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The Anishinaabek Cervical Cancer Screening Study

Submission date 25/10/2013	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 03/12/2013	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 18/11/2016	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ontario First Nations women are two times as likely to be diagnosed with cervical cancer compared to the general population. Researchers think that poor participation in cervical screening or inadequate follow-up are related to the greater incidence of cervical cancer. In this study we will work with communities to learn about First Nations women's cervical screening preferences. We want to compare two types of cervical cancer screening in First Nations populations: Pap tests and at-home human papillomavirus (HPV) test kits.

Who can participate?
Women aged 25 to 69 years who are registered with or live in the participating communities listed at http://www.accssfn.com/faq.html in Northwest Ontario, Canada.

What does the study involve?
Participating communities were randomly allocated to a method of cervical screening to first offer women in their community: either Pap tests and at-home human papillomavirus (HPV) test kits. Community-based research assistants (CBRAs) help to implement the research in their respective communities, helping to recruit women and provide education. Educational events for community members are organized and facilitated by each CBRA. Eligible women will make appointments with their CBRA. At these appointments, participants learn about informed consent, complete the questionnaire, and participate in cervical screening. Culturally-mindful tools like posters, flyers and brochures provide information to community members about HPV, cervical cancer and the study.
Pap tests are scheduled with the local clinics, collaborating healthcare providers or family physicians. Collaborating healthcare providers visit communities that are more than 60 km away from a healthcare service to ensure that Pap tests can be offered to these communities. Self-sampling kits are offered at the individual appointments. Participants are encouraged to take their sample immediately and mail it for testing but they have the option of taking the kit home. Results of Pap and HPV tests will be communicated by participants' preferred healthcare providers. This communication will allow for results to be explained. Follow-up appointments can be scheduled with these healthcare providers.
After the first offer of cervical screening, the CBRAs will follow-up consenting participants to ask about their experiences. The Research Team also meets with community representatives to

reflect on the first round of screening. After this turn-around period, the reverse method of screening (i.e. the method not offered in the first phase of screening) will be offered to non-responding women.

What are the possible benefits and risks of participating?
Participants will help inform culturally-sensitive and community-based cervical screening programming in Ontario. Participating in cervical screening will help women address health issues before they become serious. Cervical screening might help find cancer that has already started. Participants may worry less about their health by learning about their cervical cancer screening results. Some women may feel discomfort when attending a Pap test or collecting their own HPV sample. They also may feel embarrassed discussing sensitive topics like HPV or cervical cancer. This study promotes healthy cervical screening choices in First Nations communities. We hope to increase cervical screening participation and decrease cervical cancer incidence in First Nations women. This study will contribute to our understanding of the disease from a holistic perspective. We hope to find out why cancer rates are high in First Nations communities and what can be done to reduce them. We also hope to communicate our findings to a broad audience. We hope that we can help change cervical screening guidelines and health promotion programming.

Where is the study run from?
The study is centred at the Thunder Bay Regional Research Institute and Lakehead University in Thunder Bay, Ontario, Canada.

When is the study starting and how long is it expected to run for?
The study began in May 2013. Women will be invited to participate in cervical screening for 9-12 months.

Who is funding the study?
This study is funded by the Canadian Institute of Health Research (Canada).

Who is the main contact?
Dr Ingeborg Zehbe (principal investigator)
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Study website
http://www.accssfn.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MOP - 119344

Study information

Scientific Title
Engaging First Nations women in cervical cancer screening: assessing factors related to screening and uptake of self-sampling

Acronym
ACCSS

Study objectives
Our first hypothesis is that knowledge and attitude about cervical cancer and its prevention impact on screening behaviour. Our second hypothesis is that the option of self-collected sampling will increase participation in cervical cancer screening.

On 16/03/2015 the overall trial end date was changed from 01/05/2014 to 31/08/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lakehead University Research Ethics Board, 01/05/2013, REB project #: 126 12-13; ROMEO 1463139

Study design
Cluster-randomized two-armed trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)

Screening

Participant information sheet
Patient information can be found at: http://www.accssfn.com/faq.html

Health condition(s) or problem(s) studied
Cervical cancer

Interventions
Participating communities are randomized to a method of cervical screening to first offer women in their community who are between 25 and 69 years of age. In arm A, Pap tests are first offered (standard care in Ontario, 'control'), and in arm B women will be offered HPV self-collected tests ('intervention'). The method not offered in the first phase of screening will then be offered to non-responding women.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. To compare the proportions of women who participate in screening based on an offer of self-sampling versus an offer of attending for a Pap test. This will be measured after the first phase of cervical screening (approximately 4 months after baseline) and after the second phase of cervical screening (approximately 9-12 months after baseline - this is the final time point). We will use 'objective' measures, using reports from CytoBase, the provincial electronic database for Pap cytology, to capture the numerator of participants attending Pap tests, divided by the total number of participants offered to receive Pap tests. For HPV self-sampling, we'll use the number of HPV reports returned to the Research Team from the laboratory, divided by the number of participants who were offered HPV tests. We will also consider using other denominators, including the total number of women invited to participate, and estimates of the total number of women registered with the communities.
2. To compare the psychosocial impact of cervical screening based on a primary offer of self-testing with that based on a primary offer of a Pap test; psychosocial impact will be assessed by questionnaire at three time points (baseline; after the first round of screening - approximately 4 months after baseline; after the final round of screening - approximately 9-12 months after baseline). Psychosocial impact is measured using nine Likert scale questions (seven-point scale), which have been tailored from the TOMBOLA study, and one free text question that asks generally about additional comments.

Secondary outcome measures
1. To measure uptake of all types of cervical screening in 11 participating First Nations communities, represented by percentage of participants who undergo Pap tests or complete HPV self-sampling tests. This will be measured after the first phase of cervical screening (approximately 4 months after baseline) and after the second phase of cervical screening (approximately 9-12 months after baseline - this is the final time point). To evaluate the impact of screening barriers on the attendance for cervical screening, measured using questionnaire and clinical records. The numerators will be the sum of the outcome records (i.e. CytoBase records and HPV test laboratory records) divided by the total women invited, in addition to the total estimates of women in the communities.

2. To compare rates of self-reported screening attendance against objective measures of screening attendance (e.g. follow-up questionnaire will collect self-report of screening attendance). We will use self-report of screening attendance from the follow-up questionnaires at 4 months following baseline and at the final collection time point at approximately 9-12 months. The denominators will include the total number of women participating and the total number of women invited to participate, in addition to the total estimated numbers of women in the communities.
3. To measure the distribution of HPV types in the study population, measured by the number of each unique type of HPV divided by the total number of women who participated in self-sampling. We will use the genotyping data from the National Microbiology Laboratory to determine the proportions of women infected with particular strains of HPV, divided by the total samples received.

Overall study start date
08/05/2013

Completion date
31/08/2014

Eligibility

Key inclusion criteria
Inclusion criteria (cluster level):
1. First Nations community in the Robinson Superior region in Northwest Ontario
2. Ratified research agreements signed with Thunder Bay Regional Research Institute

Inclusion criteria (individual level):
1. Female participant
2. Between the ages of 25 and 69 years
3. Registered with one of the eleven participating First Nations communities (band membership as per the Indian Act) or currently living on the reserve
4. Must belong to Ontario Health Insurance Plan, a provincial insurance plan that ensures residents have universal coverage for medically necessary services

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Of approximately 1200 eligible women across 11 First Nations communities, we expect approximately 400 participants.

Key exclusion criteria

Exclusion criteria (individual level):
1. Currently pregnant (will be asked to provide sample after pregnancy)
2. Known total hysterectomy

Date of first enrolment
08/05/2013

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
Canada

Study participating centre
Thunder Bay Regional Research Institute
Thunder Bay
Canada
P7B6V4

Sponsor information

Organisation
Thunder Bay Regional Research Institute (Canada)

Sponsor details
980 Oliver Road
Thunder Bay
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P7B 6V4

Sponsor type
Government

Website
http://www.tbrri.com

ROR
https://ror.org/013kbs677

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
At least two more peer-reviewed papers are expected to be published.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/02/2014		Yes	No
Results article	results	08/10/2016		Yes	No