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NCT ID: NCT04233671

Grant Number: R61AT010802-01

Official Title: A Mindfulness and Peer Mentoring Program to Improve Adherence to Medication Assisted Treatment for Opioid Use Disorders

Document Date: July 19, 2021

MiMP R61 ANALYTIC PLAN

AIM 1 [R61]: To establish the feasibility and acceptability of the Minds and Mentors Program (MiMP) for individuals on medications for OUD (MOUD; n = 20).

Objective 1: Successfully train counselors and peer mentors, recruit and randomize 20 individuals on MOUD for OUD into the group based MiMP or TSF, and successfully implement the programs within the first two years.
Hypothesis 1: Successfully train two counselors and two peer facilitators; the MiMP will demonstrate enrollment, randomization, and retention rates ≥ 50%; and ≥ 50% of participants will positively endorse MiMP as acceptable.

Objective 2: Prior to the R33 comparing between-group differences in adherence (primary outcome), we will examine pre- to post-intervention (within-subject) changes in self-reported craving, relapse, stress, anxiety, depression, and social support (secondary outcomes) to determine whether there is preliminary evidence that these outcomes can be improved in those receiving the MiMP.
Hypothesis 2: The MiMP will produce reductions in one or more of the following: self-reported stress, cravings, depression, or anxiety, or improvements in perceived social support.

The primary outcome variable is **adherence to MOUD,** quantified as the number of days MOUD was received as indicated during the last 4 weeks of the intervention period. We expect that this can be treated as a continuous variable in regression models. However, prior to modeling we will examine its distribution, to determine if this is appropriate. If, for example, we observe large ceiling effects (many participants report very high or perfect adherence) then we may model non-adherence as the number of days when MOUD was not received. In this case we expect it would have something similar to a Poisson distribution, possibly with over-dispersion which would suggest the use of negative binomial regression. The secondary outcome of **relapse** will be treated in two ways, as a binary indicator if any relapse during the last 4 weeks of the intervention period as determined by UDS or self-report, and the total number of self-reported days of use during the last four weeks of the intervention period. The first dichotomous outcome will require logistic regression. The second approach will depend on the observed distribution and may be treated as either negative binomial or continuous. The other secondary outcome, **cravings**, can be treated as continuous, which will also be true for the ancillary outcomes including depression, anxiety, and stress, are continuous variables.

The table below shows all other secondary measures and the instruments used to measures each of the variables. These instruments are also consistent with data harmonization efforts by the NIH HEAL Initiative. Data collection will happen in accordance the timeframes stipulated above, T0 - T4. To examine within-subject and between-subject differences from pre to post intervention using repeated measures analysis of covariance (ANCOVA), including covariates, as necessary. Study outcomes will be also be examined using longitudinal regression models, including covariates, as necessary. The full model will include fixed within-subject effects to predict outcomes (stress, depression, anxiety, cravings, self-efficacy, baseline cortisol, cortisol reactivity).

Instrument	Construct	Instrument	Construct
Opioid Craving Scale	Craving	PROMIS Pain Intensity	Pain Intensity
Perceived Stress Scale	Stress	PROMIS Pain Interference	Pain Interference
Generalized Anxiety Disorder 7	Anxiety	PROMIS Pain Catastrophizing	Pain Catastrophizing
Patient Health Questionnaire-9	Depression	Sleep Scale from the Medical Outcomes Study	Sleep
Community Assessment Index	Community Integration	Patient Global Impression of Change	Treatment efficacy
PROMIS Quality of Life	Quality of life	BPI Pain Severity	Pain Severity

Cortisol Data Analyses: This type of analysis will also be used in assessment of the cortisol data (i.e., stress reactivity) to examine the effects of treatment on baseline (resting) cortisol levels and cortisol reactivity. Cortisol data is often skewed,[100] so transformations may be performed. The cortisol response will be quantified by calculating the area under the curve (AUC).[101] The trapezoidal formula is given by:

$\sum_{i=1}^{5}[t_i(m_i + m_{i+1})/2]$, where t_i is the interval between sample i and sample i+1 and m_i is the level of cortisol for sample i. In addition, the influence of pre-treatment cortisol (resting and reactivity) on responsiveness to treatment (as measured by our primary outcome variables) will be examined.

A Mindfulness and Peer Mentoring Program to Improve Adherence to Medication Assisted Treatment for Opioid Use Disorders

Please read this informed consent carefully before you decide to join the study.

Consent Form Key Information:

- Attend 12 weeks of group counseling sessions held once a week
- A counselor will lead mindfulness groups for the first 8 weeks. A peer mentor will lead the mindfulness group the next 4 weeks.
- Group counseling sessions will last about 90 minutes each time.
- Complete surveys at the beginning, at week 8, week 12, 12 weeks after sessions and 24 weeks after sessions.
- Give a saliva sample every time you complete the surveys.
- Give a urine drug screen every week.
- You may complete an exit interview at the end of the study, which will last about 30 minutes
- You will be given $15 each time you take surveys and give a saliva sample.
- You will be given transportation aid when you attend sessions in-person.

Purpose of the research study: This study will start group sessions (in-person or via telehealth) that combine mindfulness- based relapse prevention (MBRP) and peer mentoring. This is to improve regular taking of medications for opioid use disorder. We will ask you to fill out some surveys (in-person or via telehealth) at the following five times:

1. Beginning of the study
2. Week 8 of sessions
3. Week 12 of sessions
4. 12 weeks after sessions
5. 24 weeks after sessions

You may be asked to take part in an interview at the end of the study to tell us your thoughts about your time with MBRP and peer mentoring. Each group counseling session will be about 90 minutes.

What you will do in the study: Once you agree to join this study, you will be asked to fill out some surveys (in-person or via telehealth) five time. This is at the beginning of the study, at week 8 of sessions, week 12 of sessions, 12 weeks after sessions, and 24 weeks after sessions. We may ask you to take part in an interview at the end of the study. This is to tell us your thoughts about your time with MBRP and peer mentoring sessions. This interview will be audio taped. If completed using telehealth, the session will be recorded without video.

After you agree to be part of the study, you will be placed in one of two groups. These are the MBRP group or the twelve-step facilitation (TSF) groups. If you are in the TSF group, you will attend weekly sessions of the TSF for 12 weeks (in-person or via telehealth). After these sessions, you will be required to come back and fill out the same

surveys you completed at the beginning of the study at 12-week and 24-week follow up periods.

If you are in the MBRP group, you will attend 12 weekly sessions. The first 8 weeks will be with a counselor. The next 4 weeks will be with a peer mentor (in-person or via telehealth). After these sessions, you will be required to come back and fill out the same surveys you completed at the beginning of the study at 12-week and 24-week follow up periods.

For both groups, you will have to provide a weekly urine sample for the first 12 weeks of the study. Last, you may take part in an exit interview that will take about 30 minutes. This interview will be audio taped. If completed using telehealth, the session will be recorded without video.

If these group sessions are in-person, they will either be held at the University of Alabama College of Nursing, a location of Pathway Healthcare LLC or a Recovery Organization of Support Specialist (ROSS) location. This is also based on where you live. If sessions are held via telehealth, they will be hosted on a HIPAA approved system like Zoom.

Time required: No matter your group, you will need about 3 hours of your time each week for the first 12 weeks. After that you will come back for your 12-week and 24-week follow up periods. At these follow up visits, it will take about an hour and a half to complete all the surveys and give a saliva and urine sample.

Risks: The study has few risks. You might feel upset during the group session especially when talking about issues related to substance use. We will try very hard to make you feel at ease and safe.

We will go over what will happen in the study, risks and benefits. We will also tell you how we will keep your information safe. If you agree to join the study, you will sign a paper that shows you understand and are willing to join. We will then ask questions to make sure you can work with us. If you can work with us, then you will attend group counseling sessions. If in-person, all these activities will be done in a private room at either the University of Alabama, a location of Pathway Healthcare LLC or a ROSS location. Activities may also be completed via phone or HIPAA approved system.

All the information we collect from you will be stored in a locked cabinet, in a locked office at the University of Alabama. All the data that will be stored on the computer will be stored on a server that is password protected by the University of Alabama. Only people who are part of the study will have access to your information.

Benefits: There are no direct benefits to you for joining this research study. The study may help us understand whether combining MBRP and peer support helps people with

opioid problems with taking the medications as prescribed by their doctor to remain sober. It may help to see other people who are in recovery with you at weekly sessions. That may also help with feeling better emotionally. There are no other benefits for participating in this research study.

Confidentiality: All in-person activities will be completed in a private room at the University of Alabama, a location of Pathway Healthcare LLC, or a ROSS location. Activities may also be completed via phone or HIPAA approved system.

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Your information will be kept private by using ID numbers instead of names on all forms. This way, no one outside of the research team will be able to know your name. When we have the exit interview, you may use a fake name. If anyone has access to the recording of the interview, no one will know your name.

All the records we collect from you will be kept safe on a computer with a password. Only research team members will be able to see the computer files (UA BOX). The consent form you sign will be kept separately in a locked file in one of the investigators' locked offices (Dr. Mumba's office).

The information you give in the study will be handled privately. Your name and other identifying information will not be linked to the data. Because of the nature of the records, people outside the research team may be able to figure out who you are. However, research team members will do everything they can to make sure that only approved people have access to your information. The research team will make sure that they only use your study ID number on data. Your data will be reported in a way that will not identify you.

Voluntary participation: Joining this study is completely up to you. Joining this study will not affect your ability to receive any medical services that you are allowed from your doctor. You can stop at any time without penalty.

Right to withdraw from the study: You have the right to leave the study at any time without penalty. Because we will be audio-taping your exit interview, if you choose to leave this study your audiotape will be destroyed.

How to withdraw from the study: At any time, if you would like to leave the study, please contact Dr. Mumba or the project manager. Let them know and they can make

sure your study records are destroyed. These records will not be included in the data analysis. Please remember that participation is your choice. No one will be upset with you if do not to finish the study. There is no punishment for stopping. You will still receive full payment for everything you complete during the study.

You may be removed from the study because of the following reasons:
(a) increase in alcohol or drug use leading to the need for more intense care such as medical detox or inpatient services.
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(d) failure to attend sessions for four weeks back to back.

Compensation/Reimbursement: Once you agree to be part of the study and provide informed consent, you will be given $15 for completing surveys and giving the saliva samples at the five different time frames explained at the beginning.

You will be given $20 for each in-person session attended to make sure you can get a ride.

If you have questions about the study or need to report a study related issue please contact, contact:

Dr. Mercy Mumba
Assistant Professor
Capstone College of Nursing
205-348-6317/205-530-5439
mnmumba@ua.edu

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I understand that part of my participation in this research study will be audiotaped and I give my permission to the research team to audio-tape the interview.

_____ Yes, my participation in the interview can be audiotaped.

_____

Signature of Research Participant Date

_____

Print Name of Research Participant

_____

Signature of Investigator or other Person Obtaining Consent Date

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I understand that part of my participation in this research study will be audiotaped and I give my permission to the research team to audio-tape the interview.

My participation in the interview can be audiotaped.

Verbal consent provided: **Yes ☐** **No ☐**

_____

Print Name of Research Participant

_____

Signature of Investigator or other Person Obtaining Verbal Consent Date

_____

Print Name of Investigator or other Person Obtaining Verbal Consent

_____

Signature of Person Witnessing Verbal Consent Date

_____

Print Name of Person Witnessing Verbal Consent