Expansion and Spread of Makoyoh'sokoi, the Wolf Trail, a Community Led, Culturally Relevant, Physical Activity-based, Holistic Wellness Program for Indigenous Women; a Self-control, Non- Randomized, Intervention Trial in Seven Communities (10 Sites) in Alberta and Saskatchewan.

NCT ID Not Yet Assigned

January 14, 2022

Study Information and Consent Form

TITLE:	Makoyoh'sokoi – The Wolf Trail Program Expansion Project – Supporting Indigenous Women to Celebrate Good Health
SPONSOR:	The Public Health Agency of Canada (PHAC) Capital Power
INVESTIGATOR:	Dawn Boustead (Miskanawah) 403.247.5003 Dr. Sonja Wicklum (University of Calgary Department of Family Medicine) 403.955.9300

This consent form is only part of the process of informed consent. It should give you a basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

You were identified as a possible participant in this study because a healthcare worker in your community felt you may benefit from the program. Your participation in this research study is voluntary.

BACKGROUND

Educating individuals about physical activity and proper nutrition in a safe and supportive environment is essential to improve health. It is necessary to gain exposure to various activities to learn about them and decide if you enjoy them. Together, being active and eating well can decrease your risk of disease and help you feel better.

The Makoyoh'sokoi program involves a group wellness program combining physical activity classes, nutrition and health education and sharing circles. In addition, the Makoyoh'sokoi program provides in-person programming and follow-up support.

Group activities often help people to make healthy lifestyle changes. Also, sharing circle discussions give people a chance to discuss issues they are having that may be affecting their lifestyle choices. Finally, by studying this program, asking you and the other participants questions before and after the program helps us evaluate the program's benefits and make the program better for the future.

There will be multiple 24-week programs in 2021, 2022, 2023 and 2024, and we hope to have around 20-25 participants per session. If the program goes well, we will support other communities in offering the same program.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine if this program benefits participants. The program's primary focus is to encourage you to increase physical activity as per the Canadian Physical Activity Guidelines and the Canadian Sedentary Behaviour Guidelines. The guidelines recommend 150 minutes of moderate-intensity exercise per week for adults. Participation may also increase your confidence in becoming active and help you build a support system for healthy, active living. The study involves research and the completed questionnaires and testing help us to determine how effective the program is.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 1000 people in Alberta and Saskatchewan will take part in this study. The program will be run five times in 10 communities from 2022-2024.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Initial participation would start three months before the main program and include completing questionnaires (approximately 1 hour), simple fitness testing (a one mile walk and a grip strength test, approximately 30 minutes), and a visit to a clinic to draw blood and get measurements of height, weight, and blood pressure (approximately 30 minutes).

Before starting the main Makoyoh'sokoi (Wolf Trail) program, you would complete the similar questionnaires and fitness testing you completed three months prior. In addition, the main Makoyoh'sokoi program will include group sessions every week for 1.5 hours for the first 12 weeks of the 24-week program. These group sessions will consist of an exercise class, nutrition and health education, and a sharing circle. You will also be given a pedometer during the second or third session, which you may wear throughout the Makoyoh'sokoi program (24 weeks).

After the initial 12-weeks, you complete the shorter questionnaires, measurements and fitness testing again.

The second part of the program, the next 12 weeks, will include health education sessions and sharing circles every other week (6 total for 60 minutes each) and the program facilitator will continue to follow up with you providing weekly check-ins to help you continue your health journey.

The purpose of completing the questionnaires and fitness testing on multiple occasions is to isolate and investigate different parts of the program.

In order to access the results of your laboratory tests for diabetes and cholesterol we will access laboratory databases in AB through Alberta Health Services (AHS) and in SK through the Saskatchewan Health Authority (SHA). By signing this document you are consenting to having your health care data accessed by linking your personal health number (PHN) to laboratory data housed at AHS and SHA

WHAT WILL HAPPEN WHEN I AM FINISHED PROGRAM?

After the entire 24-week Makoyoh'sokoi program and a full year after the program's end, you will once again complete the questionnaires, fitness testing, blood draw, and measurements. At these times you will also be asked to participate in an exercise that will ask you to reflect on how you are doing in your health journey and a researcher will help you to make a video or take a photo and tell a story about your journey. This will take 2-4 hours to complete at each time (at the end of the 24 week program and one year later).

During the program you should have been connected to the resources you need. If you have needs that were not addressed then please contact the Project leads.

HOW LONG WILL I BE IN THIS STUDY?

As stated above the total time you will be in the study is 21 months:

- Before the program for three months, in research we call this a 'control' period, where you live life as usual.
- During the program for six months (24 weeks).
- Follow-up period of twelve months (no other activities are requested of you except completing the questionnaires, measures, fitness tests and the photo/video exercise again at the one-year follow-up.

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?

There are no known risks associated with completing the questionnaires.

Volunteers will administer the fitness testing. Before completing any of the fitness or activity portions of the Makoyoh'sokoi program, you will sign a "Health and Fitness Liability Waiver." This waiver will indicate you are aware that you are participating in physical activity classes. In addition, you affirm that you can be physically active. In rare instances, physical activity may cause unwanted side effects (e.g., heart attack, strokes, muscle strains, muscle pulls, muscle tears, broken bones, shin splints, and even death).

Blood draws are administered by certified professionals and follow all safety protocols. However, you may feel slight discomfort during the blood draw. There is a possibility of bruising or swelling while giving blood, or other possible discomforts at the site where blood is

drawn. Indicate that there may be minimal chance of infection and that discomforts experienced will be brief and transient.

During the sharing circle discussions, a talking stick will allow individuals to feel comfortable participating. Despite this, at times, you may feel uncomfortable.

If you are pregnant, breast-feeding or in a specific weight loss program you cannot participate in the study.

If you become pregnant while in the program, then your continued participation in the program can be allowed if your doctor is aware and gives consent and as long as the Program Facilitator is made aware and can discuss this with the fitness instructors. Fitness instructors have the right to limit your activity in the class if the exercise they are teaching could pose a risk to your health. However, you will not be a part of the research.

The risk of COVID-19 transmission during in-person components of the program exists. To reduce this risk we will recommend that all participants are fully vaccinated, along with all program facilitators, fitness instructors and special education guests. Communities should follow their provincial health regulations with respect to exercising in a group and switch the program to a virtual format as needed. Provincial health recommendations may change and the project lead will support the program facilitators to stay abreast of changes. As of January 12, 2022 proof of vaccination or negative Covid19 rapid antigen test results are required for fitness programming.

WILL I BENEFIT IF I TAKE PART?

Previous participants of this program have benefitted by developing a strong support network, becoming more physically active and learning how to access resources they had not accessed before. You may improve your fitness level, develop better eating habits and better understand resources available to you. You may improve your overall health. The information we get from this study may help us to provide better treatments in the future.

The research staff will provide you with a detailed record of your fitness levels, measurements and survey responses that will help you to understand your health.

Other benefits may be increased confidence and increased community support.

DO I HAVE TO PARTICIPATE IN THE RESEARCH TO BE A PART OF THE PROGRAM?

You do not have to participate in the research to participate in the program however you need to be aware that if you participate in the program and not the research we will record your presence in the program (not using your name, just simply noting you were participating).

CAN I STOP PARTICIPATING IN THE RESEARCH STUDY BUT STILL STAY IN THE PROGRAM?

You are also allowed, at any time, to refuse to participate in any part of the program. In addition, you are permitted, at any time, to withdraw from the entire program or just the research study part of the program. If you have concerns or questions or want to withdraw from this program, you may contact Sonja Wicklum by phone (403) 955-9300 or email sonja.wicklum@ucalgary.ca.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this research study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled activities. In addition, if you have poor attendance or unacceptable behaviour, such as mistreatment of fellow participants, the program's facilitators may withdraw you from the study. The researchers or the study sponsor might also decide to stop the study at any time.

If you decide to stop being in the study, or are removed from the study, or the study is stopped the researcher will ask you to complete an exit telephone interview.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT ME?

During the study, the researchers could learn something about you that they didn't expect. For example, the researchers may find out you have poorly controlled diabetes. The researchers will consult with medical experts as needed to evaluate the findings and will then share these results with you. Blood and fitness results may be shared with your doctor to monitor your long-term health. You will be helped with arranging appropriate follow up and care.

I consent for the researchers to share findings with me:

- ❑ YES
- ❑ NO

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

Financial compensation will not be paid, and you are not required to pay anything to participate.

WILL MY RECORDS BE KEPT PRIVATE?

The researchers will do their best to make sure that your private information is kept confidential, unless required by law. Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy. The research team will handle data according the Data Management Plan as outlined below:

- All identifying information will be removed from all data by the research coordinator. Identifiable information about you will be replaced with a code. A master list linking the code and your identifiable information will be kept separate from the research data.
- All de-identified data and the master list will be held by the research team lead.
- If participating from Onion Lake Cree Nation, all de-identified data sets and master lists will be held for 5 years by the Onion Lake Health Board as per the Onion Lake Ethics Committee.
- If participating from all other regions, all de-identified data sets and master lists will be held for 5 years by the project lead in the University of Calgary, Department of Family Medicine.
- All photovoice and video exercises will be shared after secondary verbal consent by the participant given to the peer-researchers. These stories and photos or videos may identify individuals and this is why a secondary consent will be obtained. The photo and video exercises will also be stored by the University of Calgary, Department of Family Medicine for 5 years and by the Onion Lake Health Board, if from that region, for 5 years.

Please note you will be asked to complete an online version of the questionnaire. The online questionnaire is hosted by "Qualtrics", which is a web survey company. Data is stored on Qualtrics servers located in Canada. The privacy statement for Qualtrics can be viewed at www.qualtrics.com/privacy-statement. **Your identifying information will not be shared or disclosed to any third party.**

The results of this program may be analyzed in the future solely for research purposes. The University of Calgary Conjoint Health Research Ethics Board will have access to the records; however, no identifiable information is public. No documents bearing names will leave the control of Dr. Sonja Wicklum or the primary investigators of this program.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

If you suffer injury due to participating in this research, the sponsors, the University of Calgary, or the Researchers will provide no compensation to you. However, you still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

PROVIDING INFORMED CONSENT

Before beginning the online questionnaire, you will be asked to check a box indicating that you have understood to your satisfaction the information about your participation in the research project and agree to participate. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. If you have further questions about matters related to this research, please contact:

Levi Frehlich (Project and Research Lead)
Contact: (403) 921 5223 or lcfrehli@ucalgary.ca

Dr. Sonja Wicklum (Principal Investigator)
Contact: (403) 955-9300 or sonja.wicklum@ucalgary.ca

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, the University of Calgary, at 403-220-7990.

Participant's Name	Signature and Date
Investigator/Delegate's Name	Signature and Date
Witness' Name	Signature and Date

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.