfulness based relapse prevention*, *MBRP*, *acceptance and commitment therapy*, *ACT*, *Buddhism*, and *yoga nidra*. Abstracts were reviewed for relevance to determine applicability of each article. Articles including only abstracts were not used.

Research journal articles, texts, and treatment manuals published prior to 2017 were used where applicable to denote seminal findings in literature that provide historical perspectives, or to compare and contrast with more recent findings.

Numerous seminal texts and articles were used as references to describe historical antecedents of mindfulness practices and psychological functioning associated with mindfulness practices and measures used to assess mindfulness.

Relevant online research articles were downloaded for further study. Relevant home and work library journals and texts on neurobiology, theoretical bases and treatment approaches for substance use disorders, mindfulness theory and practice research, treatment manuals, and clinical applications were used.

Illicit Opioid Use in America

Recent Epidemiological Trends in Illicit Opioid Use

Illicit opioid use is a severe and pervasive problem in the United States. There were 669,000 heroin abusers in 2012 (NIDA, 2014b), increasing to an estimated 745,000 in 2019 (SAMHSA, 2020a). The NIDA asserted that some 5.1 million individuals used opioid medication illicitly in 2012 (NIDA, 2014a), a number that has increased to 10.1 million individuals in 2019 (SAMHSA, 2020a). Epidemiological trends (Johannes et al.,

2010; NIDA, 2005b; 2014a) indicated that chronic pain affects some 33% of Americans and is a factor strongly implicated in opioid use disorder. The SAMHSA reported that Drug Awareness Warning Network (DAWN) data indicated a 183 percent increase in ER visits associated with illicit opioid use during the period from 2004 to 2011 (SAMHSA, 2013a), with an overall 430% increase observed for the period from 1999 to 2009. The Office of National Drug Control Policy (ONDCP; 2011) reported a 402 percent increase in prescription opioids use by Americans from 1997-2007. The NIDA (2011) reported that in 2010 seven million U.S. individuals used prescription drugs nonmedically including 5.1 million that abused opioids. This number increased to and the SAMHSA reported that . The Centers for Disease Control and Prevention (CDC; 2021) asserted that for the period from 1999 to 2019 close to 500,000 persons died from an opioid overdose, and that drug overdose deaths have increased by 400% since 1999, including a six percent increase in opioid-related deaths overall, and a 15% increase in synthetic opioid associated deaths during the year period ending in 2019.

Opioid misuse has been increasing since 2007 (NIDA, 2011). In 2014, over 2 million individuals experienced the condition of opioid use disorder (National Institute on Drug Abuse; NIDA, 2014a), a number that increased to 1.6 million in 2019 (SAMHSA, 2029a). The NIDA asserted that in 2013 more than 207 million opioid medication prescriptions were written. Some 58% of Americans were prescribed opioids in 2017 (CDC, 2019). The National Survey on Drug Use and Health for 2012 report indicated some 669,000 individuals in the U.S. had used heroin during the past year (SAMHSA,

2013b). Subsequently, the SAMHSA (2020a) reported that 745,000 persons used heroin in the year preceding 2019. The NIDA (2011; 2014b) asserted that marked increases in heroin use have resulted from an estimated near 50 percent of young individuals transitioning from prescription opioid use to heroin use. Moreover, Johannes et al. (2010) and NIDA (2014a) estimated that a third of Americans experience some form of chronic pain and this condition is strongly associated with opioid use disorder. An estimated 41 percent of individuals with chronic pain conditions abuse opioid medication (Manchikanti et al., 2007).

Of much concern is the increasing number of deaths from opioid overdoses, which quadrupled over the 10-year period preceding 2014 (NIDA, 2014a). The NIDA (2014) asserted that more individuals die from prescription opioid overdose than from all other drugs of abuse combined, and that as of 2019 more than two-thirds of all drug overdoses were opioid related. The NIDA (2020) reported that as of the end of 2018 opioid overdose was the primary cause of 128 deaths each day in the United States. The CDC (2021) reported that drug overdose deaths have increased by 400% since 1999, including a six percent increase in opioid-related deaths overall, and a 15% increase in synthetic opioid associated deaths during the year period ending in 2019. The CDC (2020) noted that in the year period ending in May, 2020 there were more than 81,000 drug overdose deaths, a number that included a 98% increase in opioid related deaths reported by several states in the western U.S., and reflected the highest number of overdose deaths ever recorded in a 12-month period. Taken together, these data trends

strongly suggest that illicit opioid use and its harmful effects are continuing to increase at a very concerning rate.

1,200 MAT programs were in existence as of the end of 2010 providing treatment services to an estimated 270,000 opioid dependent individuals (SAMHSA, 2011). The SAMHSA (2020b) reported an estimated 1.2 million individuals enrolled in MAT programs as of the end of 2019. In MAT programs are a highly effective treatment for opioid use disorder (Kosten & George, 2002; Parrino et al., 1993; SAMHSA, 2020b; Volkow, 2007b). Opioid use disorder with physiological dependence is a chronic, relapsing condition where post-remission relapse is highly likely (APA, 2013; Dennis & Scott, 2007; Kosten & George, 2002; Leshner, 1989; 2001; Parrino et al., 1993; SAMHSA, 2020b, Volkow, 2007a; 2007b). MAT participants are at risk for episodic relapse of illicit opioid use and are likely to benefit from adjunctive treatment interventions (Logan & Marlatt, 2010; Parrino et al., 1993).

Relapse-Associated Concerns

The medical, psychological, and social risks associated with relapse into illicit opioid use are of great concern (CSAT, 2005; Chalk et al., 2013). Individuals experiencing relapse are at high risk for overdose, oversedation effects, and death (CSAT; Parrino et al., 1993; SAMHSA, 2020b). Overdose death rates associated with illicit opioid use have tripled since 1990 and continue to increase (Chalk et al., 2013). The risk of relapse for persons with opioid use disorder is strongly associated with stress exposure (CSAT, 2005; Kreek, 2000; Kreek & Koob, 1998) and concomitant conditions

include hepatitis C (HCV) and human immunodeficiency virus (HIV), and their adverse medical complications. Further associated risks include complications of secondary general medical conditions, symptomatic exacerbation of concomitant psychiatric disorders, criminality engaged in to sustain illicit opioid use, and social dysfunction leading to marginalization by and alienation from familial and other potential supportive resources (Parrino et al., 1993; SAMHSA, 2020b, Volkow, 2007a; 2007b). Research findings suggest that as many as 20 percent of MAT program participants experience relapse into illicit opioid use (Kreek, 2007). Taken together, these considerations strongly suggest that any therapeutic adjunct associated with reduced relapse risk is likely to reduce harm potential and benefit the health and well-being of the MAT program participant.

Theoretical Foundation

Potential for Mindfulness-Based Treatment Adjuncts

Mindfulness-based treatment interventions are effective in treating substance use disorders and their associated craving, seeking, and using behaviors (Bowen et al., 2005; Bowen et al., 2009; Chiesa & Serriti, 2013; Garland et al., 2012; Witkiewitz & Bowen, 2010; Witkiewitz et al., 2012; Witkiewitz et al., 2005; Zgierska et al., 2009). In their evaluation of mindfulness-based treatments for substance use in an incarcerated population Bowen et al. (2006) found a significant reduction in opioid and other substance use during treatment and at three-month follow-up. Witkiewitz et al. (2005)

found that use of mindfulness and CBT practices reduced symptomatic severity of opioid and other substance abuse disorders in participants.

Mindfulness based relapse prevention (MBRP) uses mindfulness meditation and cognitive behavioral therapy practices to reduce substance use relapse (Bowen et al., 2011; Bowen et al., 2006; Bowen et al., 2009; Marlatt & Chawla, 2007). Marlatt and Chawla and Ostafin and Marlatt (2008) found that continued mindful experiencing of substance use cravings deconditions the association between substance use behavior and the craving, thereby decreasing vulnerability to relapse. Marlatt and Chawla observed that this therapy ultimately reduces substance cravings and counteracts substance addiction through facilitating awareness and acceptance of the present moment experience, where such experience is in some way disturbing or uncomfortable, thereby reducing the individual's propensity toward using substances to cope with aversive existential realities.

A relapse liability exists in opioid dependent persons. Cognitive deficits in prefrontal cortex (PFC) mediation of signals from the mesolimbic dopaminergic system increase opioid dependent individuals' vulnerability to environmental substance use cues and reduce their capability for regulation of drug craving and seeking behaviors (Childress et al., 2008; Dennis & Scott, 2007; Kosten & George, 2002). Wenk-Sormaz (2005) showed in a randomized, controlled study that meditation facilitated cognitive flexibility and affective responsivity and deconditioned maladaptive implicit cognitive and affective functioning. This suggests that engagement in mindfulness-based practices

may increase individual capability for regulating emergence of autonomic substance use cravings through upregulation of PFC functioning.

Role of Neurobiological Research Findings

Ostafin and Marlatt (2008) posited that addiction implies the existence of automatic processes that are largely nonconscious, unintentional, and difficult to control. Wenk-Sormaz (2005) observed that mindfulness practices, through their emphasis on decentered attentiveness toward phenomena and facilitation of volitional states of selective arousal, deautomatize habitual cognitive processing and facilitate awareness of cognitive processes that include intentionality, attentiveness, and awareness. Mindfulness facilitates reregulation of previously habituated substance use-related cognitive and behavioral patterns into more adaptive and beneficial processes (Ostafin & Marlatt). States of mindfulness have been empirically associated with stronger PFC structure and more adaptive regulation of limbic system signaling (Brewer et al., 2010; Ostafin & Marlatt). Taken together, these neurobiological research findings suggest that mindfulness practices may enhance control of opioid use cravings and seeking behaviors, thereby reducing illicit opioid use and resultant health risk behaviors and offering concomitants of symptomatic relief and improved quality of life for participants.

Examining the effects of MBRP on individuals participating in MAT for opioid dependence necessitates evaluation of the nature of opioid use disorder, including its neurobiological, psychological, and social concomitants, and their potential interrelationship with the constituent experiential elements that together comprise the

state described as mindfulness. To that end, the etiology, theoretical perspectives, and empirically supported treatment options for opioid use disorder with physiological dependence are investigated, together with a description of how the condition is evaluated and treated within the context of a MAT environment. Neurobiological structure and functioning relevant to opioid use disorder are explicated. A brief description of the history and development of MAT programs is offered, along with a synopsis of the current MAT program philosophy and approach to opioid use disorder treatment.

Following this, the nature of mindfulness and mindfulness practices are discussed. Neurobiological structure and functioning relevant to states of mindful attention are evaluated, and the implications of these findings for use of MBRP as an adjunctive treatment for opioid use disorder are explored. Finally, relevant aspects of contemporary psychological treatment approaches incorporating mindfulness practices are described, the use of treatment interventions based on these models is explicated, and the relevance of these theoretical constructs and interventions for treatment of opioid use disorder within the context of MAT programs is offered.

Theoretical Bases for Substance Use Disorders

Three predominant theoretical explanations for the etiology of substance use disorders exist. Physical dependence theory explains substance use disorders (SUDs) as arising from neurobiological changes associated with drug exposure and continued use (Koob & Kreek, 2007). Positive-incentive theory asserts that SUDs occur because of the

interrelationship between hedonic drug effects and expectations about those effects held by the substance user (Kolb & Wishaw, 2009). Classical conditioning theory emphasizes the effects of drug exposure over time on unconscious cognitive functioning (Koob & Kreek, 2007; Koob & Moal, 1997; Nestler & Aghajanian, 1997).

Physical Dependence Theory

Koob and Kreek (2007) observed that physical dependence theory asserts through repeated drug administration the individual develops tolerance and dependence. Tolerance is observed when sensitivity to drug effects decreases. Alteration of the dose-response curve results in attenuated drug effects given continued dosing at the same level, with resultant need to increase the drug dosage to regain desired drug effects. Dependence is observed when the individual maintains optimal levels of the drug within his or her physiological system in order to prevent the onset of withdrawal syndrome, the constellation of aversive symptoms uniquely characteristic to each substance when drug administration is discontinued or reduced.

Koob and Moal (1997; 1998) asserted that dependence arises through hedonic homeostatic dysregulation, as central nervous system neurotransmitter levels adjust in response to exogenous drug molecule exposure, a condition referenced as allostasis (Koob & Moal, 1997; 1998). Thus, in response to continued administration of exogenous opioids natural opioid (endorphin) production is downregulated. Should the exogenous opioid supply be reduced, the individual experiences the characteristic aversive signs and symptoms of opioid withdrawal, including dilated pupils, sweating, tearing, agitation,

nausea, and diarrhea, among others (Parrino et al., 1993). Initial treatment approaches suggested that through detoxification a substance dependent individual could gradually reduce her or his physical dependence on the substance and eventually achieve a state of drug abstinence without associated withdrawal discomfort (Koob & Kreek). However, as Koob and Kreek observed, the majority of detoxified individuals relapse into substance use, leading to considering treatment alternatives to detoxification.

Positive Incentive Theory

Positive-incentive theory attempts explanation of substance use disorders through suggesting that the euphoria associated with substance use is the primary motivator for continued substance use, rather than abstinence syndrome avoidance (Kolb & Wishaw, 2009). This theory is based on the hedonic hypothesis (Kolb & Wishaw), suggesting that pleasure associated with substance use is the primary motivator for continued use. Moal and Koob (2007) noted that two interrelated functions are central to positive-incentive substance use theory: the positive incentive value, describing the individual's anticipated pleasure of substance effects; and the hedonic value, the actual pleasurable effects of the drug that the individual experiences.

Kolb and Wishaw (2009) observed that with repeated drug administration, the positive incentive value increases, thereby explaining the substance user's transition along the substance use continuum from initial drug exposure, to regular use, to abuse, and thence to dependence. This suggests why some individuals do not become addicted to substances, because their perceptions that attribute positive incentive value to a

substance are insufficient to motivate them to use the substance repeatedly. A related explanation in some cases is that positive incentive value for some substance using individuals does not change with repeated exposure as it does with their substance dependent counterparts. Moal and Koob (2007) noted that the compulsion to continue administrating the drug is largely driven by its perceived positive-incentive value, which facilitates sensitization to anticipated drug effects, whereas the individual will tend to become increasingly desensitized toward the hedonic effects of the substance. This suggests why many substance abusers and dependents continue to use, and their substance use cravings actually increase, despite their experiencing of decreased hedonic drug effects. A limitation of the positive-incentive theory is that it fails to account for classical conditioning effects associated with continued substance use and fails to explain the phenomenon of nonconscious interoceptive and exteroceptive cueing associated with substance craving and withdrawal states (Childress, 2008; Koob & Kreek, 2007).

Classical Conditioning Theory

Learning theory, as applied to substance use disorders, suggests that repeated instances of substance using behavior result in classical conditioning effects, thereby fostering interrelated psychological and neurobiological constituents of substance dependence (Koob & Kreek, 2007; Koob & Moal, 1997; Nestler & Aghajanian, 1997). Conscious and nonconscious associations motivate the individual to continue substance use through repeated contemporaneous pairings of substance administration with hedonic drug effects (Childress et al., 2008). Koob and Kreek asserted that continued exogenous

drug administration raises the hedonic reward threshold experienced by the user, thereby fostering continued increases in drug administration in order to achieve the desired drug effects.

Koob and Kreek (2007) asserted that this conditioning is similar to that involved in other intrinsically rewarding behaviors such as eating, drinking, and sexual activity. Such behaviors are associated with upregulation of the neurotransmitter dopamine throughout various components of the mesocorticolimbic pathway of the mesotelencephalic dopamine system of the brain (Koob & Moal, 1997; Kosten & George, 2002). Neurotransmissions from the ventral tegmental area to the nucleus accumbens are implicated in dopamine upregulation associated with addictive behavioral conditioning (Kosten & George). Moal and Koob (2007) posited that addiction develops through changes in striatal regulation mechanisms; specifically, through increased dorsal striatum activity along with activation of hypothalamic stress circuits, along with concurrent reduction in prefrontal cortex mediation of these centers. Koob and Kreek observed that the prefrontal cortex mediates relapse associated with drug-priming effects, the amygdala is implicated in cue-activated relapse, and the hypothalamus mediates relapse associated with stressors.

Moal and Koob (2007) described contingent drug tolerance as that associated with drug effects experienced by the substance user. The individual tends to experience these effects within the situational context associated with original conditioning to the drug effect, thereby creating classically conditioned compensatory response tolerance effects.

Situational stimuli become predictive of drug effects, such that normative levels of substance tolerance may not exist in novel situations, thus exacerbating the risk of overdose, even with previously administered amounts of the same substance the individual is dependent on. Both interoceptive and exteroceptive situational stimuli are conditioned with continued substance administration and tend to increase drug sensitization effects. Situational compensatory conditioning effects likely factor in the phenomenon experienced by many individuals with opioid use disorder histories, who, despite years of abstinence and recovery, may experience the onset of opioid withdrawal symptoms when exposed to an environmental cue associated with prior drug use experience (Parrino et al., 1993). Situational compensatory conditioning effects suggest why some individuals with considerable substance use experience situational specific opioid overdose.

Substance Use Pathology

Substance use occurs along a continuum, ranging from: (a) non-pathological, experimental or casual use; to (b) escalating drug abuse with resultant harmful effects; and thence to (c) pathological, compulsive use associated with physical dependence on the substance (APA, 2013; Moal & Koob, 2007). Dyscontrol of substance use is evidenced despite adverse consequences (APA; Moal & Koob, 2007). This symptomatic constellation includes several additional neurobiological and behavioral effects. There is a marked propensity for relapse despite even years of abstinence. Affective dysregulation associated with substance using behaviors that fosters continued substance use (e.g.,

substance use as coping) is frequently evidenced. Also observed is compromised executive functioning that reduces the individual's capacity for regulating behavior appropriately and effectively, leading to dysfunctional behaviors at home, in the workplace, and in larger social settings. Increased compulsion and preoccupation with substance craving, seeking, and using is frequently found. Secondary illnesses associated with substance toxicity effects may occur. Co-occurring medical and psychiatric conditions that are secondary to, or exacerbated by, continued substance use are also frequently observed (Moal & Koob, 2007; Leshner, 2001). Leshner (1999; 2000) asserted that the psychological, social, and physical functional impairments associated with substance use disorder are highly unlikely to resolve without treatment.

Historically, substance use disorders have been viewed as personal and social failure. Social perspectives on persons with substance use problems have insistently regarded such individuals as immoral and amotivated (Volkow, 2007a). These negatively biased public perceptions continue to persist (Livingston et al., 2012). Substance use disorders pose a societal challenge to overcome these longstanding negative assumptions and biases misrepresenting substance use disorders as characterological problems (Volkow).

Nature of Opioid Use Disorder

This study's predominant focus is on evaluating the effectiveness of a specific mindfulness-based manualized treatment for individuals participating in MAT for opioid use disorder. A review is offered of the nature of opioid use disorder and its effects.

Understanding the neurobiological substrates of opioid use disorder provides a context within which the effects of mindfulness practice on neurobiological systems implicated in the opioid use disorder condition are more clearly apprehended and evaluated. This discussion now focuses on neurobiological structures and functions associated with substance use conditions.

Mechanism of Action

Opioid drugs are classified according to their mechanism of action in the CNS. Agonists, such as heroin, oxycodone, and methadone increase brain cell activity at specific CNS receptor sites. Antagonists, such as naltrexone, decrease brain cell activity at specific CNS receptor sites. Partial agonists, such as buprenorphine, both increase and decrease brain cell activity at specific CNS receptor sites (Koob & Moal, 2007; Parrino et al., 1993, SAMHSA, 2020).

Agonist Drug Effects

Agonist drugs increase synaptic activity (Stanford, 1988). Synapse references the microscopic space lying between adjacent neurons, where a predominant number of receptor sites are located for the purpose of neurotransmission (Koob & Moal, 2006). Direct acting drug molecules attach to receptor sites; and indirect acting drug molecules target other synaptic functions, such as neurotransmitter reuptake (Koob & Moal, 2007). Examples of direct acting drugs include heroin, morphine, methadone, and other opioids (Koob & Kreek, 2007). Examples of indirect acting drugs are amphetamine, methamphetamine, and cocaine (Koob & Kreek). Parrino et al. (1993) observed that one

reason humans may be especially vulnerable to opioid dependence is due to the structural similarities between endogenous opioid neurotransmitters such as μ-opioids (Zubieta et al., 2005), and exogenous opioid molecules, such as codeine, oxycodone, heroin, and morphine.

Homeostasis, Tolerance, and Dependence

Homeostasis references the innate tendency for physiological systems to function toward balance (Koob & Moal, 1997). The central nervous system (CNS, e.g., brain and spinal cord) operates on this principle. Use of exogenous drugs disrupts homeostasis, resulting in CNS attempts to regain neurobiological equilibrium (Koob & Moal). Koob and Moal asserted that where illicit substance use continues for extended periods, neurobiological homeostasis is impaired, resulting in a state of disequilibrium that leads to a state of hedonic homeostatic dysregulation, wherein natural neurotransmitter functioning re-regulates to maintain the new, artificial neurobiological homeostasis partially dependent upon the exogenous drug supply.

Koob and Moal (1997) posited that this hedonic homeostatic dysregulation state results in emotional distress that is frequently associated with further substance use. Continued disruption of homeostasis through substance use thus results in neurobiological and thence psychological dependence, the condition of allostasis (Koob & Moal, 1997). This state is identified in DSM5 (APA, 2013) as substance use disorder with physiological dependence. Given this condition, the individual is neurobiologically and physiologically dependent on the exogenous substance.

Tolerance is the process the body engages in to achieve homeostasis in response to exogenous substance exposure (Koob & Moal, 2006; 2007). It results in physiological adaptation to greater drug potency, more frequent drug use, or increased drug exposure through changes in method of drug administration, such as from oral use to intravenous use. Increased drug exposure results in increased tolerance, eventually resulting in using the substance to prevent the onset of abstinence syndrome rather than to obtain euphoric drug effects initially experienced (Koob & Moal, 2006; 2007; Parrino et al., 1993; Stimmel & Kreek, 2000).

Dependence and tolerance are interrelated, in that increasing drug use is directly associated with increased tolerance to the drug effects and the resultant condition of allostasis (Moal & Koob, 2007). Once allostasis occurs, continued exogenous drug exposure is necessary to prevent the onset of abstinence syndrome, the constellation of withdrawal symptoms associated with the specific drug used (Moal & Koob; Parrino et al., 1993). Thus, hedonic homeostatic dysregulation (Koob et al., 1998) leads to allostasis and at that point, the individual is physiologically dependent on the exogenous substance. Koob and Moal (1997) posited that the individual is compelled to respond to environmental disequilibrium (insufficient substance availability) with substance seeking and using behaviors in order to maintain allostasis.

Continued allostasis, or drug dependence, is fostered through exposure to hedonic effects of drug exposure predominantly reinforced through associated increases in

dopamine levels (Moal & Koob, 2007), and secondarily reinforced through associated reductions in frequency and severity of aversive abstinence syndrome effects.

Opioid drug molecules have an affinity for mu receptors in the nucleus accumbens, ventral tegmental area, and locus ceruleus brain areas; all implicated in opioid use disorder (Kolb & Wishaw, 2009; Kosten & George, 2002). Three CNS functions are implicated in opioid use disorder. The first is the initial condition of hedonic homeostatic dysregulation wherein the reward pathway is activated in response to continued exogenous opioid exposure leading to allostasis and resultant physiological dependence on exogenous opioids. The second is classical conditioning hedonic effects of exogenous opioid exposure and avoidance of aversive effects experienced in opioid withdrawal. The third is cognitive deficits that foster continued opioid use and dependence (Kosten & George, 2002; Moal & Koob, 2007).

Reward Pathway

The neurobiological system predominantly implicated in opioid use disorder is the CNS (Kolb & Wishaw, 2009). Kolb and Wishaw observed that CNS functioning regulates hunger, thirst, and sexual drives, reinforcing behaviors that address these core survival needs. These brain areas are collectively referenced as the mesolimbic dopaminergic reward pathway (Kosten & George, 2002; Moal & Koob, 2007). Reward pathway function and structure fosters conditioned behavioral responses, predominantly through increases in levels of the neurotransmitter dopamine that are temporally associated with engagement in the desired behavior (Kosten & George; Moal & Koob).

In this way, opioids and other drugs of abuse function as dopamine agonists by increasing the levels of that neurotransmitter in the brain (Koob & Moal, 1997; Koob et al., 1998).

Through operant neuronal cellular conditioning processes, these increases in dopamine levels associate the cue, which can be the drug exposure itself or any environmental factor associated with drug use, with euphoric mood (Childress et al., 2008; Moal & Koob, 2007). Childress et al. noted this neurobiological mechanism activates in response to the individual's exposure to drug-associated environmental cues, resulting in onset of drug craving, and in some cases, abstinence syndrome. Koob and Kreek (2007) observed that for persons with opioid use disorder exposure to environmental stressors precipitates the onset of drug cravings and withdrawal symptoms. Moal and Koob observed that substance use behaviors are reinforced through this reward pathway functioning such that the compulsion to seek and use drugs becomes the affected individuals' predominant focus.

Opioid-Associated Reward Pathway Activation

Given continued exogenous opioid use, mu receptors in the brain become occupied with the exogenous opioids. Moal and Koob (2007) observed that repeated ingestion of exogenous opioids activates homeostatic functioning, reducing endogenous endorphin production that results in the condition of hedonic homeostatic dysregulation. Continued exposure to exogenous opioids thence fosters the condition of neurobiological allostasis where the individual is dependent on the exogenous opioid supply in order to maintain optimal levels of pain control and mood regulation and avoid the onset of opioid

withdrawal symptoms (Moal & Koob, 2007). The individual is then physiologically dependent on exogenous opioids, thus meeting diagnostic criteria for opioid use disorder 304.00 according to DSM-5 criteria (APA, 2013); described as either mild (305.50), moderate (304.00), or severe (304.00), depending on associated symptom prevalence.

Classical conditioning effects reinforce associations between this euphoric mood and opioid use, fostering continued use of exogenous opioids. The ventral tegmental area within the brain's reward pathway increases release of dopamine in the nucleus accumbens resulting in enhanced sensations of well-being and euphoria (Kosten & George, 2002; Sun et al., 2011). Any period of exogenous opioid abstinence results in onset of aversive opioid withdrawal symptoms, further reinforcing continued ingestion of exogenous opioids (Kosten & George). Most individuals with this condition will engage in continued illicit opioid use in their attempts to feel a sense of well-being and to avoid the discomfort of opioid withdrawal.

Individuals with opioid use disorder frequently continue their illicit drug seeking and using behaviors despite severe socioeconomic consequences (Moal & Koob, 2007). Such behaviors are often asserted as evidence of the affected individual's lack of commitment to recovery from substance use, or as evincing his or her lack of sufficient willpower or poor character (Volkow, 2007a). Kosten and George (2002) suggested that the prefrontal cortex (PFC), an integral part of aforementioned neurobiological reward pathway, regulates cognitions associated with adaptive executive behaviors and thus normally inhibits engagement in high-risk behaviors. Kosten and George observed that in

individuals with opioid use disorder these sound judgment and planning capabilities are compromised, being overridden by bottom-up neurobiological signals from the brain's limbic system that support opioid drug craving, seeking, and using despite the likelihood of aversive consequences.

Moal and Koob (2007) posited that inhibitory top-down messages sent from the PFC advising against illicit opioid use and its inherent psychosocial, legal, health, and economic consequences are negated by the bottom-up signals emanating from the limbic system, regulated in part by contextual drug-associated memories stored in the hippocampus and the associated withdrawal anxiety and fear associations regulated by the amygdala. Koob et al. (1998) asserted the existence of a residual deficit state in the neurobiological reward pathway that leaves the substance dependent individual vulnerable to and predisposed toward relapse. Nestler and Aghajanian (1997) observed that chronic opioid use results in genetic adaptations that foster structural and functional changes in CNS neuronal and synaptic structures, thereby increasing the affected individual's liabilities toward opioid use disorder.

Opioid Receptor Sites

The molecular structure of opioid drugs helps them attach to opiate receptor sites in the brain (Kosten & George, 2002). Parrino et al. (1993) noted that natural opioid compounds such as codeine and morphine, semisynthetic compounds such as heroin, and synthetic compounds including oxycodone, hydromorphone, and methadone, readily occupy these receptor sites. Parrino et al. asserted that whereas there are other opioid

receptor types in the CNS, the mu receptor is predominantly implicated in the condition of opioid use disorder.

Endogenous and Exogenous Opioids

Endogenous opioids naturally occupy mu receptor sites within the CNS (Parrino et al., 1993). These endorphin and enkephalin opioid protein molecules are referenced as peptides, and under normative conditions, the CNS uses them to help regulate pain and mood (Parrino et al.). Homeostatic regulation processes cause these natural opiates to reduce or stop producing in response to exogenous opioid use. Mu opioid receptor sites are then occupied by exogenous opioid molecules reflecting the condition of allostasis (Moal & Koob, 2007; Parrino et al.).

Persistent Receptor Disorder

In their seminal research on opioid use disorder and its treatment using methadone, Dole and Nyswander (1965) observed that replacement of endogenous with exogenous opioids results in persistent receptor disorder, a process subsequently identified as hedonic homeostatic dysregulation (Koob & Moal, 1997). Where reduced levels of the exogenous opioid drug are not replaced by natural opioids, mu receptor sites are left unoccupied and the individual experiences the resultant discomfort of withdrawal symptoms (Moal & Koob, 2007). To avoid the aversive experience of opioid withdrawal individuals engage in opioid drug seeking behavior thereby explaining the chronic relapsing nature of opioid dependence.

Opioid Abstinence Syndrome

Opioid abstinence syndrome (OAS), or opioid withdrawal, occurs in individuals that have physiological dependence on exogenous opioids and experience abrupt discontinuance of the drug supply. Kosten and George (2002) asserted that in opioid withdrawal reduced levels of mu receptor site occupation within the locus ceruleus elevates noradrenaline levels resulting in a constellation of aversive signs and symptoms (see Table 1). OAS frequently results in opioid craving and seeking behavior because the affected person seeks immediate relief from the resultant physical discomfort. Simply ruminating on the possibility of experiencing OAS frequently results in discomfort anxiety (Ellis et al., 1988) that motivates the opioid dependent person to engage in drug seeking and using behavior regardless of potential life consequences (Kosten & George).

Frequently used illicit opioids include those with a short half-life of about four hours, such as hydrocodone and heroin (Parrino et al., 1993). This brief half-life means that unless the drug is readministered about every four hours, mu receptor site occupation will decrease resulting in the onset of opioid withdrawal symptoms (Kosten & George, 2002). Further, as opioid tolerance and dependence increase, the individual must either increase frequency of his or her opioid drug use or use a more potent form of the drug in order to stave off withdrawal symptoms (Dennis & Scott, 2007). Opioid dependent individuals seeking MAT program services frequently report increasing opioid use to avoid the discomfort of OAS rather than to enhance euphoria (Parrino et al.). The

following table indicates signs and symptoms associated with opioid abstinence syndrome:

Table 1

Objective and Subjective Opioid Withdrawal Signs and Symptoms

Objective	Subjective
Runny nose (rhinorrhea)	Diarrhea
Dilated pupils	Nausea
Tearing eyes (lacrimation)	Insomnia
Sweating (diaphoresis)	Chills
Gooseflesh (piloerection)	Abdominal pain
Yawning	Muscle/joint aches
Sneezing	Anxiety
Coughing	Crawling skin sensation
Salivating	Irritability
Gagging/vomiting	Jitteriness
Restlessness	Opioid craving/seeking/using

Note: Adapted from "State methadone treatment guidelines (Technical Assistance Publication Series # 7)," by Parrino et al., 1993, pp. 106-113. Published in the public domain by U.S. Department of Health and Human Services, Substance Abuse and Mental Health Administration, Center for Substance Abuse Treatment.

Environmental cues can trigger onset of OAS. Cue reactivity in substance use disorders is strongly associated with substance cravings, urges to use, and onset of objective and subjective substance withdrawal signs and symptoms (Childress et al., 2008; Dennis & Scott, 2007). Childress et al. suggested that cue reactivity occurs nonconsciously in response to environmental triggers prior to conscious awareness of or volitional control over neurobiological and related physiological responses to the environment. Parrino et al. observed that individuals with opioid use disorder frequently

experience onset of OAS from encountering situations similar to those in which prior opioid use occurred. The inherently aversive nature of opioid withdrawal and the ready availability of its environmental precipitants suggest the need for effective cognitive behavioral interventions to regulate these involuntary symptoms.

Considered together, the neurobiological functions of mesolimbic reward pathway activation, hedonic homeostatic dysregulation, allostasis, cognitive deficits, and opioid abstinence syndrome strongly suggest that the opioid dependent person, without treatment intervention, will tend to be increasingly preoccupied with illicit opioid craving, seeking, and using, regardless of potential adverse consequences (Kosten & George, 2002; Leshner, 2001; Moal & Koob, 2007). These considerations further suggest that in order to be effective, any form of treatment for the condition of opioid use disorder must increase the affected person's capabilities for mediating these neurobiological liabilities. This proposal now examines use of methadone medication in the context of MAT programs, an evidence-based treatment intervention that effectively addresses the preceding problems and facilitates a return to normal human functioning for the opioid dependent person.

