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Cervical screening self-test study

Submission date 28/07/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 16/08/2017	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/09/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cervical cancer is a disease that can affect women. It is caused by a virus called human papillomavirus (HPV). Cervical screening is a way that pre-cancers and cancers can be detected early in women. Women from 20 to 69 years of age are recommended to screen for cervical cancer every 3 years. Some women do not get screened. Screening is done with a Pap smear test (Pap test) which takes samples of cervical cells to test for cancer. When someone doesn't get a Pap test, they may get a reminder from their doctor. The aim of this study is to evaluate whether sending a cervical screening self-testing kit instead of a reminder letter will help more women take the test.

Who can participate?
Women aged 30 to 69 years old who have not had a Pap test in 36 months and no history of abnormalities or have had a pap test in 15 months with a history of abnormalities.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a self-testing kit with instructions in the mail, and they can collect a sample for screening at home. Participants then send their samples back to the health centre. Those in the second group receive a letter asking them to arrange a Pap test appointment with their doctor. Participants are followed up and offered the appropriate care based on the results of their samples.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
Eastern Health Cervical Screening Initiatives Program (Canada)

When is the study starting and how long is it expected to run for?
April 2017 to March 2018

Who is funding the study?
Build in Canada Innovation Program (Canada)

Who is the main contact?
1. Ms Brianne Wood
2. Associate Professor Catherine Popadiuk

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Protocol serial number
2017 183

Study information

Scientific Title
Cervical Screening Self-Test Study: A randomized controlled trial comparing a mailed HPV self-sampling kit to an invitation letter for Pap testing in Newfoundland, Canada

Study objectives

Self-sampling will increase the uptake among the underscreened, compared to a mailed invitation for a Pap test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted to Health Research Ethics Board (part of the Health Research Ethics Authority in Newfoundland) on July 26, 2017

Primary study design
Interventional

Study design
Single-centre randomised parallel controlled trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Cervical cancer and cervical cancer screening

Interventions
A simple randomisation scheme is generated (using the allocation ratio) using R statistical software by a study analyst. This randomisation scheme (i.e. intervention versus control) is assigned to the list of potentially under-screened women, by someone external to the study. A team member exports a list of encrypted health card numbers from the registry, which are assigned unique 5-character study identifiers (Study IDs). These Study IDs are then randomly allocated to the intervention arm or control arm. Once this is complete, the allocation arrangement can be linked back to the exported data from the registry to allow for mail-out, and baseline measurements to compare arms (using age, community, and Pap history).

Participants in Arm 1 receive one invitation to Pap test letter.

Participants in Arm 2 receive a mailed self-sampling kit (“HerSwab”) from the study team (i.e. the research coordinator), and a questionnaire assessing participant demographics and acceptability of this cervical screening modality.

Arm 2 participants are informed that they may participate either by collecting a sample with HerSwab, or by getting a Pap with their primary care provider.

An HerSwab™ kit comes with the HerSwab™ sampling device, a storage bag for the sample and device to be stored post-collection, patient collection instructions. HerSwab™ is a medical device developed by Eve Medical that allows women to self-collect vaginal samples. This tool has been used in cervical screening and sexually transmitted infection testing settings, and has been evaluated in several research settings. Samples will be transported to the laboratory via dry transport (ie. without a transport medium). HerSwab™ has been CE marked and has received Health Canada licensing (no. 94847).

Kits are mailed out over a three-month period directly from the research team at Eastern Health, and samples are accepted over a six month period at the laboratory for processing. The

instructions recommend women mail their samples immediately after collection, though the research indicates the sample are unaffected by dry transport for 10 days or more.

Women who are HPV positive will be offered one of three follow up options:
1. To follow up with their primary care provider
2. To follow up with Dr. Jacqueline Elliott (study general practitioner who will be available for women who are not attached to a primary care provider or wish to see someone other than their regular health care provider).
3. To follow up at one of the “Open Clinics”, which are local clinics that provide Pap tests to the public. A listing of open clinics will be included with the result letter.

Three months following study initiation, the registry runs a report to determine the follow-up status of the HPV positive women, and if necessary, send a registered letter second notice of results to the women again referring her for follow up with one of the three options above.

After follow up, women who are HPV 16 or 18 positive, and cytology negative receive communication from the study to participate in screening as part of the CSI 12 months after they collected an HPV sample. Women who are positive with strains of HPV other than 16 or 18, and cytology negative, return to the normal screening interval.

Participants in Arm 1 are followed up according to standard care. Individuals who have abnormal cytology are recommended to attend for another Pap test by their health care provider. All results are managed by the registry, and all participants in Arm 1 are automatically return to the Program.

Intervention Type
Device

Primary outcome(s)
The number of women who complete "screening" is calculated by summing the number of respective self-sampling kits that were mailed to the lab for testing (records counted by the laboratory) and the number of Pap tests recorded in the registry at three months and six months. For intention to treat analysis, any type of screening will be counted in the analysis, divided by the respective number of women allocated to each arm.

Key secondary outcome(s)
1. Proportion of women who prefer self-sampling to Pap testing is assessed based on survey responses, stratified by screening participation (self-sampling at home versus Pap testing versus self-sampling in clinic vs no intention to screen) at six months following the final invitation
2. Proportion of women who participate in screening per protocol, as well as any screening, assessed using the records
3. Proportion of women who find self-sampling acceptable is assessed based on survey responses to the question "In the future, would you prefer to see a health professional or take your own sample for cervical screening?" Acceptability will be measured by reporting proportions of women who agree to the following two statements.
4. Proportion of women who find Pap-testing acceptable is assessed based on survey responses to the question "In the future, would you prefer to see a health professional or take your own sample for cervical screening?" (Acceptability will be measured by reporting proportions of women who agree to the following statement.
5. Proportion of target population reached is measured by any screening record, divided by the total number of allocated individuals (adjusting for returned mail) at six months.

*The following outcomes will be measured if time and resources allow, but they will not be calculated within the 1-year time frame of the Build in Canada Innovation project. As a result, they may not be reported with the rest of the trial results.
5.1. CIN2+ cases detected in participants in the intervention arm is measured using health administrative records through the registry within three years of the initial invitation
5.2. Estimated cost per CIN2+ detected in the intervention arm is measured using simulation models that are populated with aforementioned outcomes
5.3. Proportion of women found positive for HPV in the intervention arm who follow up on subsequent interventions is measured using the cervical cancer registry and health administrative records within three years of the initial invitation
5.4. Proportion of women in both arms who participate in subsequent screening is measured is measured using the cervical cancer registry and health administrative records within three years of the initial invitation

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Female
2. Ages between 30 and 69 years
3. Lives in Eastern Health jurisdiction
4. Has not had a Pap test in 36 months and no history of cytological abnormalities OR has not had a Pap test in 15+ months with a history of positive cytology. These women were included on previous edition of the cytology recall list, and have not participated in screening since.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Women with known total hysterectomies

Date of first enrolment
01/10/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
Canada

Study participating centre
Eastern Health Cervical Screening Initiatives Program
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Sponsor information

Organisation
Eve Medical

Funder(s)

Funder type
Government

Funder Name
Build in Canada Innovation Program

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date. We would like to identify what information is appropriate for sharing and what information will be required to be confidential. Because this study is being run using waived consent (by mirroring standard practice of a cervical cancer screening program), it is unlikely that the datasets can be made publicly available, as we are not obtaining informed consent of this aspect from participants.

IPD sharing plan summary
Data sharing statement to be made available at a later date