PROTOCOL: A Pilot Feasibility Study of Mindfulness-Oriented Recovery Enhancement with Pregnant Women with Opioid Use Disorder

Clinicaltrials.gov Identifier: NCT04824521

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DOCUMENT DATE: February 10, 2021

ATTACHMENTS:

Study Protocol

Data Collection Forms

Data Analysis Plan

STUDY PROTOCOL

OBJECTIVES

The primary objective of this study is to evaluate the feasibility and acceptability of a behavioral health intervention (Mindfulness-Oriented Recovery Enhancement) delivered via telehealth to pregnant women diagnosed with substance use disorder. We have been awarded a pilot grant through the University of Montana Center for Population Health Research to complete this research. We propose to recruit thirty pregnant women with substance use disorder from clinics, community organizations, and social media to participate in eight sessions of Mindfulness-Oriented Recovery Enhancement (MORE) via Zoom. We propose to conduct all study visits remotely via Zoom and are therefore asking to be able to consent participates remotely via Zoom as well.

Study visits would include (1) a pre-treatment assessment, (2) eight therapy sessions, (3) a mid-treatment assessment after four therapy sessions, and (4) a post-treatment assessment (see attached study timeline). During the pre-, mid-, and post-treatment assessment visits, participants will be asked to complete self-report measures (see attached), two structured clinical interviews (see attached) and a semi-structured qualitative interview (see attached). Participants will be asked to complete a brief questionnaire (see attached) before and after each session. The primary aims of this study are as follows.

Aim 1: To adapt the in-person MORE intervention for telehealth delivery.
Aim 2: To assess the overall feasibility and acceptability of this telehealth intervention.
Hypothesis: MORE delivered via telehealth will be both feasible and acceptable to participants.

DESIGN

In this study, we intend to recruit pregnant women with SUD. This study is specifically focused on evaluating the feasibility and acceptability of a behavioral health intervention for this population.

Women are eligible to be a part of the study if they (1) are 18 years old or older, (2) are able to speak and understand English, (3) are pregnant at the time of consent, (4) meet criteria for substance use disorder in the past year according to the Mini Neuropsychiatric Interview, and (5) have access to the internet and a smart device (though a tablet may be provided). Whether a participant meets criteria for SUD will not be known until the interview is conducted during the pre-assessment, but since we will be collecting sensitive information (i.e., symptoms of substance use disorder), we need to complete the informed consent process.

Participants will be recruited through two approaches. We will reach out to OBGYN providers, healthcare systems, pain management clinics, substance use treatment provides, health departments, community groups, and harm reduction services to advertise the study. These providers will be given flyers (see attached) to post and distribute to patients/clients. We will also advertise online through social media (see attached).

Potential participants will be instructed to call, text, or email the research team to participate in the study. To be a part of the study, women must
(1) be 18 years old or older,
(2) be able to speak and understand English,
(3) be pregnant at the time of consent, and
(4) meet criteria for substance use disorder in the past year according to the Mini Neuropsychiatric Interview (see attached)
(5) have access to the internet and a smart device (a table may be provided).

Again, we will not know if the participant meets criteris for SUD until the interview is conducted during the pre-treatment assessment.

METHODS

Here we provide an outline of the study procedures for study participants.

1. Potential participants will contact study staff via phone, text, or email to enroll in the study.

2. Study staff will describe the study in detail, answer questions, and evaluate the potential participant for eligibility criteria.

3. If the potential participant is still interested in the study and meets all inclusion criteria, they will then set up a virtual appointment via Zoom to complete the pre-assessment visit.

4. During the pre-assessment visit, study staff will engage the participant in the informed consent process. After completing the informed consent process, participants will complete self-report measures, structured clinical interviews, and a semi-structured qualitative interview.

a. Participants will be asked to complete a battery of self-report measures including a demographic questionnaire and measures of parenting confidence and self-regulation (see below) via Qualtrics.

b. Study staff will conduct the Mini Neuropsychiatric Interview and the NIDA Modified Assist Tool (see attached).

c. Participants will engage in a semi-structured qualitative interview (see attached).

5. After completing the pre-treatment assessment via Zoom, study staff will schedule the first tele-health appointment.

6. Participants will complete four tele-health appointments via Zoom. These therapy sessions will last about one hour. Participants will complete a short questionnaire before and after the session (see attached). MORE sessions will begin with formal mindfulness practice followed by a debrief of the formal practice, psychoeducation, and an experimental exercise. Sessions will focus on the application of mindfulness, cognitive reappraisal, and savoring in managing pain, substance use, and stress related to parenting and relationships. All sessions will be audio-recorded, reviewed and scored using a fidelity measure by research assistants trained in MORE to ensure fidelity to the treatment.

7. Outside of therapy sessions, participants will be asked to complete fifteen minutes of homework per day during which they will practice mindfulness, reappraisal, and savoring techniques. Mindfulness techniques will include body scan (during which participants focus on sensations in their bodies), mindful breathing (during which participants focus on the sensation of breathing), and open monitoring mindfulness practice (during which the focus of attention is awareness itself and participants simply notice as thoughts and sensations arise). Mindful reappraisal is the application of mindfulness to restructure (or change) unhlepful thoughts to reduce negative feelings and unhelpful behavior. Savoring is the application of mindfulness to focus on and inhance pleasurable thoughts, feelings, and sensations.

8. After four therapy sessions, participants will complete a mid-treatment assessment via Zoom. Participants will complete the same self-report measures, structured clinical interviews, and semi-structured qualitative interview which they completed in the pre-treatment assessment.

9. Participants will complete the four remaining therapy sessions.

10. After completing the remaining therapy sessions, participants will complete a post-treatment assessment via Zoom. Participants will complete the same self-report measures, structured clinical interviews, and semi-structured qualitative interview which they completed in the pre-treatment and mid-treatment assessments.