Methadone Medication Use and Effects

Introduction to Methadone Medication

Parrino et al. (1993) observed that methadone is a synthetic opioid analgesic with a half-life of 24-36 hours. Medication formulations include 40 mg wafers, 10 mg tablets, and a 10mg. per ml. oral liquid solution. Parrino et al. suggested that methadone

medication is effective because of its neuropharmacological mechanisms including mu opioid receptor binding, neurological blockade, and steady state neurological regulation.

Mu Opioid Receptor Binding

When methadone metabolite molecules bind with mu opioid receptors in the brain the methadone metabolite molecules cross the blood brain barrier and occupy mu receptor sites in the brain's ventral tegmental area and locus ceruleus, both key functional areas in the mesolimbic reward pathway (Dole & Nyswander, 1965; Kosten & George, 2007). Kosten and George posited that this bonding action within the ventral tegmental area of the brain's limbic system structure elevates dopamine levels in the nucleus accumbens, resulting in nominal feelings of contentment and wellbeing, much as the average non-opioid dependent individual is likely to experience when engaged in rewarding behavior. The mu receptor sites remain occupied by methadone metabolite molecules for up to 36 hours-during which the individual feels normal levels of well-being and emotional responsiveness and does not experience OAS (opioid withdrawal signs and symptoms) or opioid cravings (Dole & Nyswander; Parrino et al., 1993). These drug effects are essential in facilitating stable mood, preventing onset of opioid withdrawal distress, and forestalling opioid use cravings that would otherwise precipitate relapse into illicit opioid use.

Illicit Opioid Blockade Effects

The efficacy of methadone medication is partly due to the affinity for its molecules demonstrated by mu receptors in the brain. In their early research, Dole and

Nyswander (1965) posited that methadone molecules would bind to mu receptor sites even in the presence of competing alternate opioid molecules including heroin. Parrino et al. (1993) observed that this mu receptor site affinity for methadone molecules resulted in the therapeutic medication effect identified as euphoric blockade. Parrino et al. noted that when methadone molecules are bound to the mu receptor sites other competing opioid molecules are prevented from binding, with resultant reduction or elimination of hedonic and other drug effects that would otherwise be experienced through exposure to exogenous (presumably illicit) opioids. Thus, there is a marked reduction in the classically conditioned effects normally associated with exogenous illicit opioid use. Because the methadone maintained individual experiences significantly reduced relapse precipitants he or she is much less likely to continue using illicit opioids.

Steady State

Methadone medication has a lengthy half-life of up to 36 hours (Preston et al., 2013), markedly different from the typical four-hour half-life of heroin, hydrocodone, or morphine (Batki et al., 2005; Parrino et al., 1993). Daily ingestion of methadone results in an adaptive form of allostasis, referenced as steady state, where the methadone blood levels have reached reasonably optimal consistency and mu receptor sites in the CNS have fully bound with methadone molecules (Batki et al.; Parrino et al.). Batki et al. suggested that MAT program patients normally achieve steady state regulation within five days. An additional pharmacological property of methadone is that once steady state is achieved the individual can be maintained indefinitely at the same dosage level and

experience continued beneficial drug effects without increasing either tolerance or dependence (Batki et al.; Parrino et al.). Thus, individuals participating in MAT programs utilizing methadone pharmacotherapy avoid the aversive effects of hedonic homeostatic dysregulation as they benefit from the adaptive allostasis afforded by methadone medication.

The benefits of methadone maintenance include alleviation of the signs and symptoms of opioid abstinence syndrome, reduction and eventual elimination of illicit opioid craving and drug seeking behaviors; and inhibition of euphoria associated with illicit opioid abuse (Parrino et al., 1993).

Kreek (2000) asserted that MAT program participation using methadone medication is associated with more adaptive neuronal functioning within the reward pathway systems and improved stress response capabilities. Kreek and Koob (2007) suggested that because stress exposure has been determined to be a significant relapse precursor in opioid dependent individuals, the beneficial stress coping effects of methadone medication use are likely to prevent relapse or reduce its severity and duration, thereby enhancing well-being and resilience in the patient with opioid use disorder. Parrino et al. (1993) asserted that methadone pharmacotherapy within the context of the MAT program is safe and effective; the medication is prescribed and administered by licensed medical personnel extensively trained in the treatment of substance use disorders. Parrino et al. further noted that because daily methadone

pharmacotherapy reduces or eliminates illicit opioid use in most patients, associated risks to physiological and psychological health are correspondingly reduced.

Risks Associated with Methadone Medication Use

As with any medication, there are risks associated with the use of methadone. Within the context of its use at MAT programs, these risks are usually minimal. Methadone acts as a central nervous system depressant and can cause sedative effects including drowsiness, respiratory depression, coma, and death (Batki et al., 2005; Parrino et al., 1993). Although there has been a marked increase in methadone associated mortality (Fingerhut, 2008), these problems have been predominately associated with private physician pain treatment administration, whereas MAT program use of methadone continues to be safe and effective (SAMHSA, 2020). Consistent with using any drug with potentially sedating effects, methadone-maintained patients must use caution when operating motor vehicles or dangerous machinery. Parrino et al. suggested that in some cases methadone medication increases sedative effects of other medications exerting sedative effects, such as benzodiazepines. Batki et al. advised that methadone could increase the sedative effects of alcohol, advising against concurrent ingestion. The Food and Drug Administration (FDA; 2007) warned that ingestion of even a single methadone dose may be lethal for a person not physically dependent on opioids. In keeping with this proscription, the SAMHSA (2020) recommended a very low methadone dosage (5mg to 10 mg daily) when initiating methadone treatment.

Side Effects of Methadone Medication

All medications have side effects that need to be considered when use is indicated. Methadone acts as a central nervous system depressant and can cause sedative effects including drowsiness, respiratory depression, coma, and death (Batki et al., 2005; Parrino et al., 1993). The FDA (2007) and Parrino et al. (1993) asserted that common side effects of methadone medication include mild constipation (typical with most opioids), sweating, changes in libido, and lethargy.

Parrino et al. (1993) posited that severity of these side effects recedes over time. The MAT program physician plays a key role in assisting the patient with managing these side effects. The FDA (2007) asserted that individuals maintained on methadone medication will experience the condition of physiological opioid dependence, thus abrupt discontinuance of the medication results in rapid onset of opioid abstinence syndrome with resultant physiological discomfort, psychological distress, and elevated relapse risk.

Benefits of Treatment in MAT Programs

Participation in MAT using methadone is associated with significant reductions in criminal activity (Parrino et al.), illicit opioid use, alcohol misuse, and other drug use (Batki et al., 2005). After stabilization on methadone medication, the properly maintained methadone patient is fully functional (Batki et al.). Positive behavioral changes are learned or reacquired as treatment continues. The patient gains insight through participation in ongoing supportive counseling largely based on therapeutic approaches inclusive of accurate empathy, acceptance, and genuineness (Miller & Rollnick, 2002;

Rogers, 1957; 1961; 1979; 1980), and through development of the therapeutic alliance with his or her counselor (McCann et al., 1994). These functional improvements result in learning or reacquisition of adaptive lifestyle changes. The MAT program patient thence benefits from substantial improvements in intrapersonal and interpersonal functioning.

MAT treatment is associated with significant reductions in societal costs associated with opioid use disorder. Overutilization of public health systems associated with drug misuse, active drug craving, and seeking are lessened, and interaction with the legal system is significantly reduced, thereby lessening associated costs (Parrino et al., 1993). Reduction in health risks associated with opioid injection use is significantly reduced (SAMHSA, 2020). In California, the annual cost for methadone maintenance for a single individual is approximately $5,000 annually, minimal in comparison to the yearly prison expenses of up to $60,000 annually (Gerstein et al., 1994). Gerstein et al. found the cost-benefit ratio for MAT patients maintained on methadone was $1.00/$7.00. These data suggest multiple societal benefits exist for maintaining individuals with opioid use disorder in MAT programs.

Clinical Effectiveness of Methadone Medication

Research over the past several decades suggests that participation in MAT programs using methadone pharmacotherapy is a highly effective treatment approach for individuals with opioid use disorder (Ball & Ross, 1991; California Society of Addiction Medicine, 2008; Leshner, 1999; 2001; Rothbard et al., 1999). The combination of daily methadone medication pharmacotherapy, medical care, and counseling support provided

for MAT program participants effectively mediates the neurobiological substrates implicated in the condition of opioid use disorder (Childress et al., 2008; Dennis & Scott, 2007; Kosten & George, 2002). In addition, MAT programs are cost-effective forms of treatment (Barnett, 1999; Doran et al., 2003). Despite the effectiveness of this comprehensive treatment approach, relapse risk remains as high as 69 percent for a significant number of MAT program participants (Rosencrantz et al., 2007); particularly those who have not yet stabilized in treatment or are exposed to severe environmental stressors (Kreek, 2002; 2007). This suggests that any additional treatment interventional approach readily accessible to a majority of MAT program patients that effectively reduces relapse frequency and severity is likely a clinically useful treatment adjunct. This proposal evaluated one such treatment adjunct: MBRP (Bowen et al., 2011).

Conceptual Framework

In this section historical antecedents of mindfulness-based practices are explored. The theoretical and interventional elements of various clinical approaches based on mindfulness practices will be examined. Given that mindfulness practices reflect a unique and specific approach to attentional mediation the psychological and neurobiological factors of attentional regulation are evaluated. Following this, research evaluating the neurobiological substrates of mindfulness practices is examined, and the implications of this research for addressing the neurobiological dysfunction associated with the condition of opioid use disorder are explained.

Historical Antecedents of Mindfulness Practices

Mindfulness-based practices arose from Vipassana, a term used to connote breathing or insight meditation (Jain et al., 2007). Vipassana denotes a contemplative approach utilizing awareness of breathing as a means of focusing attention. Present-day mindfulness practices evolved from Buddhist teachings originating some 2,500 years ago. These early philosophical and contemplative learnings were preserved as an oral tradition, eventually being documented in written form in two disquisitions: the Anapanasati Sutra and the Satipatha Sutra (Goldstein, 2013; Kabat-Zinn, 1982; Rosenberg, 1999). Gunaratana (2002) and Kabat-Zinn (1982) observed that individuals studying mindfulness practices are taught to approach their learning with skepticism and curiosity.

Mindfulness practices reflect use of a critical, investigative mindset where experiential phenomena are evaluated with each mindfulness practitioner's perceptions, attitudes, and attentional mediation capabilities forming the basis for his or her experiential evaluation. Empirical investigations of mindfulness approaches for treating illness were initially conducted to evaluate mindfulness-based stress reduction (MBSR; Kabat-Zinn, 2003) as a treatment for chronic pain secondary to cancer, and to address other physical conditions such as dermatitis. Subsequently, multiple mindfulness-based treatment approaches have been developed and empirically examined.

Attentional Regulation

Mindfulness practices are predominantly focused on regulating attention. A background in attentional regulation and its implications for mindfulness and substance use is explored in the following.

Cowan (1988) said selective attention is composed of an executive regulation function, attentional orienting function, perceptual filtering capability, and habituation. Pessoa and Ungerleider (2005) said these functions are limited by maximal processing capacity, or cognitive loading effects, and by processing motives, where the individual attends to data based on its salience and valence properties. They further noted that unattended processing attenuates. These perspectives suggest that humans are capable of attending volitionally to data in the internal and external environments, and yet retain the capability for responding automatically to some data percepts, and concurrently assimilating and responding to new data as well (Yiend et al., 2005). Mirams et al. (2012) observed that attention data sources subject to selective regulation include interoceptive, referencing internal somatic sensations, proprioceptive, referencing positional and spatial sensory data, and exteroceptive, referencing within the external environment detected by any of the senses.

Mindfulness-based approaches to attentional regulation offer a comprehensive awareness of these same attentional functions (Kabat-Zinn, 2002; 2009; Stahl & Goldstein, 2010), achieved through cultivation of metacognitive awareness (Teasdale, 2002; Whitfield, 2006), where the person attends to all experience, regardless of salience

features. This suggests that individuals tend to respond to perceived negative stimuli through attributing negative valence, associated with aversion characteristics in mindfulness nomenclature, whereas they tend to respond to perceived positive stimuli through attributing positive valence, associated with mindful acceptance.

Cowan (1997) asserted that novel stimuli likely attract attention involuntarily due to their inherent elevated threat potential. Siegel (2012) asserted that the brain is structured to be highly sensitive toward novel stimuli, in part because previously unencountered experience poses potentially greater survival risk. Hanson (2009, 2013) and Kiken and Shook (2011) observed that the brain tends toward a negative bias, using this protective sensitivity to over broadly interpret even innocuous stimuli as threatening. Emotional associations evoked through phenomenological exposure thus direct volitional attentional processing. In the cases of opioid use urges and cravings, opioid withdrawal, elevated environmental stressor exposure, and functional cognitive deficits, the person with opioid use disorder will likely benefit from improved attentional regulation skills that mediate adverse of effects of negative biasing. Taken together, these assertions suggest potential for more effective regulation of involuntary attentional phenomena as the mindfulness practitioner learns to experience novel data as transient phenomena that can be processed acceptantly and nonjudgmentally, rather than fearfully or anxiously.

Stahl and Goldstein (2010) and Hanson (2009, 2013) asserted that mindfulness-based approaches offer a more balanced means of voluntary attentional regulation, through reducing emotional reactivity and increasing adaptive responding to

environmental stimuli. Ortinski and Meador (2004) posited that through conscious awareness the individual attends to environmental stimuli and exerts a volitional behavioral response. This resonates with mindfulness-based attentional regulation approaches where all elements of internal and external stimuli are apprehended and processed in accord with the individual's pre-established intentionality.

Mindfulness and Attentional Regulation

Ives-Deliperi et al. (2011) said downregulation of midline cortical activity during states of mindfulness meditation, specifically involving the AI, left ventral ACC, right PFC, and bilateral precuneus. In a controlled MRI investigation, Leung et al. (2013) found that loving-kindness focused mindfulness meditators had significantly greater gray matter volume in the right angular and posterior parahippocampal gyri and left temporal lobe, brain areas implicated in affect regulation and empathy. In a controlled study using comparative MRI evaluations, Hölzel et al. (2011) found significant increases in brain gray matter post-MBSR intervention in previously naïve meditators, with marked increases in structural density found in brain areas associated with improved functioning of contextual memory, emotional and affective regulation, self-awareness, and situational and social perceptual and cognitive functioning. Tang (2013) asserted that mindfulness meditators experience functional connectivity changes within the default mode network associated with enhanced present-moment awareness and reduced emotional reactivity. Using MRI neuroimaging, Zeidan et al. (2011) found that mindfulness meditation significantly reduced participant perceptions of pain intensity associated with functioning

in the ACC and AI, consistent with the findings of Tops et al. (2014), and pain aversive effects associated with activation of the orbitofrontal cortex. The Zeidan et al. study is limited by small number of participants (n = 15). Tang and Posner (2013) noted that whereas neurobiological imaging is beginning to reveal brain structure and functioning implicated in mindfulness practices, improved study controls and participant randomization are needed in order to more clearly identify specific factors of mindfulness associated with neurobiological substrates.

The neurobiological functioning implicated in mindfulness practices appears to mediate much of the aforementioned attentional neural functioning. In the treatment of anxiety and depression, mindfulness practices appear to be effective in promoting adaptive neurobiological reregulation that supports associated improvements in psychosocial functioning. In their meta-analysis, Chiesa and Serriti (2010) found that EEG readings of mindfulness meditators evidenced a connection between predominant frontal alpha and theta brainwave activity, linking them to the relaxed but attentive condition typically found in mindfulness meditation practitioners. Theta burst brainwave activity was more predominant in experienced meditators, suggesting an association between ongoing meditative practice and the ability to achieve deep relaxed meditative states of awareness, e.g., bare attention (Epstein, 1995). Moreover, Chiesa and Serriti observed that some studies suggested that MBSR and MBCT treatment effects produced increased alpha wave activity in the left-sided anterior region associated with positive mental states and beneficial immune system effects. Such effects could prove beneficial

in ameliorating the psychological discomfort associated with depressive and anxious symptoms. Chiesa and Serriti cautioned that many of these studies lack sufficient controls and participant randomization, thereby limiting their generalizability.

Enhanced Attentional Mediation Capabilities

Lutz et al. (2008) said focused meditation practice, as found in mindfulness approaches, fosters increased capability for sustaining selective attentional focus and redirecting attention when distraction occurs. In their comparative evaluation between mindfulness meditators and arithmetic calculators, Hölzel et al. (2007) said states of mindfulness meditation were associated with stronger activations in the bilateral rostral anterior cingulate cortex and dorsal medial prefrontal cortex. This condition is associated with enhanced attentional control over distractors (Hölzel et al., 2007). Increased activation of the medial prefrontal cortex, right anterior insula, and right hippocampus is thought to be associated with enhanced attention and interoceptive awareness, as well as more adaptive emotional processing (Chiesa & Serriti, 2010; Hölzel et al., 2007). In their cross-sectional controlled study of mindfulness meditators vs. non-meditators van den Hurk et al. (2010) found that attentional orienting, efficiency, and executive functioning processes were significantly more effective in meditators than in controls. In another controlled study evaluating the neural correlates of executive performance monitoring, Teper and Inzlicht (2013) similarly found that mindfulness meditators made fewer cognitive errors and exhibited greater error-related negativity of briefer duration with associated reductions in emotional reactivity. Teper and Inzlicht posited that the

beneficial effects of reduced negative emotional reactivity and enhanced performance monitoring capabilities were instrumental in achieving these executive regulatory improvements.

Limitations of Hölzel et al. (2007) include small effect size due to limited participant sample size (n = 40). There were no controls for extraneous participant variables such as substance use, duration of meditation experience, or contemplative methods used. In addition, Hölzel et al. used correlational analyses, leaving open the possibility that increased amounts of grey brain matter may attract meditators, rather than result from meditative experience. Limitations of the Teper and Inzlicht (2013) study include possible extraneous variable confounding from multiple meditative practices utilized by the experimental group participants, and the lack of an empirical measure for participant emotional reactivity. Limitations of van den Hurk et al. (2010) include cross-sectional design, limited effect size due to small number of participants (n = 40), and extraneous within experimental group variability through use of two meditational approaches: Vipassana and concentration.

Mindfulness as Adaptive Attentional Regulation

Garland et al. (2010) said exposure to mindfulness training significantly reduced the implicit responses of participants with alcohol use disorder to alcohol-associated environmental cues, supporting the contention that increased mindfulness facilitates adaptive regulation of autonomic responding to substance use cues. This finding is consistent with the observations of Lutz et al. (2008) suggesting improved attentional

regulation is associated with meditative practices. Garland et al. found that implicit attentional biases orienting and alerting toward alcohol use significantly decreased through mindfulness practice, suggesting that implicit maladaptive memory and attentional processes are effectively mediated through regular mindfulness practice. Further findings included significant reductions in perceived stress levels and marked reductions in thought suppression associated with more adaptive mediation of alcohol use cravings. Generalizability from the findings of Garland et al. is limited due to small participant sample size and lack of a control group.

Chiesa and Serriti (2010) said mindfulness meditation is associated with increased bilateral activation of the dorsal medial prefrontal cortex and rostral anterior cingulate cortex, both areas of the brain that mediate attentional regulation. Both Chiesa and Serreti, and Dakwar and Levin (2009) observed that these adaptive attentional changes associated with mindfulness meditation reduced cortical atrophy and aging-associated attentional deficits in long-term practitioners. Davis and Hayes (2011) suggested that mindfulness practices lead to attenuation of fear responses, more objective appraisal of experiential phenomena, enhanced coping skills and motivation, and reductions in maladaptive behavioral responses.

Mindfulness and Neurobiological Regulation Relevant to Substance Use Disorders

Hölzel et al. (2011a) said exposure to 8 weeks of MBSR mindfulness training facilitated adaptive changes in memory integration, emotional regulation, and regulation of self, world, and interpersonal schemas. As these elements are essential components of

executive functioning, this suggests that exposure to mindfulness practices improves aspects of executive functioning essential for managing substance use effectively.

Blume and Marlatt (2009) asserted that improvement in executive functions including attentional regulation and concentration is associated with reductions in harmful substance use. In their fMRI investigation of naïve meditators Westbrook et al. (2013) found that exposure to mindfulness practices significantly reduced craving in participants with nicotine use disorder to cigarette smoking cue exposure. Witkiewitz et al. (2012) asserted that through improved connectivity and functioning of the anterior cingulate cortex, dorsal lateral prefrontal cortex, insula, and hippocampus associated with mindfulness practices, enhanced top-down regulation of limbic and basal brain functions results in improved emotional regulation and inhibition of substance use cravings. Chiesa and Serriti (2010) asserted a number of studies have suggested that mindfulness meditation facilitates adaptive attentional control, although they advise caution in interpreting these data because of extant methodological problems in much of the research. Generalizability of these studies' outcomes is limited due to their lack of randomized controlled designs.

These neurobiological correlates of mindfulness suggest that enhanced PFC functioning associated with mindfulness practices improves PFC regulation of the limbic system, particularly the hypothalamus, hippocampus and amygdala, improving mediation of the hippocampal-amygdalal attentional orienting response. Thus, the mindfulness

practitioner learns to selectively, and more adaptively, attend to interoceptive, exteroceptive, and proprioceptive data.

Attentional and Neurobiological Liabilities for the MAT Program Patient

The neurobiological substrates associated with the MAT program patient maintained on methadone medication include an adaptive allostasis condition supported through steady state regulation (receptor occupation for extended period closely mirroring endogenous mu receptor functioning) of the mu opioid receptors located throughout the CNS. This neurotransmitter function occurs predominantly in the nucleus accumbens and locus ceruleus (Koob & Moal, 2006; Kosten & George, 2002; Parrino et al., 1999). Nucleus accumbens mu receptor occupation with methadone molecules results in upregulation of dopamine in the ventral tegmental area, associated with a perceived sense of wellbeing and contentment. However, this optimal state is inherently liable to dysregulation associated with exposure to inter- and intra-personal stressors, effects of co-occurring conditions including undertreated anxiety, depression, and posttraumatic stress disorders, and through variant methadone medication dosing patterns. Given the brain's inherent predisposition toward negativity bias (Hanson, 2013), the MAT program patient is thus liable for onset of the neurobiological concomitants and downward emotional spiraling effects of OAS onset described by Koob and Moal (1997; 2006), resulting in anxious and depressive affect that foster continued opioid use to avoid associated mental disturbances. In their meta- analysis, Hofmann et al. (2010) concluded that mindfulness-based therapies were effective in the treatment of both anxiety and

depression. Taken together, these findings suggest that mindfulness practices can effectively address the emotional dysregulation found in depressive and anxiety disorders.

Mindfulness Effects on Opioid Use Craving and Seeking

Neurobiological substrates associated with opioid craving and seeking behaviors include nonconscious activation of amygdalal and hypothalamic brain circuits, and concurrent downregulation of prefrontal cortex mediation of these functions (Moal & Koob, 2007). Further, selective attentional regulation processes regulated by the brain's negativity biasing circuitry (Hanson, 2013) suggest that the MAT program patient experiencing any destabilizing internal or external environmental stressors will tend to orient his or her attentional focus toward the distressing phenomena, thereby exacerbating the downward spiraling of maladaptive allostasis and resultant relapse behaviors. Given that mindfulness practices are associated with upregulation of the prefrontal cortex and more effective medication of the limbic system circuits (Chiesa & Serriti, 2010; Hölzel et al., 2007) it is likely that mindfulness practice can enhance adaptive prefrontal mediation of conscious and nonconscious opioid craving and seeking neurotransmission signals from the limbic system. The cognitive deficits outlined by Kosten and George (2002) suggesting that this prefrontal cortex mediation capability is grossly impaired in opioid dependent persons underscores the potential utility of mindfulness -based approaches that strengthen PFC functioning. These theoretical perspectives are supported in general by the research of Garland et al. (2010), where findings supported associations between

mindfulness practice and reductions in implicit reactivity, and more specifically in Hayes et al. (2004) where Acceptance and Commitment Therapy (ACT) based approaches to mindfulness practices were utilized with a MAT patient population and were associated with significant reductions in illicit opioid use and treatment dropout.

Having examined the theoretical perspectives on attentional processes and their relevance to mindfulness practices as evidenced by neurobiological substrates of attentional regulation and effects of mindfulness practices on attentional regulation, this proposal now turns to explication of contemporary theoretical and practice models associated with mindfulness and relevant aspects of mindful attentional regulation associated with these bodies of theory and clinical practice.

Literature Review of Key Variables and Concepts

Use of Mindfulness Practices for Treatment of Substance Use Disorders

Having considered the historical, philosophical, theoretical, and neurobiological aspects of mindfulness, this proposal now examines contemporary clinical applications of mindfulness-based practices and their effectiveness in treatment of substance use disorders. Primary focus is given to MBRP as it was developed specifically for intervention with persons having substance use disorders. MBRP is the treatment approach evaluated in this study.

Mindfulness Based Stress Reduction

MBSR is a therapeutic approach combining mindfulness mediation and hatha yoga practice (Kabat-Zinn, 2003). Baer (2003) described how MBSR programs include

an 8- to 10-week participant group-meeting schedule consisting of 2.5 hours of integrated didactic instruction and mindfulness practice. Participants are further required to practice individually on a daily basis. MBSR is the first developed and most widely researched clinical approach to mindfulness practice in the U.S. MBSR has been found effective in treating fibromyalgia, cancer, multiple sclerosis, eating disorders, chronic pain (Kabat-Zinn, 1982; 2002; 2003; 2009), and anxiety (Miller et al., 1995; Vøllestad et al., 2011). Shapiro et al. (2008) found that MBSR practice increased mindfulness, reduced depression and anxiety symptoms, increased positive affect, and reduced negative ruminations contributing to anger. Ivanovski and Malhi (2007) found that MBSR training improved emotional regulation and immune system functions. Majumdar et al. (2002) found MBSR practice significantly reduced psychological distress and increased perceptions of well-being and quality of life. Jensen et al. (2011) found that MBSR interventions reduced perceived and physiological stress in participants, and significantly improved their selective attentional capacity, perceptual threshold, and visual working memory capacity. Smith et al. (2008) in their study comparing MBSR effects with cognitive behavioral stress reduction (CBSR) found that MBSR was significantly more effective than CBSR at increasing mindfulness and reducing adverse effects of stress and pain. Using fMRI evaluative data, Kilpatrick et al. (2011) found that in comparison to controls MBSR participants showed changes in brain areas implicated in visual, attentional, and self-referential processes. Kilpatrick et al. observed that these changes were associated with enhanced attentional, sensory, and metacognitive awareness. These

studies suggest the effectiveness of MBSR in reducing stress and symptomatic severity associated with multiple medical and psychological conditions. To date MBSR has not been studied for use with persons having opioid use disorder or persons participating in MAT programs.

Mindfulness Based Cognitive Therapy

MBCT represents an amalgamation of mindfulness-based and CT treatment approaches. Building upon existing CT therapies (Beck, 1967; Beck, 1979; Beck, 1995; Beck et al., 1979; Beck et al., 1993; Butler & Beck, 1995; Clark et al., 1999; Clark et al., 2004), Teasdale, Segal, and Williams (2000) combined elements of MBSR with CT to treat refractory depression. Lau and McMain (2005) asserted that the MBCT-based approach recognizes the chronic, relapsing nature of depressive disorders and is intended to reduce frequency and severity of depressive relapse episodes. Sherer-Dickson (2004) asserted that MBCT approaches use interventions intended to foster enhanced metacognitive awareness, such that the participant attends to emerging cognitions using an enhanced knowledge base, a non-evaluative processing style, and acquired attentional monitoring and regulating skills. Lau and McMain (2005) posited that increased metacognitive awareness reduces depressive relapse through fostering decentering from maladaptive cognitions. Zoysa (2011) and Williams and Kuyken (2012) found an approach integrating mindfulness and CBT was effective in treating depressive disorder.

Williams et al. (2012) evaluated MBCT effectiveness for depressive relapse prevention in a randomized dismantling trial as a treatment adjunct to TAU and

compared to controls using cognitive psychological education (CPE) and TAU alone. The Williams et al. (2012) study limitations include that the TAU approach was non-standardized, thus potentially introducing extraneous variable effects and unmeasured between-group effects associated with sociocultural variables. Evans et al. (2008) found that MBCT treatment significantly reduced anxiety and depressive symptoms in patients with generalized anxiety disorder (GAD) as measured by pre- and posttest reductions in clinician-administered Beck Anxiety Inventory (BDI; Beck & Steer,1990), Penn State Worry Questionnaire (PSWQ; Meyer, et al., 1990), Profile of Mood States (POMS; McNair et al., 1971), and Beck Depression Inventory-II (BDI-II; Beck et al., 1996). The Evans et al. (2008) study limitations include small participant size (n = 11), thereby limiting statistical power and generalizability, use of a cross-sectional design without randomization or controls, and potential extraneous variables associated with unique participant demographic characteristics (self-selected and highly educated). King et al. (2013) found significant reductions in PTSD symptoms for the MBCT treatment group versus the TAU group especially in the avoidance and dissociative symptom clusters. King et al. (2013) study limitations included lack of randomization, small participant sample size (n = 37) thereby limiting statistical power and generalizability of results, and potential confounds from between-group distinctions in treatment duration.

In their meta-analysis of MBCT effectiveness Coelho et al. (2013) found MBCT as an adjunct to TAU effective for participants with three or more depressive episodes, though not for those with less than three depressive episodes. Moreover, Coelho et al.

observed that the evaluated study designs were either non-randomized or failed to describe their randomization methods, and did not evaluate MBCT as a single treatment, thereby suggesting potential extraneous variable effects across all studies from the combined MBCT-TAU modality. Coelho et al. (2013) study limitations include basing evaluations on study reports rather than original data, and conclusions based on comparison of studies with inconsistent methodologies.

Investigation of the literature to date did not uncover any studies of MBCT applied to individuals with opioid use disorder, or as an adjunctive treatment for those participating in MAT programs. It should be noted that several elements of MBCT, particularly those focused on facilitating adaptive cognitive restructuring, are utilized in MBRP (Witkiewitz et al., 2013b).

Mindfulness Based Rational Emotive Behavior Therapy

REBT involves enhancing development of self-acceptance and high frustration tolerance through fostering formulation of adaptive belief systems, introspective, values-driven and reality-based evaluation of cognition, affect, and behavior, and integration of intrapersonal, interpersonal, and environmental phenomenal acceptance (Ellis et al., 1998; Ellis & Dryden, 1997; Ellis & MacLaren, 2005). In a seminal paper comparing REBT to MBSR Ellis (2006) noted many similarities between the two clinical approaches, including cultivation of non-judgmental attitude, patience, beginner's mind (openness to experience), intentionality, awareness of and commitment to values and related goals, compassion, acceptance, and self-discipline. Ellis took exception to some

aspects of MBSR, including trust, especially blind trust in one's intuition, which could lead to erroneous inferences and associated behaviors, and thence emotional disturbance, and further disagreed with the MBSR approach to non-striving, asserting that even participation in mindfulness suggests a desire to strive toward some perceived or needed change. In a proposal for case-specific treatment approaches integrating elements of MBCT and REBT Whitfield (2006) proposed an integrated MBREBT approach utilizing three interventions. The first consisted of using awareness of interoceptive and metacognitive processes to experientially reinforce apprehension of the associations between beliefs and consequences. The second consisted of using awareness of interoceptive processes and acceptance to counter low frustration tolerance. The third intervention consisted of using awareness of intentions and cultivation of nonjudgmental attitude to examine and thence counter harmful irrational beliefs.

A search of available literature failed to uncover any empirical research evaluating the effectiveness of MBREBT-based treatment approaches, and no research evaluating MBREBT as a treatment for opioid use disorder or as a treatment adjunct for MAT program participants was found.

Acceptance and Commitment Therapy

Hayes et al. (2012) suggested that Acceptance and Commitment Therapy (ACT) is based on the perspective that cognition, affect, and behavior are derived within an interrelated experiential and environmental context. Hayes (2002) asserted that humans tend to reflect on their experiences and create associations between distinct aspects of

lived experience using language. Hayes described this predominant tendency as the capacity to create relational frames. Hayes and Smith (2005) asserted these relational frames often limit flexibility and adaptive responding to evolving life situations, thereby resulting in use of maladaptive coping strategies that increase human suffering. Relational framing often fuses an experience with an evaluative thought about that experience, resulting in harmful implicit associations that thence regulate cognitive and affective processes for other similar experiences. Through this cognitive fusion of relational frames, individuals developed automatized, often maladaptive responding to their experience. Hayes and Smith further asserted that fused thoughts exacerbate experiential pain and intrapersonal dysfunction through: (a) evaluation, the recollection of painful events and their associated attributions; and (b) self-conceptualization, the integration of maladaptive cognitive fusion processes into one's perception of and valuing of the self. Hayes et al. (2002) identified several relational frames commonly used by most individuals, including temporal and comparative phenomenal associations.

Hayes et al. (2012) described ACT interventions as facilitating multiple aspects of cognitive functioning including awareness and acceptance of unfolding experience from moment to moment, cultivating a contextual self-perspective using decentered observational approach, commitment to behaving in accord with chosen values, acceptant, and nonjudgmental appraisal of unfolding experience. Hayes et al. further noted an essential aspect of mental functioning they described as cognitive defusion,

where behavioral and cognitive therapeutic interventions are used to decenter from maladaptive cognitions, affective states, and associated behaviors.

ACT has been found effective in treatment of multiple conditions including seizure disorders, chronic pain, diabetes, depression, anxiety, and posttraumatic stress disorder (Bach & Hayes, 2002; Gregg et al., 2007; Hayes, & Smith, 2005; McKay et al., 2012; Varra et al., 2008; Walser & Westrup, 2007). Gratz (2007) found that ACT interventions effectively enhanced participant awareness and acceptance of emotional states, reduced impulsive behaviors, facilitated engagement in adaptive emotional regulation strategies, and reduced frequency of engagement in self-harm. In their randomized, controlled between-groups comparison study Forman et al. (2007) found that ACT-based treatments were effectively equivalent to traditional cognitive therapy interventions in reducing anxiety and depressive symptoms. Bach and Hayes (2002), in their randomized controlled trial of 80 psychiatric inpatient participants found that administration of four ACT-based therapy sessions resulted in significantly higher symptom reporting, significantly lower symptom reification, and a 50% reduction in participant rehospitalization rates. In his meta-analysis of ACT treatment efficacy Öst (2014) asserted ACT interventions used for psychiatric, somatic, and distress conditions exhibited a small mean effect size ($d = 0.42$) and in comparison to behavioral, CT, and CBT treatments showed a nonsignificant difference. In their meta-analysis of ACT treatment effectiveness, Powers et al. (2009) concluded that ACT-based interventions

were significantly more effective than controls and placebos but were no more effective than existing traditional treatments such as CT and CBT.

ACT-based treatments are effective in terms of reducing the negative social stigma and internalized shame often experienced by individuals with substance use disorders (Luoma et al., 2008; Luoma et al., 2012). Gonzaléz-Menéndez et al. (2013) said ACT was significantly more effective than CBT at 18-month follow-up in reducing substance use relapse (ACT 85.7% abstinence at 18 months; CBT 50% abstinent at 18 months).

In a single study, ACT-based treatment approaches were utilized with MAT program patients (Hayes et al., 2004), where they were combined as an adjunct to TAU and outcomes compared to a TAU-alone control group and an Intensive Twelve-Step Facilitation (ITSF) group also combined adjunctively with TAU. The group trials were run sequentially, using nonduplicated participants who participated in structured manualized versions of ACT and ITSF individual and group therapies in addition to TAU, or in TAU alone. Individual and group therapists were of at least Master's degree level and had a minimum of 2 years' experience in substance use disorder treatment. All therapists were trained prior to implementation of their respective ACT or ITSF models, whereas TAU utilized the MAT program counselors. ACT and ITSF sessions were videotaped and evaluated to assure adherence to their respective treatment models. Effects on drug use were measured by random monthly UDS results obtained pre- and post-treatment, and at six-month follow-up.

Hayes et al. found no significant differences ($p < .05$) between the groups for illicit opioid use at pre- or posttest, although a significant difference was found at six-month follow-up where 42% of the ACT adjunct participants had illicit opioid free UDS results versus 15% of the MAT-only participants using Pearson $x2(1, N = 43) = 7.51$, $p = .006$. Hayes et al. also found that ACT treatment adjunct group participants were retained in the MAT program for significantly longer periods than their TAU counterparts were. Limitations of the Hayes et al. study included a high participant dropout rate (34%), and potential confounds due to participant funding distinctions. It is unclear why the posttest UDS results were not significantly different between the groups, as were the six-month follow-up results. The reasons for the high participant dropout rate are also unknown. These outcomes suggest that ACT combined with TAU for MAT program patients may be more effective than TAU alone, but further evaluation is needed using methods that reduce the impact of participant dropout and evaluate for the posttest effectiveness. No further studies evaluating ACT as an adjunctive treatment for individuals participating in MAT programs or those having opioid use disorder were found.

This literature review now focuses on mindfulness-based treatments intended for reducing and eliminating the harmful effects of substance use conditions.

Mindfulness Oriented Recovery Enhancement

In a randomized controlled pilot study using volunteer participants ($n = 53$) living in a therapeutic community, Garland et al. (2010) evaluated the effectiveness of the ten-week Mindfulness-Oriented Recovery Enhancement (MORE; Garland et al.) treatment

intervention. The control group received standard evidence-based weekly alcohol group support based on the Matrix model (Rawson & McCann, 2006) of manualized treatment. Treatment for both groups was provided by Master's level social worker. Participant mindfulness was measured using the Five Factor Mindfulness Questionnaire (FFMQ; Baer et al., 2006). Other measures used by Garland et al. included the Penn Alcohol Craving Scale measure (PACS; Flannery et al., 1999) for measuring participant alcohol craving, the Brief Symptom Inventory (BSI; Derogatis & Melisaratos, 1983) for measuring participant psychological distress, the Impaired Alcohol Response Inhibition Scale (Guardia et al., 2007), the Perceived Stress Scale (PSS; Cohen et al., 1983) measuring participant stress levels, and the White Bear Suppression Inventory (WBSI; Wegner & Zanakos, 1994), measuring participant tendencies toward thought suppression. Garland et al. measured Alcohol-associated cue reactivity using electrocardiogram readings taken during participant exposure to visual alcohol associated cues, and participant alcohol attentional bias was measured using a computerized dot probe task containing randomized exposure to alcohol associated visual cues.

Using bivariate correlation and repeated measures ANOVA (among other tests), Garland et al. (2010) found that for the MORE participants, reductions in thought suppression were significantly correlated with changes in ECG response ($r = .49$, $p = .042$), increased impaired alcohol response inhibition ($r = .48$, $p = .045$), and reductions in post-intervention heart rate variability (HRV) recovery, ($r = .49$, $p = .045$). The findings of Garland et al. suggested that exposure to mindfulness training significantly

reduced the implicit responses of participants with alcohol use disorder to alcohol-associated environmental cues, supporting the contention that increased mindfulness facilitates adaptive regulation of autonomic responding to substance use cues. Garland et al. found that implicit attentional biases orienting and alerting toward alcohol use significantly decreased through mindfulness practice, suggesting that implicit maladaptive memory and attentional processes are effectively mediated through regular mindfulness practice. Further findings included significant reductions in perceived stress levels and marked reductions in thought suppression associated with more adaptive mediation of alcohol use cravings. Generalizability from the findings of Garland et al. is limited due to small participant sample size and lack of a control group. Another limitation is use of the Matrix (Rawson & McCann, 2006) treatment intervention for participants with alcohol use disorder, a use for which it has not been normed or validated. Although suggesting important implications for attentional regulation of substance use this study did not examine MBRP effects and did not evaluate for mindfulness effects on attentional regulation of participants with opioid use disorder.

Yoga Nidra

Yoga Nidra references a specific approach toward breathing, originally developed several thousand years ago in India. It involves mindful focus on the breath where the rhythm and duration of in- and out-breaths are intentionally manipulated to achieve a deep level of relaxation (Miller, 2010). Practitioners sit or lie in specific postures, guided through progressively longer periods of meditation using specific breathing rhythms. An

example of this unique breathing approach is internally counting to four for the inbreath and to eight for the duration of the outbreath, over periods of several minutes to an hour or more (Miller).

Stankovic (2011) reported in a feasibility clinical trial that daily Yoga Nidra practice for a duration of eight weeks effectively reduced PTSD symptom severity in a cohort of male war veterans, and that the participants reported increased sense of calm and self-efficacy. This trial is limited by small participant size (n =16) and lack of a control group. Temme et al. (2012) found that Yoga Nidra significantly reduced relapse precursor symptoms and further resulted in improved mood for individuals with substance use disorders enrolled in residential treatment. Limitations in Temme at al. included potential variability from reported inconsistent participant understanding of test measure response items, possible participant expectation bias, and relatively few female participants. Taken together, these early research efforts suggest that the Yoga Nidra contemplative approach potentially offers benefit to MAT program patients, particularly those with trauma exposure history or co-occurring posttraumatic stress disorder, but further evaluation is needed. Thompson et al. (2011) asserted that mindfulness practices are effective for persons with traumatic exposure. Further empirical research will more comprehensively evaluate these preliminary findings. At time of this writing available research is extremely limited, thus further empirical validation of this mindfulness-based approach is necessary. No published research to date has evaluated Yoga Nidra as an adjunctive treatment for MAT program participants.

Mindfulness Based Relapse Prevention

The treatment adjunct to be evaluated in this study, MBRP, is a recently developed manualized treatment approach for substance use disorders that utilizes relapse prevention strategies integrated with mindfulness meditation (Bowen et al., 2011; Marlatt & Chawla, 2007). It is based on an amalgamation of CBT approaches and mindfulness traditions. Bowen et al. (2011) described several core constructs of MBRP. The first is cultivation of a present-moment focus, wherein the individual with substance use problems learns to apprehend and accept experience as it unfolds, thereby reducing preoccupation with substance use as a means of coping with past or future concerns. The second is development of acceptant, nonjudgmental attitude toward unfolding experience, where the person learns to skillfully experience and cope with physical and emotional discomforts rather than attempting to avoid them through substance use. The third is developing increased understanding of the nature of evolving experience, whereby the person apprehends the thoughts and cravings for substance use as phenomena whose frequency and intensity will lessen over time. The fourth is cultivation of metacognitive awareness, such that the individual perceives his or her substance use in a larger context, as a conditioned response that can be attenuated or discontinued in accord with personal values and volition. The fifth is reduction in negative emotional states associated with stigmatization of substance use, where the individual experiences more effective regulation of automatized negative self-referents such as guilt, shame, and reduced sense of self-worth.

Focus on Experiential Inquiry

Bowen et al. (2011) emphasized that MBRP focuses on supporting participants' inquiry into the nature of their present moment experience rather than interpreting, analyzing, or finding solutions for the participants' unfolding thoughts, emotions, images, and sensations. Bowen et al. noted that such inquiry eventually results in increased capability for differentiation between direct experience and reactive responding to that experience, thereby facilitating increased awareness of internal processes and reducing reactivity. Further, they asserted that these inquiry processes result in enhanced awareness of shared experiences, fostering universality, a sense of compassion for self and others, and a correspondingly reduced sense of the individualized nature of problems and suffering.

MBRP Program Structure

MBRP treatment is structured as an eight-week course where participants meet once weekly in a private group setting for two hours with the group facilitator, conduct daily individual guided meditation practice exercises, and complete daily CBT-oriented homework assignments (Bowen et al., 2011). The first session consists of an introduction to the course requirements and two mindfulness meditation exercises (Bowen et al.). Each subsequent session includes a review of the homework assigned to participants during the previous session, discussion of participants' mindfulness meditation practice experience during the prior week, interactive discussion of mindfulness and relapse prevention practices and approaches, guided mindfulness meditation exercises, review

and discussion of the following weeks' homework assignments, and closing remarks (see Appendix A).

MBRP Urge Surfing Intervention

Urge surfing is a mindfulness practice designed to decondition the individual's identification with substance-associated thoughts, cravings, and urges. The practitioner envisions the craving or urge as an ocean wave that is cyclical, rising and falling in its intensity, and ultimately subsiding. Through continued practice, the individual develops the capability to tolerate the presence of substance-associated cravings and urges without carrying out the substance seeking and using behaviors, thereby resulting in a classical deconditioning effect that reduces the frequency and intensity of substance-associated cravings and urges (Marlatt & Chawla, 2007; Ostafin & Marlatt, 2008). The effectiveness of the urge surfing intervention has been empirically established with persons dependent on or abusing a variety of substances including alcohol, opioids, and stimulants (Bowen et al., 2006; Brewer et al., 2010; Marlatt & Chawla; Ostafin & Marlatt, 2008; Witkiewitz et al., 2005).

MBRP Sober Breathing Space Intervention

This mindfulness-based approach to relapse prevention utilizes mindful attending to the breath and to the individual's unfolding experience to facilitate adaptive responding in situations where relapse risk is potentially high. The at-risk person learns the acronym, SOBER, and its associated elements, as follows:

- S – Stop, taking a moment to mindfully pause, before proceeding with automatic reactivity;
- O – Observe, taking note of emerging thoughts, feelings, sensations, and images; asking. what is unfolding in awareness at this moment;
- B – Breathe, focusing attention on the breath; taking a minimum of three to six, or even more, mindful breaths;
- E – Expand, fully expanding one's awareness; examining the thoughts, feelings, sensations, and images emerging within this augmented awareness of the situation. Attempting to further explore with openness, acceptance, curiosity, without judgment; and
- R – Respond, using the enhanced depth of awareness achieved within the unfolding moment, responding mindfully, with intentionality, and compassion (Bowen et al., 2011).

MBRP Perspectives on Substance Use

From an MBRP-based perspective, substance use is a form of experiential avoidance that is frequently and largely nonconsiously activated in response to encountering aversive situations, negative thoughts, disturbing emotions, overly intense affect, physiological pain, and discomfort (Bowen et al., 2012). Bowen et al. asserted that individuals, when examining their coping behaviors associated with encountering aversive situations tend to respond reactively, with automatized, usually maladaptive behaviors. Bowen et al. suggested that mindful exploration of the thoughts, feelings, and

sensations associated with substance use disorders assists the MBRP practitioner in uncovering the nature of this automatic responding. Bowen et al. posited that as the individual explores his or her relationship to the substance of misuse and its effects, acceptantly, without judgmental distortions, it is likely that more comprehensive understanding of substance-related thoughts, feelings, cravings, urges, and associated behaviors is possible. The practitioner thence more objectively evaluates his or her experience associated with use of substances, earning to cope more adaptively with them while concurrently reducing and thence eliminating tendencies toward automatized responding associated with substance use, such as those evoked by environmental cue reactivity.

This perspective suggests that attempting avoidance generally strengthens the individual's identification with the object of the avoidance behavior, whereas mindfully accepting all aspects of experience with the object fosters disidentification, thereby reducing its conditioned power. This further suggests that mindfulness practices offer a means of adaptively changing the individual's relationship with substance dependence and other forms of addiction (Smith, 2010).

Evaluation of MBRP Research

Witkiewitz et al. (2005) conducted a preliminary investigation of the effectiveness of Vipassana meditation, one of the therapeutic elements integral to MBRP, using an incarcerated population (n = 306) of individuals with alcohol and other substance use disorders. Volunteer participants were self-assigned to a 10-week Vipassana group or to

TAU, consisting of self-help group (Alcoholics Anonymous) participation, psychoeducation, and social skills training offered at the prison facility. Using ASI Alcohol/Drugs subscale measures, Witkiewitz et al. found that at three-month follow-up the Vipassana group reported 29.3% reduction in cutoff alcohol use frequency (defined as 4 drinks per week), a significant difference ($p = .08$), whereas the TAU group reported a 13.9% reduction. They further found that at three-month follow-up the Vipassana group reported a 18.1% reduction in cutoff daily alcohol use frequency (defined as seven or more drinks per day), a trend difference ($p = .08$) whereas the TAU group reported a 0.2% increase. Witkiewitz et al. reported that limitations of this study included a very high participant dropout, with 218 participants not completing the study. Further limitations include lack of randomized participant assignment and possible participant selection bias stemming from self-selection of groups, and absence of clearly defined participant control group intervention effects.

Witkiewitz et al. (2013b) conducted a randomized controlled trial of MBRP using volunteer participants with alcohol use disorder and a mixture of other substance use disorders (45.2% alcohol, 49.9% stimulants, 7.1% opioids, 5.4% cannabis, 1.9% undetermined) enrolled at an outpatient Washington treatment facility. They found that MBRP was significantly more effective at reducing participant alcohol use cravings than the TAU group receiving psychoeducational, 12-Step (self-help), and relapse prevention group interventions. MBRP manualized treatment providers were experienced therapists with graduate degrees who were trained in MBRP, whereas TAU services providers were

licensed substance use counselors with varying levels of education and experience (Witkiewitz et al.). Therapist adherence to the MBRP manualized treatment was evaluated using the Mindfulness-Based Relapse Prevention Adherence and Competence Scale (Chawla et al., 2010). Study measures used at pre-, posttest, and at two- and four-month follow-up included the PACS (Flannery et al., 1999), used to measure alcohol and other drug use cravings; the FFMQ (Baer et al., 2006), used to measure acting with awareness and nonjudgmental elements of mindfulness; and the Acceptance and Action Questionnaire (AAQ; Hayes et al., 2004), used to measure participant acceptance (also an element of mindfulness). Witkiewitz et al. noted that random group participant assignment was achieved through use of random number sequencing. Participants were provided with gift card incentives upon completion of study measures. Witkiewitz et al. (2013b) found that MBRP participants had significantly lower alcohol use craving scores measured at midtreatment: t (125) = 2.43, p = 0.02); and posttreatment: t (101) = 2.37, p = 0.02), whereas at two-month and four-month post-treatment follow-up the MBRP participants no longer experienced significant differences from their TAU counterparts in alcohol use cravings. It is important to note that no evidence suggests these findings are predictive for use of MBRP in the treatment of opioid use disorder.

The Witkiewitz et al. (2013b) study was limited in that no objective measures of substance use, such as UDS results, were utilized, leading to overreliance on self-administered participant report measures. Further limitations included lack of an operational definition of substance craving, the use of a substance craving measure not

normed or validated for substances other than alcohol use, use of mindfulness measures that did not specifically target design factors used in MBRP, the lack of a waitlist comparison or control group, and the between-group distinctions in therapist education and training. Additionally, the causal association between substance use craving and actual relapse behavior remains unclear.

In a randomized trial of participants (n = 168) with multiple substance use disorders (45.2% alcohol, 49.9% stimulants, 7.1% opioids, 5.4% cannabis, 1.9% undetermined) Witkiewitz and Bowen (2010) evaluated for effectiveness of MBRP in reducing substance use and cravings associated with depression. This study utilized therapists with graduate degrees who were trained in MBRP, whereas TAU services providers were licensed substance use counselors with varying levels of education and experience (Witkiewitz & Bowen). MBRP sessions were audio recorded and assessed for fidelity with MBRP criteria using the Mindfulness-Based Relapse Prevention Adherence and Competence Scale (Chawla et al., 2010). Measures used by Witkiewitz and Bowen for this study included the PACS (Flannery et al., 1999) for substance use cravings, the Timeline Followback (TLFB; Sobell & Sobell, 1992) a calendar-based daily log for substance use reporting, and the BDI-II (Beck et al., 1996) for depression. Measures were administered at pre- and posttest intervals, and at two- and four-month follow-up. Witkiewitz and Bowen found that the MBRP group showed significantly reduced depression-associated substance use cravings compared to TAU during the MBRP intervention ($\eta 2 = .09$, $p < .05$) and up to two months post-intervention ($\eta 2 = .04$, $p <$

.05). Witkiewitz and Bowen noted these effects were maintained at four-month follow-up ($\eta 2 = .02$, $p < .05$) only for those participants that continued their MBRP meditative exercises. Those continuing participants showed a remarkable zero percent relapse rate at four-month follow-up.

Limitations of the Witkiewitz and Bowen (2010) study included a relatively short duration of follow-up measurement and undetermined potential extraneous variable effects arising from reliance on participant self-report, unmeasured differences in therapist skill level, and high participant attrition rates (27%). Further limitations include that multiple participants (62.7% of TAU group, 52.8% of MBRP group) were court mandated to participate in treatment and to abstain from illicit substance use, a possible confounding variable. Finally, no objective data confirming participant substance use was obtained.

Hsu, Collins, and Marlatt (2013) evaluated effectiveness of MBRP manualized treatment moderation effects on distress tolerance for participants ($n = 168$) with substance use disorders including alcohol, cocaine, methamphetamine, opioids, cannabis, and undefined other substance use who were enrolled in outpatient treatment for their substance use conditions. Participants were randomly assigned to the MBRP or TAU group, with TAU consisting of 12-step group participation, psychosocial education, and process-based intervention. Measures used included the Distress Tolerance Scale (DTS; Simons & Gaher, 2005) to evaluate participant capacity for adaptive responding to stressors, and the TLFB (Sobell & Sobell, 1992) for participant reporting about alcohol

and other drug use. Mindfulness was measured using the FFMQ (Baer et al., 2004) and convergent validity between the DTS and FFMQ was assessed.

Hsu et al. found that MBRP participant DTS results showed a significant positive correlation with all five FFMQ subscales (r =. 28; r =.41; r =.4; r =.41; r=.47; p = .001), suggesting strong convergent validity of the measures and an association between higher distress tolerance and mindfulness. They further found a significant positive association between MBRP intervention and reduction of substance use at posttest and two-month intervals, Wald $\chi 2$ (13, N =162) = 3595.33, p =.001. Hsu et al. found that MBRP participants with lower distress tolerance who received MBRP showed significant reductions in alcohol and other drug use over time compared to their TAU counterparts with lower distress tolerance through two-month follow-up.

Limitations of the Hsu et al. (2013) study include lack of objective substance use data collection, resulting in overreliance on participant retrospective self-reporting of substance use, a brief follow-up period, potential between-group variability arising from distinctions in MBRP and TAU group content and procedures, lack of waitlist control group, distinctions in education, training, and clinical approach between the MBRP therapists and the program counselors, and uncontrolled participant demographic variables.

Bowen and Kurz (2011) evaluated post-MBRP intervention moderating effects on therapeutic alliance and between-session meditative practice on mindfulness in a randomized trial of outpatient substance use program participants (n = 168) with multiple

substance use disorders (45.2% alcohol, 49.9% stimulants, 7.1% opioids, 5.4% cannabis, 1.9% undetermined). Their study utilized therapists with graduate degrees who were trained in MBRP (Bowen & Kurz). MBRP sessions were audio recorded and assessed for fidelity with MBRP criteria using the Mindfulness-Based Relapse Prevention Adherence and Competence Scale (Chawla et al., 2010). Bowen and Kurz found that participation in MBRP was significantly associated with increases in mindfulness at post-intervention. Bowen and Kurz noted that paired sample t-testing revealed a significant increase in levels of mindfulness between baseline and posttest, $t(33) = -2.43$, $p = 5.02$, and through four-month follow-up $t(33) = -2.57$, $p = 5.014$. Using regression analysis, Bowen and Kurz found that increased levels of participant mindfulness were significantly associated with an effective therapeutic alliance as measured by the Working Alliance Inventory-Short Form (WAI-S; Tracey & Kokotovic, 1989) post-treatment and at two-month follow-up, $\beta = .479$, $t(31) = 3.51$, $p = .001$ although results were not significant at four-month follow-up. Their results suggested that the strength of the therapeutic alliance is associated with increased levels of participant mindfulness and may be enhanced through MBSR practice. Implications include that an effective therapeutic alliance, enhanced through MBSR participation, may foster improved treatment outcomes for substance users, although this association was not studied.

The Bowen and Kurz (2011) study limitations include a reliance on participant self-report measures and correspondent lack of objective participant substance use data, use of a nonvalidated measure to evaluate participant between-session meditative

practice, lack of a control group, and high participant attrition rates (57%) that reduced statistical power and generalizability.

Lee et al. (2011) conducted a randomized controlled trial evaluating MBRP effectiveness for an incarcerated Taiwan population of individuals with currently asymptomatic substance use disorders for "cannabis, amphetamine, cocaine, MDMA, heroin, Ketamine, glue, and LSD" (p.479) use. The MBRP intervention was provided by licensed psychologists trained for two years in mindfulness meditation and relapse prevention. TAU consisted of substance use education. Measures used by Lee et al. include drug use Identification Disorders Test-Extended (DUDIT; Berman et al., 2007) to measure positive and negative perspectives on and frequency of illicit substance use, the Drugs Avoidance Self-Efficacy Scale (DASE; Martin et al., 1995) to evaluate for self-efficacy of substance refusal skills, and the BDI-II (Beck et al., 1996) to measure depressive affect. Participants ($n = 24$) were randomly assigned to either the MBRP or TAU groups, and Lee et al. used MANOVA to evaluate between group differences and repeated measures ANOVA to evaluate for MBRP within group changes over the 10-week duration of the study. Lee et al. found that MBRP participants experienced significantly higher negative perspectives toward drug use ($t = 2.46$, $p < 0.05$), significantly higher negative expectancies toward potential substance use ($t = -5.22$, $p < 0.01$), and significantly less depressive affect ($F(1, 9) = 110.40$, $p < 0.05$) than their TAU counterparts. The findings of Lee et al. suggest a significant association between participation in MBRP, reduced depressive affect, and increased negative perspectives

and expectancies toward substance use. These results are consistent with Hendershot et al. (2011), whose review findings asserted the importance of enhanced self-efficacy and adaptive outcome expectancies resultant from MBRP participation.

Limitations of the Lee et al. (2011) study include use of male-only participant selection, lack of measurement for depressive affect in the TAU group, lack of objective and subjective substance use measures, no long-term follow-up, and small participant size (n = 24), thereby reducing statistical power and generalizability.

Bowen et al. (2014) conducted a randomized clinical trial comparing the effects of MBRP, RP, and TAU as an aftercare treatment for a population (n = 286) of volunteer participants who had previously completed either a 28 day or 90-day inpatient rehabilitative treatment for alcohol, stimulants, opioids, cannabis, and other undetermined substance use disorders. TAU consisted of eight weeks of process-oriented support groups based on 12-Step principles. RP consisted of an eight-week intervention focused on relapse risk assessment, improving cognitive and behavioral skills, increasing self-efficacy, establishing goals, and using social support systems. The eight-week MBRP intervention was used in place of TAU, rather than as an adjunctive treatment. TAU therapists were certified counselors, whereas the RP and MBRP therapists were graduate students at the Master's degree level or higher and were extensively trained in either RP or MBRP administration. Study measures included the TLFB (Sobell & Sobell, 1992) for alcohol and other substance use, UDS results data for a percentage (0.695) of the

participants, and monitoring of recorded intervention sessions to evaluate for adherence to manualized treatment guidelines.

Bowen et al. (2014) used Cox proportional hazards regression models to estimate hazard ratios for number of days prior to participant relapse into alcohol or drug use. They found that MBRP and RP groups showed a 54% decreased risk of relapse to drug use ($\beta = -0.77$, $HR = .06$, $p = .05$) and a 59% decreased risk of relapse ($\beta = -0.89$, $HR = .41$, $p = .05$) to heavy drinking in comparison to the TAU group, and the MBRP group showed a 21% increase in relapse risk to first drug use ($\beta = .19$, $p = .05$) compared to RP. Using negative binomial hurdle statistical models to determine incidence rate ratio (IRR), at six-month follow-up Bowen et al. found no significant differences between RP and MBRP effects on drug or alcohol use, whereas RP and MBRP participants reported a significant 31% fewer days of alcohol use than their TAU counterparts ($\beta = 0.33$, $IRR = .69$, $p < .05$). Finally, Bowen et al. noted that at twelve-month follow-up there was significant difference between MBRP and RP in drug use ($\beta = -0.37$, $IRR = 0.69$, $p < .05$) and in likelihood of participant alcohol use using odds ratio (OR) measure for likelihood of drinking ($\beta = 0.43$, $OR = 1.51$, $p < .05$). These results suggest that both RP and MBRP are significantly more effective interventions for alcohol and drug use than TAU up through 12 months posttreatment, with MBRP exerting stronger inhibiting effects on substance use.

Limitations of Bowen et al. (2014) included inconsistent objective data collection on participant substance use, reliance on participant self-report measures, between-group

distinctions in levels of therapist training and education, subjective evaluation of therapist adherence to RP and MBRP models, and large differences between TAU group and the RP/MBRP groups in participant therapeutic assignment and intervention time requirements.

In general, limitations of MBRP research include a small number of randomized, controlled study designs (Bowen et al., 2011; Bowen et al., 2014). An additional concern raised by Levin, Dalrymple and Zimmerman (2014) in their randomized, controlled study comparing mindfulness factors between persons with substance use disorders and an abstinent control group is that capabilities for fostering states of mindfulness are limited in persons with SUD history. Hendershot et al. (2011) noted that further research evaluating the theoretical constructs and clinical applications of MBRP are needed, especially those incorporating study designs using randomized controlled trials.

An important consideration here is that many of the preceding MBRP studies (Bowen & Kurz, 2011; Hsu et al. 2013; Witkiewitz & Bowen, 2010; Witkiewitz et al., 2013b) were conducted using the same participant population. This suggests the possibility that unique, albeit unidentified characteristics of that population could exert unknown effects on these multiple study outcomes. Other concerning limitations of the preceding studies include the lack of objective measures for participant substance use data and that the participants were predominantly individuals with alcohol use disorder, as only 7.1% reported opioid use. Although Bowen et al. (2014) collected objective participant substance use data using UDS results, these data were not collected

consistently from all participants. A further consideration here is that these studies mostly focused on MBRP's subjective effects on substance use cravings rather than objectively measuring substance use behaviors. Two other MBRP studies (Witkiewitz et al., 2005; Lee et al., 2011) were conducted using incarcerated populations, suggesting an important limitation on generalizability of results, and the majority of these participants were presenting with alcohol use disorder histories. Of even greater importance, none of the preceding studies used MAT program patient populations to evaluate the effectiveness of MBRP for opioid use disordered populations.

Bowen et al. (2017) conducted a study of 15 participants with OUD that were enrolled in a MAT program, maintained on methadone medication, and exposed to the eight-week MBRP group manualized treatment protocol. Bowen et al. found a significant reduction in opioid cravings at $p \leq .05$ for participants at study conclusion. They further noted significant changes in reduction of depression and trauma symptoms reported by the seven participants completing the MBRP group. Limitations of this study included the small sample size (n=15) thereby limiting statistical power, insufficient attendance at the MBRP group (59% over the course of the study), and a marked reduction in number of participants enrolled at study completion compared to initial enrollment (from n=15 to n=7). An important limitation was that this study design did not include a control group or randomized participant assignment. A further limitation included the use of the Acceptance and Action Questionnaire (AAQ; Hayes et al., 2004), an instrument that evaluates for the global psychological functional factors of experiential avoidance and

psychological flexibility, but does not specifically evaluate for more direct aspects of mindfulness including curiosity and decentering as evaluated for in the TMS (Lau et al., 2006). Overall the Bowen et al. study represents an important initial feasibility evaluation for use of MBRP with methadone-maintained patients.

Lyons et al. (2019) undertook a randomized controlled study of incarcerated males with varied substance use disorders. Lyons et al. utilized a randomized cohort assignment design including an MBRP participant cohort and a control cohort using a six-week version of the Mapping-Enhanced Counseling Manuals for Adaptive Treatment (MECMAT; Joe et al., 2012). Lyons et al. used a revised version of the MBRP protocol that reduced the eight-week group period to six weeks through elimination of the mountain meditation exercise and amendment of other exercises integral to the original MBRP manualized treatment protocol. The potential effects of this revision remain unknown as Lyon's et al. did not undertake a comparative analysis between the original and revised versions. Lyons et al. found that drug cravings were significantly reduced (p=.05) for the MBRP intervention group at completion of an abbreviated (six-week) MBRP intervention in comparison to the MECMAT participant control group. To evaluate for levels of participant mindfulness they used multiple measures including the Five Factor Mindfulness Questionnaire (FFMQ; Bohlmeijer et al., 2011) and the Freiburg Mindfulness Inventory (FMI; Walach et al., 2006). Lyons et al. observed a significant increase (p=.05) in participant mindfulness for the experimental condition as measured by comparing pretest and posttest FMI results, while noting no significant change in

mindfulness in the control group. Limitations of the Lyons et al. study include the undetermined empirical efficacy of their abbreviated MBRP protocol and any resultant potential covariability, a participant attrition rate of 31% with its attendant reduction in statistical power, and potential, albeit unmeasured, covariability between the MBRP exposure experimental condition and extant jail therapeutic community effects.

Imani et al. (2015) in their randomized , controlled study evaluated effectiveness of MBRP as a treatment adjunct for 30 participants enrolled in an opioid treatment program (OTP) and maintained on either methadone or buprenorphine medication. Both the experimental and control groups included maintenance treatment as usual (TAU). Randomized participant assignment was used to determine group selection. Imani et al. used the ASI Alcohol/Drugs subscale (Leonhard et al., 2000; McLellan et al., 1985) to measure participant opioid use and the FFMQ (Bohlmeijer et al., 2011) to measure participant mindfulness. Imani et al. observed a reduction in opioid use as measured by ASI Alcohol/Drugs subscale outcomes and concurrent increase in mindfulness as measured by FFMQ outcomes but neither of these findings proved statistically significant (p=.05). Limitations of the Imani et al. study included a lack of distinction between participants prescribed methadone versus those prescribed buprenorphine, which could exert unmeasured covariability into the MANCOVA statistical analysis they used. Another limitation was a potential, albeit undetermined MBRP manual fidelity problem resultant from its translation into Farsi to facilitate communicating in the participants' native language. The effects of this translation were not measured (Imani et al.). An

additional limitation was the small number of enrolled participants (n=30) that limited statistical power and generalizability of the results. Notably, participant attrition was small, with 29 participants completing the study (Imani et al.).

In a random controlled study evaluating the effectiveness of MBRP in the treatment of individuals with stimulant use disorder Glasner-Edwards et al. (2017) found no significant post-treatment difference (p=.05) in stimulant use between the MBRP group and the control group. They noted some posttest improvement for MBRP participants that reported reductions in stimulant use and reduced symptoms of depression and anxiety, but these changes did not rise to the level of significance. The control group received eight weeks of health education group meetings run concurrently with the experimental group receiving the MBRP manualized treatment (Glasner-Edwards et al.). The FFMQ (Baer et al., 2004) was used for pretest and posttest measurement of participant mindfulness. A twelve-week contingency management protocol was run with the initial four weeks preceding the experimental and control groups implementation (Glasner-Edwards et al.). A feasibility strength of the study was the demonstrated strong MBRP protocol fidelity adherence as measured by MBRP Adherence and Competence Scale (Chawla et al., 2010) outcomes. Study limitations noted by Glasner-Edwards et al. included a 59% study participant attrition rate, with an initial 63 participants reduced to 26 remaining at study conclusion, and the unmeasured potential for covariability resultant from combining the experimental and control conditions with contingency management.

Hayes et al. (2004) evaluated the effectiveness of mindfulness-based approaches for MAT program patients, and this study, while demonstrating significant effects of the ACT-based intervention, did not evaluate for the effectiveness of MBRP. Whereas ACT and MBRP can both be regarded as mindfulness-based treatment approaches, ACT is strongly dissimilar to MBRP in its theoretical constructs, treatment approach, and interventional design. ACT is conceptually based on the theoretical constructs of relational framing (Hayes, 2002) and cognitive fusion (Hayes et al., 2012), with interventions focused toward achieving cognitive defusion with maladaptive relational frames using mindfulness-based decentering exercises. MBRP, in contrast, is based on principles of cognitive therapy, relapse prevention, and mindfulness (Bowen et al., 2011), using interventions amalgamated from these disciplines to increase participant metacognitive awareness, self-efficacy, and affect regulation, and improve coping skills, which together improve participant capabilities for effectively managing substance use cravings and reducing harmful behaviors associated with substance use.

Grant et al. (2017) found in their meta-analysis of MBRP efficacy that MBRP did not show significant reductions in substance use relapse prevention, or increased levels of mindfulness in comparison to relapse prevention, CBT interventions, or TAU. They suggested the need for larger participant sample sizes, and to find methods for reducing participant attrition, which appeared to be a common confounding factor across multiple studies they reviewed. A significant limitation in their study was that they did not

differentiate between distinct drugs of abuse, an essential consideration in the present study as it focused on persons with OUD enrolled in MAT.

Considered together, research outcomes suggest the MBRP treatment approach is likely an effective treatment for many substance use disorders and that volitional attention, when adaptively directed, appears to reduce the compelling nature of the association between substance use-associated cognitions and cravings. Despite these efforts, important MBRP research gaps remain in that as of the development of this study there has been thus far only a single study (Imani et al., 2015) using a random controlled participant assignment design to evaluate MBRP effectiveness with individuals that have opioid use disorder, are enrolled in a MAT program and are being maintained on methadone. This study was limited by a potential fidelity concern due to unevaluated translation of the MBRP manualized treatment document and undefined number of methadone-maintained participants. The only other study evaluating MBRP effectiveness for methadone-maintained individuals with OUD lacked a control group and randomized participant assignment, and was limited by a severe participant attrition rate (Bowen et al., 2017).

Rationale for Study Variables

Two measures for of illicit drug use in MAT program patients have been consistently utilized at MAT programs and in the associated substance use disorder research: random monthly urine drug screen outcomes and the ASI Alcohol/Drugs subscale outcomes (Batki et al., 2005; Parrino et al., 1993). Consistent with historical

treatment and investigative methodology, one measurement for DV utilized in this proposal to evaluate for frequency of participant illicit opioid use is the ASI Alcohol/Drugs subscale (Leonhard et al., 2000; McLellan et al., 1985). Given the strong association between opioid use cravings and opioid use behaviors (Batki et al., 2005; Parrino et al., 1993; Wasan et al., 2012), an additional DV measurement for this proposal was the OCS (McHugh et al., 2014).

A potential MV was the level of participant mindfulness as measured by participant TMS (Lau et al., 2006) outcome scores at pretest, midtest, and posttest intervals. Statistical covariance data outcomes were to be used for determining any significant mediating association between changes in participant mindfulness and changes in dependent variables outcomes.

MBRP (Bowen et al., 2011; Bowen et al., 2014; Bowen & Enkema, 2014) is a manualized treatment specifically researched and designed to address and reduce substance use-related thoughts, cravings, and reactive responding to environmental cues and stressors exposure (substance use as maladaptive coping). Given the impaired stress response of individuals with opioid use disorder (Kreek, 2000) and its associated elevated relapse risk, MBRP likely offers an effective strategy for reducing MAT program patient illicit opioid use and the onset of its harmful concomitants. Moreover, MBRP has not yet been effectively evaluated as a treatment adjunct for MAT program patients. Thus, the MBRP manualized treatment protocol was selected in order to evaluate its effectiveness as a treatment adjunct used within the context of a MAT program, and to address the

previously described research gap. The independent variable (IV) in the study was defined as two treatment levels: level one being administration of the MBRP (Bowen et al., 2012) manualized treatment intervention to the experimental group of MAT program participants concurrently participating in TAU for the proscribed eight-week period, and level two being the control group of MAT program participants participating only in TAU for the proscribed eight-week period.

Review and Synthesis

The research literature clearly indicates that opioid use disorder is a chronic, relapsing condition. Whereas MAT programs offer viable and effective treatment for this disorder, relapse for MAT program participants remains a serious concern, occurring in up to 20 percent of the treated population at any given time (Kreek, 2007). The risk of relapse is strongly associated with stress exposure in persons with opioid use disorder (CSAT, 2005; Kreek, 2000; Kreek & Koob, 1998; 2007). The medical, psychological, and social risks associated with relapse into illicit opioid use are of great concern (CSAT). Individuals experiencing relapse are at high risk for overdose, oversedation effects, and death (CSAT; Parrino et al., 1993, SAMHSA, 2020). Overdose death rates associated with illicit opioid use have tripled since 1990, and continue to increase (Chalk et al., 2013). Other associated risks include initiation or exacerbation of psychological conditions including anxiety and depression, alienation from friends and family, loss of beneficial functionality such as employment, and mounting legal problems with their associated expenses (CSAT). The social costs associated with illicit opioid use in the U.S.

are accrued mostly through overutilization of public healthcare, social support services, and criminal justice and court systems, and are estimated to amount to more than $500 billion annually (Manchikanti et al., 2012). Moreover, the annual U.S. healthcare costs associated with illicit opioid use are estimated to be greater than $ 72.5 billion (Rinaldo & Rinaldo, 2013). Taken together, the preceding considerations strongly suggest that any treatment adjunct that can potentially reduce the frequency of illicit opioid use in the MAT program patient population is thus of considerable benefit to both MAT program patients and society.

The research evaluating neurobiological substrates of opioid use disorder suggests several key functional aspects of brain function that contribute to the condition. The first is hedonic homeostatic dysregulation, where activation of the ventral tegmental area (VTA), nucleus accumbens (NAc), and locus ceruleus (LC) located within the brain's mesolimbic dopaminergic reward pathway occurs in response to repeated ingestion of exogenous (illicit) opioids through reduction in endogenous mu opioid receptor site occupation (Koob & Moal, 2006; Moal & Koob, 2007; Kosten and George, 2002). Continued hedonic homeostatic dysregulation results in allostasis, the neurobiologically conditioned phenomena of increased tolerance of and physiological dependence on illicit opioid use (Koob & Moal, 1997; 2006; 2007). The use of exogenous opioids is reinforced through classical conditioning hedonic effects that include sensations of well-being and euphoria arising from VTA mu receptor site occupation and resultant transmission of

increased dopamine levels from the VTA into the NAc and LC (Koob & Moal; Kosten & George).

Neurobiological functioning further contributing to OUD includes the phenomenon of opioid abstinence syndrome (OAS), or the state of opioid withdrawal, wherein the individual with opioid use disorder experiences a protracted constellation of increasingly severe and aversive physiological symptoms in response to discontinuance of or marked reduction in exogenous illicit opioid use (Chalk et al., 2013; CSAT, 2005; Parrino et al., 1993). OAS symptoms are precipitated by reduction in mu receptor site occupation in the LC, which thence results in upregulation of noradrenaline levels in the endocrine system that cause the marked discomfort of OAS symptoms (CSAT; Koob & Moal, 2006; Parrino et al.). Further, reduction of mu receptor site occupation in the VTA results in correspondent reduction of dopamine levels in the NAc with attendant dysphoric effects (Koob & Moal). Moreover, these aversive symptoms are immediately relieved through again ingesting illicit opioids, reducing noradrenaline levels and increasing dopamine levels, and thereby further reinforcing and perpetuating continued illicit opioid use (Kosten & George, 2002).

A third contribution factor in OUD is that of cognitive deficits, where the neurotransmitter signals from prefrontal cortex (PFC) of the brain, normally implicated in sound judgment and planning, are overridden by competing neurotransmission signals from the more primitive brain functions of the VTA, NAc, and LC. This action results in

the impaired decisional and behavioral control leading to continued illicit opioid craving, seeking, and use (Kosten & George, 2002).

Considering MBRP as a MAT Program Adjunct

The research evaluating neurobiological substrates of mindfulness suggests that recurrent use of mindfulness practices results in enhanced PFC regulation of the more primitive limbic system functioning, neurobiologically evidenced in measurable increases in adaptive PFC functioning and structural mass (Chiesa & Serriti, 2010; Hölzel et al., 2007; Hölzel et al., 2011b; Sperduti, Martinelli, & Piolino, 2011). Witkiewitz et al. (2013b), Kashdan et al. (2011), and Williams (2010) posited that these structural and functional effects result in enhanced awareness and attentional control, reduced reactivity to stress and environmental cues, and increased acceptance and management of discomfort. Witkiewitz et al. asserted the existence of several neurobiological substrates implicated in MBRP practice. Improved metacognitive awareness fosters Dorsolateral PFC, anterior cingulate cortex (ACC), ventral striatum (VS), insula, and amygdala bottom-up processing of substance use-associated stimuli without reactivity. The PFC and ACC upregulate adaptive attentional monitoring and control of cognitive, affective, and somatic functions associated with substance use cravings. Resultant improved self-regulation is reflected in adaptive inhibitory control of substance use sustained through the medial PFC, orbitofrontal cortex (OFC), and ACC; and tolerance for discomfort previously associated with substance use is improved through adaptive functioning of the ACC and VS.

Through these increased structural and adaptive functional capabilities individuals are able to more adaptively regulate their conditioned responses to internal mental and physiological conditions and to external environmental cues (Farb et al., 2012; Hölzel et al., 2011b); stimuli that would otherwise likely result in illicit substance use (Bowen & Enkema, 2014; Dickenson et al., 2013; Witkiewitz et al., 2013a; Witkiewitz et al., 2013b). Thus, the maladaptive neurobiological responses associated with hedonic homeostatic dysregulation and allostasis, as well as the neurobiological responses associated with OAS, likely could be more effectively mediated through the enhanced PFC control capabilities achieved through engagement in mindfulness practices. Zgierska and Markus (2010), in their review of the empirical literature, asserted that mindfulness practices have been found effective for addressing multiple concomitant conditions experienced by persons with substance use disorders that exacerbate relapse risk. Shorey et al. (2014) found that reduced levels of participant mindfulness were significantly associated with increased illicit substance use. Further, Shorey et al. (2013) found that individuals with substance use disorders have significantly reduced levels of mindfulness compared to healthy adults, suggesting that interventions increasing mindfulness in substance users would likely reduce tendencies toward illicit drug use as a maladaptive avoidance or coping strategy. Considered together, the concepts of neurobiological functioning, maladaptive functioning of the brain's reward pathway associated with impaired PFC regulation of lower order circuits, and the adaptive structural and

functional regulation of the PFC arising through mindfulness-based practices, underlie the research questions and hypotheses central to this pilot study.

Empirical research strongly suggests that mindfulness practices are effective in reducing substance use associated thoughts, cravings, and relapse (Blume & Marlatt, 2009; Bowen et al., 2006; Bowen et al., 2007; Bowen et al., 2009; Bowen et al., 2011; Bowen et al., 2014; Bowen & Enkema, 2014; Brewer et al. 2012; Brewer et al., 2009; Zgierska and Markus, 2010); and in reducing harmful effects of stress exposure (Baer, Carmody, & Hunsinger, 2012; Kabat-Zinn, 2002; 2003; 2009; Zgierska and Markus). Substance use-related cues, thoughts, and cravings are effectively mediated through use of mindfulness based attentional regulation (Witkiewitz et al., 2013; Hölzel et al, 2011b), suggesting that through engagement in mindfulness practices individuals with opioid use disorder likely can reduce their harmful substance use cognitions and behaviors, while concurrently improving their capabilities for adaptive stressor response.

Kabat-Zinn (2002; 2009) asserted that mindfulness approaches include intentional, decentered, acceptant attentional regulation of percepts, cognitions, and affective phenomena. Use of decentered selective attention is exemplified in MBRP by mediating substance use associated thoughts and cravings through multiple cognitive strategies. The first is conceptualization of such cognitions as impermanent mental events that need not be intrusive or compelling (Bowen et al., 2011). The second is enhancing adaptive coping with them via use of the ocean wave meditative exercise and other meditative exercises. The third occurs through use of CBT-based interventions that

together, strengthen PFC regulation of the more primitive conditioned limbic system responses (Bowen et al.).

Thus, as Witkiewitz et al. observed, MBRP interventions target brain functioning that is strongly associated with substance use and relapse. In their controlled study of MAT program patients Nejati et al. (2012) found that daily use of methadone medication fostered improved selective attentional capabilities through associated reductions in automatized illicit opioid use biases and maladaptive responding to environmental stressors. This suggests that methadone medication is unlikely to impair the selective attentional functions inherent in mindfulness practices. Taken together, these considerations suggest MBRP is potentially a viable treatment adjunct for use with individuals participating in MAT for opioid use disorder and thus its evaluation as a treatment adjunct for MAT program participants is relevant, likely addressing a key gap in the research.

Summary and Conclusion

A considerable body of research suggests mindfulness-based treatment approaches offer effective interventions for a number of conditions including anxiety, depression, chronic pain, substance use disorders, and multiple general medical conditions. Further, research evaluating mindfulness practices appear to enhance neurobiological, cognitive, and affective protective functioning. Mindfulness meditation has demonstrated effectiveness in reducing maladaptive responses to multiple aversive

conditions and enhancing adaptive responding, thereby markedly reducing human distress and suffering.

Neurobiological research evaluating mindfulness has found strong correlations between use of mindfulness-based practices and adaptive modifications to neurobiological structure and functioning. Research shows that impaired connectivity between the PFC and limbic system secondary to stress exposure, general medical illness, psychiatric illness, and substance use disorders has been implicated in symptomatic exacerbation of these conditions. Mindfulness research shows that even in naïve meditators, neurobiological changes have been observed including increases in neuronal mass within and blood flow from areas of the PFC to the limbic system, suggesting improved PFC regulation of more primitive central nervous system functions. An important area of investigation into mindfulness practices remaining unexplored to date is how such adaptive reregulation capacity could affect the neurobiological dysfunction associated with psychiatric illness, especially that specific to substance use disorders.

This pilot study attempted to address this research gap through evaluating the effects of a specific mindfulness-based intervention, MBRP, on the illicit opioid use behaviors of individuals concurrently participating in MAT. This study continues with Chapter 3, focused on specific research design, methods, and implementation strategies.

Chapter 3: Research Methods

Study Purpose

Opioid use disorder is a chronic, relapsing condition where post-remission relapse is likely (APA, 2006; 2013; Dennis & Scott, 2007; Kosten & George, 2002; Leshner, 1989; 2001; Parrino et al., 1993; Volkow, 2007a; 2007b). MAT is an effective treatment for addressing opioid use disorder (Kosten & George, 2002; Parrino et al., 1993; Volkow, 2007b). Nevertheless, given the chronic and relapsing nature of this condition, MAT program participants remain at risk for illicit opioid use relapse and are thus likely to benefit from adjunctive treatment interventions that reduce this risk (Logan & Marlatt, 2010; Parrino et al., 1993).

MBRP treatment interventions are effective in terms of treating substance use disorders and their associated craving behaviors, have not yet been investigated for their effectiveness as a MAT program treatment adjunct. This study involves addressing this gap in the research through evaluating the effects of illicit opioid use among MAT program participants.

Overview of This Chapter

This chapter includes an outline of the research design and its rationale, including research questions addressed by the study, study design, types of variables , time constraints imposed by the design, how the design addressed existing gaps in the research, and the rationale for the study intervention. Characteristics of the target population are described. Sampling strategies and procedures are identified. Procedures

for participant recruitment and data collection are identified and described. The rationale for conducting this pilot study is explicated. The MBRP manualized treatment intervention is described, and associated procedures for implementation are discussed. Measures used to evaluate DV outcomes are discussed, as well as their relevance for use in this study and reliability and validity characteristics. Study variables are operationally defined, and measurement, scoring, and interpretational methodologies are discussed. The data analysis plan is outlined, including software, research questions and hypotheses, explanation of statistical tests, evaluative methods for inclusion of covariates and controlling for confounding variables, and interpretational factors including confidence intervals. Validity threats are evaluated, including external and internal factors, as well as construct and statistical validity concerns. Ethical considerations are identified and discussed, including procedures used to assure consistency with Walden University IRB and APA ethical standards for participant research, institutional permissions, adherence to MAT program ethical standards, ethical treatment for all study participants regardless of nature or duration of their participation, and concerns regarding potential conflicts of interest. This chapter concludes with a summary of the experimental design and method of inquiry in this study.

Research Design and Rationale

This pilot study was intended to evaluate the effects of administration of a MAT program intended to develop and enhance mindfulness skills in participants concurrently enrolled in treatment for opioid use disorder with methadone maintenance

pharmacotherapy. Mindfulness-based interventions are associated with significant reductions in frequency and severity of substance use behaviors and cravings associated with substance use relapse (Bowen et al., 2006; Brewer et al., 2010; Ostafin & Marlatt, 2008; Marlatt & Chawla, 2007; Witkiewitz et al., 2005). These outcomes suggest that a mindfulness-based treatment intervention administered to participants concurrently enrolled in MAT programs using methadone pharmacotherapy may result in reductions in terms of frequency of illicit opioid use behaviors and severity of opioid cravings. This provides a context for evaluating the potential utility of conducting subsequent larger studies involving MBRP groups at multiple MAT programs, thereby evaluating MBRP manualized treatment effects in terms of statistical power associated with larger groups of study participants.

Research Questions and Hypotheses

RQ1: Is exposure to MBRP manualized treatment associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program?

$H_0 1$: Exposure to MBRP manualized treatment is not associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

$H_a 1$: Exposure to MBRP manualized treatment is associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

RQ2: Is exposure to MBRP manualized treatment associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program?

$H_0$2: Exposure to MBRP manualized treatment is not associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

H_a2: Exposure to MBRP manualized treatment is associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

Study Variables

The study was a quantitative design utilizing mixed within-between subjects design with time as the within-subjects factor and groups as the between-subjects factor. MANCOVA was to be used to evaluate relationships between the dependent and independent variables over time (Cohen et al., 2003, p. 608).

The DVs in the study were: (a) participant illicit opioid use during the eight- week study period as measured by the ASI Alcohol/Drugs subscale (McLellan et al., 1985) outcomes positive for illicit opioids and participant illicit opioid craving severity as measured by the OCS (McHugh et al., 2014).

The IV consisted of two levels: the first being provision of the MBRP (Bowen et al., 2011) manualized treatment intervention as an adjunct to TAU in the experimental

group of MAT program participants for eight-weeks, and the second consisting of TAU in the control group of MAT program participants for the concurrent eight-week period.

A potential MV was level of participant mindfulness as measured by the TMS (Lau et al., 2006) outcome scores. Investigation to determine the significance of this MV was not included in the study design, although it was the subject of limited commentary. The TMS was administered at pretest, midtest, and posttest intervals. Statistical covariance data outcomes would likely reveal any significant mediating association between changes in participant mindfulness and changes in dependent variables outcomes. A positive significant scoring difference at posttest would suggest that the participant increased his or her level of mindfulness in association with MBRP exposure, whereas the absence of a significant difference in pre- and posttest scores would suggest that there was not a change in participant mindfulness resultant from MBRP exposure. A negative significant scoring difference would suggest that the participant decreased his or her level of mindfulness in association with MBRP exposure.

The first research question for this study asked if participant exposure to the MBRP manualized treatment is associated with reductions in percentage of illicit opioid use for individuals concurrently participating in MAT for their opioid use disorder. The research design addressed this research question through its measurement of this DV associated with two levels of IV administration throughout the eight-week study period.

The second research question for this study asked if participant exposure to the MBRP manualized treatment was associated with reductions in severity of illicit opioid

craving for individuals concurrently participating in MAT for their opioid use disorder. The research design addressed this research question through its measurement of this DV associated with two levels of IV administration throughout the eight-week study period.

The study duration was 14 weeks, including phases for study participant enrollment, pre-treatment data collection, administration of the MBRP manualized treatment, posttreatment data collection, and participant debriefing. Participant enrollment procedures were to begin at the MAT program site three weeks prior to beginning the study.

Research regarding effects of mindfulness-based adjunctive interventions for MAT program participants maintained on methadone pharmacotherapy is severely limited, and thus far has not consistently included randomized, controlled designs. This study addressed these concerns through its empirical methodology utilizing a minimal number of group participants and relatively brief study period to minimize potential adverse effects on study integrity such as time and fiscal constraints.

Study Population Characteristics

The target population was individuals in the U.S. with opioid use disorder who are enrolled in MAT programs and who are maintained on methadone pharmacotherapy. At the inception of study design, there were an estimated 270,000 patients serviced by some 1,200 MAT program located throughout the US (SAMHSA, 2011). At the conclusion of study implementation there were an estimated 350,000 methadone-maintained individuals enrolled in MAT programs (Alderks, 2017). Given changes in

U.S. healthcare rules and associated increases in multiple states reflecting support for treatment of opioid use disorder, the number of individuals enrolled in MAT programs for treatment of opioid use disorder will likely continue to increase.

Sampling Procedures

Larger sample sizes reduce standard error and larger effect sizes increase statistical power (Gravetter & Wallnau, 2007). Gravetter and Wallnau observed that a type I error, where a treatment effect is falsely reported, can be reduced by decreasing alpha level, whereas a type II error, where an extant treatment effect is not detected, can be addressed through increasing effect size. They further noted that reducing standard deviation reduces variance, thereby reducing standard error and increasing power and effect size. A sufficient sample size thus must address these considerations.

Julious (2005) asserted that criteria for pilot study sample size include considerations about feasibility, precision of mean and variance, and regulatory requirements, where applicable. Julious observed that whereas larger studies have specific recommendations in the literature to assure optimal levels of standard error and statistical power at the chosen significance level, such standards have not been consistently applied to pilot studies.

Mean and variance precision characteristics include consideration that whereas increased sample size is associated with reduced standard error, sample size increases beyond 12 participants are likely to yield decreasing reductions in standard error given confidence interval of 0.95 (Julious, 2005). This suggests that for this study a sample size

of 30 participants per group ($n = 60$) was likely to minimize standard error of the mean at significance $p \leq 0.05$. To assure optimal variance precision characteristics in a pilot study Julious asserted that the sample size contain sufficient degrees of freedom such that a future study would have sufficient statistical power at chosen significance ($p \leq 0.05$) if based on the prior pilot study. As recommended by Julious, a sample size assuring 20 degrees of freedom is sufficiently large to assure 50% statistical power given $p \leq 0.05$. At $n = 45$, this study would have assured greater than 20 degrees of freedom. This study design reflected the preceding recommendations, thereby assuring equivalence between the control group and experimental group. To account for possible participant dropout, which could not be predicted, this study design was planned for number of participants $n = 60$, including group n TAU = 30 and MBRP = 30.

Participant Inclusion and Exclusion Criteria

Study participants were individuals aged 18 years or more who are concurrently enrolled in a medication assisted treatment (MAT) program located in California. Each participant had a primary DSM-5 diagnosis of 304.00 opioid use disorder, severe, on maintenance therapy (American Psychiatric Association, 2013). Federal guidelines (SAMHSA, 2015) and California State regulations (Title 9, Section 4, Part 4) require that patients meet these primary diagnostic criteria as a condition of MAT program admission, unless an infrequently utilized regulatory exception process is initiated by the program and approved by state and federal authorities. MAT program policies and procedures (BAART Programs, 2015) specify that patients cannot be admitted into MAT

unless they are minimally 18 years of age and able to provide informed consent to opioid treatment. No participants were excluded provided they completed study informed consent, maintained study participation, and maintained their concurrent MAT program participation at the study site for the duration of the study. Study enrollment will not be limited by sex, age (above adult status), ethnicity, race, educational level, or the presence (or absence) of any co-occurring psychiatric or medical conditions.

A private room at the MAT program site was used for implementing study interventions and data collection. Study materials were provided and study procedures conducted in a manner sensitive to the strengths, needs, abilities, limitations, and preferences of the participants (Commission on Accreditation of Rehabilitation Facilities [CARF], 2012).

Study participation was voluntary, and post enrollment, participants were able to withdraw at any time. Participants that did not complete the requisite informed consent process were excluded from study participation.

Continued MAT program enrollment was required in order for an individual to receive program services, including the MBRP group services (BAART Programs, 2015). Thus, participants were required to maintain enrollment in the MAT program throughout the duration of the study. In cases where a participant discontinued MAT program enrollment during the eight-week study period his or her study enrollment was discontinued.

Each participant was required to maintain adherence with MAT program participation standards for the duration of the study implementation period. For study purposes, such adherence was defined in accordance with MAT program policy requirements requiring that patients attend individual counseling sessions in accord with the schedule identified on their respective individualized treatment plan, typically once weekly for 50 minutes, and that patients ingest their methadone medication on a daily basis as ordered by the program physician (BAART Programs, 2015). MAT program requirements may additionally include patient participation in group therapy services, including but not limited to MBRP, relapse prevention, and groups for support of individuals experiencing he effects of trauma, grief, and loss (BAART Programs). Any participant that demonstrated substantial MAT program requirement nonadherence during the course of the study was discontinued from study participation and debriefed. Examples of such nonadherence would include missing more than one scheduled individual or group counseling session or more than two scheduled dosing appointments during the eight-week MBRP intervention period. The principal investigator was provided access to OTP program computer data systems to verify participant adherence with MAT program requirements.

Participant Recruitment

Participant recruitment occurred at the MAT program site selected for study implementation. For a three-week period prior to implementation phase of the study, an informational flyer (Appendix B) was distributed to all MAT program patients by

program front desk staff persons as they check in to the program for TAU services. This flyer described the study purpose and procedures, outlined participatory requirements, and provided principal investigator phone contact information to address any additional questions or concerns participants may have prior to participant enrollment and study implementation. The principal investigator was available at the program site during normal operation hours to answer questions and implement study enrollment process for interested MAT program patients. Participants were informed that a $ 25.00 debit card would be provided to all those completing the study as required. Participants were informed that discontinuing study participation prior to completion would result in ineligibility for this compensation. A private room at the MAT program site was used for study enrollment.

Participant Informed Consent Procedures

The study principal investigator facilitated the provision of informed consent for each participant, though review, discussion, and signing of the study informed consent document provided to each participant (See Appendix C). Participants were informed of the study purpose, treatment methods to be used, how they will be provided with relevant study outcome data, their right to discontinue the study at any time, and study personnel identifying information, qualifications, and contact information. The meetings with participants for purposes of effecting informed consent took place in a private office located at the program site. Informed consent participant meetings occurred during the

three weeks period prior to implementation of the eight-week MBRP manualized treatment study phase.

Informed consent procedures were carried out in a manner consistent with all Walden University IRB requirements and institutional approval letter stipulations. Additionally, this study was conducted such that all state and federal laws regulating MAT program patient privacy (HIPAA rule) and confidentiality (42CFR rule) are fully adhered to for all study participants.

Types and Sources of Information or Data

Data sources included study participant reporting of the above-described testing instrument outcomes. In order to assure privacy and confidentiality of the participants, data outcomes for each participant were associated with a unique four-digit number assigned by the principal investigator. Deidentified study participant record information collected from the MAT program computerized patient record included participant MAT program attendance records to assure participant continued in concurrent treatment for the duration of the study. Deidentified participant record information collected from the MBRP group services provider (the principal investigator) included dates of participant attendance at each MBRP group meeting group session and records of participant weekly MBRP homework assignment completion. Deidentified participant record information collected by the principal investigator from all participants included pretest, midtest, and posttest scores for the TMS (Lau et al., 2006), ASI Alcohol/Drugs subscale (McLellan et

al., 1985), and OCS (McHugh et al., 2014). Participant report of an adverse event (see Appendices E and F), if any, would also have been collected, however there was none.

Data Collection Procedures

Participants were randomly assigned to either the treatment group (n = 30) or control (TAU) group (n = 30). Random participant (n = 60) assignment to either treatment or control group was achieved through use of a randomization table. After selection, each participant was assigned a unique four-digit identifier that was associated with all study data collected about that participant. A key tying the randomized participant assignment identifying numbers to the participant names was securely maintained by the principal investigator in an encrypted file format stored on secure computer system with the encryption key known only by the principal investigator. Raw test data was retained in secure, private storage using a locked file cabinet by the principal investigator for subsequent scoring and recording data outcomes in the study database. All study data was retained in a manner that ensures adherence with participant privacy and confidentiality rules. Only participant ID numbers were noted on any study test materials. No participant names were used on any study data other than the aforementioned encrypted key log. The study database consisted of outcomes for all measures previously identified in participant recruitment and data collection procedures. A private room at the MAT program site was used for implementing study data collection. Study materials were provided and study procedures conducted in a manner

sensitive to the strengths, needs, abilities, limitations, and preferences of the participants (Commission on Accreditation of Rehabilitation Facilities [CARF], 2012).

Pretest Data Collection

The pretest data collection phase occurred during weeks three and four, prior to the first MBRP group meeting. The principal investigator met with each study participant (in both study groups) individually in a confidential, private setting at the MAT program site, and administered the pretest ASI Alcohol/Drugs subscale (McLellan et al., 1985), OCS (McHugh et al., 2014), and TMS (Lau et al., 2006) measures.

Midtest Data Collection

For Midtest data collection the principle investigator met with each study participant (in both groups) individually in a confidential, private setting at the MAT program site, and administered the midtest ASI Alcohol/Drugs subscale (McLellan et al., 1985), OCS (McHugh et al., 2014), and TMS (Lau et al., 2006) measures.

The principal investigator met with the MAT program MBRP group participants after the fourth group meeting (end of study implementation week 8) to collect data on MBRP group participation. This data collection consisted of several elements for each MBRP participant, including the dates of participant MBRP group attendance, participant completion of weekly MBRP assignments, a review of MAT program adherence data for all participants, a review of MBRP group facilitator adherence with MBRP group administration manualized procedures, and a review of any adverse event reporting. The

preceding data was recorded in a computer spreadsheet securely retained by the principal investigator for subsequent discussion.

Posttest Data Collection

Weeks 13-14 comprised the study posttest data collection phase wherein the principle investigator met with each study participant (in both groups) individually in a confidential, private setting at the MAT program site, and administered the posttest ASI Alcohol/Drugs subscale (McLellan et al., 1985), OCS (McHugh et al., 2014), and TMS (Lau et al., 2006) measures.

This data collection for each MBRP participant included the dates of participant MBRP group attendance, tracking the completion of weekly MBRP assignments, review of MAT program dosing and counseling requirements adherence, review of MBRP group facilitator adherence with MBRP group administration manualized procedures; and review of any participant adverse event reporting.

Management of Potential Adverse Effects

The principal investigator was responsible for meeting with study participants reporting adverse events. Adverse event data would have been immediately reported to the Walden IRB, however, no adverse events were reported. Documentation of adverse event data would be securely retained in a locking file cabinet accessible only to the principal investigator. Participants were informed that should they experience such events they may inform the principal investigator of their concerns and will then be immediately

excused from further MBRP group participation until the concerns can be satisfactorily resolved, if possible, or their study participation discontinued.

