Consent Form

Title of Research Study: A Pilot Study of Behavioral Activation for People with Opioid Use Disorder

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

- The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

If your doctor is also the person responsible for this research study, please note that s/he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because you are currently receiving treatment for opioid use disorder (OUD) at Broadway Family Medicine, have had a prescription for buprenorphine-naloxone (e.g., Suboxone) for at least one month, and are at least 18 years of age. In addition, your primary care provider at the clinic, who is familiar with your medical history and treatment, determined that you would be a suitable participant for this study.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.

- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to evaluate a counseling program that may benefit persons living with OUD. The goal is to identify helpful programs that can be offered in primary care and may enhance patients' recovery from OUD.

The most helpful treatments to people with OUD are medications, such as Suboxone. These medications help manage opioid cravings and reduce the risk for overdose. However, patients in recovery often have personal goals they hope to achieve, such as improving mental well-being, strengthening relationships, and gaining employment or education opportunities, to name a few.

Behavioral activation is a promising added treatment for patients receiving treatment for OUD. Through a series of brief sessions with a counselor, patients will identify things important to them in life and set goals that match their values. The structure of the meetings, along with the support and accountability of the counselor, may help the patient complete goals more successfully.

If the intervention is found to be beneficial and enjoyable to patients, then primary care clinics can choose to add this therapy for other patients with substance use disorders.

How long will the research last?

The study will include 4-6 counseling sessions over the course of 12 weeks. The first session may take up to an hour. All follow-up sessions will last about 30-45 minutes.

You will be asked to complete survey measures before, halfway through (after 6 weeks), and after the program (12 weeks). At those same survey visits, we will ask you to provide a urine sample for urine drug test. Each survey completion appointment will take up to 30 minutes.

At the end of the study, we will invite you to participate in a brief (20-30 minute) interview to give us feedback on your experience.

The estimated total participation time is about 6 hours spread over 12 weeks.

What will I need to do to participate?

You will be asked to attend 4-6 brief counseling sessions over the course of 12 weeks. These appointments will be scheduled at a time that is convenient for you. During the first session, you will discuss values and recovery outcomes important to you. Next, you will set 2-3 personal goals to work on before your next session. Follow-up meetings will be scheduled every 2-3 weeks. At the follow-up sessions, you will update the counselor on the progress you made or challenges you experienced. You and the counselor will review your personal values and update your goals for the next session.

You will be asked to complete surveys at the start, partway through, and at the end of the 12-week

program. The survey measures will ask questions about your recent feelings, behaviors, and thoughts. At each of these survey visits, we will ask you to provide a urine sample for a urine drug test. At the end of the study, we will ask you to participate in a short interview, during which you can share what you liked and what could be improved for future counseling sessions.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

Is there any way that being in this study could be bad for me?

This study has minimal risk. We anticipate no physical, legal, or economic risks to participants.

Because patients will likely discuss mental health and psychosocial concerns, participants may experience some distress when reflecting on their current circumstances. This potential discomfort is expected during the first few sessions and is expected to improve as patients progress through their counseling sessions.

There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include making progress on personal goals and improved recovery outcomes. By identifying and discussing your values, you may become more aware of what is important to you in life. Beneficial outcomes could be time limited to a few weeks or last years, depending upon the goals selected and progress achieved.

In addition to potential personal benefit to you, this study has the possible benefit of increasing knowledge about the feasibility and acceptability of delivering this counseling program for patients receiving treatment for OUD in primary care.

What happens if I do not want to be in this research?

You do not have to participate in this research. Instead of being in this research study, you could choose to seek behavioral therapy or counseling from other providers at Broadway Family Medicine or in the community. Your decision to not participate in this study will not impact your care at Broadway Family Medicine Clinic in any way.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 30 people will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

- You will complete 4-6 counseling sessions every 2-3 weeks. The program will end after 12 weeks. The first session will last about 1 hour, and follow-up sessions will be 30-45 minutes each.
- The counseling sessions will take place in a private room at Broadway Family Medicine or virtually through telehealth options (telephone visit or videoconferencing). A clinical social worker employed at Broadway Family Medicine is leading the sessions.
- A member of the research team will meet with you 3 times during the study to collect survey measures and to have you provide a urine sample for a urine drug test. These meetings will occur during week 0, week 6, and week 12 of the study.
- The counseling sessions are in addition to your standard care in the MAT program (medication-assisted treatment), in which you receive Suboxone medication and consultation with your primary care provider. Your counselor will write notes in your medical record and may communicate with your primary care provider about your care, if appropriate.
- You will be asked to provide permission to be contacted for future research.
- Audio and/or video recording of research activities will be done. Your agreement to be recorded is optional for the counseling sessions and will not prevent you from participating in the study. Recordings for counseling sessions will be used to provide feedback to the counselor. These recordings will be shared with our research team member providing supervision to the counselor (Dr. Stephanie Hooker, PhD, LP, MPH) and will be destroyed after they have been used for feedback.
- Interview responses at the completion of the study will be audio recorded and transcribed.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. You can decide to stop participating in the counseling sessions and continue to complete the survey measures. Your decision to participate, or not, will in no way impact your care or relationship with Broadway Family Medicine Clinic.

If you decide to leave the research study, contact the investigator or project coordinator so that they can record your reason for discontinuation and notify the counselor who is providing the counseling sessions.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

Data collected up the point of your withdrawal will be used in the study, but no further data will be collected. Participants who want to withdraw all their data from the study can notify the study team in writing.

Will it cost me anything to participate in this research study?

There will be no cost to you for the counseling visits and lab tests that are done for research purposes only and are not part of your regular care. You and your insurance company will be responsible for paying for all of your regular medical care you receive as part of the medication-assisted treatment (Suboxone) you receive at Broadway Family Medicine.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. Other organizations that may have access to the participants' records include medical service providers at Broadway Family Medicine, as well as the Minnesota Department of Human Services that sponsors this research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

Certificate of Confidentiality

To help protect your privacy, the Substance Abuse and Mental Health Services Administration (SAMHSA) has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children or vulnerable adults. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Data or Specimens Collected

Survey data will be stored electronically in a secure database in REDCap (Research Electronic Data Capture). Paper copies of survey data will be stored in a locked file cabinet for 7 years after the completion of the study. After that time, paper documents will be destroyed through a secure shredding service. Interviews will be audio-recorded and stored in Box – a secure cloud content management system used by the University of Minnesota. Data will be retained for at least 7 years. Only researchers affiliated with the study will have access to paper and electronic data.

Urine specimens collected for urine drug tests will be immediately processed by Broadway Family Medicine's lab technicians and destroyed.

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the investigators will contact you to let you know what they have found.

What will be done with my data and specimens when this study is over?

Your data and/or samples will not be used for any future research after this study is complete.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include dismissal from the medication-assisted treatment (Suboxone) program due to inappropriate behavior or referral to a higher level of care outside of Broadway Family Medicine. If this happens, you will be sent a letter thanking you for your participation and notifying you that you are no longer enrolled in the research study.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $120 for your time and effort in completing study measures. Specifically, you will receive $30 for completing measures before the first session, $40 for completing the measures at 6 weeks, and $50 for completing the end of study measures (at 12 weeks). In addition, we will give you $5 for every counseling session you complete to compensate you for either the data/minutes used during telehealth visits or for transportation to attend in-person visits (up to $30 in total).

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio or video record me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate study team.
_____	_____	I would like to receive reminders using Greenphire. If yes, provide the following contact information: Email Address: _____ Phone Number: _____

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent