

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

<b>Submission date</b> 04/08/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/01/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

### Contact name

Dr Dorothy Chan

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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](mailto:crec@cuhk.edu.hk)), ref: 2021.700

## Study design

Pilot randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Community

## Study type(s)

Prevention

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## 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 measure**

Decisional conflict measured using survey questions at baseline and 2 weeks

### **Secondary outcome measures**

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

### **Overall study start date**

30/03/2021

### **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  $\geq 25$  and  $\leq 44$  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  $\geq 25$  and  $\leq 44$  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

**Age group**

Adult

**Lower age limit**

25 Years

**Upper age limit**

44 Years

**Sex**

Female

**Target number of participants**

158

**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)  
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## Sponsor information

**Organisation**  
Health and Medical Research Fund

**Sponsor details**  
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**Sponsor type**  
Government

**Website**  
<https://rfs1.fhb.gov.hk/english/welcome/welcome.html>

## 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

**Publication and dissemination plan**  
The findings will be shared in conference and published in international referred journals.

**Intention to publish date**  
30/09/2024

**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?
<a href="#">Results article</a>		30/12/2024	02/01/2025	Yes	No