Although any adverse effects from study participation were considered unlikely, during the course of the study all participants reporting any unanticipated adverse effects would be assessed and appropriately referred by the principal investigator. Such assessment proved unnecessary, as no such adverse events were reported. This assessment would have included the following elements: (a) eliciting participant reporting of adverse effects thought to be associated with study participation; (b) documentation of reported adverse effects; (c) discussion of and documentation of participant consent to disclose in accord with provisions and restrictions of Federal Confidentiality Rule for Alcohol and Drug Treatment programs (42CFR); (d) report of adverse effects and referral to the MAT program physician for further evaluation and development of recommended course of treatment, if any; (e) an explanation to participant that given the reported adverse effect he or she may discontinue study participation immediately; (f) an explanation to participant that his or her MAT program enrollment status will not be affected by any reporting of adverse effects; and (g) reporting of the adverse event and its outcome to the Walden IRB. Because no adverse events were reported, implications of adverse event data were not analyzed by the me.

Participant Post-Study Debriefing

All active participants were debriefed at the conclusion of the study implementation phase by the principal investigator. No further follow-up requirements

were required of study participants, and at the debriefing meeting each participant completing the study received the participation compensation as explained during the study informed consent process. Participants that discontinued the study prior to completion of all data collection phases were offered debriefing services by the principal investigator, regardless of the reason for study discontinuance. Upon completion of the study data analyses all participants were offered a summary of the study outcomes and findings without charge. Participants in the control group were offered MBRP manualized treatment adjunct services after the conclusion of study debriefing.

Summary of Study Procedures

Table 2 depicts a summary outline of previously described study operational procedural elements:

Table 2

Outline of Study Procedures

Study Phase and Description	Period
Study information provided to potential participants	Weeks 1 and 2 (before MBRP starts)
Informed consent obtained from participants	Weeks 1-3 (before MBRP starts)
Pre–test data collection	Weeks 3-4 (before MBRP starts)
MAT Program staff provides MBRP to participants	Weeks 5-12 (MBRP administered)
Posttest data collection and participant debriefing	Weeks 13-14 (after MBRP ends)

Nature of MBRP Manualized Treatment Intervention

The MBRP manualized treatment is an eight-week structured clinical intervention course where participants meet once weekly in a private setting at the MAT program site for up to two hours (as needed to complete proscribed MBRP treatment activities) with a MAT program staff person designated by the MAT program, who will function as group facilitator; conducting daily individual guided meditation practice exercises, participating in conceptual discussion of relevant manualized treatment topics, and reviewing and completing CBT-oriented treatment assignments (Bowen et al., 2011). The first session consists of an introduction to the course requirements and two mindfulness meditation exercises (Bowen et al.). Each subsequent session includes a review of the homework assigned to study participants during the previous session, discussion of participants' mindfulness meditation practice experience during the prior week, interactive discussion of mindfulness and relapse prevention practices and approaches, guided mindfulness meditation exercises, review and discussion of the following weeks' homework assignments, and closing remarks. The MBRP manualized treatment (Bowen et al.) structure is described in detail in Chapter 2 and Appendix A of this proposal.

Study Instrumentation and Construct Operationalization

This experimental design attempted to evaluate whether there is an association between participant exposure to the MBRP manualized treatment adjunct and percentage of participant illicit opioid use. This was achieved through between groups comparison of the dependent variables for illicit opioid use, and levels of participant mindfulness. Data

outcomes evaluation using repeated measures MANCOVA were planned to be conducted at significance ($p < .05$).

The ASI Alcohol/Drugs subscale (McLellan et al., 1985) was administered at pretest, midtest, and posttest intervals by the principal investigator. ASI Alcohol/Drugs subscale scoring outcomes were reviewed by the principal investigator to assure data collection and interpretive accuracy. The OCS (McHugh et al., 2014) was administered at pretest, midtest, and posttest intervals by the principal investigator. OCS scoring outcomes were reviewed by the principal investigator to assure data collection and interpretive accuracy. The TMS (Lau et al., 2006) was administered at pretest, midtest, and posttest intervals by the principal investigator. TMS scoring outcomes were evaluated for possible mediating effects on ASI and OCS outcomes. TMS scoring outcomes were reviewed by the principal investigator to assure data collection and interpretive accuracy.

Quantitative analysis of the multiple independent and dependent study variables was planned using MANCOVA. If an inverse covariability were to be found between experimental group participant exposure to MBRP and illicit opioid substance use as predicted by the first alternative hypothesis, then the first null hypothesis would be rejected in favor of the first alternative hypothesis. This outcome would suggest that administration of MBRP manualized treatment to concurrently enrolled MAT program patients is associated with significant reductions in illicit opioid use. If an inverse covariability were to be found between experimental group participant exposure to

MBRP and illicit opioid craving as predicted by the second alternative hypothesis, then the second null hypothesis would be rejected in favor of the second alternative hypothesis. This outcome would suggest that administration of MBRP to concurrently enrolled MAT program patients manualized treatment is associated with significant reductions in illicit opioid craving.

Materials required for the administration of all test measures included printed versions of each measure, pens for indicating line item responses, and a comfortable private setting where the participants can be interviewed. These were readily available at the MAT program site. Substance use scoring outcomes were reviewed by the principal investigator to assure data collection and scoring accuracy. Finally, the strength of this study's quantitative methodology was enhanced through minimization of extraneous variable effects achieved by conducting the experiment in the MAT program environment known to the study participants.

Addiction Severity Index

The fifth edition of the ASI (McLellan et al., 1985) evaluates for examinee functioning across multiple domains, asking lifetime problem frequency for a total number of years, where the problem was evidenced at least once during any year, and problem frequency within past 30 days, where the problem was evidenced at least once. Using a Likert scale design the examinee indicates problem severity and need for treatment: not at all, slightly, moderately, considerably, or extremely (McLellan et al.).

Using a Likert scale design from 0 to 4, the examiner then indicates three evaluative items for each ASI functional domain: Problem severity ratings; The examinee's ability to understand the test questions; and the examinee's ability to answer test items honestly and accurately (McLellan et al., 1985).

The ASI demonstrates strong concurrent reliability ($\alpha = .89$) and consistent validity and reliability scores for widely diverse substance use disordered populations (Leonhard et al., 2000; McLellan et al., 1985). Butler et al. (2001) found that one-month test-retest reliability of the ASI drug use domain index is strong ($\alpha = .77$), as is criterion reliability for the drug use domain index ($r = .67$).

Mäkelä (2004) found inconsistent reliability in non-English version ASI interviewer severity ratings and composite scoring, attributed to insufficient interviewer training and combined composite scoring methodologies that may artificially reduce index score levels. McLellan, Cacciola, and Alterman (2004) asserted the ASI is in revision with the intention of improving reliability. The standard English version of the ASI will be used in this study, and will be administered by the principal investigator, who has extensive experience in ASI administration and interpretation.

This study used the ASI Alcohol/Drugs subscale data pertaining to illicit opioid use. This ASI subscale is scored through weighted summing of individual item results within each subscale. Index composite score ranges from no problem severity (0.00) to very high problem severity 1.00 (Cacciola et al., 1997). Scoring methodology includes dividing each test item response by 30 (reporting period in days), summing the results,

and dividing by the total number of test items (McGahan et al. 1986). The final two test items asking for examinee reporting of problem disturbance level and desire for treatment are divided by 4, then by 13 (McGahan et al.). A composite subscale score for the drug use domain at or near 1.00 thus indicates severe substance use. The ASI Alcohol/Drugs subscale is in the public domain.

Opioid Craving Scale

This study used the OCS to measure severity of participant cravings for illicit opioids. The OCS consists of three visual analogue scale items measured in 0 (no desire for opioids) to 10 (strong desire for opioids) for item one, and in severity from 0 (no severity) to 10 (extremely strong severity) for the remaining two items. The first scale asks the participant to evaluate the strength of desire to use opioids during the past 24 hours. The second scale asks the participant to rate how strong desire to use opioids has been during the past week when exposed to an environmental cue associated with opioid use. The third scale asks the participant to recall the most recent environment and time of day where he or she used opioids and rate the likelihood of opioid use if the participant were in that environment at that time today (McHugh et al., 2014). The scoring methodology for this scale consists of averaging the three individual scale outcomes together for a composite craving severity score (McHugh et al.).

The OCS appears to demonstrate strong reliability and validity. Using Spearman's rho, Mann-Whitney *U,* and Kruskal-Wallis testing, McHugh et al. (2014) found that the OCS demonstrated strong internal consistency and reliability (.85 to .92, $p < .001$), and

strong concurrent and predictive validity for illicit opioid use (*OR* = 1.17, 95% *CI* = 1.11, 1.22 , $p < .54$). For the OCS, a composite score close to 0 would suggest little to no craving, whereas a composite score close to 10 would suggest severe craving likely predictive of illicit opioid use. The OCS is in the public domain.

Toroto Mindfulness Scale

The TMS measures two factors considered essential components of mindfulness: curiosity and decentering. In psychometric evaluations by Lau et al. (2006), the TMS evinced high internal consistency (α = .95), with statistically significant factor loadings for curiosity (α = .56) and decentering (α = .82), and internal consistency of the two scales were (α = .86) and (α = .87). Lau et al. noted that composite reliability scores were robust for curiosity (*CR* = .93) and decentering (*CR* = .93). Criterion validity is supported by significantly higher scores evidenced on both factors for post versus pre MBSR training groups, as well as for mindfulness meditators with greater than one-year experience versus those with less than one year of meditation experience (Lau et al.).

Lau et al. (2006) described how the measure consists of 13 questions associated with factors contributing to mindfulness, requiring approximately three minutes for administration. The examinee indicates level of agreement with the test item statement using the Likert scale design: 0 - not at all, 1 - a little, 2 – moderately, 3 - quite a bit, or 4 - very much.

Curiosity index scores are derived from individual test item scores for 3, 5, 6, 10, 12, and 13; while decentering scores are obtained from individual test item scores for 1,

2, 4, 7, 8, 9, and 11 (Lau et al., 2006). Higher scores indicate increased clinical evidence of mindfulness effects in the test subject (Lau et al.). The TMS appears psychometrically sound and will require little administration time. The TMS is in the public domain.

Operationalization of DVs and IVs

Only data collected during the study implementation period was used. This period was defined as two weeks prior to start of MBRP group services to participants, concluding two weeks after conclusion of same. No archival data was used. For the first research question, the DV was frequency of illicit opioid use as measured by ASI Alcohol/Drugs subscale scoring outcomes. For the second research question, the DV was participant OCS scoring outcomes.

Each ASI Alcohol/Drugs subscale outcome score greater than zero for opioids indicates the participant used illicit opioids for one or more days during the past month and will be considered as an illicit opioid positive result. An example of an ASI Alcohol/Drugs subscale result positive for illicit opioids is where any illicit opioid use is reported for five of the past 30 days. Each Opioid Craving Scale composite scale score of five (moderately severe craving) or greater is considered as representative of participant illicit opioid craving.

The IV consisted of two treatment levels: provision of the MBRP (Bowen et al., 2011) manualized treatment intervention to the experimental group of MAT program participants (in addition to TAU) for the proscribed eight-week period, and the control group of MAT program participants (TAU only) for the proscribed eight-week period.

Any experimental group participant not attending at least six of the eight MBRP group sessions while consistently participating in TAU at the MAT program was considered as not meeting the IV requirement, identified as a study dropout, and this outcome so noted in the study data analysis. Where possible, dropout participants were debriefed and their data was not used for the quantitative analysis of the study.

The control group experienced TAU as it is consistently practiced within the context of the MAT program, excluding MBRP group participation. For the control group any participant not consistently participating in TAU for the eight-week study period was considered as not meeting this IV requirement, identified as a study dropout, and this outcome so noted. Study dropout participant data was not be utilized for purposes of study quantitative data analysis. The only between groups variable was administration of the MBRP manualized treatment.

Data Analysis Plan

Statistical Software and Data Validation

Software planned for use in data analysis in this study was the Statistical Package for the Social Science (SPSS; International Business Machines, 2009), with the alpha value set at .05 for all statistical procedures used. All outcomes data were planned to be uploaded into a computer running SPSS software and results that will be calculated by the SPSS program. Each participant data entry record was to be reviewed against the original documentation provided by the study site coordinator to assure data entry integrity. A complete descriptive data analysis procedure was to be run on all study

variables using the SPSS program, thereby crosschecking to assure that data outliers or entry errors are not significantly skewing data outcomes. Finally, the SPSS Data Validation procedure was to be run to assure that missing or erroneous data entries are not influencing data analyses outcomes. The principal investigator was responsible to assure that all outcomes data were accurately transcribed, that appropriate statistical tests were run, and that inferences made from these results would be interpreted accurately in accord with the statistical model used (MANCOVA) and experimental design utilized.

Despite the data analysis plan described above the principal investigator was unable to carry out as planned due to unforeseen high levels of participant dropout. This confound led to an insufficient number of participants remaining in the MBRP group (n=3), thereby invalidating data analysis due to inability to achieve sufficient statistical power.

Research Questions and Hypotheses

RQ1: Is exposure to MBRP manualized treatment associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program?

H_01: Exposure to MBRP manualized treatment is not associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

H_a1: Exposure to MBRP manualized treatment is associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

RQ2: Is exposure to MBRP manualized treatment associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program?

H_02: Exposure to MBRP manualized treatment is not associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

H_a2: Exposure to MBRP manualized treatment is associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

Data Analysis Methods

This study planned for use of a quantitative, randomized, controlled design utilizing repeated measures of dependent variables and a single measure of a between groups independent variable. It reflected a mixed within-between subjects design with time as the within-subjects factor and groups as the between-subjects factor.

Quantitative Methodologies

Cohen et al. (2003) said MANCOVA is used for statistical evaluation research designs where there are multiple DVs and IVs. This supports a study design and correspondent statistical model for evaluation of relationships between multiple, distinct

IVs and DVs over time. Cohen et al. further suggested that requisite properties for the MANCOVA test include utility when examining non-nominal multivariate factors, calculating partial variance, determining multivariate significance, and calculating "measures of association, parameter estimation, hypothesis testing, and statistical analysis" (p. 609) within a unified conceptual statistical approach. Given the complexity of multivariate data gathered over distinct periods in this study, MANCOVA testing was considered the most effective method of statistical analysis.

Gravetter and Wallnau (2007) and Cohen et al. (2003) suggested that when an experiment consists of three or more treatment conditions use of t-tests would result in accumulation of type I errors from each test, collectively known as the experiment-wise alpha level. A single MANCOVA test can simultaneously test all means using one alpha level, thereby avoiding the inflated alpha error effect. Real world participant sampling suggests the possibility that unequal sample sizes must be compared due to unanticipated phenomena such as participant drop out. MANCOVA provides a valid test with sufficient sample size where groups are sufficiently large: $n \geq 12$ for pilot studies (Julious, 2005), and sample size differences are not too great.

The preceding MANCOVA methodology assumed that a minimum of number of participants ($n \geq 12$) would complete the entire study, would consistently attend study MBRP group meetings, and would participate in and complete study measures as scheduled for the pretest, midtest, and posttest measure administration. The most direct and comprehensive way to assure these assumptions were made was to enroll a sufficient

number of participants such that even with participant dropout the minim number of participants would remain.

Threats to Validity

External Validity Threats

An important consideration here is that of extraneous variables caused by TAU effects. Generally, TAU for the MAT program patient includes daily methadone pharmacotherapy administered by a program nurse, weekly individual counseling sessions, and appointments with program medical staff where indicated (Batki et al., 2005). Inconsistencies in TAU services frequency or quality may exert unknown effects on participants, possibly influencing substance use behavior, study participation, or test item response data. This study was designed to control for these potential extraneous variables through use of random participant assignment and a control group.

Other validity threats could arise through distinctions in MAT program counseling styles and therapeutic approaches used, or from differences in counselor education, training, and experience. Batki et al. (2005) and McCann et al. (1994) asserted there is considerable variability in therapeutic approaches and counselor education and training at MAT programs. At the MAT program site used for the study clinical approaches attempts were made to support consistency in clinical approach through use of mandatory organizational training and work implementation standards based on implementation of standardized policy and procedure (BAART Programs, 2013). All counselors at the site were trained in a central approach based on acceptance, empathy,

genuineness, and unconditional positive regard (Miller et al., 1999; Rogers, 1961; 1980), and in use of motivational interviewing practices (Miller & Rollnick, 2002). Whereas the preceding TAU variables argue for caution in interpretation of experimental results, the inclusion of randomized participant assignment and a control group was intended to protect study outcomes from these potential validity threats.

Distinctions in participant lived experience, personality, and behavior may have exerted unknown confounding effects. Extraneous variability could arise from varied levels of participant knowledge and skill level relevant to mindfulness practices, or from naïve participant mindfulness states and traits. These distinctions could result in differences in participant conceptual and experiential levels of mindfulness, thereby exerting effects on individual participant meditation practice and efficacy of mindfulness practices integration. Random participant assignment and use of a control group in this study design were planned to reduce such potential effects.

Lau and McMain (2004) asserted that key to effective mindfulness research is the use of research personnel experienced in mindfulness practices prior to teaching others. This study addressed this potential source of variability through use of the principal investigator, who held the requisite training and experience in use of the MBRP manualized treatment; as the MBRP group facilitator.

Internal Validity Threats

Nastasi and Schensul (2005) observed that confirmation bias may occur in quantitative research approaches when the observer is focused on hypothesis testing such

that extraneous, relevant data is overlooked and illusory correlations are formulated. Johnson and Onwuegbuzie (2004) cited multiple internal validity threats, including foreclosure effects, where relevant data is erroneously ruled out, and discounting error, where an expected association is found and other potentially relevant associations are not considered. The study attempted to address confirmation bias potential through use of randomized participant assignment, use of a control group, use of data crosschecking methods, and critical exploration of study limitations.

In this study selection, bias could arise through reliance on voluntary participant enrollment, where individuals with certain, potentially confounding characteristics seek study participation. Participants could be predisposed toward an interest in mindfulness practices or have historical experience with such practices that confounds study outcomes. These potential participant-biasing effects were controlled through pretest, midtest, and posttest measures administration, and through use of a control group.

Quantitative investigational approaches may be limited in that their operationalization methods fail to accurately or sufficiently reflect participant understandings of the treatments and measures offered during the course of the study (Johnson & Onwuegbuzie, 2004). This issue was addressed through use of clearly established quantitative interventional and evaluative methods and procedures implemented within the experiential context of the MAT program familiar to study participants, thereby likely facilitating participant comprehension of and accurate responding to the measures and procedures used in this investigative effort.

Regression and correlation analyses must be interpreted with caution. Linear correlations cannot be used to determine causal relationships or the reason for them (Gravetter & Wallnau, 2007). Correlational evaluations are vulnerable to limitations posed through unintended effects of data range limitations, outliers, regression toward the mean, and insufficient sample size. In this study, correlations between measured pretest, midtest, and posttest outcomes were intended for use in asserting a causal relationship exists between MBRP manualized treatment effects and any observed correspondent reduction in illicit opioid use.

Ethical Procedures

Agreement for Participant and Data Access

This study was conducted at a MAT program site located in the California Bay Area. The agency that operates the MAT program at this site is BAART Programs, Inc. This study was implemented in accordance with specific permissions allowing MAT program site and patient access and use of patient data as delineated by the BAART Programs (See Appendix D). All such access and use was conditional upon strict adherence by all study investigative personnel to regulatory standards regarding MAT program patient privacy and confidentiality restrictions and provisions and delineated in the Health Insurance Portability and Accountability Act (HIPAA; U.S. Department of Health and Human Services, 2003); the confidentiality regulations for drug and alcohol patient treatment programs (Confidentiality of Alcohol and Drug Abuse Patient Records Rule, 1987); the standards for research as promulgated by the NIH Office of Extramural

Research (2008); and existing BAART Programs policy and procures pertaining to research conducted at a program site delineated in the BAART Programs Policy and Procedures Manual (2015). Individual participant data gathered during the course of this study was private and confidential, and was not shared with the MAT program personnel.

Institutional Permissions

Ethical considerations for this study included assuring advance Walden Institutional Review Board approval and obtaining consent of the sponsoring program's senior management team and board of directors (APA, 2010). Institutional permission for participant and data access and usage were obtained from BAART and BayMark Programs (See Appendices D, H). Walden University IRB Approval was obtained and the approval number was 05-11-18-0067220.

The study participants were informed of the study purpose, methods to be used, and data outcomes and conclusions. Participants were informed of their right to discontinue the study at any time and were provided needed qualifications and contact information for study personnel. All participants were debriefed after study intervention and data collection was ended. Although not anticipated, unintended effects on participants, including any identified adverse effects, would have been evaluated by the principal investigator and referrals made if indicated. All participants were to receive a copy of the final research report without charge. The study was conducted in accord with established research guidelines (NIH Office of Extramural Research, 2008) and MAT program privacy and confidentiality regulations relevant to research conducted on site

(Confidentiality of Alcohol and Drug Abuse Patient Records Rule, 1987; NIH Office of Extramural Research; U.S. Department of Health and Human Services, 2003).

Considerations in Participant Recruitment

Assurance of participant confidentiality and privacy is essential to protect participants from unauthorized disclosure, to ensure requisite trust for complete and accurate participant data reporting, to assure adherence to American Psychological Association ethical standards (APA, 2010), and to protect study personnel and the MAT program organization from undesirable legal consequences (Creswell, 2003; Confidentiality of Alcohol and Drug Abuse Patient Records Rule, 1987; U.S. Department of Health and Human Services, 2003). All participants in this study were recruited based on provision of informed consent, and all discussion pertaining to the informed consent process was carried out in a confidential, private setting at the MAT program site. Participants were provided with principal investigator contact information in order to facilitate timely responses to any emerging participant questions or concerns. All such queries were to be responded to as soon as possible, at the most within seven calendar days, although no adverse events were reported.

Intervention Considerations

To the fullest extent possible, the principal investigator assured that biases were not allowed to affect the study, and the research plan included fully discussing any bias-based limitations in the research report (APA, 2010; Creswell, 2003; NIH Office of Extramural Research, 2008). An extensive body of mindfulness research suggests that

mindfulness-based practices and research are beneficial to participants, and have not resulted in any harm (Brantley, 2007; Brewer et al., 2010; Chang et al., 2004; Davidson et al., 2003; Farb, Anderson, and Segal, 2012; Jain et al., 2007; Kabat-Zinn, 2002; 2009; Modinos et al., 2010; Shapiro & Schwartz, 2000; Witkiewitz et al., 2005; Zeidan et al., 2013). Multiple studies using the MBRP manualized treatment have been implemented and concluded without any observed or reported harm to participants (Bowen et. al., 2006; Bowen et al., 2009; Bowen et al., 2011; Marlatt, 2006; Marlatt & Chawla, 2007; Witkiewitz et al., 2005). In their systematic review of multiple meditation studies Arias et al. (2006) found some case reports of practitioners participating in extended mindfulness retreats experiencing the onset of recurrent dissociative effects. They found other case reports where practitioners experienced a sense of detachment or affective flattening, or of increased awareness of uncomfortable personal or life situations. However, overall Arias et al. found that most mindfulness practice participants perceived overall benefit from their meditative experiences. Considered altogether, these studies suggest that the risk to mindfulness practice participants is minimal. Given that the MBRP group services were provided by the principal investigator, and that this study evaluated data collected concurrently from both TAU without the group and including the group, risk to study participants was considered minimal. In the unlikely event that an adverse condition had arisen from participation in this study, clinical evaluation and referral would have been provided to the affected participant without charge.

Data Collection, Use, and Storage

The principal investigator was responsible for assuring privacy and security of all participant test documentation in accord with confidentiality and privacy rules pertaining to MAT programs. All documentation of participant informed consent, and study raw data and outcomes was stored in a private, locking file cabinet accessible only to the study principal investigator. All study data relevant to each participant was associated with a unique participant ID number assigned by the principal investigator. A data key was securely retained in a separate password protected computer file retained by the principal investigator that linked participant names to their unique ID numbers. Aside from this procedure, no participant names, birthdates, social security numbers, addresses, phone numbers, email addresses, or other information that could potentially be used by unauthorized persons to identify any participant was collected, stored, or used as part of the study implementation procedures. Study outcome data was planned to be summarized and made available without charge to interested study participants and to the BAART Programs administrative staff with oversight responsibility for the study. Study materials, including all testing data and outcome measures and SPSS database information were, and will continue to be, securely retained for a period of five years as required by Walden University standards. Once that time period has elapsed all study data will be securely destroyed.

Assuring Participant Privacy and Confidentiality

Information in the MAT program patient record is referred to as Protected Health Information (PHI), and conditions for collection and use of PHI are set forth in the body of federal rules known as the Health Insurance Portability and Accountability Act (HIPAA; U.S. Department of Health and Human Services, 2003). MAT program patients have specific rights pertaining to how their PHI is used by the program and disclosed to others. PHI encompasses any health record information that is under the control of the program, and any personal information known about the patient that could be used to identify the patient. Generally, MAT programs use PHI to assist them in providing treatment services, sharing patient information with other agencies or individuals given that a written consent to disclose is in effect, and for disclosure to the patient.

PHI data is subject to the minimum disclosure necessary principle, suggesting that only the minimum information required for achieving the authorized disclosure may be communicated, and to the need to know principle, meaning that only individuals with a need to know in order to carry out indicated patient services are informed of PHI (U.S. Department of Health and Human Services, 2003; BAART Programs). All patients must receive a notice about how the program will use and disclose their PHI (U.S. Department of Health and Human Services).

The federal rules also provide for unique MAT program patient confidentiality protections under the body of rules commonly identified as 42 CFR (Confidentiality of Alcohol and Drug Abuse Patient Records Rule, 1987). Alcohol and drug treatment

programs are prohibited from disclosure of any patient information without the written consent of the patient, and any further or subsequent disclosure of such authorized information is prohibited without additional specific written consent. The 42 CFR delineates the specific elements required for a patient's consent to disclose and describes circumstances and procedures for legal proceedings where such disclosure may be requested with and without patient consent. Through utilization of unique participant identifying numbers throughout data collection and analyses the research procedures used in this study did not involve collection or disclosure of any patient identifying data, and thus did not violate any privacy or confidentiality rules.

The NIH Office of Extramural Research specifies a number of conditions that human participant research must satisfy, including protections against participant harm, right to participant discontinuance at any time, and assurance of informed consent processes for each participant (NIH Office of Extramural Research, 2008). This study rigorously adhered to all such NIH research requirements.

Additional Ethical Considerations

The principal investigator had oversight of all aspects of participant study involvement. The principal investigator is trained, experienced in, and responsible for evaluating administration of the MBRP treatment protocol (Bowen et al., 2006; Bowen et al., 2009; Bowen et al., 2011) to study participants during the eight-week study period.

Upon completion of the study, participants who remained in the study for the full implementation period received a $ 25.00 gift card as compensation for their participation

efforts. This was intended to foster consistency in study participation throughout the implementation period.

Summary of Study Design and Methodology

This was a quantitative randomized controlled single-site pilot study design using repeated measures of DVs and IVs. It reflected a mixed within-between subjects design with time as the within-subjects factor and groups as the between-subjects factor. MANCOVA was planned for use to statistically evaluate relationships between multiple, distinct IVs and DVs over time (Cohen et al., 2003).

The study principal investigator provided the MBRP manualized treatment adjunct. Study participants met individually with the principal investigator in a private setting at the study site for pretest, midtest, and posttest administration of the TMS to the experimental and control groups.

All treatment groups participated in TAU correspondence with that of the typical MAT program participant, which included planned daily program attendance, daily administration of the medication(s) prescribed by the MAT program physician, and once weekly individual counseling sessions of 50 minutes duration.

The IV for the quantitative methodology used in this study consisted of two adjunctive treatment levels: the first being administration of the MBRP manualized treatment intervention to the experimental group of MAT program participants for the proscribed eight-week period; and the second consisting of the control group of MAT program participants for the proscribed eight-week period. The DVs were ASI

Alcohol/Drugs subscale outcomes collected at pretest, midtest, and posttest intervals and OCS outcomes collected at pretest, midtest, and posttest intervals.

Testing for existence of a significant experimental effect was planned through use of quantitative analyses of within- and between-groups effects on pretest, midtest, and posttest outcome scores of the ASI Alcohol/Drugs subscale (McLellan et al., 1985) and the OCS (McHugh et al., 2014). Comparative data evaluation using repeated measures MANCOVA was planned to be conducted ($p < .05$), although as previously mentioned could not be carried out due to very high participant dropout rate.

Temporal association of MBRP manualized treatment participation with significant reductions in illicit opioid use would have suggested that the first null hypothesis was not supported and the first alternative hypothesis was supported. Temporal association of MBRP manualized treatment participation with significant reductions in illicit opioid cravings would have suggested that the second null hypothesis was not supported and the second alternative hypothesis was supported. No significant increases in mindfulness within the experimental group over time as measured by TMS (Lau et al., 2006) outcomes would have suggested the absence of mindfulness effects as a MV. In general, the presence of a significant negative (inverse) correlation between increased levels of mindfulness and decreased frequency of illicit opioid use and/or cravings would have suggested that mindful states are a factor influencing participant mediation of illicit opioid use and cravings.

This study documentation now proceeds to Chapter 4 wherein data outcomes, statistical analyses, and implications of results and findings are discussed.

Chapter 4: Results

Introduction

In Chapter 4, data collection outcomes are reported, including a discussion of implementation discrepancies in the study design resulting from feasibility impediments. Statistical analyses considerations are offered, and implications of study implementation and data collection results and findings are discussed.

Summary of Study Design and Methodology

This study involved using a quantitative randomized controlled single-site pilot study design with repeated measures of dependent and independent variables. I used a mixed within-between subjects design with time as the within-subjects factor and groups as the between-subjects factor. MANCOVA was used to statistically evaluate relationships between multiple distinct IVs and DVs over time.

Research regarding the effects of mindfulness-based adjunctive interventions on MAT program participants is severely limited, and thus far has not involved randomized controlled designs. The study involved using a minimal number (n=54) of group participants and a brief study period minimizing potential adverse effects on study integrity involving time and fiscal constraints.

Research Questions and Hypotheses

RQ1: Is exposure to MBRP manualized treatment associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program?

H_01: Exposure to MBRP manualized treatment is not associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

H_a1: Exposure to MBRP manualized treatment is associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

RQ2: Is exposure to MBRP manualized treatment associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program?

H_02: Exposure to MBRP manualized treatment is not associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

H_a2: Exposure to MBRP manualized treatment is associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

Study Variables

The study involved use of a quantitative mixed within-between subjects design with time as the within-subjects factor and groups as the between-subjects factor. MANCOVA was used to evaluate relationships between DVs and IVs over time.

The DVs in the study were participant illicit opioid use during the 8-week study period (concurrent with MBRP group participation) as measured using the ASI

Alcohol/Drugs subscale (McLellan et al., 1985) and participant illicit opioid craving severity as measured by the OCS (McHugh et al., 2014).

The IV in the study consisted of two levels: the first being the MBRP manualized treatment intervention as an adjunct to TAU for the experimental group of MAT program participants for the requisite eight week period, and the second being TAU in the control group of MAT program participants for the concurrent eight week period.

A potential MV in the study was the prestudy level of participant mindfulness as measured using the TMS (Lau et al., 2006). Positive significant differences between pretest and midtest or posttest scores would suggest that the participants' level of mindfulness as measured by the TMS increased in association with MBRP exposure, whereas the absence of significant differences in pretest, midtest, and posttest scores would suggest no significant changes in terms of participant mindfulness were associated with engagement in MBRP treatment. A negative significant scoring difference would suggest that participant level of mindfulness as measured by the TMS was inversely associated with MBRP group exposure. Although not the focus of this study, the effects of this potential mediating variable were observed through TMS administration during the pretest, midtest, and posttests.

RQ1 was about participant exposure to MBRP manualized treatment and associations with reductions in terms of percentage of illicit opioid use for individuals concurrently participating in a MAT program for their opioid use disorder. I addressed

this research question by measuring DVs associated with two levels of IV throughout the 8-week study period.

RQ2 was about whether participant exposure to MBRP manualized treatment is associated with reductions in severity of illicit opioid craving for individuals concurrently participating in a MAT program for their opioid use disorder. I addressed this research question by measuring this DV associated with two levels of IV throughout the 8-week study period.

Data Collection

The study included phases for study participant enrollment, pre-treatment data collection, administration of the MBRP manualized treatment, posttreatment data collection, and participant debriefing. Participant enrollment procedures began at the MAT program site three weeks prior to beginning the study. Participant enrollment and data collection procedures were conducted by the principal investigator.

The MBRP manualized treatment adjunct was administered to study participants by the principal investigator. The principal investigator provided pretest, midtest, and posttest administration to all participants with ASI Alcohol/Drugs subscale (McLellan et al., 1985), the OCS (McHugh et al., 2014), and the TMS (Lau et al., 2006).

All treatment groups participated in TAU as typically provided to MAT program participants. This included daily program attendance, daily administration of the medication prescribed by the MAT program physician; and once weekly individual

counseling sessions of 50 minutes duration. Exceptions to TAU participation were noted where they occurred.

The IV for the quantitative methodology used in this study consisted of two treatment levels, the first being administration of the MBRP (Bowen et al., 2011) manualized treatment adjunct (in addition to TAU) as an intervention to the experimental group of MAT program participants for the proscribed eight-week period, and the second consisting of the control group of MAT program participants experiencing TAU only for the proscribed eight-week period.

The DVs included the ASI Alcohol/Drugs use subscale (McLellan et al., 1985) outcomes collected at pretest, midtest, and posttest intervals and the OCS (McHugh et al., 2014) outcomes collected at pretest, midtest and posttest intervals. TMS (Lau et al., 2006) pretest, midtest, and posttest scores were also collected to monitor for any potential MV effects, but were not included in the study RQs and hypotheses.

Study Implementation and Data Collection

The study duration was planned for 14 weeks, including phases for study participant enrollment, pre-treatment data collection, administration of the MBRP manualized treatment, posttreatment data collection, and participant debriefing.

Phases of the study implementation at the MAT program site are outlined in the following table:

Table 3

Outline of Study Implementation at MAT Site

Planned Study Phase and Description	Period of Implementation
1. Study information provided to potential participants	Weeks 1 and 2(before MBRP starts)
2. Informed consent obtained from participants	Weeks 1-3 (before MBRP starts)
3. Pretest data collection	Weeks 3-5 (before MBRP starts)
4. MBRP treatment provided to selected participants	Weeks 6-9 (MBRP begins)
5. Midtest data collection	Weeks 10-16 (MBRP concludes)
6. Posttest data collection and participant debriefing	Weeks 17-20

After discussion with the MAT clinic director at the program site it was agreed that the most effective weekday of study implementation was Wednesday, as this day typically had the highest rate of MAT patient attendance. Given the full-time employment requirements of the principal investigator, only one day per week could be designated for study implementation purposes. Participant recruitment took place over a three consecutive week period prior to the implementation of pretest data collection. Study information was provided and informed consent obtained during this period. At the conclusion of the participant recruitment phase 52 participants were enrolled in the study. Random participant group assignment for both participant groups, Treatment as Usual (TAU only) and Experimental (TAU plus MBRP), was completed by the principal investigator based on statistical random number table selections prior to the end of week three.

Pretest data collection began in week three and continued through week five. This phase took a week longer than planned in study design because of the time required to contact individual participants, many of whom no-showed for scheduled pretest administration appointments. At the conclusion of this study phase participant dropout left 16 participants available (see table four below). These and subsequent participant attendance influences on study participation and outcomes are discussed in in further detail in the forthcoming section of this chapter evaluating treatment fidelity.

Phase four of study implementation (weeks 1-4 of MBRP group) began on week six of study implementation. The principal investigator administered weeks one through four of the MBRP manualized treatment protocol to the selected group participants during this period. During this phase marked inconsistency of participant group attendance was observed. By the conclusion of this study phase a severe frequency of participant dropout for the MBRP group was observed (see table four).

Implementation of phase five of the study (weeks 5-8 of MBRP group, and midtest data collection for all participants) began in week ten, continuing through week sixteen. Midtest data collection began during the first week of this period, with all measures administered by the principal investigator. The fifth through eighth week of MBRP group administration was not completed until the fourteenth week of study implementation. Midtest measures were administered to MBRP group participants prior to group meetings to reduce potential for confounding between group participation effects and data collection.

The additional weeks of study implementation during phase five were required due to only one MBRP group participant presenting on week 13 for the final group session, and subsequent no-show of all group participants during week 14 of study implementation. Following this, during implementation week 15 the final MBRP group was again re-scheduled due to an unexpected staffing crisis occurring at the clinic facility overseen by the study principal investigator, that precluded his attendance. Thus, the final administration of the MBRP group intervention occurred on week 16 of study implementation. Inconsistent participant attendance at this final MBRP group was noted by the principal investigator.

The above described factors influencing inconsistent MBRP group attendance during implementation of this study phase are discussed in further detail in the treatment fidelity section of this study description. As previously noted during the above description of phase four, overlap between measures administration and administration of the MBRP group protocol occurred to the competing needs of timely measures data collection for both groups and continuance of MBRP treatment group participation.

Phase six (posttest administration and participant debriefing) began in week 17, continuing through week 20 of study implementation. One additional week of measures administration was required due to no-show of some participants in both study groups. Some participants were unavailable during this study period. Review and scoring of study measures, evaluation of study outcomes, and participant debriefings were subsequently completed. Only three participants were available for debriefings during the conclusion

of this study phase. As previously noted, factors influencing the attendance of study participants are discussed in further depth in the following treatment fidelity evaluation section.

Participant Descriptive and Demographic Characteristics

Study volunteer participants were randomly selected from and thus representative of the population of the larger group of individuals participating in MAT programs. The study participant characteristics include a current diagnosis of OUD (304.00) (APA, 2013) participation in the BAART MAT program used for the study, being maintained on methadone medication as a treatment for OUD, and exhibiting no signs or symptoms contraindicating study participation. All participants were at least 18 years of age.

Analysis of Fidelity in Study Implementation

Following is an analysis of the preceding factors influencing study implementation and outcomes, and thereby impacting fidelity to study design. Their ultimate effects led to irregularity of participation in study measures administration, data collection, and attendance at scheduled MBRP group meetings. These observed factors are described and evaluated in the following discussion.

Participant dropout and no-show were feasibility factors anticipated to some extent in study design. A much higher than anticipated frequency of participant dropout was observed throughout study implementation (see table four below). This effect can be seen throughout all phases of data collection, notably in the MBRP Group intervention level, where number of active participants reduced from an initially enrolled 26 to seven

in pretest phase, to three in midtest phase, and then two participants remaining in posttest phase, a 92% reduction (See table four). More globally, at conclusion of study data collection, only nine participants remained from the initial enrollment of 52, representing an 83% attrition rate in study participation. These marked reductions in participant attendance throughout the study implementation resulted in an insufficient number of participants remaining to meet the minimum necessary (n=60) for achieving sufficient statistical power.

Table 4

Participant Dropout Frequency - Both Intervention levels

Study Phase	Group	# Assigned	# Remaining	Freq. Difference	% Difference
1. Study information	NA	0	52*	0	0
2. Informed consent	NA	0	52*	0	0
3. Pre–test data	MBRP	26	7	-19	-73
collection	TAU	26	9	-17	-65
4. MBRP treatment begins	**	**	**	**	**
5. Midtest data MBRP		26	3	-23	-88
collection	TAU	26	5	-21	-80
6. Posttest dataMBRP		26	2	-24	-92
collection	TAU	26	7	-19	-73
Study conclusion	(BOTH)	52	9	-43	-83

*Total participant enrollment. **No participant dropout measured, reported, or observed during this phase. Source: Deidentified study participant data.

During phase four (pretest) of study implementation 19 MBRP Group and 17 TAU participants discontinued study participation (see Table 4). Attempts to contact participants to assess reasons for their study discontinuance, and for encouraging possible study reengagement, were unsuccessful. Methodology for these contact attempts included

developing a list of participants not presenting as scheduled, and then flagging them in the study site computer system. This attempt to control for missed participant appointments proved ineffective.

During phase five of study implementation a total of 23 MBRP Group participants dropped out, and a total of 21 Control group participants had dropped out. This represented a dropout rate of 88% of MBRP Group participants, and 80% of control participants. As noted during the above discussion of phase four, attempts to contact participants in order to assess their reasons for study discontinuance were unsuccessful. Thus, reasons for study participant dropout remain undetermined.

During phase six of study implementation a total of 24 MBRP Group participants had dropped out, and a total of 19 Control group participants had dropped out. This represented a dropout rate of 92% of MBRP Group participants, and 73% of control participants (see table 5). As noted during the above discussion of phase five, attempts to contact participants in order to assess their reasons for study discontinuance were unsuccessful.

Interventions to facilitate participant attendance were utilized, including developing a list for tracking nonadherent participants and flagging them in the study site computer system. These attempts to contact participants for study reengagement were unsuccessful. Thus, reasons for study participant dropout remain undetermined.

Table 5

MBRP Group Participant Attendance

Week Number*	No. Scheduled	Attendance Freq.	% Attending	Freq. Difference	% Non-Attending
1	26	2	07.69	-24	92.31
2	26	4	15.38	-22	84.62
3	26	6	23.08	-18	69.23
4	26	2	07.69	-24	92.31
5	26	3	11.54	-23	88.46
6	26	3	11.54	-23	88.46
7	26	3	11.54	-23	88.46
8	26	2	07.69	-24	92.32
Avg.	26	3.13	12.04	-22.63	86.75

Note. Excludes weeks where no group was conducted. Source: Deidentified study participant data.

Treatment dropout from MAT programs has been frequently observed by this writer in his role as clinic director at two different MAT program sites over the past three decades, thus some study participant dropout was unsurprising, albeit not at the frequency encountered in this study.

Although the severity of participant dropout was not anticipated in the study design, it is understandable that some dropout would occur as enrolled participants may not have been sufficiently motivated to initially or recurrently provide information regarding their opioid use, cravings, and level of mindfulness. Further, some of these participants may have discontinued due to being inhibited about providing sensitive substance use information, despite the assurance provided by the principal investigator

during implementation of informed consent procedures. Assessment of these potential contributing causes to participant dropout from the participants' perspective could not be completed due to participant unavailability. Discussion with the clinic director at the program site revealed there were multiple potential causes that so many participants dropped out. These confounding factors included participant discontinuance of the MAT program, participant incarceration, participant no-show on study implementation days,. participant transportation impediments, and participant arrival at program outside of time periods that study group and data collection procedures were available.

An additional feasibility factor that may have impacted study data collection was the recurrent difficulty several participants had with comprehending some questions included in the TMS (Lau et al., 2006). Many participants reported not understanding TMS questions. Examples of this included participant commentary during TMS administration: (a) "I was curious about what I might learn about myself by taking notice of how I react to certain thoughts, feelings, or sensations." (from TMS test item 3); (b) "I experienced my thoughts more as events in my mind than as a necessarily accurate reflection of the way things really are." (from TMS test item 4); (c) "I was receptive to observing unpleasant thoughts and feelings without interfering with them" (from TMS test item 7); (d) "I was more invested in just watching my experiences as they arose, than in figuring out what they could mean." (from TMS test item 8); (e) "I was aware of my thoughts and feelings without overidentifying with them" (from TMS test item11); and

(f) “I was curious about what I might learn about myself by just taking notice of what my attention gets drawn to” (from TMS test item 13). In such instances the principal investigator attempted to clarify the meaning of the problematic test questions but the effects of these efforts on TMS scoring are unknown. This unanticipated problem likely interfered with accuracy of TMS scoring, thereby invalidating fidelity to data collection implementation of the study.

In summary, there were multiple unanticipated feasibility confounds that impacted study implementation such that efficacy of data collection procedures and MBRP group services were invalidated by very high frequency of participant dropout, inconsistent participant attendance, MBRP group scheduling inconsistencies, and inconsistent participant comprehension of several test items included in the Toronto Mindfulness Survey.

There were no adverse effects on study participants observed by or reported to the study principal investigator throughout all phases of study implementation. This discussion of study outcomes continues with reporting on the descriptive and demographic characteristics of the study participants.

Study Fidelity Considerations and Impact on Results

This writer now takes up discussion of the outcome of pretest, midtest, and posttest results. Throughout this discussion of study results please refer to tables that follow where indicated.

In comparatively evaluating the MBRP group intervention level outcomes vs. the Control level outcomes, data in the tables below suggests that participants in the control group tended to have higher severity of substance use than their counterparts in the MBRP Group intervention level. On average, the MBRP group participants tended to have 0.11 or greater positive scoring difference than those in the Control group throughout the study data collection period. Given the comparative elevated participant attrition in the MBRP group a statistically significant between-groups comparison cannot be made. In general, the data suggest a higher level of drug use in the Control group, but attributional etiology regarding this outcome must remain speculative.

Table 6

MBRP Group Intervention Level Addiction Severity Index Drug Scale Test Results

	Pretest Score	Midtest Score	Posttest Score
	0.22	0.24	0.23
	0.36	0.21	0.12
	0.20	0.25	*
	0.11	*	*
	0.29	*	*
	0.31	*	*
	0.12	*	*
Average	0.23	0.23	0.18

Scoring Range: 0.00 – 1.00 Higher Numbers indicate increased substance use severity

*= no test data collected. Source: Deidentified study participant data.

The MBRP experimental group level within-group ASI Alcohol/Drugs subscale scores reflected several scoring trends (Refer to Table 6). There was no change in average scoring from pretest to midtest. A reduction (-0.05) in average scoring from midtest to posttest was observed. These scoring changes suggest a small, likely nonsignificant, decrease (-0.50) of MBRP participation on reported opioid use from pretest to posttest. There were four less administrations at midtest compared with pretest. There were five less administrations at posttest compared with pretest. The variance in test administration frequency exerted strong effects on scoring variance such that no statistical significance can be determined in these scoring outcomes.

Table 7

Control Intervention Level ASI Drug Scale Test Results

	Pretest Score	Midtest Score	Posttest Score
	0.54	0.46	0.50
	0.42	0.38	0.46
	0.39	0.39	0.33
	0.58	0.29	0.25
	0.27	0.21	0.30
	0.29	*	0.48
	0.38	*	0.23
	0.08	*	*
	0.08	*	*
Average:	0.34	0.35	0.36

Scoring Range: 0.00 – 1.00 Higher Numbers indicate increased substance use severity *=no test data collected. Source: Deidentified study participant data.

The TAU control group level within-group ASI Alcohol/Drugs subscale scores reflected several scoring trends (Refer to Table 7). There was a slight increase (+0.01) in average scoring from pretest to midtest. There was a further slight increase (+0.01) in average scoring from midtest to posttest. These scoring changes suggest a small, likely nonsignificant, increase (+0.02) in reported opioid use over time from pretest to posttest. There were four less administrations at midtest compared with pretest. There were two less administrations at posttest compared with pretest. The variance in test administration frequency likely exerted strong effects on scoring variance such that no statistical significance can be determined for these scoring outcomes.

Comparative evaluation (Refer to Tables 6 & 7) of the ASI Alcohol/Drugs subscale between-group outcomes suggests that participants in the TAU control group level tended to have higher severity of substance use than their counterparts in the MBRP group experimental level. On average, the MBRP group participants tended to have 0.11 or greater positive scoring difference than those in the Control group. In general, the data suggest a higher level of drug use in the TAU group but this remains a speculative observation. The cause for these differences cannot be objectively determined at this time, and comparative analysis of these test results is problematic given the disparate rates of participant dropout between the groups, as evidenced by two MBRP group participants remaining at posttest data collection, as compared to seven control group participants. Given the comparative elevated participant attrition in the MBRP group a statistically significant between-groups comparison cannot be made.

Table 8

MBRP Group Intervention Level Opioid Craving Scale Test Results

	Pretest Score	Midtest Score	Posttest Score
	0	3	5
	8	9	12
	8	1	*
	4	*	*
	0	*	*
	13	*	*
	9	*	*
Average:	6	4.33	8.5

Scoring Range: 0 – 30 Higher Numbers indicate increased craving severity *= no test data collected. Source: Deidentified study participant data.

The MBRP experimental group level within-group OCS scores reflected several scoring trends (Refer to Table 8). There was a slight decrease (-1.67) in average scoring from pretest to midtest. There was a marked increase (+4.17) in average scoring from midtest to posttest. These scoring changes suggest a marked, likely significant, increase (+2.50) in reported opioid cravings over time from pretest to posttest. There were four less administrations at midtest compared with pretest. There were five less administrations at posttest compared with pretest. The variance in test administration frequency likely exerted strong effects on scoring variance such that no statistical significance can be determined for these scoring outcomes.

Table 9

Control Intervention Level OCS Test Results

	Pretest Score	Midtest Score	Posttest Score
	4	11	15
	19	15	13
	13	16	10
	0	6	0
	0	20	2
	6	*	15
	10	*	21
	0	*	*
	0	*	*
	0	*	*
Average:	5.2	13.6	10.86

Scoring Range: 0 - 30 Higher Numbers indicate increased craving severity

Source: Deidentified study participant data.

The TAU control group level within-group OCS scores reflected several scoring trends (Refer to Table 9). There was a marked increase (+8.40) in average scoring from pretest to midtest. There was a noted decrease (-2.74) in average scoring from midtest to posttest. These scoring changes suggest a strong, likely significant, increase (+5.66) in reported opioid cravings from pretest to posttest. There were four less administrations at midtest compared with pretest. There were five less administrations at posttest compared with pretest. The variance in test administration frequency likely exerted strong effects on scoring variance, such that no statistical significance can be determined for these scoring outcomes.

Comparative evaluation (Refer to Tables 8 & 9) of the OCS between-group outcomes suggests that the TAU control group participants experienced higher levels of opioid craving (10.89) than participants in the MBRP experimental group (8.5). There were two MBRP participants remaining at posttest, and seven control group participants remaining at posttest. The causes for these differences cannot be objectively determined at this time, and comparative analysis of these test results is problematic given the disparate rates of participant dropout between the groups. Given the comparative elevated participant attrition in the MBRP group a statistically significant between-groups comparison cannot be made.

Table 10

MBRP Group Intervention Level TMS Results

Pretest Score		Midtest Score		Posttest Score		
Curiosity	Decentering	Curiosity	Decentering	Curiosity	Decentering	
14	14	18	14	22	14	
10	13	19	13	15	12	
17	9	9	13	*	*	
24	17	*	*	*	*	
20	10	*	*	*	*	
20	15	*	*	*	*	
14	11	*	*	*	*	
14	12	*	*	*	*	
16.63	12.63	15.33	13.33	18.5	13.00	(Avg.)

Scoring Ranges: 0 – 24 (Curiosity); 0- 28 (Decentering). Higher Numbers indicate increased level of mindfulness. *= no test data collected. Source: Deidentified study participant data.

The MBRP experimental group level within-group TMS scores reflected several scoring trends (Refer to Table 10). For the Curiosity scale there was a small decrease (-1.30) in average scoring from pretest to midtest. For the Decentering scale there was a very small increase (+0.07) in average scoring from pretest to midtest. For the Curiosity scale there was a notable increase (+3.17) in average scoring from midtest to posttest. For the Decentering scale there was a very small decrease (+0.33) in average scoring from midtest to posttest. For the Curiosity scale there was a notable increase (+1.87) in average scoring from pretest to posttest. For the Decentering scale there was a very small increase (+0.37) in average scoring from pretest to posttest. There were five less administrations at midtest compared with pretest and six less administrations at posttest compared with pretest. The variance in test administration frequency likely exerted strong effects on scoring variance such that no statistical significance can be determined for these scoring outcomes.

Table 11

Control Intervention Level TMS Results

Pretest Score		Midtest Score		Posttest Score		
Curiosity	Decentering	Curiosity	Decentering	Curiosity	Decentering	
24	12	13	17	22	16	
20	16	11	15	17	11	
17	12	4	3	17	13	
3	4	15	14	14	11	
13	2	9	6	20	18	
18	21	*	*	11	15	
13	12	*	*	24	19	
18	17	*	*	*	*	
9	11	*	*	*	*	
15.00	11.89	10.40	11.00	17.86	14.71	(Avg.)

Scoring Ranges: 0 – 24 (Curiosity); 0- 28 (Decentering). Higher = increased level of mindfulness *=no data collected. Source: Deidentified study participant data.

The TAU control group level within-group TMS scores reflected several scoring trends (Refer to Table 11). For the Curiosity scale there was a notable decrease (-4.60) in average scoring from pretest to midtest. For the Decentering scale there was a very small decrease (-0.89) in average scoring from pretest to midtest. For the Curiosity scale there was a marked increase (+7.46) in average scoring from midtest to posttest. For the Decentering scale there was a marked increase (+4.71) in average scoring from midtest to posttest. For the Curiosity scale there was a notable increase (+2.86) in average scoring from pretest to posttest. For the Decentering scale there was a notable increase (+2.82) in average scoring from pretest to posttest. There were four less administrations at midtest

compared with pretest, and two less administrations at posttest compared with pretest. The variance in test administration frequency likely exerted strong effects on scoring variance such that no statistical significance can be determined for these scoring outcomes.

Comparative evaluation of the between-group levels average test scores for the TMS (Refer to Tables 10 & 11) measure outcomes suggests that whereas the MBRP group scored marginally higher for posttest curiosity subscale (+0.64) the TAU group scored somewhat higher for posttest decentering subscale (+1.71). Scoring for both group levels was invalidated by the lowered (and diminishing over time) number of MBRP Group participants. There were two MBRP group participants remaining at posttest and seven TAU control group participants remaining at posttest. These disparate rates of participant dropout between the groups limited between-groups analysis. These outcomes may suggest that there is a general trend for individuals predisposed toward mindfulness to score higher on the TMS than those that are less inclined toward mindfulness, regardless of MBRP Group participation. However, given the confound of MBRP patient dropout, which is much more severe than that of the control group, this effect could not be statistically evaluated.

As a result of the impact of the multiple feasibility factors described in the preceding discussion, an insufficient number of participants remained in the MBRP Group at the conclusion of the study, thereby impeding implementation of any valid statistical analysis procedure. Thus, valid testing of the hypotheses as proposed in the

study design could not be carried out. The preceding data strongly suggest that in order to objectively determine whether MBRP group participation can reduce opioid craving and increase participant mindfulness further evaluative attempts must be made. Such attempts must address feasibility factors, in particular, patient dropout effects, and methodologies for ameliorating such effects.

Temporal association of MBRP (Bowen et al., 2011) manualized treatment participation with significant reductions in illicit opioid craving and use would suggest that the first and second null hypotheses are not supported and the first and second alternative hypotheses are supported. Due to participant attrition no significant changes in mindfulness as measured by TMS (Lau et al., 2006) outcomes were observed. Resultantly, the presence of a significant negative (inverse) correlation between increased levels of mindfulness and frequency of illicit opioid use and cravings was not established in this study. Given these findings, study outcomes cannot suggest that changes in measured levels of mindfulness arising are a MV factor influencing participant illicit opioid use and cravings.

Due to the feasibility confounds posed by high and progressively higher participant dropout, testing for existence of a significant experimental effect using quantitative analyses could not be accomplished through evaluation of within- and between-groups effects on pretest, midtest, and posttest outcomes of the ASI Alcohol/Drugs subscale (McLellan et al., 1985) and the OCS (McHugh et al., 2014). Similarly, the TMS (Lau et al., 2006) outcomes could not be used to observe any

potential MV effects. Comparative data evaluation using repeated measures MANCOVA ($p < .05$) was not conducted given these experimental confounds.

As a result of the preceding implementation problems, the first research question that asks if exposure to MBRP manualized treatment associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program could not be answered. Further, for the same reasons previously described, the second research question that asks is exposure to MBRP manualized treatment associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program could not be conclusively answered.

The preceding data strongly suggest that in order to objectively determine whether MBRP group participation can reduce opioid craving and opioid use further evaluative attempts must be made. Such attempts must address feasibility factors, in particular, patient dropout effects, and methodologies for ameliorating such effects. This writer recommends that future studies consider methodologies that reduce participant dropout in order to foster statistically significant analyses of within and between group outcomes.

Chapter 5 includes interpretations of research findings, study limitations, and recommendations for future research. Implications for social change are explored, and methodological implications are discussed, followed by a conclusion.

Chapter 5: Discussion, Recommendations, and Conclusions

Introduction

The purpose of this study was to examine the relationship between participant exposure to MBRP manualized treatment protocol as a treatment adjunct and participant opioid use and cravings. All participants were diagnosed with OUD, enrolled in the MAT program offered at the study site, and maintained methadone medication throughout the course of the study. After completing the informed consent process, participants were randomly assigned to either the experimental group using MBRP and TAU or the control group using TAU only. All measures were completed by me. The MBRP group was provided to onsite participants by me over the course of eight weeks.

The study design included two experimental group levels, one combining MBRP exposure with TAU, and the other using only TAU. The study DVs were changes in participant opioid use and opioid cravings as measured through pretest, midtest, and posttest administrations of the ASI Alcohol/Drug use subscale (McLellan et al., 1985) and the OCS (McHugh et al., 2014). The study involved using a quantitative mixed within-between subjects design with time as the within-subjects factor and groups as the between-subjects factor. Use of MANCOVA ($p < .05$) was planned to evaluate for significant relationships between DVs and the IV. The comparative data evaluation involving repeated measures MANCOVA was not conducted due to unexpected experimental confounds including a 83% participant attrition rate and highly inconsistent

participant attendance at MBRP group meetings. The study research questions and hypotheses were as follows:

RQ1: Is exposure to MBRP manualized treatment associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program?

$H_0 1$: Exposure to MBRP manualized treatment is not associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

$H_a 1$: Exposure to MBRP manualized treatment is associated with changes in frequency of illicit opioid use for individuals with opioid use disorder concurrently participating in a MAT program.

RQ2: Is exposure to MBRP manualized treatment associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program?

$H_0 2$: Exposure to MBRP manualized treatment is not associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

$H_a 2$: Exposure to MBRP manualized treatment is associated with changes in severity of illicit opioid use cravings for individuals with opioid use disorder concurrently participating in a MAT program.

The research gap addressed in this study was identified via an extensive review of literature regarding effectiveness of MBRP manualized treatment as an intervention for individuals with OUD. The aforementioned research review effort yielded two studies that evaluated the effects of MBRP manualized treatment adjunct on individuals with OUD who were currently enrolled in a medication MAT program and prescribed methadone medication as a treatment for their condition.

This study represented a first effort to evaluate and increase understanding of the relationship, if any, between participation in MBRP manualized treatment and changes in opioid use cravings and using behaviors for methadone-maintained individuals participating in a MAT program.

If findings in the present study indicated the MBRP treatment adjunct was effective in terms of reducing participant opioid use and cravings, individuals with OUD would likely benefit from MBRP participation in terms of how to more effectively manage their opioid craving and using behaviors, thereby significantly improving their quality of life.

Interpretation of Findings

Findings of this study include that the study design, while carefully considered, did not account for multiple implementation feasibility factors that served as significant confounds in study data collection an analysis. The largest single such factor was participant dropout, which by the conclusion of the study was greater than 90% of the originally enrolled participants. Attempting to determine what may have contributed to

such a high dropout rate provided difficult because of limited participant contact with the primary investigator. The high participant dropout rate resulted in such a small number of participants (two posttest MBRP group participants remaining) that statistical analysis of participant pretest, midtest, and posttest data using MANCOVA methodology could not be conducted with validity at significance $p <= 0.05$.

Limitations of the Study

This study outcome evidenced the critical importance of fully anticipating feasibility factors potentially affecting consistency of participant retention when conducting a study at an opioid treatment program site. Limitations included the predominant confounding effect of participant dropout on study outcome. The high rate of participant dropout experienced in this study severely limited the ability to conduct a valid statistical analysis of the testing outcomes because the number of MBRP group participants was reduced to two at time of posttest data collection, thereby preventing data collection for the minimum number of participants required to complete a valid MANCOVA data outcome analysis. In addition, the inability to develop a valid statistical analysis of data resulted in being unable to offer associated analyses of theoretical research associated with mindfulness, opioid use, and neurobiological functioning.

Participant Attendance Confounds

Participant attendance inconsistencies were repeatedly encountered throughout study implementation. These included: (a) no-shows, referencing nonappearance to the program site as scheduled, on days the MBRP group was being conducted; (b) no-shows

on study data collection days; (c) discontinuance of the MAT program and thus no longer eligible for study participation. (In these cases, the patients never returned to the program during the study implementation period, so it was impossible to attempt their reengagement in the OTP or the study); (d) incarceration and resultant nonattendance at the OTP; (e) hospitalization and resultant nonattendance at the MAT program; (f) transfer to another MAT program and thus no longer presenting for services at the study site; (g) encountering difficulties obtaining transportation to the MAT program; (h) instances where patients arrived too late to receive MAT program services or participate in study activities on a given day; (i) reported inability to stay for study participation as scheduled, despite receiving MAT program services on such days; (j) reported symptoms of a general medical illness that precluded such patients from staying for study activities after receiving their MAT medication as scheduled; (k) instances where a participant experienced childcare needs that precluded them from participating in study activities; (l) instances where participants reported an intention to return for MBRP group services after receiving MAT program services but did not do so for undetermined reasons; (m) instances of conflicting time schedule between study participation requirements and MAT program services, such as cases where a patient was required to participate in a counseling session or meet with the program physician. (In such instances, the OTP requirements took precedence over the study participation); and (o) instances where a study participant had a conflicting responsibility offsite, such as a medical, social services, or legal appointment.

The central limitation relative to all the above situations was that the principal investigator could only be at the study site once weekly. This meant that study participants had only the once weekly opportunity to attend the scheduled study activity. Whereas the data collection could be rescheduled for the following week, the group meetings proceeded once weekly in accord with the MBRP manualized treatment protocol. Ideally, there would have been alternate weekdays for offering MBRP group services to address this contingency, but due to time constraints the principal investigator could only be at the study site once weekly. Therefore, for example, if a participant missed the MBRP group there was no opportunity to reschedule. Additionally, any of the above factors, singly or in combination, may have influenced participant dropout.

Program Operational Confounds

Another feasibility confound involved program operational considerations, including but not limited to an unanticipated program dispensing nurse staffing crisis that interfered with MBRP group administration for one week. The effects of the resultant MBRP group meeting schedule change on study outcomes were not measurable but may nevertheless have been significant.

An unexpected confound arose through the occurrence of errors in flagging participant alerts in the MAT program computer system. Although a list for participant appointments was provided by the principal investigator to program administrative staff the morning of each study implementation day, for unknown reasons some participants were not flagged. These oversights likely caused missed data collection and interfered

with MBRP group session attendance. It is also possible that in some instances participants simply ignored the study flags and left the MAT program without completing their assigned study activities. The effects of this confound on overall study participation could not be evaluated and thus remain undetermined.

In addition, a potential study design confound was experienced by the principal investigator during administration of the TMS (Lau et al., 2006) to study participants. Multiple participants in both IV group levels reported a lack of understanding regarding some TMS test items, especially those that were more abstractly worded. These test line items and related participant reporting are discussed in the following:

TMS test item three states: "I was curious about what I might learn about myself by taking notice of how I react to certain thoughts, feelings, or sensations." (Lau et al., 2006). For this test item, many participants reported not understanding what it meant to learn about themselves through noticing their reactions to the various aspects involved in apprehending their life experience. The principal investigator attempted to explain this line item through use of verbiage such as "understand yourself more fully through becoming aware of your emotions, thoughts, feelings, and sensations in your body."

TMS test item four states: "I experienced my thoughts more as events in my mind than as a necessarily accurate reflection of the way things really are" (Lau et al., 2006). For this test item, many participants reported not understanding what it meant to experience their thoughts as "events in the mind." The principal investigator attempted to explain this line item using verbiage such as "do you think you are accurately

understanding what happens around you, or might you be seeing things differently than what is actually occurring?"

TMS test item seven states: "I was receptive to observing unpleasant thoughts and feelings without interfering with them" (Lau et al., 2006). For this test item, many participants reported not understanding what it meant to "observe their unpleasant thoughts and feelings without interfering." The principal investigator attempted to explain this line item excerpt using verbiage such as "do you think you are really understanding what happens around you, or might you be seeing things differently than what is actually occurring?"

TMS test item eight states: "I was more invested in just watching my experiences as they arose, than in figuring out what they could mean." (Lau et al., 2006). For this test item, many participants reported not understanding what was meant by "watching my experiences as they arose." The principal investigator attempted to explain this line item excerpt as "are you able to step back from an experience and just allow it to happen, rather than getting caught up in what it means for you?"

TMS test item eleven states: "I was aware of my thoughts and feelings without overidentifying with them" (Lau et al., 2006). For this test item, many participants reported not understanding what "overidentifying" with their thoughts and feelings meant. The principal investigator attempted to explain this line item excerpt as "getting caught up in thoughts and feelings such that a person sees them as part of their identity

rather than simply as experienced events;" e.g., discerning the difference between "I am angry" versus "I am experiencing some anger."

TMS test item thirteen states: "I was curious about what I might learn about myself by just taking notice of what my attention gets drawn to" (Lau et al., 2006). For this test item, many participants reported not understanding what was meant by "taking notice of what my attention gets drawn to." The principal investigator attempted to explain this line item meant to "see what stands out most strongly in a situation or experience."

As seen in the above described cases the principal investigator was left to determine an ad hoc explanation conveying the relevant concepts inherent in the test line items to the study participant, but the effects of such an interpretive process were impossible to measure, and thus the effects for TMS instrument scoring remain undetermined. There was no means of evaluating whether the alternative line item explanations offered by the principal investigator were sufficiently consistent with their meaning as delineated in the original test instrument. Further, there was no means of determining the efficacy of these explanatory alternatives in facilitating participant comprehension. At times, several such explanatory attempts using varied descriptive language were made in order to better facilitate participant understanding. After each explanatory attempt the principal investigator asked the involved participants if they felt that they now understood the line item in question, but there was no means of assessing

whether affirmative participant responses to that query in these instances reflected an understanding sufficient to support valid line item responses.

Anecdotal participant reporting suggested that the majority of study participants were educated at a twelfth grade or lower level. Further, the majority of study participants were of African American race. These two cultural aspects may have been contributing factors associated with the above described difficulties reported by some participants in understanding the language used in some TMS line items. These considerations suggest the TMS measure may have been developed with limitations posed by inherent cultural and educational biases. Further, there may exist some inherent difficulties in participant understanding posed by unknown limitations associated with concurrent MAT program enrollment. These feasibility confounds likely interfered with accuracy of TMS scoring, thereby invalidating fidelity to TMS data collection and scoring procedures. They suggest the need for a revised mindfulness measure sensitive to various participant educational, cultural, and MAT setting associated needs and limitations that facilitates development of test line items readily and consistently understandable to participants in the MAT program setting.

MBRP Group Participation Confounds

Group protocol adherence by participants was a feasibility confound observed by the principal investigator. In addition to exhibiting markedly inconsistent meeting attendance, most participants reported that they either misplaced their meditation practice CDs or were not able to use them to facilitate meditation practice exercises due to

unavailability of a CD player for their use. Another observed feasibility confound was that most participants reported that they had either lost their assigned worksheets or forgot to bring them to the group meeting for discussion purposes. These feasibility problems impaired study validity through exerting unknown but potentially significant effects on the efficacy of the MBRP group treatment adjunct. Chawla et al. (2010) developed a fidelity measure for use in implementation of the MBRP manualized treatment. They created a scale that evaluates for the adherence and competence factors affecting MBRP treatment fidelity. Zgierska et al. (2017) identified multiple elements for evaluating fidelity of MBSR group treatment provided to persons with alcohol use disorder. Zgierska et al. found that study design best assured fidelity to the MBRP manualized treatment when therapists facilitating the MBRP groups were sufficiently trained in and had clinical experience with the MBRP treatment. Further identified elements supporting MBRP treatment fidelity included participant adherence with weekly MBRP group attendance, assignment completion, and daily meditation practice (Zgierska et al.). An additional intervention reported by Zgierska at al. that enhanced MBRP treatment fidelity was research staff monitoring of participant adherence with the protocol and phoning participants who were not completing assignments, meditations, or group attendance as scheduled. A final identified feasibility element was reported participant satisfaction with the group (Zgierska et al.).

MBRP Group Participant Perspectives

A critical feasibility factor in this study involved participant perception regarding the MBRP treatment adjunct. It is likely that participants would continue for the full duration of study implementation if they perceived their participatory experience as useful or beneficial for them. In accord with the MBRP protocol administration participants in this study, the MBRP group participants were asked to complete a form provided to them by the principal investigator that asked for their views on the group procedures and how participation affected them. This form, entitled "Reflections on the Course Worksheet" (Bowen et al., 2011, p. 170) is outlined below and includes deidentified participant responses to the worksheet line items as collected from participants by the principal investigator during the final MBRP group session. There are three sets of participant responses despite only two group participant attendees in the final MBRP session. One nonattending participant turned in his responses at another time. The line item responses are delineated here.

Line item one asks "What did you find most valuable about this course? What, if anything, did you learn?" (Bowen et. al., 2011, p. 170). Participant responses to this line item included: (a) "I learned to stop, and observe in my curious mind,"; (b) "Being able to be in the moment. Time for self.,"; and (c) "Thinking in a more enlightened way. [That] others can learn about meditation." (From deidentified study participant data).

Line item two asks "What, if anything, has changed for you over the past eight weeks as a result of your participation?" (Bowen et. al., 2011, p. 170). Participant

responses to this line item included: (a) “I have learned to stop and be mindful in tense situations, not to be reactionary.”; (b) “Being able to focus better.”; and (c) “Not too much, having had prior similar [meditation] experience. Have learned more about self.” (From deidentified study participant data).

Line item three asks: “Was there anything that got in the way of your learning or growth, or that might have improved the course for you?” (Bowen et. al., 2011, p. 170). Participant responses to this line item included: (a) “Negative personalities.”; (b) “No”; and (c) “Nothing.” (From deidentified study participant data).

Line item fours asks: “Other comments?” (Bowen et. al., 2011, p. 170). Participant responses to this line item included: (a) “I believe this is a universal group that can help people in all aspects of life.”; (b) “None.”; and (c) “Meeting time of group. Consider different time for employed [participants]. Evening? Early morning?” (From deidentified study participant data).

Line item five asks: “On a scale of 1 (not at all) to 10 (very), how important has this program been to you?” (Bowen et. al., 2011, p. 170). Participant responses to this line item included: (a) “10. It has taught me to stop, think, observe, and respond mindfully and calmly.”; (b) “10. Improving coping without drug use overall.”; and (c) “7. Gave me something that I enjoyed and liked [the] topic.” (From deidentified study participant data).

Line item six asks: “On a scale of 1 (not at all) to 10 (very), how likely are you to continue engaging in formal mindfulness practice (e.g., body scan, sitting meditation,

mindful stretching/yoga) after this course?" (Bowen et. al., 2011, p. 170). Participant responses to this line item included: (a) "9. It helps strengthen my patience."; (b) "10. Will continue meditation." And (c) "10. Most definitely." (From deidentified study participant data).

Line item seven asks: "On a scale of 1 (not at all) to 10 (very), how likely are you to continue engaging in informal mindfulness practice (e.g., SOBER breathing space, mindful eating, walking, daily activities) after this course?" (Bowen et. al., 2011, p. 170). Participant responses to this line item included: (a) "10. I continually practice informal mindfulness daily because of this group."; (b) "8. [No rationale for rating provided]." (Sooter, 2019). And (c) "9-10. Definitely." (From deidentified study participant data).

Overall, the preceding line item responses suggest that the MBRP group participants felt they improved their capabilities for observing their personal experience and responding to situations they encountered more effectively. One response to line item four ("Other Comments?") regarding group meeting scheduling suggests that the participant saw the need for more scheduling flexibility, likely reflecting an important study design consideration. The scaled responses for line item five referencing importance of the group suggest that reporting participants valued their MBRP group experience highly and gained some meditative and situational coping skills through their group participation. The scaled responses for line item six referencing likelihood of engaging in continued formal mindfulness practice suggest that reporting participants were highly likely to continue formal meditation. The scaled responses for line item

seven referencing likelihood of engaging in continued informal meditation practice suggest that reporting participants were highly likely to continue informal meditation. Taken together, the responses suggest a generally favorable participant perspective toward the MBRP group experience, despite the fact that none of the respondents were able to attend every group as scheduled. An important limitation is that despite the predominantly positive nature of these responses, they do not represent statistically significant findings.

Further feasibility factors for this study relevant to participant group attendance likely included the knowledge base, facilitative skill, and therapeutic effectiveness demonstrated by principal investigator in his role as group facilitator. A broad knowledge of mindfulness related concepts including methods of formal and informal meditation practice was essential for effective implementation of the MBRP group manualized treatment. Facilitator knowledge of cognitive behavioral therapy and its related therapeutic skills were also necessary, as the MBRP group protocol includes elements of mindfulness-based meditative practice integrated with CBT based participant exercises (Bowen et al., 2011). Facilitative practices deemed essential for this group process must include group process informed by evidence-based theory and extensive clinical practice (CSAT, 2005). The facilitator must be able to effectively welcome, establish rapport with, and sustain therapeutic alliances with the individuals in the group in order to facilitate participant engagement and retention (CSAT, 2005; Miller and Rollnik, 2002).

The principal investigator for this study had some 31 years of prior experience in provision of clinical services to individuals with Opioid Use Disorder (American Psychiatric Association, 2013), including individual and group counseling for patients enrolled in the MAT program as well as clinical supervision of program staff. In addition, the principal investigator completed a Master's degree in Psychology along with multiple years of participation in the Walden University Clinical Psychology doctoral program. Further, the principal investigator completed over 1500 hours of supervised clinical practice, providing treatment to patients with substance use, psychiatric, and co-occurring disorders. The principal investigator also provided multiple administrations of the MPRP manualized treatment to individuals in residential treatment for substance use disorders. Finally, the study principal investigator has been a practitioner of mindfulness meditation for some 20 years. Taken together, this constellation of clinical and personal experience suggests the clinical investigator was well qualified to facilitate the study MBRP group. This further suggests that ineffective MBRP group facilitation was likely not a feasibility factor adversely affecting implementation of this study.

MBRP Manualized Treatment Fidelity Considerations

As facilitator, the principal investigator was responsible for assuring fidelity to the clinical interventions and processes delineated in the MBRP group manual (Bowen et al., 2011). Given his extensive clinical experience as described above, including that specific to facilitation of MBRP group services, it is likely that the MBRP group meetings were for the most part conducted in accord with the manualized treatment requirement. The

one exception was the previously described one-week interruption in study implementation caused by a temporary nursing staff shortage in the MAT program directed by the principal investigator. The resultant adverse feasibility effects on MBRP group facilitation were not assessed but may have been significant. Bassett et al. (2016) described treatment fidelity as the level of consistency between the intervention provided and that specified in the treatment protocol. Clearly, the unanticipated interruption to the weekly MBRP group schedule was inconsistent with study design and implementation, and resulted in fidelity adherence liabilities that likely impaired effectiveness of the MBRP manualized treatment used in this study. Utilizing suitably trained and experienced research staff for MBRP group facilitation would likely assure improved fidelity with the MBRP manualized treatment in future studies.

Measures Administration Considerations

An additional consideration in study implementation was the effectiveness of the principal investigator in administering the measures utilized in the study. These measures were the ASI Alcohol/Drugs subscale (McLellan et al., 1985), the OCS (McHugh et al., 2014) and the TMS (Lau et al., 2006). The principal investigator cultivated a knowledge base reflecting the research outcomes and administration recommendations for these instruments. Additionally, the principal investigator had several years of experience in administering, scoring, and interpreting multiple psychological tests. Given the above, it is likely that strong fidelity existed in administration of the measures used in the study.

Participant Logistical Considerations

A significant factor impeding consistent group attendance was likely that reported by one participant in their response to line item four requesting additional comments, where the participant observed that group meeting time may have conflicted with participant employment schedules. Although not specifically mentioned in the participant responses, the recurrent temporal association between no-shows for study group and measures administration appointments and competing participant schedule requirements, such as medical, legal, childcare, educational, transportation, and other social needs suggests these appointments frequently interfered with participant attendance for study activities. The most immediate approach to address these conflicting scheduling needs would be to offer several groups each week at times participants are most likely to be available for group attendance. The frequency of favorable participant responses to the worksheet line items suggests that overall the MBRP group was a positive experience for participants, and that the group requirements and procedures as implemented were not a negative factor. It nevertheless remains possible that the responding participants did not fully or accurately convey elements of the group experience that other participants who dropped out may have regarded as reasons for their discontinuance. This again suggests the need to rule out the known scheduling conflicts in order to better evaluate for possible unknown confounding factors impeding MBRP group attendance.

Other studies evaluating the effects of mindfulness on substance use and relapse prevention have identified various feasibility factors during study implementation. In

their study evaluating the effects of MBRP group participation on substance use Zgierska et al. (2008) noted that out of 19 participants four dropped out prior to completing the study. They further noted that out of the remaining 15 participants 89% completed the full eight weeks of the MBRP group protocol.

In their study of low-income women with substance use disorders in concurrent substance use treatment Amaro et al. (2014) observed that 36% of the participants completed the MBRP group protocol. They attributed the dropout rate to multiple factors including participant relocation, relapse and subsequent treatment program discontinuance, and participant nonavailability due to conflicting schedules with legal, social services, and medical appointments.

Bowen et al. (2009) conducted a pilot study evaluating MBRP effectiveness for individuals with multiple substance use disorders. They reported that 65% of study participants (n=168) completed all of the MBRP groups sessions, and that 57% completed a two-month follow-up while 73% completed a four-month follow-up. They noted that 86% of study participants remaining after completion of the MBRP group protocol reported continued engagement in mindfulness meditation practices.

In his study of a mindfulness-based treatment adapted from MBSR and used to treat incarcerated youth with substance use disorders, Himelstein (2011) reported an 80% completion rate for study participants (n=60). He observed that the participants not completing the study had been transferred out of the incarceration facility and were thus unable to complete the mindfulness group protocol.

Bowen et al. (2017) identified low participant attendance and retention as adverse feasibility factors in their study examining effects of the MBRP manualized treatment with MAT program patients maintained on methadone. Out of 15 initial participants, seven participants completed the study, a dropout rate of 53%. Bowen et al. asserted the need for further research that might identify ameliorative strategies for these participatory impediments including examination of factors affecting participant motivation and otherwise interfering with participant retention.

In their study evaluating MBRP effectiveness for incarcerated persons with substance use disorders Lyons et al. (2019) reported that out of 189 initial participants 126 completed the study, representing a dropout rate of 34%. While considerably less dropout than experienced in the present study, an important distinction in this comparison is that due to their incarcerated status the Lyons et al. study participants could be more readily accessed and follow-up measures more readily implemented to better support MBRP group attendance and overall study participant retention. These findings demonstrate commonality with the participant dropout experienced in this study, and point to the need for development of design counterstrategies that could reduce this confound. Such efforts might include logistical support, including establishing transportation support and adaptive scheduling of study MBRP group appointments to reduce potential conflicts with participant existential needs.

Taken together, the studies discussed above suggest the finding of various feasibility confounds also found during implementation of this study. The primary

feasibility concern evidenced in most studies was participant dropout, with relocation of participants posing another observed confound. These studies, however, did not experience feasibility problems, primarily dropout, of such severity that requisite implementation requirements and statistical analyses could not be completed. Thus, generalizability of study outcomes could not be determined. This suggests the need for further studies examining participant dropout factors and study design methodologies that may effectively reduce them.

Recommendations

Strategies to Improve Feasibility

The preceding discussion of study design and implementation feasibility problems suggests the need for consideration of strategies that may effectively reduce or eliminate them. As previously mentioned, one limitation that impeded implementation of this study was that the entire study was overseen and implemented solely by the primary investigator. This meant that there were no additional resources available for participant pretest, midtest, and posttest data collection, or for facilitating the MBRP group. The principal investigator, due to having full-time job responsibilities elsewhere, could only be present at the study site once each week, and had no available qualified personnel having the requisite knowledge, experience, and skill set for administration of measures used in the study or MBRP group facilitation.

This availability limitation resulted in the inability of the principal investigator to offer scheduling of data collection appointments and MBRP group services on multiple

days and times that might have resulted in improved participant group attendance and participant study retention, especially in cases where participants no-showed. A viable solution for addressing participant no-shows and scheduling conflicts would be to assure that a suitable number of research staff persons is recruited and trained for data collection and MBRP group facilitation under the supervision of the principal investigator. This substantial research staff could then offer study data collection and MBRP group facilitation on differing weekdays and times to best assure participant attendance.

Financial resources sufficient for compensating needed research personnel might be necessary. As an alternative, research personnel could be recruited from qualified college and university students who would likely be willing to engage in study implementation for the learning experience alone, rather than requiring financial compensation. This student recruitment strategy was utilized to good effect in several studies referenced earlier that evidenced significantly higher participant retention and MBRP group attendance rates (Amaro et al., 2014; Bowen et al., 2009: Bowen et al., 2017; Himelstein, 2011; & Zgierska et al., 2008) then that experienced during the course of this study. Given the above distinctions in participant retention between this study and the others, it is likely that availability of more research personnel is essential for effective study implementation and should be an included element in study design.

An additional feasibility confound encountered in this study involved the previously discussed difficulty participants reported in understanding several of the TMS measure line items. The line item reinterpretive solution used by the principal

investigator in this study was likely ineffective as it introduced several potential line item administration validity confounds in addition to potential inconsistencies in and inaccuracy of participant responses. Further, the effects of these confounds could not be measured, and remain unknown.

To prevent further similar validity concerns for measures evaluating aspects of participant mindfulness an alternative evaluative measure should be considered. One such instrument is the FFMQ (Baer et al., 2008) utilized in the Bowen et al. (2009) study. The FFMQ measure includes 39 line items wherein respondents use Likert scale response ratings that assess for the presence of five factors thought to be representative of various aspects of mindfulness: observing; describing; acting with awareness; nonjudging of inner experience; and nonreactivity to inner experience (Baer et al., 2008). Alpha coefficients for the five factors of FFMQ range from .67 to .92, suggesting good internal consistency (Baer et al.). Bowen et al. (2008) reported no difficulties in participant understanding and successful completion of the FFMQ. These considerations suggest the FFMQ would likely be an effective alternative measure of participant mindfulness in studies with design similar to this one.

Inconsistent participant attendance was a feasibility factor that adversely affected outcomes of this study in both the TAU and MBRP IV levels. It was likely strongly associated with the marked participant dropout observed during study implementation. In most situations where a study participant no-showed she or he also no-showed for the MAT program. In rare instances a small number of participants received MAT program

services prior to their study implementation activities, and left the study site without participating as scheduled. The no-show behavior common to both situations reduced participant engagement with the study, a problem exacerbated by further no-shows with resultant additional loss of study engagement. Further, in such instances the affected MBRP group participants were unable to participate and thereby benefit from the group processes, which likely fostered a correspondent reduction in perceived benefits from group participation that would further reinforce the no-show behavior. In addition, no-shows for the MAT program services tended to destabilize the patient in treatment, thereby further reducing the likelihood of study participation.

Molfenter (2013) described several methods found to more effectively address patient no-shows in MAT programs. These included providing appointment reminder phone calls, creating a welcoming program environment through inclusion of behaviors such as offering warm patient greetings from program staff, reducing wait times for receiving program treatment services, utilizing contingency management interventions and motivational interviewing practices, and creating more supportive relationships with outside persons and agencies, such as social and legal services. Bowen et al. (2017) reported similar findings reflecting the effectiveness of study staff engagement with MAT program staff. Molfenter further found that the most effective of these strategies was assuring a reduction in wait times for program services. The correspondence between MAT program no-shows and participant no-shows observed in this study suggests that employing these strategies to facilitate higher consistency of patient program attendance

will likely reduce the frequency of participant no-shows for MBRP group meetings and study measures administration appointments.

Additional procedures for reducing participant no-shows could include assuring frequent and consistent communication between study research staff and MAT program staff that would facilitate effective participant attendance monitoring and supportive intervention where indicated. MAT program counselor staff should be informed of the requirements for study participation so that they can assist in scheduling MAT program and outside agency appointments such that they do not conflict with scheduled study participant appointments. MAT program counselors could further facilitate participant attendance by assisting them in addressing any relevant situational factors that increase likelihood of no-shows, such as finding consistent and adequate transportation and childcare, where applicable.

The effectiveness of the $ 25.00 gift card as participant compensation for study completion was not evaluated during study implementation. Only three participants completed the study, and none assigned to the MBRP group attended all eight meetings. Parkinson, Meacock, Sutton, Fichera, Mills, Shorter, Treweek, Harman, Brown, Gillies, and Bower (2019) identified three elements of incentive rewards: reimbursement for participant expenses, reimbursement for participant time spent in study activities, and additional incentive rewards for study participation and completion as required; the latter being the reward strategy used in this study. Parkinson et al. (2019) found that providing incentives during the study recruitment phase or at study conclusion was less effective

than providing incentives at designated times throughout study implementation. Parkinson et al. (2019) further found that incentives were significantly more effective at motivating participation when structured in manner reflective of the context in which the study occurs, such as assuring the reward is sufficient to be meaningful to the participants. These findings suggest that rewards could be more effective in facilitating participant adherence if offered periodically throughout the study and tied to completion of interim study phases, e.g., pretest, midtest, and posttest in the case of this study. The value of incentive awards should be carefully considered to assure participants will find their awards sufficient given the time spent in study activities, and such compensation should be weighed relative to assessed participant valuing of the reward amount.

In summary, the preceding study design and implementation discussion suggests that having a sufficient number of well-trained research staff available at the study site is essential. Additionally, use of a mindfulness measure that is culturally sensitive toward and readily understandable by all study participants will increase validity in this evaluative area. Efforts by MAT program staff to more effectively engage and retain patients and provide more efficient services will likely foster correspondent improvements in participant attendance for study activities implementation. MAT program counselor support in resolving study participant problems that contribute to no-shows, such as finding consistent transportation and childcare where needed, should be considered. Finally, compensation to participants for study completion should be awarded

at suitable intervals over the duration of study implementation, with care taken to assure such compensation is sufficient to meet participant valuing of the reward amount.

Additional Recommendations for Future Research

This writer suggests that focus for future research include full consideration of study design elements that may be adversely impacted by the feasibility confounds experienced during implementation of this study. Participant no-show for MAT program services was not evaluated in this study although no-shows appeared to exert a strong adverse effect on study participation, in that participants who no-showed for MAT program services also no-showed for study activities scheduled for that day. Future study designs should consider inclusion of collaborative MAT program and research staff strategies that will likely reduce participant no-shows. These would include reducing wait times for receiving MAT program treatment services, facilitating collaboration between MAT program staff and research staff in scheduling and supporting participant study-related appointments, providing participant appointment reminder phone calls, assuring a welcoming program environment, and fostering supportive relationships with outside persons and agencies.

Other effects of participant no-shows that should be considered in future study designs include associated increase of participant opioid craving onset and resultant increased relapse potential, which could destabilize the participant in MAT and resultantly impede consistency of study participation. Future studies may need to include use of measures that evaluate for and facilitate effective interventions for patient MAT

program attendance problems, severity of substance use relapse potential, and further include ameliorative strategies to minimize the frequency of these potential implementation confounds.

A further important consideration in future study design is contingency planning for possible MAT program operational concerns that may arise and interfere with study implementation. Effective collaboration with MAT program administrative staff is essential to study implementation, and should be included as a component of study design.

Future studies should include measures that readily understandable by study participants to assure fidelity of measures administration. An example of such a measure could be the FFMQ (Baer et al., 2003) used to measure elements of participant mindfulness.

Multiple weekly MBRP group meeting times should be utilized to assure consistent participant attendance. Additionally, alternate media should be considered for distribution of guided mindfulness mediations to participants. At present CDs are used less frequently than other media options such as portable computer memory devices, e.g., USB (universal serial bus) drives, cell phones, and computer programs that are available on the internet. Having MBRP group worksheet assignments and meditation exercises distributed via these more modern communication options would likely facilitate more consistent participant adherence to these required elements essential to assuring fidelity to specified MBRP group implementation standards. Use of the mindfulness-based

relapse prevention adherence and competence scale developed by Chawla et al. (2010) would likely assure more effective monitoring and evaluation for fidelity during implementation of the MBRP manualized group treatment.

Alternate participant incentive strategies could be considered in order to reduce participant no-shows and foster more consistency in participant attendance at scheduled study group meetings and measures administration activities. In their literature review Stizer and Petry (2006) found that contingency management practices are effective in improving patient attendance for medication and therapy sessions in MAT program settings. Parkinsen el al. (2019) asserted that monetary incentives are more effective than their alternatives, although some findiings suggest that they can in some cases reduce intrinsic motivation for participants. Parkinsen at al. observed that timing of incentives is critical, that payouts should be temporally associated with completion of key study tasks assigned to participants. Further, they recommended parsing out incentive payouts over the duration of the study implementation to better sustain participant motivation. Considered together, these findings suggest that future studies should utilize incentive compensation over time as important participant requirements are met to enhance participant motivation, engagement, and retention. Such a strategy would likely more effectively support consistent rates of participant MPRP group attendance and attendance for pretest, midtest, and posttest data collection.

An additional study approach could include use of a design similar to this one but involving two distinct MAT program sites. This would offer the advantages of greater

initial participant enrollment and likely sufficient retention of enough participants to achieve sufficient power for statistical analysis. Outcomes of the two sites could be compared using MANCOVA analysis to determine if significant, distinct effects are found between the two sites. This approach would likely reduce extant confounds arising from unique factors affecting study implementation at only one site. The two sites might exhibit distinct prevalence of participant demographic, social, medical, or psychiatric conditions that facilitate broader generalization characteristics with the total population of individuals with opioid use disorder.

Qualitative study design approaches may be considered for future studies. Use of both structured and unstructured data gathering using naturalistic observation and participant interviews (Berkwits & Inui, 1998) would foster awareness of feasibility considerations that could then support subsequent quantitative study design better structured to avoid those identified feasibility confounds. For example, participant data could identify factors interfering with participant attendance gathered through direct observation and interview techniques that when categorized result in study design that minimizes potential for such quantitative study implementation barriers to occur. Additionally, MAT program patient interviews might reveal useful information through soliciting patient observations regarding elements of study implementation that would be useful for future study design approaches, such as pragmatic factors that influence participant attendance.

Future research could consider evaluation of alternative manualized treatment approaches. It may be that alternative measures of participant mindfulness such as the FFMQ; (Baer et al., 2003) could be utilized to rule out the understandability problems encountered with use of the TMS (Lau et al., 2006) measure in this study. Additionally, multiple measures of mindfulness could be used to evaluate for differences between the TMS and FFMQ outcomes, for example. The OCS (McHugh et al., 2014) measure used in this study was readily understood by participants, as was the ASI Alcohol/Drugs subscale (McLellan et al., 1985), so it may be that these measures could be retained for use in future studies.

Future research may need to evaluate for the impact of the covid disease 2019 (COVID19) epidemic on frequency and severity of OUD-associated relapse and overdose. In their study evaluating changes in medical services and treatment outcomes for Veterans Administration patients with OUD, Abdel-Sattar et al. (2021) found that the availability of OUD treatment services for veterans was adversely impacted due to reductions in treatment facility staffing and hours of operation. Abdel-Sattar et al. noted that VA patients with OUD reported a 25% increase in relapse rates, a 45% increase in overdose rates, and 45% increase in emergency room visits during the study period. Abdel-Sattar et al. further noted that multiple patients surveyed expressed a need for OUD treatment medication dosage increases and greater availability of psychological and social support services.

Haley and Saitz (2020) found there were significant increases in opioid misuse overdoses and deaths during 2019, primarily associated with illegal fentanyl use and the combined use of opioids and methamphetamine during the year period. However, Haley and Saitz further found the need for additional studies to confirm these findings. The Centers for Disease Control (CDC; 2020) reported an increase from prior years to 81,000 drug overdose deaths for the period from June 2019 through May 2020, with reports from multiple areas across the US revealing a 50% to 98% increase in opioid use related deaths, depending on the reporting area, the western area of the US showing the highest frequency of opioid deaths. The CDC further found that the synthetic opioid fentanyl was the drug most frequently associated with opioid overdose deaths, increasing by more than 38% over the reporting year ending May 2020.

Given the continued presence of the COVID19 epidemic, these findings argue for effective treatment solutions that incorporate the additional factors individuals with OUD encounter when isolated and experiencing concomitant conditions such as depression, anxiety, and trauma associated with the loss of significant others.

Implications

Potential Impact for Positive Social Change

The prevalence of OUD and its associated adverse public health problems, including overdose deaths, impaired physical and mental health, impairments to social functioning, and societal costs associated with these conditions has been clearly established. The CDC (2021) reported that an approximated 500,000 individuals died

from an opioid overdose during the period from 1999 to 2000. The CDC described the opioid use epidemic as occurring in three waves. The first wave began with a marked increase in opioid prescriptions during the decade beginning in 1990 (CDC). The second wave ensued in the year 2010 and was characterized by a significant increase in heroin overdose deaths (CDC). The third wave started in the year 2013, continuing to the present, and has been characterized by a marked shift to and predominance of synthetic opioid deaths (CDC). This more recent trend has worsened in association with the COVID19 pandemic, as noted in the CDC (2020) report describing a 38.4% increase in opioid overdose deaths for the year period ending in May, 2020. These trends strongly suggest that opioid misuse in the U.S. is a severe, pervasive, and worsening problem of epidemic proportions.

There are multiple socioeconomic costs associated with the opioid epidemic. Florence et al. (2021) observed that the aggregate economic costs of opioid use in the U.S for the year 2017 were estimated at $1,021 billion dollars, comprised of $471 billion dollars associated with opioid use disorder costs, and $550 billion dollars for opioid overdose. These costs reflect healthcare including hospitalizations and emergency room care, opioid use treatment, criminal justice involvement, lost work productivity, and reduced quality of life for the individuals experiencing OUD (APA, 2013). Persons with OUD experience the preceding costs at an immediate level, experiencing substantial harm to their personal well-being, interpersonal relationships, and familial functioning.

Although MAT programs offer evidence-based, effective treatment for individuals with OUD, relapse remains a significant risk. These severe and pervasive problems argue for more extensive research regarding treatments, such as MBRP, that may increase effectiveness of methadone-maintained MAT program patients. Research evaluating such potential interventions may ultimately result in establishing clinically effective treatment options that integrate with existing opioid use disorder treatments, enhancing the effectiveness of existing opioid use disorder treatment and thereby reducing the public health, behavioral, social, and legal problems as well as the severe human suffering concomitant with illicit opioid relapse.

This research supported positive social change through attempted evaluation of the MBRP (Bowen et al., 2011) manualized treatment used as a treatment adjunct that can be provided at the MAT program site, with minimal impact on existing MAT program operations and staffing. The multiple feasibility problems encountered during study implementation determined information about study feasibility confounds that will support future research through providing enhanced understanding of study feasibility problems to be considered when developing future similar study designs.

Conclusion

This study represented an attempt to evaluate effectiveness of participant exposure to MBRP manualized treatment (Bowen et al., 2011) used as an adjunct to treatment as usual provided in the context of a MAT program setting. Participants were voluntarily enrolled in the study and were randomly assigned to either the MBRP group

or treatment as usual. The ASI Drug/Alcohol subscale (McLellan et al., 1985), OCS McHugh et al., 2014), and TMS (Lau et al., 2006) measures were administered at pretest, midtest, and posttest intervals to provide data planned for within and between groups MANCOVA analysis. Participant retention and inconsistent MBRP group attendance proved to be severely limiting study implementation feasibility factors such that reliable, consistent data could not be collected to achieve a valid statistical analysis of study data outcomes. Several suggestions for future research that may more effectively address feasibility confounds encountered in this study have been offered for consideration.

The increasingly severe opioid use epidemic observed in the United States over the past decade strongly suggests that future studies evaluating effectiveness of adjunctive treatment interventions such as MBRP for individuals with opioid use disorder concurrently enrolled in a MAT program are essential. It is critical that treatment effectiveness for persons with OUD is enhanced through research that leads to additional evidence-based treatments and interventions that will more effectively address the social and fiscal deficits and, most importantly, the human costs associated with the opioid use epidemic.

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Appendix A: Outline of the MBRP Manualized Treatment Protocol

Week one, consisting of participant orientation to the course requirements (Bowen et al., 2011):

- review of the nature of mindfulness;
- overview of course structure and approach;
- clarification of privacy and confidentiality requirements;
- mindfulness exercise focused on eating a single raisin (similar to that used in MBSR);
- the body scan mindfulness exercise (also similar to that used in MBSR), and
- psychoeducation regarding association between automatized responding and relapse.

Week two, focused on substance use triggers identification and observation of associated phenomena (Bowen et al., 2011):

- review and discussion of challenges encountered during mindfulness meditation sessions and how to cope with them;
- the nature of aversion, craving and desire, restlessness and agitation, drowsiness and sleepiness, and doubt;

- guided exercises including body scan meditation; urge surfing meditation (see description below) for addressing substance use cravings; and mountain meditation for affective calming;
- homework assignment involving daily formal and informal meditation exercises;
- completion of CBT worksheet focused on substance use trigger identification and indicating associated responses;
- completion of daily meditation tracking sheet; and
- brief closing meditation on silence.

Week three, focused on cultivating a mindful approach to daily living (Bowen et al., 2011):

- participant check-in;
- review of past week's assignments;
- guided exercises including awareness of hearing meditation, breath meditation, and SOBER breathing space meditation (see description below);
- review of meditation exercise and practice tracking homework assignments; and
- brief closing meditation on silence.

Week four, focused on use of mindfulness to cope with substance use and associated risk behaviors (Bowen et al., 2011):

- participant check-in;

- review and discussion of prior week's homework assignments;
- guided exercises including awareness of seeing meditation, sitting meditation on sound, breath, sensation, and thought, and walking meditation;
- group discussion of relapse risks;
- use of SOBER breathing space mediation in an elevated risk situation; review of homework assignments; and
- brief closing meditation on silence.

Week five, focused on balancing acceptance and effective behavioral responding (Bowen et al., 2011):

- participant check-in;
- review and discussion of prior week's homework assignments;
- guided exercises including sitting meditation on sound, breath, sensation, thought, and emotion, SOBER breathing space meditation with paired participants, and mindful movement meditation exercise;
- group discussion about use of the SOBER breathing space;
- review of homework assignments; and
- brief closing meditation on silence.

