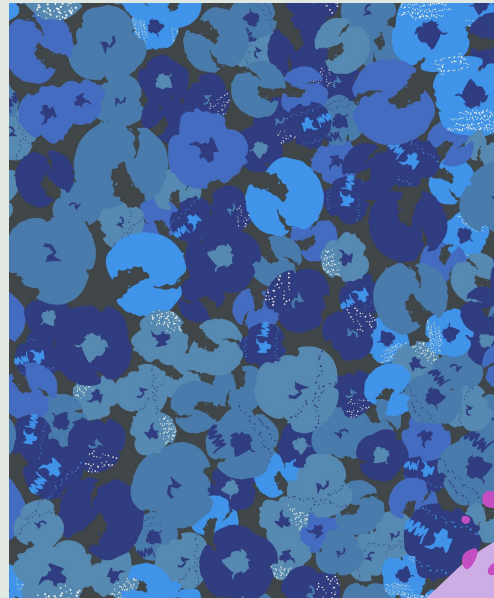


**A Comparative Analysis of  
12-Step Group Therapy and  
Medication for Opioid Use  
Disorder on Treatment  
Adherence and Abstinence  
in Patients with Opioid Use  
Disorder**

NOAP Presentation

**Derrick C. Glymph, PhD, DNAP,  
CRNA, CHSE, COL., USAR,  
FAANA, FAAN**



**Disclosure  
Statement**

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I have no financial  
relationship with any  
commercial interest related  
to the content of this  
presentation

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I will not be discussing off-  
label use during this  
presentation

**Objectives-**  
**The learner will**  
**be able to:**

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List FDA approved medication  
for OUD

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Describe steps in 12-step  
Program

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Compare Outcomes of two  
Programs

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Predict difference in outcomes  
using specific variables



## Introduction

41.1 million people in the US over the age of 12 needed addiction treatment.

2.7 million people who need TX for OUD are not receiving it. Losing battle!

20% of OUD patients have misused a prescription opioid at least once in their lifetime.

50% of individuals who start on MOUD remain adherent.

(Cicero et al., 2015; Compton et al., 2016; Kern et al., 2020; Mattson et al., 2017, NSDUH, 2020).



**Empirical studies indicate most OUD patients need at least three months of adherence to treatment to significantly reduce or stop opioid use.**

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



# DSM-V Criteria for Substance Use Disorder

Impaired Control

Social Problems

Tolerance and Withdrawal

Risky Use

11 Criteria under the above Categories

- Mild: 2-3 criteria met
- Moderate: 4-5
- Severe: 6 or greater

## Clinical Opioid Withdrawal Score (COWS)

Patient's Name _____ Date and Time ____/____/____	
Reason for this assessment _____	
<b>Resting Pulse Rate:</b> _____ beats/minute <i>Measured after patient is sitting or lying for one minute</i> 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 3 pulse rate greater than 120	<b>GI Upset over last 1/2 hour</b> 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 4 multiple episodes of diarrhea or vomiting
<b>Sweating over past 1/2 hour not accounted for by room temperature or patient activity:</b> 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 <del>severe sweating</del> on face	<b>Tremor observation of outstretched hands</b> 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
<b>Restlessness Observation during assessment</b> 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds	<b>Yawning Observation during assessment</b> 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
<b>Pupil size</b> 0 pupils pinpoint or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	<b>Anxiety or Irritability</b> 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable or anxious 4 patient so irritable or anxious that participation in the assessment is difficult
<b>Bone or joint aches If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored</b> 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	<b>Gooseflesh - skin</b> 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection
<b>Runny nose or tearing Not accounted for by cold symptoms or allergies</b> 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	Total Score _____ The total score is the sum of all 11 items Initials of person completing assessment: _____

Score 5-12 = mild, 13-24 = moderate, 25-36 = moderately severe, more than 36 = severe withdrawal  
 This version may be copied and used clinically.

