ISRCTN15605975 https://doi.org/10.1186/ISRCTN15605975

Women Warriors Program - a holistic health and active living program for Aboriginal women

Submission date
13/08/2018

Recruitment status
No longer recruiting

Registration date
11/10/2018

Overall study status
Completed

Last Edited
20/01/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Aboriginal rates of diabetes are estimated to be 10.3% and 7.3% for First Nations and Métis off reserve respectively, and as high as 17.2% for First Nations on-reserve. Overweight and obesity rates are also high in the Aboriginal population; prevalence rates are similar for off-reserve First Nations (26.1%), Inuit (23.9%) and Métis (26.4%) but higher for on-reserve First Nations adults (36.0%). It is important to acknowledge the younger age structure of Aboriginal peoples. Aboriginal children make up 28% of total Aboriginal population versus 16.5% for non-Aboriginal children of the non-Aboriginal population, numbers were 18.2% and 12.9% respectively for youth aged 15-24. Lastly, Aboriginals are typically diagnosed with diabetes at a younger age. It is well established that physical activity, nutrition and education programming are effective diabetes prevention strategies. Even modest changes in diet and exercise can lead to reductions of > 50% in the incidence of diabetes among individuals with impaired glucose (blood sugar) regulation. Lifestyle strategies to support weight management efforts can also impact obesity, which may reduce the rates of many other diseases including heart disease and cancer. However, physical activity and nutrition cannot be addressed in isolation. Psychosocial, socio-economic and environmental factors must also be considered, including addictions, mental health, employment status, education level, food security, housing, transportation, safety, etcetera in order for health programming to be successful. Most studies regarding the health issues in the Aboriginal populations in Canada have focused on on-reserve Aboriginal peoples or Aboriginals living in large, urban centers. There is a lack of research on off-reserve, small urban and rural centers. There has been government and tribal support for developing Aboriginal community centers in these locations to provide a cultural meeting place. Moreover, they often have some degree of health and wellness programming. Research indicates that developing pragmatic, community interventions for diabetes and obesity prevention is challenging and many programs with excellent intentions have been run with limited long-term success. Careful attention to process, implementation of clinical guidelines (while cultural needs are respected), adequate evaluation and ongoing adaptation of programs is needed to attain relevant outcomes. The aim of this study is to find out whether the Women Warriors 8-week wellness program can increase physical activity levels and confidence in exercising, and be effectively integrated into the community.

Who can participate?
The focus is on urban Aboriginal women but the study will include all women wishing to participate

What does the study involve?
All participants attend the 8-week Women Warriors program (WWP), a physical activity-based, holistic health program for Indigenous women. Participants are given a pedometer at the start of the program. Each session includes 45-60 minutes of exercise, a sharing circle to discuss barriers and facilitators to lifestyle change, and short, group-tailored, nutrition education and resource introduction (guest speakers are invited that represent different supports available to the participants in the community, an example is a local diabetes educator or social worker) for a total time of 1.5 – 2 hours. A private Facebook group is created during the program to be used to encourage each other in between sessions and after the program is completed. Interviews are conducted with facilitators after the program and focus groups and interviews are conducted with participants, exploring issues influencing physical activity levels and changes in their behavior. Anthropometric measures (height, weight, waist circumference and blood pressure), physical activity, questionnaire results and health-related quality of life are all measured before and after the program. Self-report pedometer logs and surveys before and after the program are used to assess physical activity levels (average weekly steps, weekly time being moderate-vigorously physically active and types of physical activity), perceived barriers to physical activity participation, and comfort participating in physical activity.

What are the possible benefits and risks of participating?
The main benefits to participants will be developing a sense of empowerment and building a supportive community. Participants will also benefit from being exposed to different types of physical activity and an increase in their overall physical activity to guideline recommended levels. Other benefits will include improved nutrition, stabilization of weight and improved quality of life. There will be community building amongst the participants themselves, and with the greater Aboriginal cultural community, non-Aboriginal fitness community, culinary community and traditional Canadian healthcare community. There will also be a facilitated self-awareness component using materials developed for the program. These self-awareness tools are intended to guide participants to better identify their own health issues and guide them to seek support from professionals as needed. Risks associated with a physical exercise program include fatigue, injury and cardiovascular stress, with the most extreme risk of death. The diabetic participants need to ensure that no blisters or wounds appear on their feet after the exercise class. In addition, they should monitor their blood sugars during and after class. The discomforts may include shin splints, sore muscles, shortness of breath, and fatigue. Standard care includes proper warm-up and cool down, good hydration and juice boxes on site for diabetic lows.

