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Medication-Assisted Treatment Versus 12-Step Group Therapy: A Comparative Analysis of Adherence and Abstinence In Patients With Opioid Use Disorder

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Medication-Assisted Treatment vs. 12-Step Group Therapy:

A Comparative Analysis of Adherence and Abstinence in Patients with Opioid Use Disorder

by

Derrick C. Glymph

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy in Nursing Science
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Dedication

To my parents Joyce Glymph and Raymond L. Glymph who passed away over 18 years ago. Thank you both for always believing in me.

Acknowledgements

"But they who wait for the Lord shall renew their strength; they shall mount up with wings like eagles; they shall run and not be weary; they shall walk and not faint." [Isaiah 40:31](#)

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Abstract

The purpose of this dissertation was to do a comparative analysis of the effects of medication-assisted treatment (MAT) and 12-step group therapy on adherence and abstinence in adult patients with opioid use disorder (OUD). The specific aims were (1) to compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT and adult OUD patients enrolled in 12-step group therapy at three months and six months after initiation of treatment, and (2) to compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy after controlling for age, marital status and gender. Findings of the study indicate when comparing MAT to 12-step group therapy, there was not a significant difference in treatment adherence and illicit opioid abstinence in adult OUD patients at three ($\chi^2(1) = 0.00, p = 0.990$) and six months ($\chi^2(1) = 0.459, p = 0.498$) after initiation of treatment. Study findings indicate that female gender was a significant predictor of adherence to the treatment programs at both three ($b = 1.41; p < 0.02$) and six months ($b = 2.52; p < 0.003$). Marital status and age were not significantly associated with adherence or abstinence. Considering the integration of a randomized controlled trial, longer periods to access for adherence and abstinence after treatment initiation, as well as exploring about patients' perceptions, will be of assistance to improve the future direction of research associated with the OUD population.

Chapter 1: Introduction

The following chapter outlines the genesis of the current opioid epidemic, the criteria of opioid use disorder, and medications approved by the Food and Drug Administration (FDA) for opioid use disorder (OUD) and 12-step group therapy. Following the introduction is the study's statement of problem, purpose of study, specific aims, definition of relevant terms, and the significance of this study related to nursing.

In 1995, Dr. James Campbell, President of the American Pain Society, launched the campaign "Pain is the Fifth Vital Sign," transforming the entire medical system and healthcare providers views regarding the use of opioids for non-cancer pain (Campbell, 1996). The campaign initiated the genesis of the current opioid epidemic in the United States (Campbell, 1996; Cicero et al., 2015; Compton et al., 2016; Kern et al., 2020; Mattson et al., 2017). Subsequently, opioid over-prescribing for chronic pain and misuse has significantly amplified over the last two decades (Cicero et al., 2015; Compton et al., 2016; Kern et al., 2020; Mattson et al., 2017). Sixteen million individuals worldwide meet the criteria for OUD and three million reside in the United States (Chang et al., 2018; Kern et al., 2020), where more than 130 people die each day from opioid overdoses (Knopf, 2018; Compton et al., 2016). The Substance Abuse and Mental Health Service Administration (SAMHSA) reported in its 2018 National Survey on Drug Use and Health (NSDUH) national report that 2.1 million people diagnosed with OUD in the United States over the age of 12 have OUD and 20% of the 2.1 million people have misused a prescription opioid at least once in their lifetime (Bose et al., 2018; Volkow et al., 2019). In 2018, the Centers for Disease Control and Prevention (CDC) reported that 700,000 people in the

United States died from drug overdose between 1999-2017. In response to the growing crisis, the Office of National Drug Control Strategy, a component of the Executive Office of the President, made it one of the national priorities to address complications of substance use disorder and opioid-associated addiction and help with recovery (Connery, 2015; Rieckmann et al., 2016; Topmiller et al., 2018).

Opioid Use Disorder is a chronic health condition that requires long-term treatment. Empirical studies also indicated that most OUD patients need at least three months of adherence to group treatment to significantly reduce or stop their opioid use (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Mendola et al., 2016; NIDA, 2020). Recent enrollment in recovery/treatment programs for prescription opioid abuse was highest among the age groups of 45-50 and 55-65 (Han et al., 2017; Knopf, 2018; Lilly, 2018). However, the World Health Organization (WHO, 2019) reported that three months of adherence to OUD treatment occurs less than 50% of the time in industrialized countries, posing a significant public health problem because of non-adherence to treatment (Han et al., 2015; Harvey et al., 2020; Humphreys et al., 2018; Neighbors et al., 2019; Sabaté & Sabaté, 2003; Zheng et al., 2017).

Criteria Utilized to Diagnose an Opioid Use Disorder

The *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; *DSM-5*; American Psychiatric Association, 2013) serves as the principal authority for diagnosis criteria and treatment of opioid use disorder (OUD). The *DSM-5* replaced previous terms *opioid abuse* and *dependence* with OUD, and defines it as the maladaptive use of opioids, prescribed or illicit. An individual is diagnosed with OUD if at least two of the eleven following symptoms are perceived by an individual within the past 12 months: (1) opioids are taken longer and taken in greater amounts than intended, (2) unsuccessful attempts to cut down or control use, (3) increased time

spent getting drugs or using drugs to recover, (4) craving of opioids, (5) recurrent use resulting in a failure to fulfill obligations at work or home, (6) continuing to use despite recurrent social or interpersonal conflict exacerbated by opioids, (7) not engaging in important social events, (8) recurrent opioid use in situations that are physically hazardous, (9) continued use despite awareness of having a recurrent physical or psychological problem, (10) tolerance to opioids, or (11) presence of withdrawal symptoms. Categories of diagnosis include mild (two to three symptoms), moderate (four to five symptoms), or severe (six to eleven symptoms) (Hasin, 2012; Zoorob et al., 2018). Following an OUD diagnosis clinicians can recommend that the patients enter treatment programs (Marsden et al., 2019; Timko et al., 2019). A person diagnosed with OUD is considered as being adherent to treatment and abstinent of illicit opioids if no symptoms are experienced for at least three months (Marsden et al., 2019). However, craving, tolerance, and withdrawal symptoms are excluded if a patient is fully enrolled and adherent to OUD treatment medication-assisted treatment (MAT) or 12-step group therapy (Marsden et al., 2019).

Medication-Assisted Treatment (MAT)

Opioid treatment programs (OTPs) in the United States increased from 11% in 2003 to 58% in 2016. Correspondingly the number of OTPs that offer FDA-approved medication-assisted treatment (MAT) has increased from 5% in 2003 to 21% in 2015 (Alderks, 2017; Mattson et al., 2017). MAT consists of the three FDA-approved OUD medications methadone, buprenorphine, and naltrexone, in combination with counseling and behavior therapies which prevent opioid relapse and stabilize or maintain treatment (Carroll & Weiss, 2017; Humphreys et al., 2018; Kim et al., 2015; Korthuis et al., 2017; Levin et al., 2016; McElrath, 2018).

All three FDA-approved OUD medications-methadone, buprenorphine, and naltrexone have ligands that bind to the central mu-opioid receptor as the molecular target for their therapeutic activity (Connery, 2015; McElrath, 2018).