Scoring

Scores range from 0 to 47

Withdrawal:

- mild (5-12)
- moderate (13-24)
- moderately severe (25-36)
- severe (>36)

## Definitions

**MOUD:** Three FDA-approved OUD medications methadone, buprenorphine, and naltrexone, in combination with counseling and behavior therapies that prevent opioid relapses a wholistic approach to stabilize and maintain treatment (Carroll & Weiss, 2017; Humphreys et al., 2018; Kim et al., 2015; Korthuis et al., 2017; Levin et al., 2016; McElrath, 2018).

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

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

## A Review of Treatment Acronyms

Medication Assisted Treatment: the use of medications with counseling and behavioral therapies to treat substance use disorders and prevent opioid overdose.

- MAT: Medication Assisted Treatment
- MAT: Medication for Addiction Treatment
- **MOUD: Medication for Opioid Use Disorder (preferred)**
  
- OAT: Opioid Agonist Therapy (methadone, buprenorphine)
- OBOT: Office Based Opioid Treatment (buprenorphine, naltrexone)
- OBAT: Office Based Addiction Treatment (all forms of MOUD and treatment of any substance use disorder)
- OTP: Opioid Treatment Program (methadone predominantly; can provide buprenorphine)

## Treatment Programs

Medication for Opioid Use Disorder (MOUD)

12 Step Group Therapy

### Latest Update: Congressional Action

On December 23, 2022, Congress passed Consolidated Appropriations Act, 2023 (also known as Omnibus bill). Behavioral health and substance use prevention, treatment and recovery will see benefits from the new laws.

In Summary the following 2 Acts (passed and signed into law) will have impact on Addiction Medicine:

**Mainstreaming Addiction Treatment Act (MAT):** this Act eliminates the 'X' Waiver requirement to prescribe buprenorphine, eliminates the Federal patient limits and reporting requirements (SAMHSA issued statement on 1/12/23 'effective immediately')

**Medication Access and Training Expansion Act (MATE):** this Act has several components and will require a one-time 8 hour training in evaluation, treatment, and management of Substance Use Disorders for all new medical providers applying for DEA license and others at next renewal of their DEA license.

**\*\*\*The Implementation of MATE Act:.** The SAMHSA/CSAT and DEA issued guidance with active date starting June 27, 2023.

Evidence-Based Practice: MOUD  
(Medication for Opioid Use Disorder)

•**Methadone**

- Full opioid agonist
- Available since 1970s
- In US only available in certified OTP programs with strict regulations around administration
- Strong evidence base- increases retention in treatment and reduces mortality

•**Buprenorphine** (Suboxone®, Bunavail™, Zubsolv®, Subutex, Sublocade injection, buprenorphine and buprenorphine/naloxone tab generic)

- Partial opioid agonist (has ceiling effect- safer for overdose risk)
- FDA approved for OUD since 2002 and able to be prescribed in outpatient settings with DATA waiver (Primary care, etc)
- Initially only physicians (MD/DO) were able to get 'X' Waiver, then Comprehensive Addiction and Recovery Act (CARA) of 2016 approved Nurse Practitioners and Physicians Assistants, with prescribing limits, but X waiver requirement removed at end of 2022
- Strong evidence- increases retention in treatment and reduces mortality

•**Injectable Extended Release (ER) Naltrexone** (Vivitrol®)

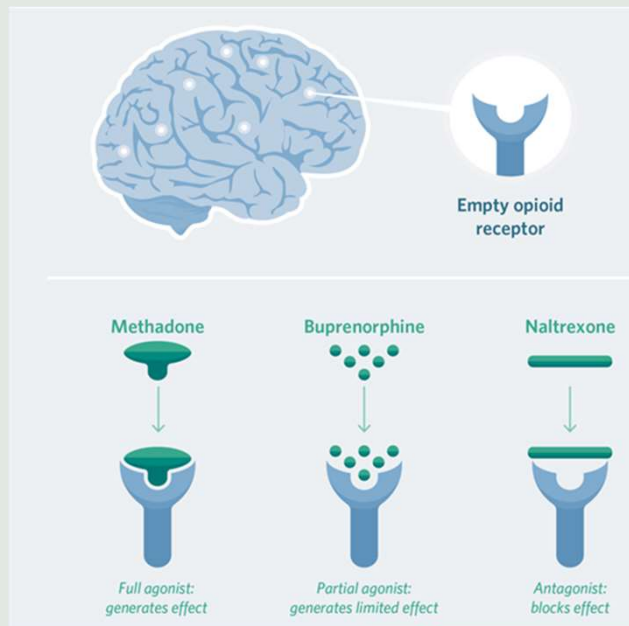
- Opioid antagonist
- FDA approved in 2010
- Evidence not as robust for OUD- increases retention in treatment; difficulty in initiation

from *Treating Addiction in the Chronic Care Model: The Value of Hub and Spoke.*  
Elizabeth Salisbury-Afshar, MD

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# MOUD

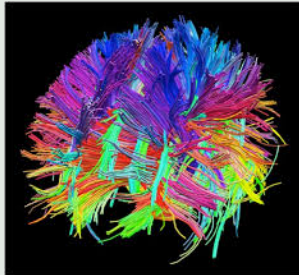
Three FDA-approved OUD medications, Methadone, Buprenorphine, and Naltrexone, in combination with counseling and behavior therapy



## Addiction as a Brain Disease

National Institute on Drug Abuse, American Society of Addiction Medicine, American Medical Association, amongst others:

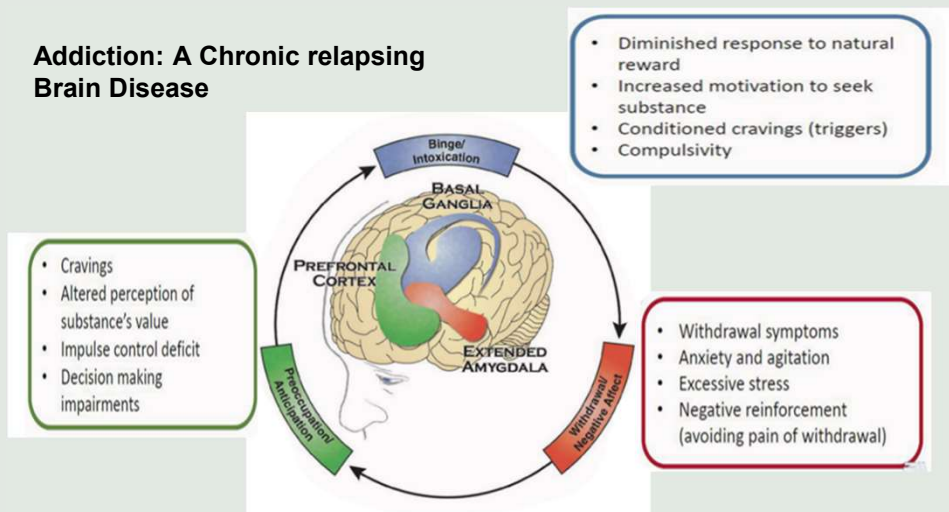
Addiction is a **chronic, relapsing brain disease** with compulsive drug seeking and use despite harmful consequences



The 4 C's of Addiction:

1. Compulsion
2. Craving
3. Consequences
4. Control

### Addiction: A Chronic relapsing Brain Disease



Adapted from HHS (2016), Facing Addiction in America available at : <https://addiction.surgeongeneral.gov/sites/default/files/chapter-2-neurobiology.pdf>



## *Psychosocial Therapies to treat OUD*

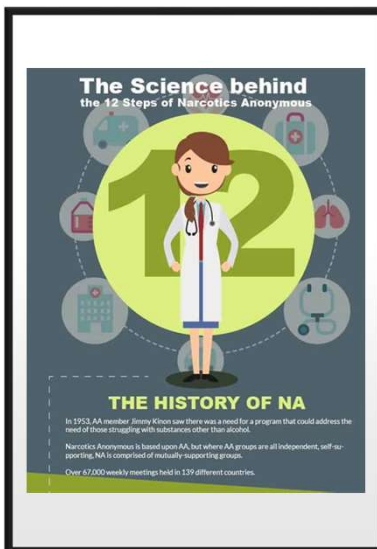
Twelve Step Facilitation

Cognitive-Behavioral Therapy

Motivational Enhancement Therapy

Community Reinforcement

Contingency Management



- Avoids FDA-approved medications
- NA utilizes peer support
- Outlines what one achieves during the recovery process
- The goal is for the patient to stop using and to become abstinent from illicit opioids



### **12-Step “Six pack”**

- 1. Don’t drink or use drugs,**
- 2. Go to meetings**
- 3. Ask for help**
- 4. Get a sponsor**
- 5. Join a group**
- 6. Get active (Caldwell & Cutter, 1998).**

## **Statement of the Problem**

- Less than 50% of adult patients adhere to MOUD 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).
- Limited evidence exists on how demographic, socioeconomic, behavioral, and psychological variables predict treatment adherence and illicit opioid abstinence of adult OUD patients that are enrolled in MOUD 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).

## Significance to Nursing

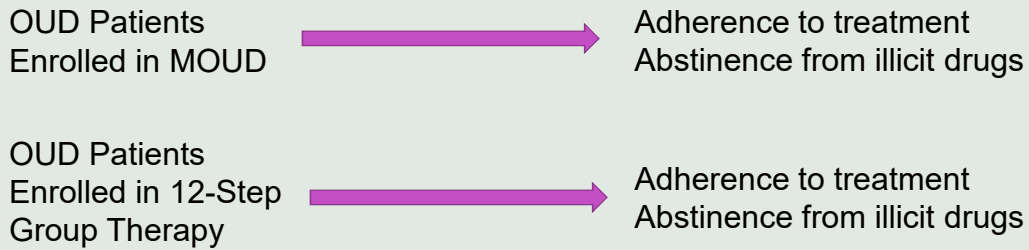
- More urgent than ever: Opioid epidemic has caused 700,000 deaths and led 2.1 million people to misuse prescription opioids in the U.S (WHO, 2019).
- FDA-approved MOUD and 12-step group therapy for OUD are effective at increasing treatment adherence and abstinence from illicit opioids.
- Treatment dropout rates and the relapse to illicit opioid use after treatment initiation remains high (Bose et al., 2018; Han et al., 2017; Lilly, 2018; Volkow et al., 2019).

## Gaps in the Research

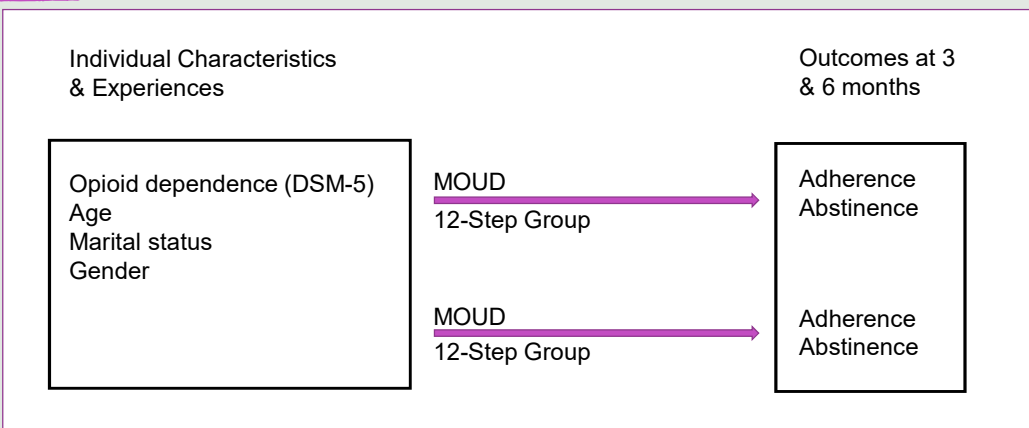
Areas that have received limited attention:

- RCT and longitudinal studies
- Predictors of adherence and abstinence
- SDOH factors for adherence
- Perception of OUD patients as it relates to adherence and abstinence

## Study Design Prospective, Quasi-Experimental



## Conceptual Framework



Adapted from Nola J. Pender (1996) Health Promotion Model (HPM)

## Aim 1

- To compare treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MOUD 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 MOUD and 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 MOUD 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 1:** Treatment adherence and illicit opioid abstinence of adult OUD patients are not different between those enrolled in MOUD to those enrolled in 12-step group therapy after controlling for age, marital status, and gender.

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# METHODS

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## Population



Adults who meet DSM-V Dx  
of OUD and lived in Florida

## Sample

Individuals who actively received treatment at an outpatient treatment center located in the southeast region of Florida.



## Inclusion and Exclusion Criteria



### Inclusion Criteria

- Age > 18 years old
- *DSM-V* Dx of OUD
- Enrolled in MAT or 12-step group therapy for at least six months

### Exclusion Criteria

- Age < 18 years old
- Individuals with major mental disorders or illnesses documented by *DSM-V* (e.g., Schizophrenia, Catatonia, Psychosis, or dissociative disorders).

# IRB

 <p style="text-align: center;">EXEMPT DETERMINATION</p> <p>October 5, 2021</p> <p>Derrick Glymph 945 NW 203rd Avenue Pembroke Pines, FL 33029</p> <p>Dear Dr. Derrick Glymph:</p> <p>On 10/5/2021, the IRB reviewed and approved the following protocol:</p> <table border="1"> <tr> <td>Application Type:</td> <td>Initial Study</td> </tr> <tr> <td>IRB ID:</td> <td>STUDY005185</td> </tr> <tr> <td>Review Type:</td> <td>Exempt 4</td> </tr> <tr> <td>Title:</td> <td>MAT vs 12-Step Group Therapy: A Comparative Analysis of Treatment Adherence and Abstinence in Patients with Opioid Use Disorder</td> </tr> <tr> <td>Funding:</td> <td>None</td> </tr> <tr> <td>Protocol:</td> <td>MAT vs 12-Step Group Therapy: A Comparative Analysis Study Protocol Glymph review 10.5.21.docx; No Consents</td> </tr> </table> <p>The IRB determined that this protocol meets the criteria for exemption from IRB review.</p>	Application Type:	Initial Study	IRB ID:	STUDY005185	Review Type:	Exempt 4	Title:	MAT vs 12-Step Group Therapy: A Comparative Analysis of Treatment Adherence and Abstinence in Patients with Opioid Use Disorder	Funding:	None	Protocol:	MAT vs 12-Step Group Therapy: A Comparative Analysis Study Protocol Glymph review 10.5.21.docx; No Consents	 <p style="text-align: right;">3501 Johnson Street, Hollywood, FL 33021 Phone (954) 265-1857   E-mail: irb@mhs.net FWAR 00003898   IRB Registration # 00003075</p> <p>October 20, 2021</p> <p>Andrew Migliaccio, MD 3400 N. 29th Ave. Hollywood, FL 33020</p> <p>IRB Project#: MHS 2021.126</p> <p><b>Project Title:</b> MAT vs 12-Step Group Therapy: A Comparative Analysis of Treatment Adherence and Abstinence in Patients with Opioid Use Disorder</p> <p><b>Submission Type:</b> Human Subjects Research Application – Initial Review (Reference# 007675)</p> <p>Dear Investigator:</p> <p>The Memorial Healthcare System Institutional Review Board (IRB) has reviewed the proposed activity referenced above and determined that it is <b>exempt</b> from the requirement for IRB oversight as outlined in 45 CFR 46.101 or</p>
Application Type:	Initial Study												
IRB ID:	STUDY005185												
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# Data Acquisition

- IT department of the study site provided access to EMR based on the study inclusion and exclusion criteria.
- Data was extracted from patients' EMRs by the IT department.
- Data was shared with PI via a password-protected Excel sheet.
- Data was then imported into SPSS 27® and coded for analysis.