Where is the study run from?
1. Lloydminster Native Friendship Centre (Canada)
2. Village Square Leisure Centre (Canada)
3. Onion Lake Health Board Inc. (Canada)

When is the study starting and how long is it expected to run for?
January 2015 to December 2020

Who is funding the study?
Province of Alberta Government, Recreation and Physical Activity Division (Canada)

Who is the main contact?
Dr Sonja Wicklum

Contact information

Type(s)
Public

Contact name
Dr Sonja Wicklum

Contact details
Department of Family Medicine
University of Calgary
Calgary
Canada
T2N 4N1

Additional identifiers

Study information

Scientific Title
Evaluation of the Women Warriors - Eight Weeks to Healthy Living - Program as a unique model of delivery of wellness programming to Aboriginal and non-Aboriginal women in small urban and rural centers

Study objectives
Can the Women Warriors 8 week wellness program increase physical activity levels, increase confidence in exercising, and be effectively integrated into the communities of Lloydminster, Onion Lake and Calgary in the province of Alberta, Canada?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Calgary Conjoint Health Research Ethics Board, 05/01/2016, ID number REB15-2452

Primary study design
Interventional

Study design
Multi-centre prospective observational study

Study type(s)
Other

Health condition(s) or problem(s) studied

Interventions

The Women Warriors program (WWP) is a physical activity-based, holistic health program for Indigenous women. It has been running in Lloydminster, AB for 3 years with great success. Currently, the Onion Lake Cree Nation (OLCN) (near Lloydminster) and a consortium of Calgary organizations will be running programs in their communities. The program is 8 (2016, 2017, 2018 – Calgary) – 12 (2018 – OLCN – decision made to lengthen program) weeks long, offered three times per year and consists of 1 session per week. Many participants re-enroll, largely because of its unique, culturally relevant design. Participants are given a pedometer at the start of the program. Each session includes 45-60 minutes of exercise, a sharing circle to discuss barriers and facilitators to lifestyle change and short, group-tailored, nutrition education and resource introduction (guest speakers are invited that represent different supports available to the participants in the community, an example is a local diabetes educator or social worker) for a total time of 1.5 – 2 hours. A private Facebook group is created during the program to be used to encourage each other in between sessions and after the program is completed. Follow-up at 6 months (2016, 2017, 2018) and 1 year (2018 – OLCN).

The WWP was run in Lloydminster in 2016 (4 sessions) and 2017 (3 sessions) and expanded to Calgary (2 sessions) and OLCN (2 sessions) in 2018/19. There have been slight variations to the assessment and the program over time as per WWP developer and community requests. Therefore you will see in brackets the years to which certain measurements apply. The long-term plan is to complete a control trial in multiple communities with one consistent evaluation strategy.

A mixed-methods research approach is used. Qualitative data will be obtained through individual interviews with facilitators post-program and focus groups and individual interviews of participants, exploring programmatic and community issues influencing physical activity (PA) levels and exploring changes in their behavior. Inductive thematic analysis of interviews will be completed. Quantitative data will include anthropometric measures (height, weight, waist circumference and blood pressure), physical activity (PA) data, questionnaire results and health-related quality of life (HRQoL) measures (SF-36 and EQ-5D™ in 2016, EQ-5D™ only in 2017, 2018). These will be completed pre and post-program. Self-report pedometer logs and surveys pre- and post-program will assess PA levels (average weekly steps, weekly time being moderate-vigorously physically active and types of PA), perceived barriers to PA participation, and comfort participating in PA. Pedometers were chosen to assess PA because they were successfully used in the WW pilot (2015), provide immediate motivational feedback to participants, are cost effective and are validated.

The EuroQol EQ-5D (EQ-5D™) was chosen because of its established/preferred use by Alberta Health Services for the Alberta residents. There are challenges with respect to QoL tools for the Indigenous population and although there is some evidence that the SF36 may be a valid tool in this population it appeared to be the case in very selective situations. This, in combination with its cost and length, and the first attempt to use it (2016) have resulted in the choice of the EQ-5D™. Follow-up EQ-5D™ at 12 months (2016, 2017, 2018) and 1 year (2018 – OLCN).

Baseline and follow-up data will be presented as means with standard deviations (SD) for continuous variables and proportions with 95% confidence intervals for categorical variables. Changes pre- and post-program and one year post-program will be evaluated using a one-way (ANOVA) for continuous variables and chi-square test for categorical data. Longitudinal analysis of data for participants who complete more than one program will be done. A statistician will complete the statistical analysis. The primary and co-investigators will be responsible for

ensuring data collection, analysis and reporting. The Onion Lake Cree Nation will retain their own data as per First Nations principles of OCAP®. The University of Calgary will retain the Calgary-based program's data.