Methadone has been around since the 1960s and was the primary medication for combating opioid addiction (McCance-Katz, 2018). Methadone is a long-acting full opioid agonist and a schedule II-controlled substance by law. In 2002, buprenorphine was approved by the FDA and replaced methadone as the primary medication for combating opioid addiction. Buprenorphine is a schedule III-controlled substance and a partial agonist at the mu-opioid receptor (Jones et al., 2015). Naltrexone a non-addictive medication, which has been around since 1984 is an antagonist at the mu-opioid receptor and prevents opioids from activating its receptor (Jones et al., 2015). The combination of these medications with evidence-based psychosocial therapy makes up medication-assisted treatment (MAT) for treating opioid addiction (McCance-Katz, 2018; Topmiller et al., 2018). MAT relieves the withdrawal symptoms and psychological cravings caused by the chemical imbalances in the body (Levin et al., 2016; McElrath, 2018). These medications used in MAT have also been used in treatment of alcohol use disorder and other addictions (Connery, 2015; Rieckmann et al., 2016; Topmiller et al., 2018). Methadone and buprenorphine have demonstrated effectiveness at retaining patients in treatment programs, decreasing illicit opioid use, decreasing rates of hepatitis B, and reducing overdose mortality (Haight et al., 2019; Klein & Seppala, 2019; Lofwall et al., 2018; Neumann et al., 2020; Rosenthal et al., 2016; Ruglass et al., 2019;). Although FDA-approved MAT medications have demonstrated to be effective in treatment programs dropout rates, relapse to illicit opioid use remains high due to OUD patients' multiple episodes of treatment initiation and

cessation (Haight et al., 2019; Harvey et al., 2020; Lofwall et al., 2018; Neumann et al., 2020; Rosenthal et al., 2016; Ruglass et al., 2019).

12-Step Group Therapy

One type of treatment program known as 12-step group therapy avoids using FDA-approved medications by utilizing peer support to assist those suffering from addiction and replaces drug misuse behavior with constructive and rewarding activities (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Mendola et al., 2016). The goal of 12-step group therapy is for the patient to stop using drugs and to become completely abstinent from illicit opioids (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Mendola et al., 2016). Moreover, 12-step group therapy leads to improved interpersonal relationships and increased adherence to treatment and opioid abstinence (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Mendola et al., 2016). Narcotics Anonymous (NA), founded in 1953 is a peer-led organization that provides 12-step group therapy (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Mendola et al., 2016). This organization connects peers who share the same addiction and provides fellowship, emotional support, and strategic coping skills (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Mendola et al., 2016).

Members of NA share with each other their success and challenges at overcoming addiction. Each member focuses on recovery, self-actualization, behavior changes, interpersonal realization, and spiritual principles that apply to their everyday life. The 12-steps outline what one achieves during the recovery process in which opioid abusers must admit their powerlessness over drugs, take a moral inspection of themselves, admit the nature of their wrongs, make a list of individuals whom they have harmed, and make amends to those people

(Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Mendola et al., 2016).

Empirical evidence indicates OUD patients that participate in 12-step group therapy have an increased likelihood of abstinence for prolonged periods of time (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Mendola et al., 2016). Despite its long history of success, attendance and engagement is often low with high dropout rates (Donovan et al., 2013). There is a lack of rigorous evaluation of this well-established treatment due to the anonymity of the 12-step group therapy program (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Mendola et al., 2016)

Conceptual Framework

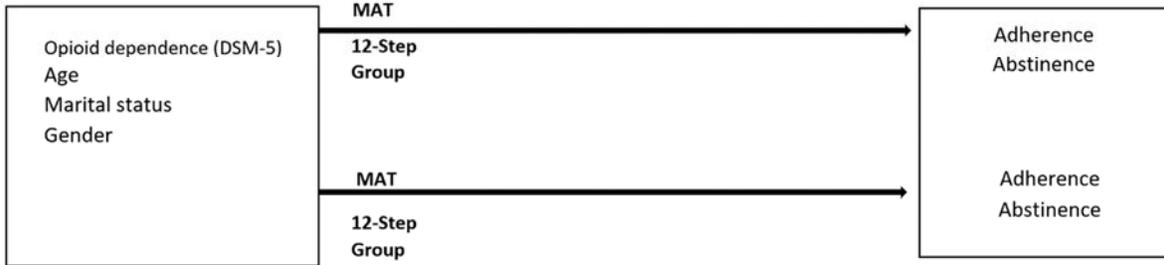
The conceptual framework that guided this study is adapted from Nola J. Pender's (1996) Health Promotion Model (HPM). The model explores the complex biopsychosocial processes that motivates an individual to engage in activities and behaviors to enhance their health. The constructs of the HPM include characteristics and experiences, behavior-specific cognitions and affect, and behavioral outcomes of health-promoting behavior. According to Pender et al. (2006), the interrelatedness of the constructs helps establish an opportunity for health-promoting behavior to occur. The modified model for this study is based on the literature review of the empirical research (see Figure 1). The concepts from the HPM model that were explored for this study include individual demographics (age, gender, and race), socioeconomic (marital status), variables associated with treatment adherence and illicit opioid abstinence of OUD adults in MAT or 12-step group therapy at three months and six months.

Figure 1: Modified Health Promotion Model

Logic Model-HPM

Individual Characteristics & Experiences

Outcomes at 3 & 6 months



Note. This figure compares treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to patients enrolled in 12 step-group therapy at three months and six months after initiation of treatment.

Statement of the Problem

Less than 50% of adult patients adhere to MAT or 12-step group therapy three months after initial enrollment (Harvey et al., 2020; Kern et al., 2020; Proctor et al., 2017; Sabaté & Sabaté, 2003). In addition, limited evidence exists on how demographic, socioeconomic, behavioral, and psychological variables are associated with treatment adherence and illicit opioid abstinence of adult OUD patients that are enrolled in MAT or in 12-step group therapy (Gustafson et al., 2016; Han et al., 2017; Jones et al., 2015; Kumari et al., 2016; Levin et al., 2016; Rieckmann et al., 2016; Sabaté & Sabaté, 2003).

Although MAT is associated with increased treatment adherence (Gustafson et al., 2016; Han et al., 2017; Jones et al., 2015; Kumari et al., 2016; Levin et al., 2016; Rieckmann et al., 2016; Sabaté & Sabaté, 2003), comparatively higher rates of abstinence have been observed for the OUD patient that engages and adheres to 12-step group therapy, as measured by urine

toxicology tests (Abdollahi & Haghayegh, 2020; Costello et al., 2019; Humphreys et al., 2020; Labbe et al., 2013). Studies have found that participants who attend peer support groups are more than twice as likely to be opioid abstinent at 18 months (Proctor et al., 2017; Weiss et al., 2019). In contrast, OUD participants who did not have a high record of attending 12-step group therapy had a higher rate of opioid relapse (Abdollahi & Haghayegh, 2020; Costello et al., 2019; Humphreys et al., 2020; Labbe et al., 2013). Consequently, it is important to further describe and understand what variables are associated with MAT or 12-step group therapy treatment adherence, as well as barriers to treatment adherence and illicit opioid abstinence in adult OUD patients enrolled in MAT or 12-step group therapy. It is also imperative to understand if there is an association between demographic, socioeconomic behavior, and psychological variables with adherence to MAT or 12-step group therapy. Identifying which treatments and variables may have high or low treatment adherence may improve OUD patients' adherence and improve their outcomes of becoming free of illicit opioids (Marsden et al., 2019).

Purpose of the Study

The purpose of this study was to compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to adult OUD patients enrolled in 12-step group therapy at three months and six months after initiation of treatment. In addition, the study compared treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy after controlling for age, marital status, and gender.

Specific Aims

Aim 1: To compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy at three months and six months after initiation of treatment.

Hypothesis 1: There is a significant difference in treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT and adult OUD patients enrolled in 12-step group therapy at three months and six months after initiation of treatment.

Aim 2: To compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy after controlling for age, marital status, and gender.

Hypothesis 2: Treatment adherence and illicit opioid abstinence of adults OUD patients is not different between those enrolled in MAT to those enrolled in 12-step group therapy after controlling for age, marital status, and gender.

Significance to Nursing

Adherence to effective treatment for OUD is more urgent than ever as the opioid epidemic has caused 700,000 deaths and led 2.1 million people to misuse prescription opioids in the United States (Bose et al., 2018; Han et al., 2017; Lilly, 2018; Volkow et al., 2019). According to the World Health Organization (WHO, 2019), less than 50% of industrialized countries report three months of adherence to OUD treatment (Han et al., 2015; Harvey et al., 2020; Humphreys et al., 2018; Neighbors et al., 2019; Sabaté & Sabaté, 2003; Zheng et al., 2017). Empirical evidence has shown that FDA-approved MAT and 12-step group therapy for OUD are effective at increasing treatment adherence and abstinence to illicit opioids (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Carroll & Weiss, 2017;

Humphreys et al., 2018; Kim et al., 2015; Korthuis et al., 2017; Levin et al., 2016; McElrath, 2018; Mendola et al., 2016). However, treatment dropout rates and the relapse to illicit opioid use after treatment initiation remains high (Haight et al., 2019; Harvey et al., 2020; Lofwall et al., 2018; Neumann et al., 2020; Rosenthal et al., 2016; Ruglass et al., 2019). In 2018, Substance Abuse and Mental Health Services Administration (SAMHSA) reported that when opioid users seek treatment, they find that health professionals lack the sufficient skills, education, and certification to implement the most effective, evidence-based treatment for OUD.

Nurses are at the frontline of the opioid epidemic and are well-positioned to make significant contributions to OUD research. Therefore, it is critical that nurse researchers studying the public health opioid crisis understand the barriers to treatment adherence and illicit opioid abstinence that adult OUD patients face while enrolled in MAT or 12-step group therapy. It is also critical that clinicians and researchers understand the influence of demographic, socioeconomic, behavioral, and psychological variables on treatment adherence and illicit opioid abstinence of adult OUD patients. This study aims to contribute to the empirical evidence on treatment adherence and illicit opioid abstinence in patients enrolled in MAT or 12-step group therapy. As a result, it is anticipated that in achieving the aims of this study, nursing scientists will be able to improve OUD patients' outcomes by identifying specific variables associated with treatment adherence and illicit opioid abstinence (Marsden et al., 2019).

Limitations

A limitation of the study is that it may not be applicable to the general population based on the specific inclusion criteria.

Definition of Relevant Terms

The following terms are defined for the purpose of this analysis and are used throughout the study:

Adherence: continued participation in OUD treatment and no withdrawal symptoms experienced for a period of three months (Marsden et al., 2019).

Drug tolerance: When an individual's body becomes used to the effects of the drug overtime (McElrath, 2018).

Medication-assisted treatment (MAT): Treatment that uses a combination of prescribed FDA-approved medication and behavioral therapy (Humphreys et al., 2018).

Non-adherence: A positive blood test or urine toxicology test result for illicit opioids for a period of three months (Marsden et al., 2019).

Opioid abstinence: A negative blood test or urine toxicology test result for illicit opioids for a period of three months (Marsden et al., 2019).

Opioid use disorder (OUD): A maladaptive pattern of prescribed or illicit opioid use (American Psychiatric Association, 2013).

Withdrawal: The occurrence of symptoms following the reduction or abstinence of long-term drug use. These symptoms occur after drug tolerance to a substance has occurred and vary according to the substance. Symptoms can include negative emotions such as stress, anxiety, or depression as well as physical effects such as nausea, vomiting, muscle aches, and cramping (McCance-Katz, 2018).

Summary

Chapter 1 provides an overview of the current opioid epidemic in the United States and describes treatment options available for individuals diagnosed with opioid use disorder (OUD).

Two treatment programs, medication-assisted treatment (MAT) and 12-step group therapy, have shown varied yet successful outcome for adult patients, however, patients often do not adhere to treatment plans and revert to illicit opioid use. This study has two aims: 1) To compare the treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy at three months and six months after initiation of treatment; and 2) To compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in 12-step group therapy after controlling for age, marital status, and gender. It is critical that nurses, who see and treat patients with substance use disorders every day, can identify specific variables associated with treatment adherence and illicit opioid abstinence to ultimately improve health outcomes of OUD patients.

Chapter 2: Review of Literature

Chapter 2 focuses on the review of literature and conceptual framework that guided this study. The review of the literature focuses on adherence to opioid use disorder (OUD) treatment and illicit opioid abstinence. The chapter reviews the empirical literature of predictors of adherence to OUD treatment and illicit opioid abstinence and examines the variables of age, gender, race, education, income, marital status, physical activity, religion, and perceived stress. Finally, the chapter identifies gaps in the literature and discusses the future direction of OUD treatment adherence.

Adherence and Abstinence to Opioid Use Disorder Treatment

Twenty percent of all OUD patients are non-adherent to their treatment (Klein & Seppala, 2019; Timko et al., 2019). Many patients do not take their medication-assisted treatment (MAT) Food and Drug Administration (FDA) medications daily as prescribed, which worsens treatment adherence (Ober et al., 2018). The problem with both MATs and 12-step group therapy is that non-adherence often results in illicit opioid misuse behavior and treatment dropout (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Lofwal et al., 2014). Studies in both treatment modalities show that adherence to treatment for at least three months have resulted in significant illicit opioids abstinence (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Mendola et al., 2016).

Intervention

Medication-Assisted Treatment/Medication-Assisted Treatment

The demand for the three FDA-approved MAT medications for OUD patients has significantly increased (Lee et al., 2018; Liebschutz et al., 2014; Lofwall et al., 2018; Mokri et al., 2016; Rosenthal et al., 2016; Sullivan et al., 2017; Tanum et al., 2017). The evidence supports the use of opioid agonist methadone for OUD treatment adherence and illicit opioid abstinence (Ali et al., 2017; Haight et al., 2019; Liebschutz et al., 2014; Lofwall et al., 2018; Rosenthal et al., 2016). Multiple empirical studies indicate methadone as the most understood medication to treat OUD (Lee et al., 2018; Liebschutz et al., 2014; Lofwall et al., 2018; Mokri et al., 2016; Rosenthal et al., 2016; Sullivan et al., 2017; Tanum et al., 2017). Methadone has shown superiority over buprenorphine and naltrexone in OUD treatment adherence and illicit opioid abstinence and remains the gold standard for OUD medication treatment (Ali et al., 2017; Haight et al., 2019; Liebschutz et al., 2014; Lofwall et al., 2018; Rosenthal et al., 2016).

Conversely, buprenorphine extended release (BUP-XR), is the first FDA-approved subcutaneous implant medication that patients take once every month for OUD, has shown similar rates of treatment adherence and illicit opioid abstinence as methadone (Ling et al., 2020). BUP-XR had significantly higher abstinence rates compared to buprenorphine/naloxone (BUP/NX) oral medication for OUD. The mean percentage of opioid abstinence when using BUP-XR was 41.3% ($n=29.7$) for BUP-XR doses of 300 mg (Haight et al., 2019; Lofwall et al., 2018; Rosenthal et al., 2016). Patients using BUP/NX have also demonstrated increased rates of illicit opioid abstinence and a better safety profile than naltrexone (Lofwall et al., 2018; Rosenthal et al., 2016). Tanum and colleagues conducted a randomized control trial (RCT) consisting of 232 opioid dependent adults to compare illicit opioid use when prescribed naltrexone extended

release (NTX-XR) compared to BUP/NX. They found that there was significantly lower illicit opioid use ($p < 0.001$) in the NTX-XR group (Tanum et al., 2017). In another study, Neumann and colleagues conducted a randomized control trial (RCT) of 19 opioid-addicted patients to compare methadone (n=9) and BUP/NX treatments (n=10). After following the patients for six months Neumann found that treatment retention did not differ between the two groups (Neumann et al., 2020). All three MATs showed improved adherence to treatment compared to placebo with no significant differences between groups (Haigh et al., 2019; Lee et al., 2018; Liebschutz et al., 2014; Lofwall et al., 2018; Mokri et al., 2016; Neumann et al., 2020; Rosenthal et al., 2016; Sullivan et al., 2017; Tanum et al., 2017; Ruglass et al., 2019; Sullivan et al., 2019). Although methadone, buprenorphine and naltrexone have shown promise, future studies regarding their treatment adherence and illicit opioid abstinence need to be explored.

12-Step Group Therapy/Alternative Group Therapy

The behavioral treatment most used internationally for stopping illicit opioid use is 12-step group therapy (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Lo Coco et al., 2019; Mitchell et al., 2013; Watkins et al., 2017; Weiss et al., 2019). Yet, despite its global reach, 12-step group therapy continues to have a high dropout rate (Donovan et al., 2013). The literature supports the effectiveness of OUD patients achieving abstinence at three months when patients consistently adhere to 12-step group therapy meetings (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Lo Coco et al., 2019; Mitchell et al., 2013; Watkins et al., 2017). The gold standard for treatment adherence and illicit opioid abstinence is 12-step group therapy (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Lo Coco et al., 2019; Mitchell et al., 2013; Watkins et al., 2017). Alternative types of group therapy were also found to be effective at increasing illicit opioid abstinence (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Lo Coco et al., 2019;

Mitchell et al., 2013; Watkins et al., 2017). Watkins et al. (2017) conducted a RCT on the effectiveness of collaborative care group therapy on 377 adult OUD patients. Findings indicate that 32.8% of the patients in collaborative care reported illicit opioid abstinence at six months compared to 22.3% of patients not enrolled in group therapy. Future studies on alternative group therapies such as collaborative care on OUD treatment adherence and illicit opioid abstinence need to be explored.

Medication-Assisted Treatment/Group Therapy

Methadone/Group Therapy. Group therapy was found to be more effective at reducing opioid cravings and improving treatment adherence in a quasi-experimental pre-test, post-test study of a convenience sample of 30 male patients with opioid addiction (Hemmat et al., 2018). Moreover, Azkhosh and colleagues (2016) conducted a RCT (N=60) on opioid dependent individuals (20 participants per group) comparing the Narcotics Anonymous (NA) 12-step group therapy to methadone treatment. Azkhosh also found that group therapy was more effective at adherence to treatment and shown to be statistically significant (Azkhosh et al., 2016). The MAT requirement for some level of counseling has resulted in decreased treatment adherence according to multiple studies (Ruglass et al., 2019; Schwartz et al., 2017). Furthermore, OUD patients that take methadone and stop behavioral counseling treatment had increased illicit opioid relapse within a 12-month period compared to patients in 12-step group therapy (Schwartz et al., 2017). Few studies have compared methadone to group therapy, however, the studies that do compare the two treatments conclude that group therapy is generally more effective at treatment adherence.

Buprenorphine/Group Therapy. Buprenorphine/naloxone (BUP/NX) has been shown to be as statistically significant in OUD treatment adherence as methadone (Suzuki et al., 2015).

However, a limited number of studies compare BUP/NX with group therapy for treatment adherence and illicit opioid abstinence (Lofwall et al., 2018; Rosenthal et al., 2016; Suzuki et al., 2015). In a pilot study of 12 OUD patients, Suzuki and colleagues compared group therapy to buprenorphine treatment and found that 53% of group therapy patients remained in treatment at six months ($p < 0.0001$) and had decreased anxiety and opioid craving compared to patients treated with buprenorphine (Suzuki et al., 2015). Pizzicato and colleagues used prescription drug monitoring program's (PDMP) de-identified data in a retrospective cohort study on 10,669 patients who initiated buprenorphine treatment. The study found that after 180 days of buprenorphine treatment 2,834 patients (26.6%) were adherent to buprenorphine treatment (Pizzicato et al., 2020). The study also found that 35-44 age group and male gender 1,693 (59.7%) were associated with greater treatment adherence. Conversely, OUD patients who received low doses of BUP/NX (<16 mg/day) were three times more likely to be non-adherent to buprenorphine treatment in their first six weeks compared to OUD patients that received higher doses of BUP/NX (>16 mg/day) (Muruganandam et al., 2019; Pizzicato et al., 2020).

Naltrexone/Group Therapy. Naltrexone extended release (NTX-XR) has been effective in abstinence of illicit opioids for OUD patients (Lee et al., 2018). Multiple studies have demonstrated NTX-XR to have superiority over group therapy in maintaining abstinence from illicit opioids at six months (Fiellin et al., 2013; Ling et al., 2013; Pan et al., 2015; Sullivan et al., 2019). However, because of the opiate antagonist nature of this FDA-approved drug it has exhibited some challenges with patient treatment adherence (Sullivan et al., 2019). Sullivan and colleagues found that NTX-XR combined with behavioral therapy had twice the rate of treatment adherence at six months compared to those who took oral naltrexone with behavior therapy (Sullivan et al., 2017).

Multiple empirical studies have separately examined the effectiveness of both MAT and 12-step group therapy for adult OUD patients (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Haigh et al., 2019; Lee et al., 2018; Liebschutz et al 2014; Lo Coco et al., 2019; Lofwall et al., 2018; Mitchell et al., 2013; Mokri et al., 2016; Neumann et al., 2020; Rosenthal et al., 2016; Ruglass et al., 2019; Sullivan et al., 2017; Sullivan et al., 2019; Tanum et al., 2017; Watkins et al., 2017; Weiss et al., 2019). A few studies found that MAT enrolled patients had better treatment adherence at three and six months than patients who receive a placebo or no medication (Chen et al 2013; Neumann et al., 2013; Timko et al., 2016; Woody et al., 2016). A few studies revealed that 12-step group therapy attendance or treatment adherence declined at three months and six months (Alexandre et al., 2003; Fiellin et al., 2013; Ling et al., 2013; Pan et al., 2015). However, there are no empirical studies in the literature that compare MAT to 12-step group therapy. Conclusively, research is needed to compare the treatment adherence and illicit opioid abstinence of adults enrolled in MAT to adults enrolled in 12-step group therapy at three-months and six-months after initiation of treatment.

Demographic Variables and Treatment Adherence/Illicit Opioid Abstinence

Empirical studies have found demographic variables age, gender, and race, to be significant when considering illicit opioid abstinence (Chang et al., 2017; Huang et al., 2018; Neighbors et al., 2019). In summary, there is a positive relationship between age, gender, and race with adherence (Chang et al., 2017; Huang et al., 2018; Neighbors et al., 2019). In a secondary data analysis of 570 OUD patients from eight substance abuse treatment centers in the United States, Harvey and colleagues (2020) found that increased age 33.86 (SD=9.63), full-time employment, and enrollment in 12-step group therapy had a significant effect on illicit opioid

abstinence at three months than younger age 33.86 (SD=9.63), unemployment, and non-enrollment in 12-step group therapy.

The number of deaths due to opioid misuse in the United States is significantly higher for the 25-44 age group compared to the 55 and above age group (Rudd et al., 2016). In a sample size of 37,038 individuals that were seeking, requesting, and enrolling in opioid treatment programs (OTP) during this opioid epidemic, the largest group comprised of individuals aged 50 and above (Han et al., 2015; Han et al., 2017, Lilly, 2018). Moreover, the young adult age group was found to be a predictor of increased treatment dropout (Dayal et al., 2017; Haddad et al., 2013; Viera et al., 2020). Among patients receiving methadone maintenance treatment for OUD, first-time opioid users at 18 years old were significantly associated with increased risk of having a physiological or psychological disorder ($p<0.02$) compared to first-time users at 31 years or older (McHugh et al., 2018; Naji et al., 2017).

There is little evidence regarding gender specific predictors for OUD (Kerridge et al., 2015). However, in a survey on non-medical prescription opioid use ($N=1,661$), researchers found that opioid use was greater among men (4.4%) than women (3.9%) (Kerridge et al., 2015). Researchers studying opioid specific treatments found men and women were equally likely to be treated for OUD with MAT (Kerridge et al., 2015). However, an examination of 12-step group therapy programs revealed men were more likely to participate on a lifetime basis than women (Kerridge et al., 2015). These gender differences pertaining to OUD treatments are consistent with previous studies (Compton et al., 2016; Dayal et al., 2017; Haddad et al., 2013; Han et al., 2017; Huang et al., 2018; Kerridge et al., 2015; Viera et al., 2020; Wang et al., 2013).

Demographic and socioeconomic variables race, marital status, and income level are also predictors of OUD (Harvey et al., 2020). Individuals with OUD are more likely to be white men

over age 50 and more likely to be enrolled in OTPs (Han et al.,2017; Kerridge et al., 2015; Wang et al., 2013). Sittambalam and colleagues found that, in a sample of 220 participants in which 17% (n=37) were African American, all remained adherent to MAT treatment more than three months (Sittambalam et al., 2014). Future research studying these variables is needed to identify the best predictors for opioid abstinence and treatment adherence.

Socioeconomic Variables and Treatment Adherence/Illicit Opioid Abstinence

Socioeconomic variables have been identified by the literature as predictors of OUD treatment adherence (Compton et al., 2016; Dayal et al., 2017; Haddad et al., 2013; Han et al., 2017; Huang et al., 2018; Kerridge et al., 2015; Viera et al., 2020; Wang et al., 2013). Variables used to measure an individual's socioeconomic status include income, education, occupation, and marital status (Compton et al., 2016; Dayal et al., 2017; Haddad et al., 2013; Han et al., 2017; Huang et al., 2018; Kerridge et al., 2015; Viera et al., 2020; Wang et al., 2013).

According to the 2018 National Survey on Drug Use and Health (NSDUH), education level is a predictor of OUD treatment adherence. In addition, the NSDUH survey found that adults not adhering to OUD treatment were more likely to report not having a high school education. In contrast, those with some college education and college graduates reported greater treatment adherence and illicit opioid abstinence which is consistent with previous studies (Compton et al., 2016; Dayal et al., 2017; Haddad et al., 2013; Han et al., 2017; Huang et al., 2018; Kerridge et al., 2015; Viera et al., 2020; Wang et al., 2013). Nearly every empirical study found that patients with lower annual family incomes (<\$20,000) were more likely to drop out of OTPs compared to those with higher annual family incomes (>\$75,000) who were more likely to adhere to treatment ($n=26$, 41.1%) and maintain illicit opioid abstinence ($n=26$, 35.5%)

(Compton et al., 2016; Dayal et al., 2017; Haddad et al., 2013; Han et al., 2017; Huang et al., 2018; Kerridge et al., 2015; Viera et al., 2020; Wang et al., 2013).

The literature indicates that social support is the main reason for OUD patients to remain treatment adherent and illicit opioid abstinent (Han et al., 2017; Huang et al., 2018; Kerridge et al., 2015; Viera et al., 2020). Studies identified OUD patients with a spouse or partner as having higher treatment adherence (Han et al., 2017; Huang et al., 2018; Kerridge et al., 2015; Lappan et al., 2019; Viera et al., 2020).

Behavioral Variables and Treatment Adherence/Illicit Opioid Abstinence

The behavioral variables physical activity and religion can modulate adherence to OUD treatment. The literature supports physical activity and religious coping as factors that increase treatment adherence and illicit opioid abstinence (Lynch et al., 2017; Medlock et al., 2017). Epidemiological data also establishes that regular exercise or physical activity is associated with an increase in treatment adherence and illicit opioid abstinence (Henchoz et al., 2014; Lynch et al., 2017; Stone et al., 2012). More specifically, participation in sports and increased physical activity is associated with increased treatment adherence and illicit opioid abstinence (Veliz et al., 2017). In accordance with related findings, a lack of physical activity was associated with non-adherence to treatment (Veliz et al., 2017).

The literature also supports the association between active engagement in religion and adherence to 12-step group treatment (Medlock et al., 2017; Stone et al., 2006). The 12-step program is not based on religious or spiritual terms and defines a “higher power” as anything that a member believes is adequate (Abdollahi et al., 2020; Azkhosh et al., 2016; Humphreys et al., 2020; Mendola et al., 2016).

Social support and religious coping were indicated as a way for OUD patients to deal with stress and adhere to their treatment (Medlock et al., 2017). In an inpatient detoxification center, 331 patients self-reported that positive religious coping led to less frequent illicit opioid use and increased treatment adherence to 12-step group therapy programs (Medlock et al., 2017).

These findings are consistent with previous studies that associate religion with higher rates of 12-step group therapy program participation (Cornish & Wade, 2010; Stone et al., 2006; Medlock et al., 2017).

Psychological Variables and Treatment Adherence/Illicit Opioid Abstinence

Opioid Use Disorder patients have significantly higher levels of perceived stress, emotional disorders ($p < 0.001$), and depression ($p < 0.01$) (Alabau et al., 2016; Carrol et al 2017). Researchers have identified perceived stress as an indicator of illicit opioid relapse and a risk factor for treatment adherence (Alabau et al., 2016; Carroll et al., 2017; Epstein et al., 2014; Preston et al., 2017). Perceived stress is directly correlated with increased opioid craving, opioid use, and poor treatment adherence (Alabau et al., 2016; Carroll et al., 2017; Epstein et al., 2014; Preston et al., 2017). In contrast, MacLean and colleagues found the impact of stress on OUD to be unclear and recommended that more research be done to target stress behavior (MacLean et al., 2019). Identifying factors of stress and perceived stress can help lead to increased treatment adherence and illicit opioid abstinence in OUD adults enrolled in MAT or 12-step group therapy.

Identification of Gaps and Recommendations for Future Research

Gaps in research identified by means of this literature review include the lack of studies comparing treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT and 12-step group therapy in a longitudinal approach. In addition, there is limited research exploring about predictors that impact treatment adherence and illicit opioid abstinence,

including age, marital status, and gender. Research addressing these gaps will facilitate understanding about treatment adherence and illicit opioid abstinence, and to enhance interventions to meet the needs of OUD patients.

Conclusion

This literature review demonstrates that MAT and 12-step group therapy are effective at increasing OUD patient treatment adherence and illicit opioid abstinence. The literature review also identified age, gender, race, education, income, marital status, physical activity, religion, and perceived stress as potential modifiers of treatment adherence and illicit opioid abstinence. However, research gaps remain regarding comparison of MAT to 12-step group therapy and regarding longitudinal research on variables such as, age, marital status, and gender to identify and improve treatment adherence and illicit opioid abstinence for adults with OUD.

Chapter 3: Research Methodology

Methods

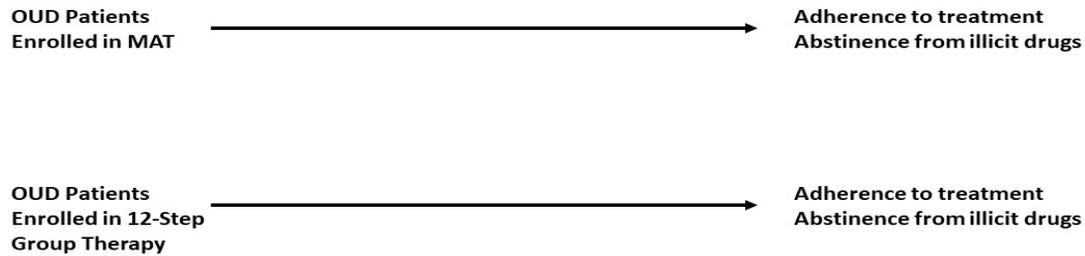
Chapter 3 will discuss the research methodology for the study. The chapter is organized into the following topics: study design, setting, population and sample, instruments, protection of human subjects, data management, data analysis, and limitations.

Study Design

The study used a prospective, quasi-experimental design, involving opioid use disorder (OUD) patients enrolled in either medication-assisted treatment (MAT) or enrolled in 12-step group therapy (Figure 2). The electronic medical health records data from patients already enrolled in either MAT or 12-step group therapy treatment for at least six months were examined.

Aim 1 of this study compared the treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy at three months and six months after initiation of treatment. The dependent variable is adult OUD patients' adherence to treatment and abstinence to illicit opioids. Aim 2 compared treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy after controlling for age, marital status, and gender. Aim 2 included three independent variables supported by the research literature as identified predictors for treatment adherence and illicit opioid abstinence: age, marital status, and gender.

Figure 2: Research Design



Note: This figure demonstrates a prospective, quasi-experimental design and the two dependent variables of adherence to treatment and abstinence from illicit drugs.

Setting

The setting of the study is a for-profit adult mental and behavior health treatment center for adults located in the southeast region of the United States. This outpatient center offers evidence-based treatment including MAT and 12-step group therapy. The facility is fully accredited by The Joint Commission and certified and accredited by Substance Abuse and Mental Health Services Administration (SAMHSA) as an opioid treatment program.

Population and Sample

The target population is made up of patients diagnosed with OUD who live in Florida. The sample consists of patients who were receiving treatment at an outpatient treatment center located in the southeast region of Florida. Inclusion criteria were as follows: a *DSM-5* (APA, 2013) confirmed diagnosis of OUD, enrollment in MAT or 12-step group therapy for at least six months, and individuals 18 years or older. Exclusion criteria were as follows: no diagnosis of OUD, participation in intervention other than MAT or 12-step group therapy and individuals under the age of 18. Individuals with major mental disorders or illness documented by *DSM-5*

(e.g., Schizophrenia, Catatonia, Psychosis, or dissociative disorders) were excluded from participation in this study.

Data Acquisition

The information technologist (IT) department of the study site provided access to medical records based on study inclusion and exclusion criteria. The data were deidentified and extracted from the patients' electronic medical records by the IT department. The data were then shared with the principal investigator via password protected Excel sheet database. The data were then imported into SPSS 27® and coded for analysis.

Operational Definitions

Adherence: participants were positive for FDA approved MAT buprenorphine and other substances that were prescribed. If OUD patients tested positive for marijuana (THC) they were still considered adherent (Memorial Behavior Clinical Site Protocol).

Non-adherence: considered non-adherent if 14-panel urine drug screen was positive for opioid or cocaine or medication not prescribed in the 14-panel urine drug screen at three and six months after initiation of treatment (Memorial Behavior Clinical Site Protocol).

Measures

Electronic Medical Records

The demographic data—age, marital status, gender, and race—and 12-step group therapy attendance was collected retrospectively from electronic medical records (EMR) chart review of patients who met the inclusion criteria of the study. The assumption was that the data recorded in the EMR was recorded accurately, clearly, and with integrity.

Adherence and Abstinence

Treatment adherence and illicit opioid abstinence was measured using the Point of Care Marketplace Urine Drug Screen TM. The test uses a urine sample from the patient to detect up to 14 drugs. The 14-panel urine drug screen consisted of Amphetamine (AMP), Barbiturates (BAR), Buprenorphine (BUP), Benzodiazepine (BZO), Cocaine (COC), Ecstasy (EDDP), Methadone Metabolite (MDMP), Methadone (MET), Opiates 300 (OPI), Oxycodone (OXY), Phencyclidine (PCP), Tricyclic Antidepressants (TCA), and Marijuana (THC).

The C region shows validity of a test result and T region shows results of the test. The appearance of a line in the C region indicates a valid result. However, if no line is present in the C region of the test strip means test results are invalid for this strip. In the T region the appearance of a line indicates a negative result. However, no line in the T region indicates a preliminary positive result. The appearance of buprenorphine and no other illicit drugs that were not prescribed would indicate treatment adherence and illicit opioid abstinence. This test was administered on a daily, weekly, and monthly basis to MAT and 12-step group therapy patients and recorded in the EMR.

Procedures

Protection of Human Subjects

Protocol approval was obtained from the University of South Florida (USF) Institutional Review Board (IRB) # 003185 and from Memorial Healthcare System IRB # 2021.126.

Measure to Protect Human Subjects

To protect confidentiality of the human subjects in this research study, data from all study patients were de-identified from the electronic medical record (EMR) numbers. The Senior Analyst at Memorial Healthcare assigned a unique identification number to each participant

during the data collection process. Additionally, data collected was limited to EMRs of adult patients that met the inclusion criteria of this study. To extract the retrospective data from the EMR, a waiver of consent and HIPAA was requested from the IRB. A waiver of consent and HIPAA was necessary because the PI did not have the necessary contact information to obtain consent from the eligible participants.

Potential Risk to Participants

This was a minimal risk study, as the collection of data involved a retrospective chart review for data extraction, however, the risk of a breach of confidentiality existed if the temporary key code linking the patient identification number to the unique identifier of the patient was compromised. No experimental procedures or interventions were implemented as part of this study.

Potential Benefits to the Participants

There was no direct benefit to participants nor to society. However, this study may provide empirical evidence to future OUD patients who are enrolled in MAT or 12-step group therapy about which treatment may improve their treatment adherence and illicit opioid abstinence greater than three and six months. The potential future benefit outweighs the risk for this minimal risk study.

Alternatives to Participants

This study encompassed a retrospective electronic record review of available data. The alternative to participation was no participant involvement in this study (no extraction of partial medical records).

Screening

The PI screened the EMR for patients that met the inclusion criteria. The PI reviewed and extracted patient data from each EMR and entered the data into a Microsoft Excel spreadsheet before uploading it directly into the SPSS database. Once the sample size was met, the PI ceased record review and data collection.

Data Management

Data Storage

All data were stored in a computer that was password protected and secured by a firewall. The data were organized and stored on an IBM® statistical package for the social sciences (SPSS 27 ®). All human subjects' medical record numbers were kept on a password protected database in Microsoft Excel and were linked only with the identification number assigned for this study. After data collection ceased, the key with the medical record number was destroyed by deletion of the file. The remaining data are linked only to the identification numbers which were de-identified. The data was backed up to an encrypted hard drive, stored in a locked filing cabinet in the office of the PI, and is only accessible by the investigator via their University of South Florida (USF) account. The database will be maintained for a minimum of five years per USF policy.

Paper copies of data will be limited to forms that were not available electronically and are kept in a locked cabinet in a locked office of the PI and maintained for a minimum of five years after the completion of the study. After five years the paper copies will be destroyed using a confidential document shredding service per USF policy.

Data Analysis

Data analysis was performed using the SPSS® version 27.0 (IBM, Armonk, NY). A univariate and bivariate analysis of demographic variables was performed to describe variables. Chi-square test was performed to determine the difference for categorical outcome variable adherence. Two binary logistic regression models were done at 3-months and 6-months to predict adherence of outcome adherence and abstinence controlling for age, marital status, and gender.

Aim 1

To compare the treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy at three months and six months after initiation of treatment.

Hypothesis 1

There is a significant difference in treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT and patients enrolled in 12-step group therapy at three months and six months after initiation of treatment.

Analysis Plan. The statistical hypothesis test for Aim 1 in this study was done with a Chi square test to determine if there was a significant difference in treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT and adult OUD patients enrolled in 12-step group therapy at three months and six months after initiation of treatment.

Aim 2

To compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to the treatment adherence and illicit opioid abstinence of adult patients enrolled in 12-step group therapy after controlling for age, marital status, and gender.

Hypothesis 2

Treatment adherence and illicit opioid abstinence of adults OUD patients is not different between those enrolled in MAT to those enrolled in 12-step group therapy after controlled for age, marital status, and gender.

Analysis Plan. The statistical hypothesis test for Aim 2 was done with two binary logistic regression models at 3-months and 6-months to predict adherence to treatment and abstinence from illicit drugs using the dichotomous dependent variable. The test controlled for covariates age, marital status, and gender.

Anticipated Results

The anticipated results were that the study's longitudinal nature will show a difference in treatment adherence and illicit opioid abstinence for adult OUD patients enrolled in MAT or 12 step group therapy demonstrated at three months and six months. More specifically, it was anticipated that age, marital status, or gender would demonstrates significantly longer treatment adherence and illicit opioid abstinence when enrolled in MAT at three months and six months after initiation of treatment.

Scientific Advancement

Findings from this study will guide future research related to adult OUD patients by identifying the difference in treatment adherence and illicit opioid abstinence for adults enrolled in MAT or 12-step group therapy.

Chapter 4: Results

This chapter presents the results of the study. First the descriptive characteristics of the sample are presented, followed by the study findings for Aim 1 and Aim 2 comparing treatment adherence and illicit opioid abstinence with opioid use disorder (OUD) patients enrolled in medication assisted treatment (MAT) or 12-step group therapy. In addition, follow-up findings are included for patients at three and six months after initiation of treatments, including comparison between groups after controlling for age, marital status, and gender.

Sample

This was a retrospective electronic medical records (EMR) randomized chart review from June 1, 2017-September 28, 2021. A total of 134 OUD medical records of patients were available for review with 100 meeting inclusion criteria for this study. The final sample consisted of 81 adults with OUD enrolled in MAT (n=47) or 12-step group therapy (n=34).

Demographic Characteristics

Participants in this study were primarily male (51.1%) MAT and (52.9%) 12-step group therapy, with a mean age of 43.2 ± 11 years MAT and 40.4 ± 13 12-step group therapy, single (63.8%) MAT and (61.8%) 12-step group therapy, White Caucasian, and English language dominant (97.5%) (see Table 1).

Table 1: Sample Baseline Characteristics (N=81)

Variable	MAT (<i>N</i> =47)	12-Step Group (<i>N</i> =34)	f (%) or mean ± SD
Current Age	43.2 ±(10.7)	40.4±(12.9)	
Gender			
Male	24(51.1%)	18(52.9%)	
Female	23(48.9%)	16(47.1%)	
Race			
White Caucasian	30(63.8%)	20(58.8%)	
Hispanic Latino	12(25.5%)	4(11.8%)	
Black/AA	5(10.6%)	10(29.4%)	
Marital Status			
Single	30(63.8%)	21(61.8%)	
Married/Legally Separated	8(17%)	5(14.7%)	
Divorced/Widowed	9(19.1%)	8(23.5%)	
Language			
English	45(95.7%)	34(100%)	
Spanish	2(4.3%)		

Note. Abbreviations: SD: Standard Deviation; AA: African American; 12-step: 12-Step Group Therapy; MAT: Medication Assisted Treatment.

Aim 1

To compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in 12-step group therapy at three and six months after initiation of treatment.

Hypothesis 1

There is a significant difference in treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in 12-step group therapy at three months and six months after initiation of treatment.

Analysis for Aim 1 and Hypothesis 1

Adherence/Abstinence

A 14-panel urine drug screen (14-UDS) screen was utilized to determine adherence to treatment and abstinence to illicit opioids in both treatment programs at three months and six months after initiation of treatment. The participants were considered non-adherent if the 14-UDS showed a presence of or had an opioid, or cocaine, or medicines that were not prescribed when tested at three and six months after initiation of treatment.

A total of 47 patients enrolled in MAT were compared to 34 patients enrolled in 12-step group therapy by using the 14-UDS test results at the three and six months after initiation of treatment program. Adherence for each treatment programs at three months indicated that MAT patients were 76.6 % adherent and for 12-step group therapy patients were 76.5% adherent. Adherence at six months for MAT was 68.1% (n=32) and for 12-step group therapy 76.5% (n=26) (see Table 2).

A two-way contingency table analysis was conducted to evaluate the hypothesis that there is a significant difference in treatment adherence and illicit opioid abstinence in adult OUD patients enrolled in MAT or 12-step group therapy at three months and six months points in time after initiation of treatment. There was not a significant difference between treatment groups at three months $\chi^2(1) = 0.000, p = 0.990$, and at six months $\chi^2(1) = 0.459, p = 0.498$ (see Table 2).

Aim 2

To compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT to treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in 12-step group therapy after controlling for age, marital status, and gender.

Hypothesis 2

Treatment adherence and illicit opioid abstinence of adults OUD patients is not different between those enrolled in MAT to those enrolled in 12-step group therapy after controlling for age, marital status, and gender.

Analysis for Aim 2 and Hypothesis 2

Binary Logistic regression was conducted to determine the extent to which the enrollment in MAT as opposed to 12-step group therapy was associated with different levels of treatment adherence and illicit opioid abstinence of adult OUD patients at three months and six months, after controlling for age, marital status, and gender. Model fit statistics revealed the model fits the data since the Hosmer-Lemeshow Goodness-of Fit test is not significant for either regression indicating an acceptable model. Regression coefficients, Odds Ratio, and their confidence interval (CI) are presented in Table 3. Treatment program was not significantly associated with adherence ($B = 0.254, p = 0.667, OR = 1.289, 95\% CI [0.406, 4.098]$). However, gender was significantly associated with adherence and abstinence at three months and six months ($B = 1.410,$

$p = 0.021$); ($B=2.520$, $p= 0.003$). The odds ratio for gender at three months $OR = 4.096$, 95% CI [1.231, 13.628] and OR ratio for gender at six months $OR = 12.231$, 95% CI [2.347,65.845] indicated adherence and abstinence more likely for women. Marital status and age were not significantly associated with adherence (see Table 3 & 4).

A second binary logistic regression was conducted to determine the extent to which enrollment in MAT compared to 12-step group therapy was associated with different levels of treatment adherence and illicit opioid abstinence of adult patients after controlling for age, marital status, and gender. Model fit statistics revealed the model fits the data since the Hosmer-Lemeshow Goodness-of-Fit is not significant ($-2 \text{ Log Likelihood} = 80.226$ and Hosmer-Lemeshow Goodness-of-Fit $= 10.590$, $p = 0.158$). The Hosmer-Lemeshow Goodness-of-Fit tested the null hypothesis that there is no difference between the predicted probabilities and observed adherence and abstinence. The Omnibus Test of Model Coefficients shows the generated model was not significantly different from the constant only model, $\chi^2(7) = 19.266$, $p = 0.007$ (see Table 4).

Summary

Study findings indicate there was no significant difference in adherence and abstinence when comparing OUD treatments MAT and 12-step group therapy. However, gender was identified as a predictor of adherence and abstinence after controlling for age, marital status, and gender. Overall, findings indicated that from the participants that were adherent, women were more adherent than men at three and six months.

Table 2: Adherence to Treatment Program at 3 and 6 Months

Treatment		MAT	12-Step
Adherence at 3 months	YES	36(76.6 %)	26(76.5%)
	NO	11(23.4%)	8(23.5%)
Total		47(100 %)	34(100%)
Adherence at 6 months	YES	32 (68.1%)	26(76.5%)
	NO	15 (31.9%)	8(23.5%)
Total		47(100%)	34(100%)

Note: 3-months $\chi^2(1) = 0.000, p = 0.990$; 6-months $\chi^2(1) = 0.459, p = 0.498$

Abbreviations: MAT; medication assisted treatment; 12-Step; 12-Step Group Therapy.

Table 3: Logistic Regression Analysis Summary for Predictors of Adherence and Abstinence at 3 Months

Variables	B	S. E	Wald	Significance	Odds Ratio	95% CI
Current Age	-0.292	0.288	1.023	0.312	.747	0.424 1.314
Gender						
Male						
Female	1.410	0.613	5.286	0.021*	4.096	1.231 13.628
MAT/12-Step	0.254	0.590	0.185	0.667	1.289	0.406 4.098
Single			0.696	0.706	0.000	
Married/Legally Separated	-0.682	0.830	0.675	0.411	0.506	0.099 2.572
Divorced/Widowed	-0.429	1.012	0.180	0.671	0.651	0.090 4.730
White Caucasian			2.085	0.353	0.000	
White Hispanic	0.113	0.718	0.025	0.875	1.120	0.274 4.574
Black/ AA	-1.147	1.027	1.249	0.264	0.317	0.042 2.375
Constant	-0.627	1.468	0.182	0.670	0.534	

Note. Df = 7 Hosmer-Lemeshow Goodness-of Fit = 10.59, $p = 0.158$ (N = 81), * significance

0.05. Abbreviations: MAT; medication assisted treatment; 12-Step; 12-Step Group Therapy;

AA; African American

Table 4: Logistic Regression Analysis Summary for Predictors of Adherence and Abstinence at 6 Months

Variables	B	S. E	Wald	Significance	Odds Ratio	95% CI
Current Age	-0.357	0.344	1.075	0.300	0.700	0.356 1.374
Gender						
Male						
Female	2.520	0.851	8.779	0.003*	12.431	2.347 65.845
MAT/12-Step Group	0.469	0.686	0.467	0.494	1.598	0.417 6.125
Single			1.125	0.570	0.000	
Married/Legally Separated	0.612	1.102	0.308	0.579	1.844	0.213 15.979
Divorced/Widowed	-0.358	1.373	0.068	0.794	0.699	0.047 10.297
White Caucasian			2.791	0.248	0.000	
White Hispanic	0.092	0.839	0.012	0.913	1.096	0.212 5.678
Black/ AA	1.373	1.005	1.866	0.172	3.947	0.550 28.295
Constant	-2.961	1.923	2.370	0.124	0.052	

Note. Df=8 Hosmer-Lemeshow Goodness-of Fit = 5.989, $p=0.648$. ($N=81$), * significance

0.05. Abbreviations: MAT: medication assisted treatment; 12-Step: 12-Step Group Therapy;

AA: African American.

Chapter 5: Discussion

The purpose of this chapter is to discuss the findings of this study. The chapter includes the following topics: discussion, strengths, limitations, impact of this dissertation on the state of the science, and future direction.

Discussion

The goal of this study was to perform a comparative analysis of adherence and illicit opioid abstinence of adult opioid use disorder (OUD) patients enrolled in medication assisted treatment (MAT) and adult OUD patients enrolled in 12-step group therapy at three months and six months after initiation of treatment. Furthermore, the study aimed at comparing adherence and illicit opioid abstinence in OUD patients enrolled in MAT and 12-step group therapy after controlling for age, marital status, and gender. Based on the researcher's knowledge, this prospective longitudinal study at three and six months after initiation of treatment is the first study comparing two forms of treatments for OUD.

Study results indicate that there was not a significant difference in adherence and illicit opioid abstinence at three and six months between programs MAT and 12-step group therapy. Study findings are consistent with reports that support both MAT and 12-step group therapy as treatment programs associated with improved adherence to treatment and illicit opioid abstinence (Abdollahi et al., 2020; Azkhosh et al., 2016; Topmiller et al., 2018).

The second aim of this study was to compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MAT and 12-step group therapy, after controlling for age, marital status, and gender. Gender was the only variable that was significant for

adherence and abstinence at three months, $p < 0.021$, and six months, $p < 0.003$, in their treatment programs. There is little evidence regarding gender specific predictor in the literature (Kerridge et al., 2015). Neither age nor marital status were predictors of adherence and abstinence. A longer longitudinal study of treatment abstinence and adherence may identify other variables with the potential to impact the outcomes of interest.

The opioid epidemic was a public health crisis prior to the coronavirus, or COVID-19, pandemic (Alexander et al., 2020; Volkow, 2020). The pandemic has threatened everyone's social determinants of health (SDOH), particularly the marginalized OUD patients (Alexander et al., 2020). The acute disruption in treatment programs due to rising rates of COVID infection and mandated isolations and shutdowns have created a strain to access mental health care resources. (Alexander et al., 2020; Volkow, 2020). Exploring further how social determinants of health impact access to treatment programs and influence adherence and abstinence for the OUD population is of essence.

Understanding the predictors of OUD will assist in improving outcomes and SDOH. The cost of 12-step group therapy is relatively inexpensive, and it is readily available to OUD patients. However, laboratory monitoring using the 14-panel urine drug screen costs approximately \$80 dollars per month. Despite the lower cost and logistic benefits associated with 12-step group therapy, attendance and participation is very inconsistent and participants have a high rate of relapse (Medlock et al., 2017). In contrast, the National Institute on Drug Abuse (NIDA) states that MAT treatment's outpatient costs range from \$460 to \$1,176 per month. The CDC considers MAT the gold standard and best treatment option for OUD patients (McCollister et al., 2018). However, there remains a significant cost barrier and a gap in trained providers.

Strengths

The use of a quasi-experimental design facilitated the evaluation of two interventions thus improving the level of evidence associated with adherence and abstinence for a sample of OUD patients. The two comparative treatment groups were very similar in sample size and demographic characteristics, thus increasing the researcher's confidence that if differences emerged, were due to the treatments evaluated, and not due to patient differences (Abdollahi et al., 2020; Azkhosh et al., 2016; Topmiller et al., 2018).

Limitations

The selection of participants for this study was limited to the use of electronic health records at one clinical site. Data were limited to what others reported, what was available in the medical record, and by access provides by a Senior Analyst. These limitations were minimized by randomly selecting participants that met inclusion criteria of both treatment programs from electronic medical records. However, conducting a prospective randomized longitudinal study may have been beneficial to prevent these limitations. The quasi-experimental design does not allow for randomization to experiment or the ability to control. It also cannot test for a causal relationship.

The majority of the sample consisted of single, white, English-speaking participants. This sample does not represent the population of the Southeast region of Florida. As a result of this limitation generalizability of the study findings to other ethnic groups is not possible.

The study only included OUD participants treated with the Food and Drug Administration (FDA) approved medication, buprenorphine. As a result, individuals using other MAT FDA-approved medication were not included. Furthermore, participants in the 12-step

group therapy were not observed during their participation in the treatment program, limiting the ability to determine if other factors influenced abstinence and adherence.

Impact of Dissertation on the State of the Science

No study to date has examined or compared the impact of OUD treatments MAT and 12-step group therapy by utilizing outcome variables adherence and illicit opioid abstinence and integrating a 14-panel urine drug screen for assessing adherence and abstinence. Although empirical evidence states that both MAT and 12-step group therapy are effective OUD treatments, a gap remained in comparing these two types of treatment for OUD. (Abdollahi & Haghayegh, 2020; Azkhosh et al., 2016; Haigh et al., 2019; Lee et al., 2018; Liebschutz et al 2014; Lo Coco et al., 2019; Lofwall et al., 2018; Mitchell et al., 2013; Mokri et al., 2016; Neumann et al., 2020; Rosenthal et al., 2016; Ruglass et al., 2019; Sullivan et al., 2017; Sullivan et al., 2019; Tanum et al., 2017; Watkins et al., 2017; Weiss et al., 2019). In this dissertation, my research findings have 1) provided preliminary evidence on treatment adherence for adults enrolled in MAT or 12-step group therapy, and 2) provided preliminary evidence on predictors of adherence to treatment program utilizing specific demographics of age, marital status, and gender.

Future Direction of Research

This study sought to examine adherence and illicit opioid abstinence in adult opioid disorder patients enrolled in MAT or 12-step group therapy at a facility in a southeast region of the United States. Although findings demonstrated that there were no significant differences in adherence and illicit opioid abstinence between MAT and 12-step group therapy, future studies analyzing adherence and abstinence of OUD patients enrolled in MAT or 12-step group therapy in a randomized control trial, integrating a longitudinal approach are of essence. In addition,

exploring the OUD patient's perceptions of barriers to treatment adherence and abstinence, may assist to better understand adherence and abstinence, based on patients' experiences.

This dissertation study identified no statistical difference between treatment groups, and gender as predictor of adherence and abstinence. Among those OUD participants that were adherent to their treatment program, women had higher adherence than men at three and six months. Improving the identification of predictors of adherence has the potential to facilitate understanding of adherence and abstinence patterns associated with treatment programs for OUD patients. These preliminary findings will be of assistance in the planning and implementation of future studies, and consequently, improving the future direction of the science that guides the management of adults with opioid use disorder. The integration of a randomized controlled trial to explore longer longitudinal treatment adherence and abstinence will assist with a more rigorous research process that enhances the value of research findings.

The perceptions of adherence and abstinence of OUD patients were not explored in this study. The integration of qualitative methods will be of assistance to understand OUD patients' beliefs and experiences, as it relates to adherence and abstinence. For instance, this dissertation study identified that women had higher adherence at three and six months after treatment initiation. Improving understanding of gender differences may be of assistance in the development of interventions tailored to gender specific needs. Providing continuity to this area of research will be of assistance to improve the future direction of marginalized OUD patients as it relates to adherence and abstinence, including social determinants of health with the potential to impact this vulnerable population.

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