## Operational Definitions

- **Adherence:** Participants were positive for FDA-approved MOUD 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

- Demographic data tool—age, marital status, gender, and race.
  - Collected retrospectively from EMR
- Treatment adherence and illicit opioid abstinence by both groups MOUD & 12-step group therapy
  - Point of Care Marketplace Urine Drug Screen™
  - Urine sample from the participants to detect up to 14 drugs located in EMR



## Analysis Plan

- Univariate and bivariate analysis of demographic variables was performed to describe variables
- **AIM 1: Chi-square test**
  - To determine if there is a significant difference in treatment adherence and illicit opioid abstinence of adult OUD patients enrolled in MOUD and adult OUD patients enrolled in 12-step group therapy at three months and six months after initiation of treatment.
- **AIM 2: Two binary logistic regression models at three months and six months**
  - To predict adherence and illicit opioid abstinence of adult OUD patients using the dichotomous dependent variable. The test controlled for covariates age, marital status, and gender.

## Results

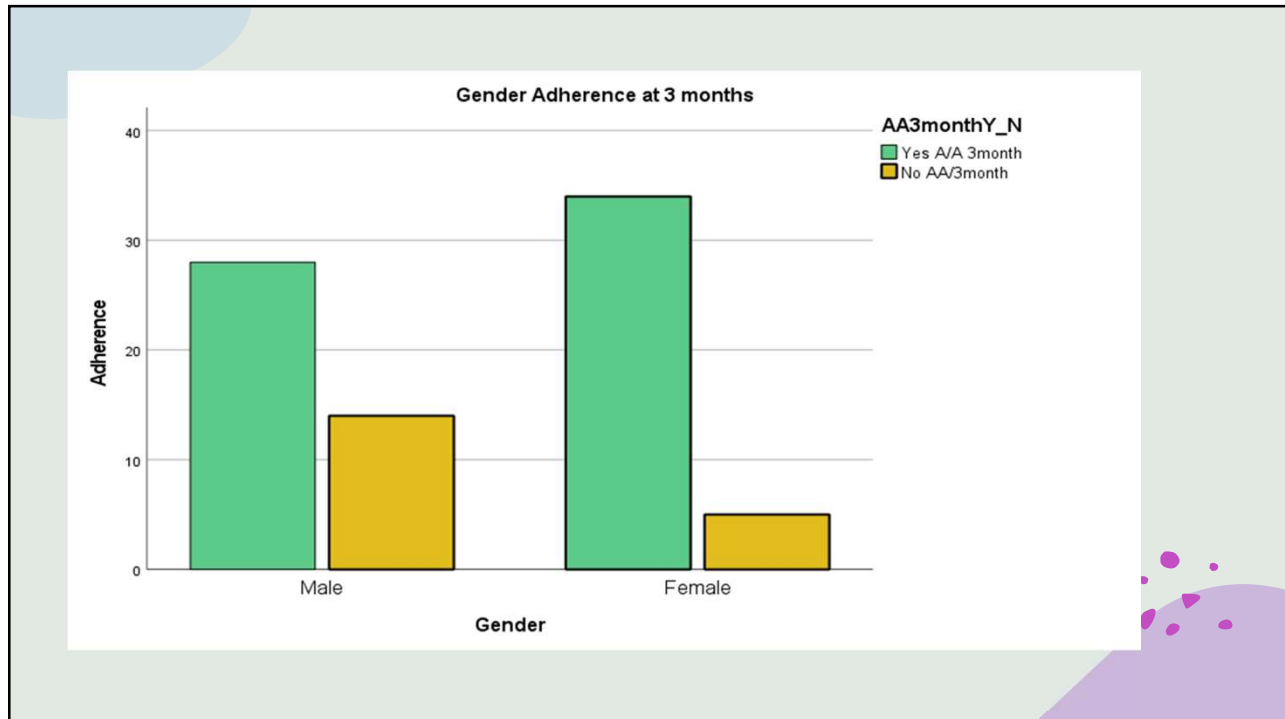
<i>Sample Baseline Characteristics (N=81)</i>			
<b>Variables</b>	<b>MAT (N=47)</b>	<b>12-step Group (N=34)</b>	<b>f (%) or mean ± SD</b>
Current Age	43.2 ±(10.7)	40.4±(12.9)	
<b>Gender</b>			
Male	24(51.1%)	18(52.9%)	
Female	23(48.9%)	16(47.1%)	
<b>Race</b>			
White Caucasian	30(63.8%)	20(58.8%)	
Hispanic Latino	12(25.5%)	4(11.8%)	
Black/AA	5(10.6%)	10(29.4%)	
<b>Marital Status</b>			
Single	30(63.8%)	21(61.8%)	
Married/Legally Separated	8(17%)	5(14.7%)	
Divorced/Widowed	9(19.1%)	8(23.5%)	
<b>Language</b>			
English	45(95.7%)	34(100%)	
Spanish	2(4.3%)		
<i>Note.</i> Abbreviations: SD: Standard Deviation; AA: African American; 12-step: 12-Step Group Therapy; MAT: Medication Assisted Treatment.			

<i>Adherence to Treatment Program at 3 and 6 months</i>			
Treatment		MAT	12-Step
Adherence at 3months	YES	36(76.6 %)	26(76.5%)
	NO	11(23.4%)	8(23.5%)
<b>Total</b>		47(100 %)	34(100%)
Adherence at 6 months	YES	32 (68.1%)	26(76.5%)
	NO	15 (31.9%)	8(23.5%)
<b>Total</b>		47(100%)	34(100%)
<i>Note:</i> 3-months $\chi^2 (1) = 0.000, p = .990$ ; 6-months $\chi^2 (1) = 0.459, p = .498$			
Abbreviations: MAT; medication assisted treatment; 12-Step; 12-Step Group Therapy.			

**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	

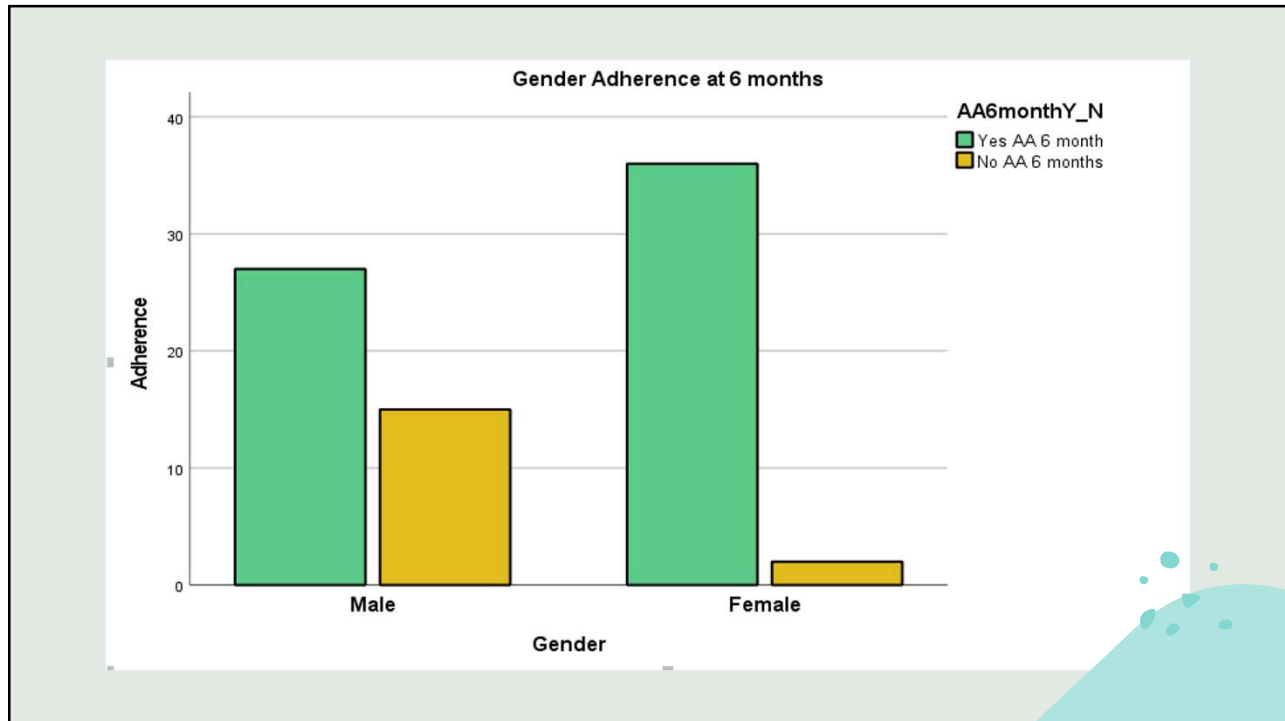
*Note.* Df = 7 Hosmer-Lemeshow Goodness-of Fit = 10.59,  $p = 0.158$  (N =81), \* significance 0.05.  
 Abbreviations: MAT; medication assisted treatment; 12-Step; 12-Step Group Therapy; AA; African American



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 = 9.967,  $p = .27$ , (N = 81), \* significance 0.05.  
 Abbreviations: MAT: medication assisted treatment; 12-Step: 12-Step Group Therapy; AA: African American.



## Summary

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- Study findings indicate there was no significant difference in adherence and abstinence when comparing OUD treatments MOUD and 12-step group therapy.
- Among the OUD participants that were adherent, there were more women than men.
- Findings indicated that women were more adherent than men in this sample at three months and six months.

## Discussion

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## Strengths

- The two interventions that are commonly used for OUD
- Very similar in sample size and demographic characteristics



## Limitations

- Sample size
- The selection of participants was limited to one for-profit clinical site
- Data collection was dependent on data that already existed