Intervention Type
Behavioural

Primary outcome(s)
Measurements will be taken a t1 (start of first program), t8 or 12 (end of first program), tX (start of any subsequent programs) and tX+8/12 (end of any subsequent programs) and t1 + 12 months. Groups will be analysed based on number of times they have completed the program and sub-analysed based on ethnicity. In 2016 and 2017, 6 month follow-up was desired but limited by funding. In 2018, one-year follow-up is intended. In descriptions below when one year follow-up (t1 + 12 months) is indicated it only applies to the 2018 programming.
1. The feasibility and acceptability of the WW-EP as a unique model of delivering wellness programming to Aboriginal and non-Aboriginal women in Lloydminster, Onion Lake, and Calgary, AB. This will be assessed based on attendance, individual and community response.
2.1. Knowledge of physical activity opportunities in Lloydminster, measured using pre-post questionnaires at t1, t8/12 and t1 +12
2.2. Sense of a 'community of support' for making healthy lifestyle changes, measured using pre-post questionnaires at t1 and t8/12 and t1 + 12, and qualitative interviews 1-4 weeks post-program
2.3. Confidence in consistent use of a pedometer as a method to track walking, measured using pre-post questionnaires at t1 and t8/12 and t1 + 12
2.4. Physical activity (PA) levels, measured using:
2.4.1. 2016 – adapted PA questionnaire, 2017, spring 2018 – WHO – Global Physical Activity Questionnaire® (GPAQ®), Fall 2018 (OLCN and Calgary programs) – International Physical Activity Questionnaire (iPAQ®), at t1 and t8/12 and t1 + 12
2.4.2. Weekly pedometer step counts during the program; in 2016 there was no wash-in, in 2017 and 2018 there was/is a wash-in period of one week followed by weekly self-recorded total steps for the duration of the program
3. Confidence at being able to develop and maintain an exercise routine, assessed using pre-post questionnaires and 2.4.1. above (PA questionnaires) at t1 and t8/12 and t1 + 12

Key secondary outcome(s)
1. Quality of life, measured using:
1.1. 2016: SF-36™ and EQ-5D™ t1 and t8/12
1.2. 2017: EQ-5D™ t1 and t8/12
1.3. 2018: EQ-5D™ t1 and t8/12 and t1 + 12
2. Confidence in eating a healthy diet, high in fiber and fruits and vegetables, measured using pre-post questionnaires at t1 and t8/12 and t1 + 12, likert scale used
3. Facilitators/barriers to healthy lifestyle changes, identified using qualitative interviews 1-4 weeks post program
4. Anthropometrics: weight, waist circumference, body mass index, % body fat (as per bio-impedance capable scale) at t1 and t8/12 and t1 + 12
5. Systolic and diastolic blood pressure, measured at t1 and t8/12 and t1 + 12

Completion date
30/12/2020

Eligibility

Key inclusion criteria
1. Women Warriors targets mothers and their children, regardless of ethnicity or age
2. Individuals > or = 18 yrs of age or 5 yrs - 18 yrs of age with the consent of a parent or legal guardian

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Total final enrolment
164

Key exclusion criteria
1. Pregnant or lactating
2. Currently enrolled in an organized weight-loss program or taking prescription weight loss medication (with the exception of liraglutide for the indication of Type 2 diabetes)

Date of first enrolment
27/02/2016

Date of final enrolment
30/12/2019

Locations

Countries of recruitment
Canada

Study participating centre
Lloydminster Native Friendship Centre
4602 49 Ave
Lloydminster
Canada
S9V 0T2

Study participating centre
Village Square Leisure Centre
2623 56 St NE

Calgary
Canada
T1Y 5J1

Study participating centre
Onion Lake Health Board Inc.
Box 70
Onion Lake Sk.
Canada
S0M 2E0

Sponsor information

Organisation
University of Calgary

ROR
https://ror.org/03yjb2x39

Funder(s)

Funder type
Government

Funder Name
Province of Alberta Government, Recreation and Physical Activity Division

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The data sets are anonymized immediately and hard-copy questionnaires are stored in a secure cupboard in a secure room in the Department of Family Medicine at the University of Calgary. All participants have consented to have their data analysed and are able to withdraw their data at any point during the program. The 2018 programming in Onion Lake is different in that the reservation will store anonymized data and the researchers have an agreement to access this data for analysis only. All three years of study have had ethics approval from the Conjoint Health Research Ethics Board at the University of Calgary and the 2018 Onion Lake program has also had approval of the Onion Lake Ethics Committee.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Quantitative results	01/10/2019	20/01/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes