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# 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

**Registration date**
10/01/2014

**Overall study status**
Completed

**Last Edited**
28/10/2014

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 womens 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 form 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
Mr Michel Zbinden

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Rue de la Fontenette 9
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure
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.

### Secondary outcome measures

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.

### Overall study start date
15/07/2012

### 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

### Age group
Adult

### Sex
Female

### Target number of participants
302

### 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)

**Sponsor details**
Bureau de la solidarité internationale
15, rue Pierre-Fatio
Geneva
Switzerland
1204

**Sponsor type**
Government

# 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

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## 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 |