

Impact of an educational intervention on women's knowledge and confidence in human papillomavirus self-sampling

Submission date 17/12/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/01/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/10/2014	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Human papillomavirus (HPV) self-sampling (Self-HPV) has the potential to be used as a primary cervical cancer screening method in low resource settings. Before introducing a new method of screening, especially a self-screening method, women should be aware of the importance of screening and women must accept to collect the samples themselves. However, reports reveal that in Sub-Saharan Africa, women's knowledge about HPV and cervical cancer is low. In addition, although women gladly welcome self-HPV testing, they do not feel comfortable in handling the device and are more confident in the results obtained by a gynaecologist. The aim of this study was to evaluate whether an educational intervention would improve women's knowledge and confidence in the Self-HPV method.

Who can participate?

Women aged between 25 and 65 years old eligible for cervical cancer screening were enrolled in four health care centers in Yaoundé and the surrounding countryside.

What does the study involve?

Participants were randomly allocated to receive either standard information (control group) or standard information followed by an educational intervention (interventional group). Standard information included explanations about what the test detects (HPV), the link between HPV and cervical cancer and how to perform HPV self-sampling. The educational intervention consisted of a culturally tailored video about HPV, cervical cancer, Self-HPV and its relevancy as a screening test.

What are the possible benefits and risks of participating?

Benefits were an early free screening and the cost of treatment is paid by the sponsor's study. There were no risk of participating in this study.

Where is the study run from?

This study run from the Faculty of Medicine, University of Geneva, Geneva, Switzerland, the Department of Gynecology and Obstetrics, University Center Hospital, Yaoundé, Cameroon,

the Department of Gynecology and Obstetrics, Gynecologic Division, Geneva University Hospitals, Geneva, Switzerland and the Geneva Foundation for Medical Education and Research, Geneva, Switzerland.

When is the study starting and how long is it expected to run for?
This study started in July 2012 and ran for a month.

Who is funding the study?
This study was supported by a grant from International Solidarity Geneva, the University Hospitals of Geneva and UBS Geneva (Switzerland).

Who is the main contact?
Mr Michel Zbinden
Mr Gaëtan Sossauer

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Impact of an educational intervention on women's knowledge and confidence in human papillomavirus self-sampling: a randomized controlled trial in Cameroon

Study objectives
Human papillomavirus (HPV) self-sampling (Self-HPV) has the potential to be used as a primary cervical cancer screening method in a low resource setting. Our aim was to evaluate whether an educational intervention would improve womens knowledge and confidence in the Self-HPV method.

Ethics approval required
Old ethics approval format

Ethics approval(s)

National Research Committee of Cameroon, ref: 159/CNE/SE/2012

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Educational video improves cervix cancer knowledge

Interventions

Participants were randomly chosen to receive standard information (control group) or standard information followed by educational intervention (interventional group).

1. Standard information included explanations about what the test detects (HPV), the link between HPV and cervical cancer and how to perform HPV self-sampling.
2. The educational intervention consisted of a culturally tailored video about HPV, cervical cancer, Self-HPV and its relevancy as a screening test.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Assess the impact of an educational intervention on womens knowledge about HPV. A 7-item questionnaire was addressed to participants, with 3-point scale answers.

Key secondary outcome(s)

Assess the impact of an educational intervention on womens confidence regarding the Self-HPV test. We conducted a scientific literary review of the questionnaires on cervical cancer knowledge, attitudes and confidence about Self-HPV, in order to base our methodology on previous studies.

The acceptability indices were scored on a 4-point scale. For each method, we calculated mean scores for embarrassment, pain, anxiety, discomfort, degree of relaxation (reverse score) and confidence (reverse score). Responses were on a 4-point scale as follows: not at all, slightly, moderately and very. A total acceptability score for each method was calculated by adding the mean scores of each of these 6 items. A higher score indicates a more negative attitude toward the test. The willingness to perform Self-HPV was tested by the following two questions: Do you agree to perform regularly Self-HPV? and Would you recommend the Self-HPV to friends and/or family?. Willingness to test oneself at home was also assessed and possible answers were yes, no and do not know.

Completion date

12/08/2012

Eligibility

Key inclusion criteria

1. Women aged between 25 and 65 years old eligible for cervical cancer screening
2. Willing to give written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Pregnancies
2. Previous hysterectomies or cervical surgery

Date of first enrolment

15/07/2012

Date of final enrolment

12/08/2012

Locations

Countries of recruitment

Cameroon

Switzerland

Study participating centre

Rue de la Fontenette 9

Geneva

Switzerland

1227

Sponsor information

Organisation

International Solidarity Geneva (Solidarité Internationale Genève) (Switzerland)

Funder(s)

Funder type

Government

Funder Name

International Solidarity (Solidarité Internationale), Geneva (Switzerland)

Funder Name

The University Hospitals of Geneva (Switzerland)

Funder Name

UBS, Geneva (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/10/2014		Yes	No