Cover Page

Study Title

"Implementation of a Shared Decision-Making Aid for Reducing Stigma against Drug Use and HIV Harm Reduction in a Rural Setting"

Identifiers: NCT05352412

Unique Protocol ID: 202107155

Date: March 25, 2022

We invite you to participate in a research study being conducted by investigators from Washington University in St. Louis.

You are being asked to participate in this research study because you have a history of opioid use. The purpose of the study is to learn about adherence to treatment and medications of opioid use disorder. The National Institute on Drug Abuse is funding this research study.

If you agree to participate, we would like you to answer survey questions about different treatments for opioid use order, demographics and treatment history, if applicable. The survey will be given to you at 4 different time points over the course of 3 months. You are free to skip any questions that you prefer not to answer.

After completing the survey, you will be randomized to either receive the current standard of care or to complete a decision aid survey. This randomization is done by the survey tool itself. Randomization is like tossing a coin. There is a 50/50 chance of receiving either option. We will not know until the initial survey is completed who will be randomized to which arm.

If you are randomized to receive the decision aid, you will be asked to complete a decision aid survey, which is an interactive web-based app presented on a tablet with five sections: (1) Overview of OUD and available treatment; (2) Comparison of the benefits among available current medication options (methadone, buprenorphine, naltrexone) and no treatment; (3) Comparison of what "life is like" with each option, including adverse medical and social consequences, side effects, route of administration and cost; (4) Expectations for treatment duration and effects of medication if it is self-discontinued; (5) Harm reduction for overdose prevention, naloxone use, and infection prevention. The results from the survey will be shared with your provider so that they are aware of your concerns/preferences to help with this shared decision making for your treatment of opioid use disorder. We will also ask you to complete a survey regarding your demographics and treatment history for opioid use disorder. If you agree to participate, you will complete the decision aid today.

If you are randomized to not receive the decision aid, you will still receive the current standard of care.

Regardless of randomization, you will complete a follow-up survey 3 more times over the course of the next 3 months. The follow-up survey will be completed today, 2 weeks and 90 days. You will also be compensated for each time that you complete the survey, up to 4 times total.

If you do not want to participate, please let a member of the research team know. We will not contact you again for participation.

Approximately 60 people will take part in this study at Washington University.

There are no known risks for being in this study.

You will not benefit personally. However we hope that others may benefit in the future from what we learn as a result of this study.

You will not have any costs for being in this research study.

You will be paid for being in this research study. We will ask you to provide your social security number (SSN) in order for us to pay you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes. You may also need to provide an address for us to mail your gift card to you. You will receive a $15 gift card to a local grocery each time you complete the survey. This could be up to a total of $60 should you complete the survey 4 times.

We will keep the information you provide confidential by having you create a unique patient ID code number that will be used to link your responses and study data to, rather than your name. This means that all of the data will be kept completely anonymous and there will be no links to your name or any identifiable information.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

Federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records pertaining to this research. If we write a report about this study we will do so in such a way that you cannot be identified.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time. Any data that was collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you do not wish to participate in this study or want to end your participation in the study, please let a member of the research team know via phone call or in person**.**

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Michael Durkin, 314-454-8354. If you feel you have been harmed from being in the study, please contact**:** Dr. Michael Durkin, 314-454-8354. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Thank you very much for your consideration of this research study.