- The quasi-experimental design does not allow for randomization to experiment or the ability to control; it also cannot test for a causal relationship
- Generalizability of the study findings is not possible
- Only one FDA medication, buprenorphine, was used in MOUD
- Perceptions of barriers to adherence were not considered for any of the participants

## Implications for Practice

- There has been no study to date that examined or compared the impact on adherence and abstinence specifically with opioid use disorder treatments MOUD and 12-step therapy utilizing a 14-panel urine drug screen for assessing adherence and abstinence.
- Empirical evidence states that both MOUD and 12-step group therapy are basically 50% effective at treating opioid use disorder (Volkow, 2020).

## Implications for Research

### **Evaluation of other predictors**

- Gender and adherence
- Psychosocial support
- Socioeconomical
- Social Determinants of Health

### **Methods**

- Longitudinal and RCT approach
- Mixed-method approach
- Larger sample size



## Social Determinants of Health (SDOH)

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- The marginalized OUD patients, acute disruption in treatment programs due to the rise in COVID-19 infections, and mandated isolations and shutdowns have created a strain on access and mental health (Alexander et al., 2020; Volkow, 2020).
- Understanding the predictors of OUD will assist in improving outcomes and SDOH.

## Future Direction

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- Exploring further OUD patients enrolled in MOUD or 12-step group therapy in a randomized control trial to explore longer longitudinal treatment adherence and abstinence.
- Exploring OUD patients' perceptions of barriers to treatment adherence and abstinence.

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