Week six, focused on understanding the nature of thoughts (Bowen et al., 2011):

- participant check-in;
- review and discussion of prior week's homework assignments;

- guided exercises including sitting meditation on thoughts and SOBER breathing space meditation;
- group discussion on observing and labeling thoughts;
- group discussion on association between maladaptive thoughts and substance use relapse;
- psychoeducation and group discussion on the relapse cycle, including elements of adaptive mindful responding to substance use triggers and maladaptive automatized responding;
- review of homework assignments;
- discussion and preparation for end of the course; and
- brief closing meditation on silence.

Week seven: focused on establishing and assuring continued well-being (Bowen et al., 2011):

- participant check-in;
- review and discussion of prior week's homework assignments;
- guided exercises including meditation on compassion and SOBER breathing space meditation;
- exercise on creating a daily activities worksheet that compares and contrasts practitioner affective experience associated with positive and negative situations;
- discussion on the nature of relapse: when, where, and how it begins;

- exercise on creating individualized relapse prevention strategy reminder cards for practitioners to carry with them;
- review of homework assignments; and
- brief closing meditation on silence.

Week eight: focused on developing and maintaining support systems for continued mindfulness practice and sustaining recovery from substance use (Bowen et al., 2011):

- participant check-in;
- review and discussion of prior week's homework assignments;
- guided exercises including body scan meditation and concluding meditation;
- group discussion of the need for support networks; discussion of participant perspectives on the course experience;
- discussion of participant intentions for continuing mindfulness and recovery work;
- closing circle exercise; and
- brief closing meditation on silence.

Appendix B: Study Flyer For Participants

Welcome to all MAT program participants!

You are invited to take part in a research study for the doctoral dissertation of Stephen Sooter, MS, from Walden University that is evaluating the effects of Mindfulness Based Relapse Prevention (MBRP) on illicit opioid use for patients participating in this Medication Assistant Treatment (MAT) program. This study will be used to find out if MBRP participation can help MAT patients prevent or reduce relapse to illicit opioid use.

If you participate you will be randomly assigned to either a treatment as usual (TAU) study group or to an experimental study group which includes TAU and the Mindfulness Based Relapse Prevention (MBRP) weekly group meetings offered here at the program. If participating, you will be asked to provide answers to two brief surveys at the beginning of the study, in the middle, and at the end, and to consent to disclosure of other program information including your drug use during the study period and your MBRP session attendance. If you satisfactorily complete the 8-week study you will be eligible for a $ 25.00 gift card. You may discontinue the study at any time without penalty, and your MAT program status will not be affected in any way by discontinuing the study.

Your information will be assigned to a random number. No names or other private identifying information will be used without your written permission. All study data will be retained in a way that fully protects your privacy and confidentiality.

The study is planned to start on Wednesday, August 21, 2016. Please contact Stephen Sooter, the principal investigator for the study if you are interested in finding out more about this study.
Thanks for your consideration.

Appendix C: Informed Consent Form

INFORMED CONSENT

You are invited to take part in a research study that is evaluating the effects of participation in Mindfulness Based Relapse Prevention (MBRP) on illicit opioid use for patients participating in this Medication Assistant Treatment (MAT) program. The MBRP is designed to find out if mindfulness meditation and other therapeutic practices can help persons with opioid use disorders prevent relapse to illicit opioid use.

The researcher is inviting persons who are currently enrolled in MAT program treatment using methadone medication to be in the study. This form is part of a process called "informed consent" to allow you to understand this study before deciding whether to take part.

This study is being conducted by a researcher named Stephen Sooter, who is a doctoral student in the clinical psychology program at Walden University. The MBRP group facilitation is being offered at the BAART MAT program site and is being conducted by the study principal investigator.

Background Information:
The purpose of this study is to evaluate the effectiveness of the MBRP treatment in reducing illicit opioid use for MAT program patients.

Procedures:
If you agree to be in this study, you will be asked to:

- participate in your MAT program dosing and counseling services as you normally do;
- Meet individually with the principal investigator to take a short test called the Addiction Severity Index Drug/Alcohol Scale at the beginning, middle, and end of the study;
- Meet individually with the principal investigator to take two very short tests (15 questions or less) about mindfulness: once at the beginning and again at the end of the study; and
- if you are in the study experimental group:
    a. meet once weekly for about 1.5 hours in the MBRP group;

b. complete weekly homework assignments that are related to the group process, which require very little time and are easy to do;
c. bring completed homework assignments to the weekly group meetings; and
d. practice guided meditation exercises on your own for a few minutes each day; you are provided a CD of the exercises for this purpose, which you can keep after the study ends.

Here are some sample test questions:

Below is a collection of statements about your everyday experience. Using the 1–6 scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what *really reflects* your experience rather than what you think your experience should be.

1	2	3	4	5	6
Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never

1. _____It seems I am "running on automatic" without much awareness of what I'm doing.
2. _____I rush through activities without being really attentive to them.
3. _____I get so focused on the goal I want to achieve that I lose touch with what I am doing right now to get there.
4. _____I do jobs or tasks automatically, without being aware of what I'm doing.
5. _____I find myself listening to someone with one ear, doing something else at the same time.
6. _____I drive places on "automatic pilot" and then wonder why I went there.
7. _____I find myself preoccupied with the future or the past.
8. _____I find myself doing things without paying attention.
9. _____I snack without being aware that I'm eating.

Voluntary Nature of the Study:

This study is voluntary. Everyone will respect your decision of whether or not you choose to be in the study. No one at BAART Programs or at this MAT program site will treat you differently if you decide not to be in the study. If you decide to join the study now, you can still change your mind later. You may stop at any time. If you stop participating in the study your MAT program will not be affected in any way.

Risks and Benefits of Being in the Study:
Being in this type of study is unlikely to involve any discomfort above and beyond what you might normally encounter or experience in your daily life. Some persons may experience a small amount of stress due to the testing and group participation requirements explained above, although these are not extensive or overly time consuming. Being in this study poses minimal risk to your safety and wellbeing. The study includes a reporting and intervention procedure to assist you if you experience any adverse effects resulting from your participation.
Potential benefits of this study include the completion of initial research for the MAT program population that may help develop such relapse prevention programs for use in MAT programs throughout the BAART system and beyond. Any such relapse prevention methods are likely to improve quality of life for the participants and reduce risk of relapse and the harm that can follow from it.

Payment:
Each participant that completes the full two-month study period, participating as required, will receive a $ 25.00 gift card in acknowledgement of his or her study participation. Should you elect to leave the study before completion, not complete requested tests, or not participate in all eight MBSR weekly group meetings (if required for you) you will not receive the gift card. Gift cards will be distributed to all study participants within two weeks after the study ends.

Privacy:
Any information you provide will be kept confidential and private. The researcher will not use your personal information for any purposes outside of this research project. Also, the researcher will not include your name or anything else that could identify you in the study reports. Hardcopy data will be kept secure by being retained in a locking file cabinet at the program site. Electronically stored data will be securely retained for a period of at least 5 years, as required by Walden University.

Contacts and Questions:
You may ask any questions you have any now. Or if you have questions later, you may contact the researcher via and/or via email at the email address. If you want to talk privately about your rights as a participant, you can call Dr. Leilani Endicott. She is the Walden University representative who can discuss this with you. Her phone number is Insert ONE number depending on location of participant 612-312-1210 (for US based participants) OR 001-612-312-1210 (for participants outside the US). Walden University's approval number for this study is [IRB will enter approval number here] and it expires on [IRB will enter expiration date].

The researcher will give you a copy of this form to keep for your records.

Statement of Consent:
I have read the above information and I feel I understand the study well enough to decide about my involvement. By signing below, I understand that I am agreeing to the terms described above.

Printed Name of Participant: _____

Date of consent: _____

Participant's Signature: _____

Researcher's Signature: _____

Appendix D: Institutional Approval Letter

BAART
Addiction Research and Treatment, Inc.
Administrative Office
1111 Market Street, Third Floor
San Francisco, CA 94103
Telephone: (415) 552-7914 www.baartprograms.com Fax: (415) 552-3455

August 7, 2014

Institutional Review Board
Walden University
100 Washington Avenue South, Suite 900
Minneapolis, MN 55401

RE: Research Approval for Doctoral Dissertation of Stephen Sooter

Dear Walden IRB members:

This letter documents my approval of the doctoral dissertation research project proposed by Stephen Sooter, MS entitled: "The Effects of Mindful Attentional Regulation on Illicit Opioid Use for Individuals Participating in Medication Assisted Treatment: A Pilot Study." It is my understanding that this research will be conducted at a clinic site owned and operated by BAART Programs, Inc., hereinafter referenced as the organization. I am the Chief Executive Officer of BAART Programs, Inc.

I understand that participant recruitment will occur at the BAART Programs Medication Assisted Treatment (MAT) program site selected for study implementation. For a two-week period prior to implementation phase of the study, an informational flyer will be distributed to all MAT program patients. This flyer will describe the study purpose and procedures, outline participatory requirements, and provide principal investigator contact information to address any additional questions or concerns participants may have prior to participant enrollment and study implementation. The requisite informed consent process will be conducted with all participants, who will have the right to voluntarily withdraw from the study at any time. All participants who complete the study will receive an incentive consisting of a debit card in the amount of $ 25.00. Participants will be informed that discontinuing study participation prior to completion will result in study incentive ineligibility.

I acknowledge that this research will be conducted in accord with established research guidelines and program confidentiality and privacy rules pertaining to MAT programs and the guidelines of the National Institutes of Health office of Extramural Research. Each participant will be assigned a random identifier, used exclusively for study data collection, analyses, and result dissemination such that no patient identifying information will be disclosed. All study data will be retained in a manner that ensures all applicable participant privacy and confidentiality rules are rigorously adhered to.

I understand that data to be collected from each participant during the eight-week course of the study will include:

- age;
- gender;
- duration of concurrent MAT program treatment episode in days;
- primary and secondary DSM-5 diagnoses;
- dates of attendance at each MBRP group meeting group session (attendance frequency);
- record of weekly homework assignment completion (frequency of homework assignments completed);
- Toronto Mindfulness Scale (TMS) pre- and post-test scores;
- Mindful Attention Awareness Scale (MAAS) pre- and post-test scores;
- ASI Drug/Alcohol Scale pre- and post-test scores; and,
- random UDS outcomes data collected during the two-month study implementation phase.

In addition, I understand that the principle investigator will collect, evaluate, and disseminate study implementation feasibility data in his completed doctoral dissertation and through participant debriefing procedures in order to provide a context for evaluating potential utility of conducting subsequent larger studies. Aspects of feasibility to be evaluated will include:

- Study recruitment and retention rates;
- study protocol participant adherence rates and processes influencing adherence;
- fiscal needs for ensuring study completion;
- personnel needs for study completion;
- impact of study processes and procedures on the MAT program functioning;
- participant responses;
- estimates of treatment effect;
- estimate of variance of treatment effect;
- problems encountered during study implementation; and
- outcome implications and recommendations for full study.

I acknowledge that all participants will be debriefed at the conclusion of the study by the principle investigator. Although any adverse effects from study participation are considered extremely unlikely, during the course of the study all participants will be assessed and referred as needed in order to address any unanticipated effects arising out of study participation. All participants will receive a summary of the study outcomes and findings without charge. The principal investigator will be available to meet with any study participants that have questions or concerns after this initial debriefing, and/or after disclosure of study outcomes and findings. No further follow-up requirements will be required of study participants, and at the debriefing meeting with the study site coordinator each participant will receive the participation incentive reward as explained during the study informed consent process.

I further acknowledge that study procedures will require the use of private, confidential office space. A private office located at the clinic site for the purposes of provision of informed consent and administration of the above-referenced test measures. Additionally, the study will utilize a larger private office space suitable for administering the independent variable of the study, the Mindfulness Based Relapse Prevention (MBRP) manualized treatment. I understand that during the eight week period of independent variable administration treatment outcomes including participant random urine drug data, participant report of substance use, and participant report of mindfulness measures outcomes will be gathered by the principle investigator for further analysis and incorporation into the research report.

I understand that the organization's program personnel at the study site will not be used to participate in or supervise any aspect of this research project. Any concerns arising regarding this research or its effects on study participants will be managed on site by Stephen Sooter, MS, the principle investigator, in consultation with Chet Lesniak, PhD, his doctoral dissertation committee chairperson, and David Yells, PhD, his doctoral dissertation committee methods member and consultant. I will be immediately apprised of any such concerns.

I acknowledge that the principle investigator and the organization agree to assume liability for the administration of the MBRP manualized treatment intervention and any resultant effects on the study participants. However, as strongly suggested by prior research conducted using MBRP and similar mindfulness-based interventions in substance use disorder treatment settings, no adverse effects on participants are anticipated.

The organization welcomes this study, including its constituent treatment interventions, data collection procedures, and administration of measures of mindfulness and substance use as an adjunct to normative MAT program operations conducted during the course of the study. I recognize that this study addresses an important gap in the research literature that will further illuminate the research and treatment fields regarding feasibility and use of mindfulness treatment adjuncts for individuals with opioid use disorder.

Sincerely,

Evan Kletter, PhD
Chief Executive Officer
BAART Programs, Inc.

Appendix E: Adverse Event Report

Participant Report of Adverse Event

Participant ID Number: _____

Date of Event: _____

Participant Report of Event:

Description of Adverse Effects:

☐ Participant Consent to Disclose above information to MAT program physician obtained (see attached).

☐ Participant referral to MAT program physician made.

☐ Participant informed of right to discontinue study participation immediately.

☐ Participant informed that study discontinuance will not in any way affect continued enrollment in the MAT program.

☐ Program physician provided a copy of this adverse event report.

I, the undersigned Principal Investigator in this study, hereby certify that the above documentation is true and accurate, and that all action indicated above has been implemented in accord with study procedural requirements.

Principal Investigator Signature/Date: _____

Appendix F: Adverse Event Report Consent Form

AUTHORIZATION FOR USE AND DISCLOSURE OF
PROTECTED HEALTH INFORMATION

Name of patient:	**Date of Birth:**

I hereby authorize the use and disclosure of protected health information about the above patient as follows:

From (*Name of person, class of persons, or organization authorized to make the requested use or disclosure):* *(check whichever is applicable)* **Stephen Sooter, MS** **Study Principal Investigator**	**To** (*Name of person, class of persons, or organization authorized to receive and use my protected health information):* Program Physician **BAART Programs** **1124 International Blvd.** **Oakland, CA 994606**

Description of patient's protected health information to be used or disclosed:
Study participant report of adverse event experienced during study participation.
Principal Investigator's description of adverse events.
☐ Patient must initial this box if this consent authorizes furnishing HIV test results or other HIV identifying information.

Patient's protected health information is being used or disclosed for the following purpose(s):
Provide clinically indicated assessment and intervention in response to reported experiencing by study participant of adverse event.

I understand that I have the following rights with respect to this Authorization:

1. The recipient of the protected health information may not further disclose the information unless the recipient obtains another authorization from me or unless the disclosure is specifically required or permitted by law.
2. I may not be required to sign this Authorization as a condition to obtaining treatment or payment or my eligibility for benefits.
3. BAART Programs will provide me with a copy of this Authorization.
4. I may revoke this Authorization at any time by mailing or personally delivering a signed, written notice of revocation to BAART Programs at the clinic where I am a patient. Such revocation will be effective upon receipt, except to the extent that the recipient has taken action in reliance on this Authorization.
5. I understand that I am entitled to notice if BAART Programs will use or disclose the protected health information for marketing and receive payment for the use or disclosure of my protected health information.

BAART Programs ☐ will ☑ will not receive compensation for the use or disclosure of my protected health information.

This authorization will expire on/when: within one year of date of signing, unless otherwise specified.

Signature of Patient/Personal Representative*

Describe Personal relationship to patient

Date

Address and Telephone number of Patient/Representative:

*The personal representative is any of the following:

- A conservator of the patient's person;
- An agent appointed by the patient under a power of attorney for health care if the patient does not have capacity to sign the authorization;
- Any other individual who has the legal authority to make health care decisions on the patient's behalf; or

If the patient is deceased, an executor or administrator of the patient's estate or, if none, a spouse or, if no spouse, any responsible family member.

Appendix G: Curriculum Vita

Stephen Sooter, MS

Objective To obtain a teaching position as an Addiction Studies Adjunct Instructor

Experience **1993–2019** **Clinic Director, BAART Programs**
Antioch, CA

- Overall responsibility for all aspects of program operations.
- Ensure program compliance with all applicable federal & state regulations.
- Facilitation of CARF Accreditation, Medi-Cal Certification, and DHCS Licensing.
- Outreach and education to communities, families, and other groups.
- Patient group counseling and assessment policies and procedures development.
- Directed startup of Oakland program operations in fall, 2007.

2012-2016 **Psychological Assistant** **Bay Area, CA**

- Provision of individual, group, and couples psychotherapy services at multiple sites under supervision of Dr. Ron Perry, PsyD.
- Provision of training, group, and individual supervision to psychological interns.
- Provision of individual psychotherapy to adults with psychiatric and co-occurring disorders at Healthy Partnerships in Fairfield, Ca.
- Implementation of mindfulness based relapse prevention group services to pregnant and parenting women at Wollam House residential treatment, Pittsburg, Ca.
- Development and implementation of group psychotherapy services using Mindfulness Based Stress Reduction therapeutic approaches and interventions.
- Development and implementation of group psychotherapy services using Acceptance and Commitment Therapy therapeutic approaches and interventions.
- Provision of Mindfulness Based Relapse Prevention group and individual services.

2012- 2013 **Psychological Practicum/Internship** **Walden University**

- All services provided under supervision agreement between Walden University and Dr. Ron Perry, PsyD.
- Provision of individual and group psychotherapy services to pregnant and parenting women at Wollam House residential treatment facility, Pittsburg, Ca.
- Provision of individual psychotherapy services for adults with substance use disorders at Chance for Freedom in Concord, Ca., and Pittsburg, Ca.
- Provision of individual, group psychotherapy services for persons with psychiatric and co-occurring disorders at offices of Drs. Ron Perry, PsyD and Carolyn Schuman, MD in Berkeley, Ca.
- Development of psychological intern training manual.

2010-2012 Academic Residencies Walden University

- June 16-20, 2010 – orientation in academic residency requirements. Academic research and writing skills.
- January 7-20, 2011 – introduction to cognitive and personality assessment. Quantitative, qualitative, and mixed-methods research design and implementation methodologies. Interviewing and observational strategies.
- July 15-28, 2011 – psychological testing: research, approaches, and administration for Brief Symptom Inventory, MMPI-2, NEO-PI, Rorschach, WAIS-IV, WISC-IV, WIAT, Woodcock-Johnson III; cognitive, behavioral, personality, and mental status assessment.
- August 4-8, 2011 – American Psychological Association ethical principles, standards, and professional codes of conduct. Evidence-based treatment approaches and interventions: motivational interviewing practices, integrated group psychotherapy practices, cognitive behavioral therapy practices, and brief interpersonal therapy practices.
- January 6-19, 2012 – diagnosis, case conceptualization, and psychological report writing using American Psychiatric Association DSM criteria. APA dissertation writing style requirements. Statistical design and data analysis. Research presentation. Group process: clinical approaches, ethical and legal considerations. Mindfulness in clinical practice.

1992–1993 Supervising Counselor, BAART Programs Pittsburg, CA

- Assist clinic director in managing program operations.
- Conduct quality assurance review of patient records.
- Orientation, training, and administrative/clinical supervision of counseling staff.
- Support of program policies & procedures implementation and adherence monitoring.

1988–1992 Counselor, BAART Programs Pittsburg, CA

- Provide individual counseling services for up to 40 clients with substance use disorders.
- Maintain patient record documentation in accordance with regulations.
- Developed and facilitated pregnant patient support group.

Education

- Doctor of Philosophy in Clinical Psychology, Walden University, currently in progress.
- Doctoral dissertation proposal: The Effects of Mindful Attentional Regulation on Illicit Opioid Use for Individuals Participating in Medication Assisted Treatment: A Pilot Study
- Master of Science, Psychology, Walden University, February 2010.
- Certification in Chemical Dependence Studies, CSUH, 2005.
- Bachelor of Arts, Music, California State University Hayward, June 1988.
- Honors Citation, CSUH Department of Psychology, December 1986.
- National Dean's List, 1987.

- Associate of Arts, with honors, Los Medanos College, June 1984.

Professional Affiliations

- Psychological Assistant (PSB36626) California Board of Psychology
- Affiliate Member, American Psychological Association (APA; 9006-9898)
- Professional Member, National Association for Alcoholism & Drug Abuse Counselors (NAADAC; 103307)
- Member, Western Psychological Association (WPA; 5887400)
- Certified Addictions Treatment Counselor, CAADE (S0412271058)
- Registered Addiction Specialist certification, Breining Institute (S0412271058)
- Composer Member, American Society of Composers, Authors, & Publishers (ASCAP)

Personal Interests

Psychological, philosophical, neurobiological, and physical sciences; mindfulness practices; music composition and performance; walking; baseball; football.

Appendix H: Letter of Cooperation for Data Management

Letter of Cooperation For
Data Management

This letter of cooperation describes the components of data collection, procedures to be followed, and the roles and responsibilities of the organization known as BAART Programs, Inc. ("BAART Programs") in the doctoral dissertation research study being conducted by Stephen Sooter, MS as partial fulfillment of his requirements in the Walden University Clinical Psychology PhD program. It is understood that BayMark Health Services, Inc. ("BayMark") is the parent organization of BAART Programs, and that David
K. White, as the Chief Executive Officer of BayMark, is authorized to review and sign this Letter of Cooperation as required.
Stephen Sooter is the Principal Investigator for this study, and is employed by BAART Programs and as a Treatment Center Director at the Antioch, California program site. BAART Programs has reviewed this study design, documentation, and implementation procedures, as presented by Stephen Sooter. BAART Programs has authorized the release of certain data to Stephen Sooter pursuant to a Data Use Agreement, for the purpose of his dissertation analysis. Walden University oversight of this study is limited to the final dissertation analyses only.

Part I: Participant Consent:

Consent from each potential study participant will be obtained prior to enrollment in the study as follows:

- A consent compliant with HIPAA and 42 CFR part 2 to disclose from each participant authorizing the following:
    a. The principal investigator to meet with him or her and review elements of BAART informed consent and participate in post-data collection period debriefing;
    b. Disclosure to the principal investigator of the pre-test, mid-test, and post-test measures outcomes data used in the study;
    c. Verification of MBRP group participation and homework assignment completion for the duration of the study by the principal investigator;
    d. Verification of each participant's MAT program participation in daily medication dosing as prescribed by the program physician and individual counseling services as required by the program;
    e. Disclosure by the principal investigator to the on-site BAART Programs physician of any event or condition associated with study implementation that exerts adverse effects on the participant; and
    f. Provision that each participant has the right to revoke his or her consent to

disclose at any time without any adverse action from the principal investigator, BAART Programs, or BayMark.

- Informed consent for each participant to participate in the study, which will authorize the following:

a. The principal investigator to meet with him or her and review elements of the BAART Programs' informed consent and participate in post-data collection period debriefing;
b. Random assignment of participants by the principal investigator to either the adjunct MBRP group participation or the treatment as usual only study group levels;
c. Administration and outcomes data collection, scoring, and analyses by the principal investigator of the Addiction Severity Index Drug & Alcohol Scale (McClellan et al., 1985) at pre-, mid-, and post-test intervals;
d. Test administration and outcomes data collection, scoring, and analyses by the principal investigator of the Opioid Craving Scale (McHugh et al., 2014) at pre-, mid-, and post- test intervals;
e. Test administration and outcomes data collection, scoring, and analyses by the principal investigator of the Toronto Mindfulness Scale (Lau et al., 2006) at pre-, mid-, and post- test intervals;
f. Disclosure to the principal investigator of each adjunct MBRP group-assigned participant's MBRP group participation and homework assignment completion for the duration of the study;
g. Verification of each participant's continued MAT program participation for the duration of the study as determined by methadone medication dosing and individual counseling session participation;
h. Hard copy participant data collection by the principal investigator that is securely stored in a locking file cabinet retained at the program site where the principal investigator works;
i. Electronic participant data collection that is used and stored by the principal investigator using methods that assure the privacy and confidentiality of each study participant;
j. Disclosure of any event or condition associated with study implementation that exerts adverse effects on the participant to the program physician at the study site; and
k. Each participant's right to discontinue his or her participation in the study without any adverse action from principal investigator, BAART Programs, or BayMark.

Part II: Provision of the MBRP Group Services:

- Once all requisite participant consents have been effected, the principal investigator will use a random number table to assign study participants to either the treatment as usual (TAU) control group or the TAU plus MBRP group experimental group, resulting at the outset in equal or approximately equal numbers of participants in each group;
- The MBRP Group services will be provided at the study site by the principal investigator;
- The principal investigator will be responsible for administering test measures and collecting pre- test (prior to beginning MBRP group), mid-test (after four weeks of MBRP group) and post-test (after final week of MBRP group) MBRP group participation and homework completion data. This data consists of verification of MBRP group attendance (or absence} and verification of MBRP group homework assignment completion .

Part Ill: **Pre-Test, Mid-Test, and Post-Test Data Collection Measures:**

The principal investigator is responsible for administration and data collection of the following measures at pre-test, mid-test (after four weeks of MBRP group services), and post-test (after eighth week of MBRP group services)intervals:

- The Addiction Severity Index (ASI) Alcohol/Drugs subscale (McClellan et al., 1985);
- The Opioid Craving Scale (OCS; McHugh et al., 2014); and
- The Toronto Mindfulness Scale (TMS; Lau et al., 2006).

Part IV: Pre-test Data Analysis:

- Given the complexity of multivariate data gathered over distinct periods in this study, Multivariate Analysis of Covariance (MANCOVA) statistical testing will used.
- Software used for data analysis in this study implementation phase will be the Statistical Package for the Social Sciences version 24 (SPSS; International Business Machines, 2018), with the alpha value set at .OS for all statistical procedures used. All outcomes data will be uploaded into a computer running SPSS software and results that will be calculated by the SPSS program.
- De-identified statistical data outcomes will used by the principal investigator to create data tables for further study data analysis and outcome reporting.
- After pre-test computerized data entry is completed, the principal investigator will run a statistical data analysis comparing the Opioid Craving Scale outcome pre- and mid-test scale scores, and comparing the ASI Alcohol/Drugs subscale pre- and mid-test scores.
- Each participant data entry record will be crosschecked against the original documentation provided by the study site coordinator to assure data entry integrity.
- A complete descriptive data analysis procedure will be run on all study variables using the SPSS program, thereby crosschecking to assure that data outliers or entry errors are not significantly skewing data outcomes.
- Finally, the SPSS Data Validation procedure will be run to assure that missing or erroneous data entries are not influencing data analyses outcomes.
- The principal investigator will be responsible to assure that all outcomes data are accurately transcribed, that appropriate statistical tests are run, and that inferences made from these results are interpreted accurately in accord with the statistical model used (MANCOVA) and experimental design utilized.
- De-identified statistical data outcomes will used by the principal investigator to create data tables for further study data analysis and outcome reporting.

Part IV: Mid-Test Data Analysis:

- Given the complexity of multivariate data gathered over distinct periods in this study, Multivariate Analysis of Covariance {MANCOVA) statistical testing will used.
- Software used for data analysis in this study implementation phase will be the Statistical Package for the Social Sciences version 24 (SPSS; International Business Machines, 2018), with

the alpha value set at .OS for all statistical procedures used. All outcomes data will be uploaded into a computer running SPSS software and results that will be calculated by the SPSS program.

- After mid-test computerized data entry is completed, the principal investigator will run a statistical data analysis comparing the Opioid Craving Scale outcome pre- and mid-test scale scores, and comparing the ASI Alcohol/Drugs subscale pre- and mid-test scores.
- Should any significant *(p*= .05) increases in either the Opioid Craving Scale scores or the ASI Alcohol/Drugs subscale scores be determined, the principal investigator will proceed with implementation of data safety measures (see Data Safety Agreement).
- Each participant data entry record will be crosschecked against the original documentation provided by the study site coordinator to assure data entry integrity.
- A complete descriptive data analysis procedure will be run on all study variables using the SPSS program, thereby crosschecking to assure that data outliers or entry errors are not significantly skewing data outcomes.
- Finally, the SPSS Data Validation procedure will be run to assure that missing or erroneous data entries are not influencing data analyses outcomes.
- De-identified statistical data outcomes will used by the principal investigator to create data tables for further study data analysis and outcome reporting.
- The principal investigator will be responsible to assure that all outcomes data are accurately transcribed, that appropriate statistical tests are run, and that inferences made from these results are interpreted accurately in accord with the statistical model used (MANCOVA) and experimental design utilized.
- De-identified statistical data outcomes will used by the principal investigator to create data tables for further study data analysis and outcome reporting.

Part V: Post-Test data Analysis:

- Given the complexity of multivariate data gathered over distinct periods in this study, Multivariate Analysis of Covariance (MANCOVA) statistical testing will used.
- Software used for data analysis in this study implementation phase will be the Statistical Package for the Social Sciences version 24 (SPSS; International Business Machines, 2018}, with the alpha value set at .OS for all statistical procedures used. All outcomes data will be uploaded into a computer running SPSS software and results that will be calculated by the SPSS program.
- After post-test computerized data entry is completed, the principal investigator will run a statistical data analysis comparing the Opioid Craving Scale outcome pre- and post-test scale scores, and comparing the ASI Alcohol/Drugs subscale pre- and post-test scores.
- Should any significant *(p*= .OS} increases in either the Opioid Craving Scale scores or the ASI Alcohol/Drugs subscale scores be determined, the principal investigator will proceed with implementation of data safety measures (see Data Safety Agreement).
- Assuming there are no significant post-test increases in participant opioid use or cravings, the principal investigator will run statistical analyses of the data on the password protected, encrypted computer.

- A complete descriptive data analysis procedure will be run on all study variables using the SPSS program, thereby crosschecking to assure that data outliers or entry errors are not significantly skewing data outcomes.
- Finally, the SPSS Data Validation procedure will be run to assure that missing or erroneous data entries are not influencing data analyses outcomes.
- De-identified statistical data outcomes will used by the principal investigator to create data tables for further study data analysis and outcome reporting.

Part VI: Data Retention and Destruction:

- All hard copies of study test measures will be retained in a secure locking file cabinet located at the BAART Programs Antioch location, which will be accessible only to the principal investigator and to BayMark Administrative personnel so authorized by the Chief Executive Officer of BayMark Health Services.
- All hard copy test measure data will be randomly assigned a participant identification number that will be used for organizing participant records in the computerized study database.
- A data key will be securely retained in a separate password protected, encrypted computer file retained by the principal investigator that links participant names to their unique ID numbers. Aside from this procedure, no participant names, birthdates, social security numbers, addresses, phone numbers, email addresses, or other information that could potentially be used by unauthorized persons to identify any participant will be collected, stored, or used as part of the study implementation procedures.
- The principal investigator will enter the participant pre-test, mid-test, and post-test data onto a secure, password protected and data encrypted computer file system stored on a computer accessible only to the principal investigator.
- Similarly, the principal investigator will enter MBRP group attendance (number of groups attended) and homework completion (number of homework assignments completed) data.
- At time of entry, the principal investigator will crosscheck data to assure accuracy of the computerized data entries.
- After the requisite five-year study data retention period has expired, the principal investigator will assure secure destruction of all hard-copy and electronic study data records.
- In the event that the employment relationship between BAART/BayMark and the principal investigator is terminated, Stephen Sooter will destroy all study data no later than the final day of his employment, unless otherwise directed by BAART and BayMark..

Signature and Date of Principal Investigator: _____

Stephe

Signature and Date of BAART Progra _____ 2/19/18

Notification of Study Approval
by
BayMark Pilot Study Research Committee

The BayMark Pilot Study Research Committee has reviewed and approved the proposed study of Stephen Sooter, a graduate student at Walden University enrolled in the Clinical Psychology PhD Program, based on his research proposal entitled "The Effects of Mindful Attentional Regulation On Illicit Opioid Use For Individuals Participating in Medication Assisted Treatment: A Pilot Study." Reviewed and approved constituent elements of the study intended for implementation at the designated BAART Programs site include, but are not necessarily limited to, the following:

- Summary of Study Design and Procedures
- Letter of Cooperation for Data Management
- Outline of the Mindfulness Based Relapse Prevention (MBRP) treatment protocol
- Participant Informed Consent
- Study Information for Participants letter
- Participant Report of Adverse Event

The principal investigator, Stephen Sooter, will assure that the BayMark Pilot Study Research Committee is fully informed regarding all aspects of study design, implementation, and effects on participants throughout the study implementation and data analyses periods.

The BayMark Pilot Study Research Committee will monitor all aspects of study implementation and data outcomes as determined necessary.

BayMark Pilot Study Research Committee:

Jason Carmichael, VP Quality and Clinical Compliance

Patrice Oliver, Director Nursing Education and Compliance

Frank Bauman, COO