Facebook Intervention for Preventing Opioid Relapse Among American Indian Women: Wiidookaage'win Pilot Preparatory Study (Aim 1)

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Wiidookaage'win

IRB#: 22-000477

Principal Investigator: Dr. Christi Patten and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in research is your choice. You do not have to participate if you don't want to. If you decide to join, you can stop at any time. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to see how well a Facebook group for Native women recovering from illicit opioid use would work. You have been asked to take part in this research because you are a Native woman recovering from illicit opioid use, and you are currently taking medication for opioid use disorder.
What's Involved	After consent: 1. You will complete an eligibility screening urine drug test and additional screening mental health questions. 2. You will answer some questions about yourself, opioid use and treatment, spirituality, and mental health. 3. You will actively participate in a Facebook group focusing on recovery from opioids for 30 days. 4. After the 30 days are up, you will answer some questions about your experience in the group, talk about your recent drug use, and do another urine drug test.

Key Information	The risks of this study are minor and may include discomfort with answering questions about yourself and engaging with Facebook posts. There is also a minor risk that the health information you share might be leaked despite our best efforts to keep the group private and secret. You might continue to experience withdrawal symptoms and side effects from your medication. However, we do not expect that withdrawal symptoms will be a major health risk since you will have not used opioids illicitly for at least 30 days. Possible benefits include that you may fully recover from illicit opioid use and learn new skills to help you and your community deal with stress and trauma after the group is over. You do not have to participate in this research. Instead of being in this research study, your choices may include local inpatient and outpatient services or behavioral health programs.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in this study is entirely your choice. You do not have to participate. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. If you choose not to participate, we will destroy your screening information.

If you need time to decide, please say so. We will give you a pre-paid return envelope for you to return the signed form later if you decide to take part in this research study. If we do not hear from you, we will check in after one week.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator(s):** Christi Patten, PhD **Phone:** 1-833-880-2600 **Study Team:** Wiidookaage'win Study Team **Phone:** 1-833-880-2600 **Institution Name and Address:** Mayo Clinic 200 First St., SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Subject Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu

Other Information:
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.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because:

1. You are an American Indian or Alaska Native adult woman in Minnesota
2. You self-reported not using opioids illicitly within the past 30 days
3. You are currently taking medication for opioid use
4. You are comfortable speaking and reading English
5. You either have or will create a Facebook account for this study

Why is this research study being done?

Native organizations in Minnesota wanted the Principal Investigator to help with the opioid epidemic among the Native community. The Minnesota Indian Women's Resource Center designed the study concept with the Principal Investigator.

The purpose of this study is to find out if Facebook will work as a platform to support opioid recovery among Native women. We do not know how easy and acceptable it is to use a Facebook group for this purpose. This study may not help you, but we hope the information from this study will help us develop a successful gender-specific Facebook group program for Native women in recovery.

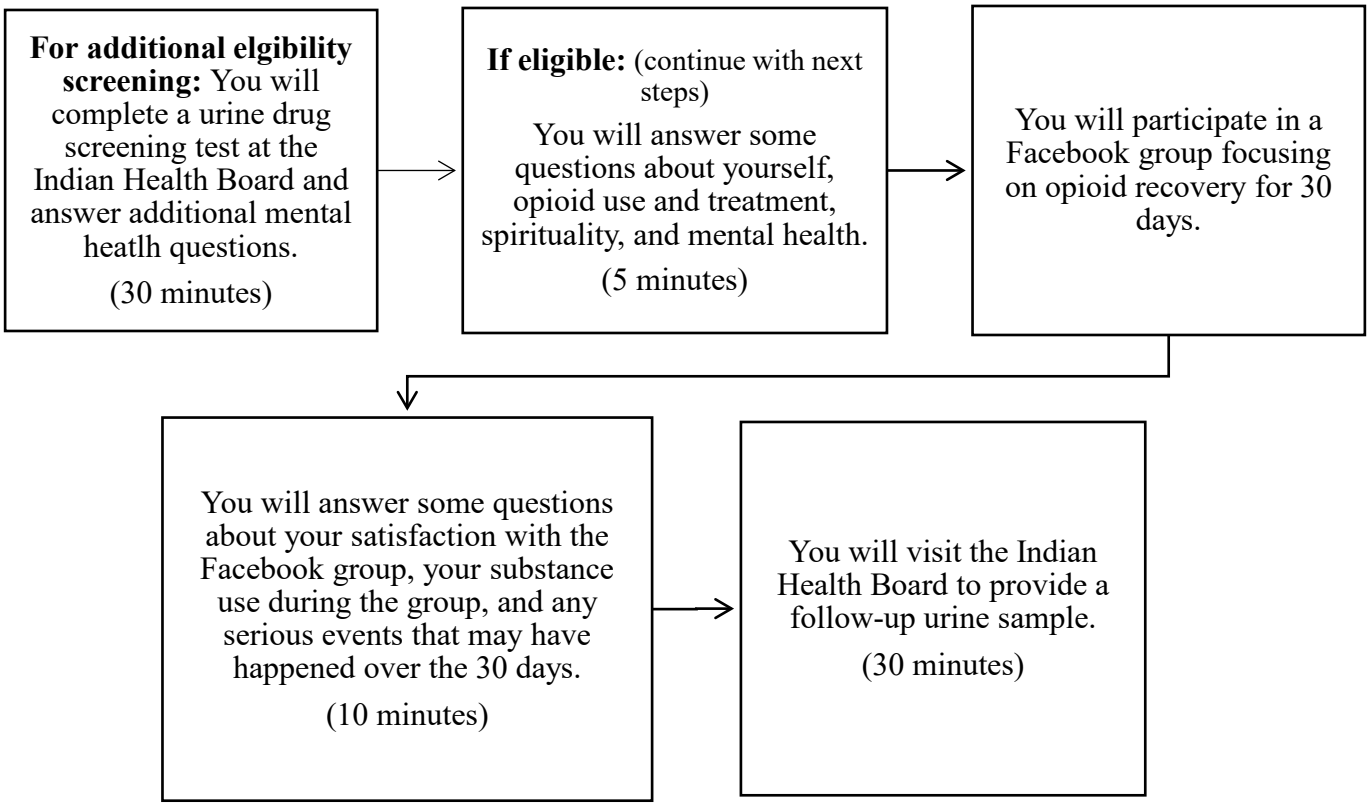
Information you should know

Who is Funding the Study?
Mayo Clinic and the National Institute on Drug Abuse (NIDA) are funding the study.

Information Regarding Conflict of Interest:
This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies. We have no conflicts of interest to report.

How long will you be in this research study?

If eligible, you will be in the study for about 2 months. We will ask you to complete two separate visits at the Indian Health Board for a urine drug test, one for eligibility screening purposes and the second one as part of the study. All other visits will be over the phone or online. If your first urine drug test comes back positive, you will not be able to continue with the study. We will destroy all screening data if you are not eligible.



What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

We will test your urine for opioids, amphetamine, barbiturates, buprenorphine, benzodiazepines, cocaine, methadone metabolite, methamphetamine, ecstasy, methadone, morphine, oxycodone, phencyclidine, tricyclic antidepressants, and marijuana. The results of the urine drug test won't become part of your medical record, but they will remain part of your study record.

You may consent to receive a newsletter from the study team covering this study's most clinically relevant research results.

What are the possible risks or discomforts from being in this research study?

You will be asked some sensitive screening questions related to suicide ideation that may make you uncomfortable. We will provide additional resources if needed.

You may feel inconvenienced by taking time out of your day to travel for the urine sample and answer questions about yourself. The urine drug test is similar to what you would do at a routine care visit. If you have a positive result, you may feel embarrassed or uncomfortable in front of the research staff who did your test. At any time, if you choose to inform us of a pregnancy and that you are currently using substances for nonmedical purposes, we will be required to report it to Project CHILD in Hennepin County to comply with the mandatory reporting requirements in Minnesota Statute 260E.31.

It is impossible to predict what the other participants will post on the Facebook group, so some posts may make you upset, make your cravings stronger, bring up stressful memories, or cause you to relapse. We do not know how a Facebook group program for AIAN women recovering from opioid use will affect them because none have existed before. You may alert the study team if a specific post or comment upsets you.

Since you are taking medication for opioid use disorder, you may continue to feel withdrawal symptoms and/or side effects from your medication. These may include:

Opioid Withdrawal Symptoms	Medication Side Effects
• Bad mood • Feeling sick to your stomach • Throwing up • Muscle aches • Runny nose • Dilated pupils • Goosebumps • Sweating • Diarrhea • Yawning • Fever • Trouble falling and staying asleep	• Constipation • Headache • Feeling sick to your stomach • Dizziness • Feeling tired • Sweating • Dry mouth • Achy muscles • Trouble falling and staying asleep • Dilated pupils • Restlessness • Decreased attention span • Itchy skin

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. Your information will not be shared with anyone else except for the research team, and the group moderators will emphasize that everything shared in the private, secret group stays in the private, secret group. We may organize Facebook Live guest speaker events with AI/AN experts in Native culture and opioid recovery. We ask that you do not share personal information about yourself with speakers coming into the group so that your identity and personal health information can remain protected. We may also have members of the research team hold Facebook Live events, in which case, this restriction does not apply.

Your study ID will be destroyed at the end of the study, and the urine sample will be destroyed once the results are ready.

Are there reasons you might leave this research study early?

If you do not pass the eligibility screening urine drug test or fail the additional screening questions, you will not be able to participate in the study further. We will destroy all screening data if you are not eligible.

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit via phone, which will take about 15 minutes. At this visit, you will complete the follow-up survey outlining your experience in the Facebook group, your opioid use and medication use throughout your participation, your spirituality, your mental health, and any serious events that may have happened to you throughout your participation.

If you decide to leave the research, contact the Principal Investigator so that the investigator can decide if any additional tests should be done for your safety. You may be removed from the Facebook group if that is what is best for you.

What if you are injured from your participation in this research study?

Where can I get help?
If you think you have suffered a research-related injury such as an emergency department visit, hospitalization, or overdose, you should immediately notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for research-related injuries will be billed in the ordinary manner to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may not make your health better. The Facebook group can be thought of as a supplement rather than a replacement for medication and/or treatment. However, it is possible that the Facebook group may help you learn new skills that will help you and your community cope with stress and trauma. You may fully recover from illicit opioid use.

What other choices do you have if you choose not to participate?

You don't have to be in this research study to get help for your recovery from opioid use. Your other choices may include local inpatient or outpatient services as well as behavioral health programs. These can be found at various clinics in Minneapolis, MN, including the Indian Health Board, Minnesota Indian Women's Resource Center, Native American Community Clinic, and Community-University Health Care Center. Talk to the Principal Investigator or your doctor if you have any questions about any of these programs.

What tests or procedures will you need to pay for if you take part?

You will not need to pay for the urine drug test, which is done just for this research study. However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If the results of the urine drug test performed for research may be useful for your health care, you may be notified. If you decide to follow up, any further medical testing will be considered part of your clinical care and will not be paid for by the research study. Costs will be billed to you or your insurance.

If you have questions about any costs to you that may result from taking part in the research, please reach out to the Principal Investigator.

Will you be paid for taking part in this research study?

You will get a cash card valued at $25 for doing the baseline survey and $50 for the follow-up survey. You will get $50 for your first screening urine sample and $50 for your second sample to compensate for completing and travelling for in-person testing. If you do everything for the study, you will get paid a total of $175.

We also will provide every participant with a small smudge kit (sage and cedar) and journal to use as an option when participating in activities.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). If you get at least $600 in research payments in a calendar year, a tax Form 1099 will be sent to you.

Will your information or samples be used for future research?

Your information and samples collected for this study will not be used or shared for future research studies, even if the identifiable information such as your name or date of birth is removed.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Your data will be de-identified and coded with numbers in Mayo Clinic's password-protected Research Electronic Data Capture (REDCap) software. Your screening data will only be used to describe the population that was either found to be ineligible for this study or were uninterested in participating. Your urine sample will be destroyed immediately after recording the results. Research materials are kept in a folder protected by the password-protected Mayo Remote Access Client.

Also, we have obtained a **Certificate of Confidentiality** from the Department of Health and Human Services (DHSS). The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, 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. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this research. This means that you and your family must also actively protect your own privacy.

The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.

The research team may share your information with:

- DHHS, to complete federal responsibilities for audit or evaluation of this research;
- Public health agencies, to complete public health reporting requirements;
- Mayo Clinic representatives, to complete responsibilities for oversight of this study;
- Your primary care physician if a medical condition that needs urgent attention is discovered;
- Appropriate authorities as needed to prevent serious harm to yourself or others.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Research procedures, including tests, interviews, and questionnaires.

Your health information will be used and/or given to others to:

- Do the research
- Report the results
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study
- The sponsors of this study and the people hired by the sponsors to help do this research.
- The Mayo Clinic Institutional Review Board that oversees the research
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature