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Effects of a web-based decision aid to support decision-making on cervical screening by Chinese working women aged 25–44

Submission date
04/08/2022

Recruitment status
No longer recruiting

Registration date
04/08/2022

Overall study status
Completed

Last Edited
02/01/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Cervical screening is a test to check the health of the cervix (the lower part of the uterus (womb) that connects the uterus and vagina). During the procedure, a small sample of cells are collected from the cervix using a small soft brush and these cells are analysed for certain types of human papillomavirus (HPV) or for abnormal changes in the cervical cells. Some types of HPV (known as "high-risk") can cause abnormal changes to the cells in the cervix. The results of the cervical screening will indicate whether further investigation is needed. Abnormal cell changes over time could develop into cervical cancer but not all cell changes will develop into cancer.

This study aims to assess the acceptability and feasibility of a Web-based decision aid to support decision-making on cervical screening by Chinese working women, and to examine the preliminary effects of the decision aid on the knowledge level, risk perception, decisional conflicts, clarity of values, screening decision and screening uptake by these women.

Who can participate?
Chinese working women aged between 25 and 44 years.

What does the study involve?
Participants will be allocated to one of two groups with an equal chance of being in either group (like tossing a coin). One group will receive the intervention (access to the Web-based decision aid) and the other group will receive usual care (a brief fact sheet about cervical cancer prevention),
The research nurse will share the link for the Web-based decision aid with the participants and briefly explain how to use the icons in the decision aid. The participants will then choose a time and place of their convenience to read the decision aid.
After 2 weeks, a survey will be distributed to all participants to collect data on their knowledge about cervical cancer screening, risk perception, clarity of values, screening decision, and uptake of screening. A telephone interview will be also conducted to assess the acceptability of the intervention.

What are the possible benefits and risks of participating?
It is hoped that the participants who receive access to the Web-based decision aid will have a better understanding of cervical cancer and screening options and that the decision aid will clarify the participants' values and help them to make screening decisions.

Where is the study run from?
Health and Medical Research Fund (Hong Kong)

When is the study starting and how long is it expected to run for?
From March 2021 to September 2023

Who is funding the study?
Health and Medical Research Fund (Hong Kong)

Who is the main contact?
Dr Dorothy Chan, dorothycns@cuhk.edu.hk

Contact information

Type(s)
Principal investigator

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Dr Dorothy Chan

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of a web-based decision aid to support decision-making on cervical screening by Chinese working women aged 25–44: An exploratory trial

Study objectives
1. The web-based decision aid is acceptable and feasible in Hong Kong Chinese working women aged 25–44 years
2. The decision aid can help in reducing decisional conflicts and improving their clarity of values concerning cervical cancer screening
3. The decision aid can help in improving knowledge of cervical cancer and screening, and risk perceptions about the disease
4. The decision aid can enhance the participant's screening decision and the actual screening uptake

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2022, Joint Chinese University of Hong Kong- New Territories East Cluster Clinical Research Ethics Committee (8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, Hong Kong; +852 3505 3935; crec@cuhk.edu.hk), ref: 2021.700

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Block randomisation with a block size of eight, will be used to allocate eligible participants to the intervention group or the control group in a 1:1 ratio. Randomisation will be performed by a statistician, who will not be involved in the study, using a computer-generated allocation sequence.
A trained research nurse will deliver the intervention by sharing the link of the Web-based decision aid with the participants in the intervention group after they complete the baseline survey. Participants will then read the Web-based decision aid in their own time and at a convenient location. To evaluate their adherence, participants will be re-contacted 1 week after joining the study to determine if they have used or encountered difficulty in using the decision aid. Appropriate support will be given if they express difficulty. The participants in the control group will receive the usual care: a brief fact sheet about cervical cancer prevention.
Participants will be contacted to complete a follow-up survey 2 weeks later and a telephone interview will be conducted to assess the acceptability of the intervention.
The repeated-measure outcomes of knowledge, risk perception, decisional conflicts and

screening decision will be compared between the groups using a generalised estimating equation model. The screening uptake will be compared using a chi-square or Fisher's exact test. Content analysis will be performed to evaluate the acceptability of the decision aid.

Intervention Type
Behavioural

Primary outcome(s)
Decisional conflict measured using survey questions at baseline and 2 weeks

Key secondary outcome(s))
1. Knowledge about cervical cancer screening measured using survey questions at baseline and 2 weeks
2. Risk perception measured using survey questions at baseline and 2 weeks
3. Clarity of values measured using survey questions at baseline and 2 weeks
4. Screening decision (choice predisposition and choice questions) measured using survey questions at 2 weeks
5. Screening uptake measured using survey questions at 3 months
6. Acceptability of the intervention measured using a telephone interview at 2 weeks

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/02/2024:

1. Chinese women with a Hong Kong Identity Card
2. Aged ≥25 and ≤44 years
3. Engaged in a part-time or full-time job
3. No history of cervical cancer or total hysterectomy
4. A history of sexual activity
5. Able to read or communicate in Chinese or Cantonese
6. No history of a Pap test/HPV DNA testing in their lifetime or no Pap test/HPV DNA testing in the past 3 years
7. Willing to use and have at least one computer, tablet, or smartphone

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Previous inclusion criteria:

1. Chinese women with a Hong Kong Identity Card
2. Aged ≥25 and ≤44 years
3. Engaged in a part-time or full-time job
3. No history of cervical cancer or total hysterectomy
4. A history of sexual activity
5. Able to read or communicate in Chinese or Cantonese
6. No history of a Pap test/HPV DNA testing in their lifetime or no Pap test/HPV DNA testing in the past 5 years
7. Willing to use and have at least one computer, tablet, or smartphone

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
44 years

Sex
Female

Total final enrolment
158

Key exclusion criteria
Cannot read the decision aid by themselves

Date of first enrolment
01/10/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
Hong Kong

Study participating centre
Boys' and Girls' Clubs Association of Hong Kong (BGCA)
Hong Kong (China)
Hong Kong
852

Sponsor information

Organisation

Health and Medical Research Fund

Funder(s)

Funder type
Government

Funder Name
Health and Medical Research Fund

Alternative Name(s)
, HMRF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Hong Kong

Results and Publications

Individual participant data (IPD) sharing plan
Data related to the outcome measures will be available on request to the PI, Dr Dorothy Chan (dorothycns@cuhk.edu.hk) after 30/09/2023.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/12/2024	02/01/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes