Impact of health education intervention on cervical cancer and screening for women in Ghana

Submission date 18/03/2019	Recruitment status No longer recruiting	 Prospectively registered Protocol 	
Registration date	Overall study status	Statistical analysis plan	
22/03/2019 Con	Completed	[X] Results	
Last Edited 15/11/2019	Condition category Cancer	Individual participant data	

Plain English summary of protocol

Background and study aims

Cervical cancer is a leading cause of death among women. However, it is preventable, as there are technologies for early detection and treatment of precancerous lesions. The main aim of this study is to determine the effect of a health education intervention on cervical cancer and screening beliefs and perceptions of women in the Komenda, Edina, Eguafo, and Abirem District in the Central Region.

Who can participate? Women aged 11 to 70 at selected churches in Elmina and Kissi in the Central Region of Ghana

What does the study involve?

The study will involve women in Elmina and Kissi completing questionnaires on cervical cancer and screening after which health education on cervical cancer and screening is offered to women in Elmina only for six weeks and data is collected again from both groups.

What are the possible benefits and risks of participating?

Women will receive information on cervical cancer and screening. Those in the intervention group will benefit from health education on cervical cancer and screening, which can enable them to adopt behaviours to prevent cervical cancer. The study will not result in any physical, social or psychological risks, but participants are being cautioned that some of the questions may cause emotional discomfort.

Where is the study run from? University of Cape Coast (Ghana)

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

Who is funding the study? Directorate of Research, Innovation and Consultancy of the University of Cape Coast (Ghana) Who is the main contact? Dr Nancy Innocentia Ebu Enyan nebu@ucc.edu.gh

Contact information

Type(s) Scientific

Contact name Dr Nancy Innocentia Ebu

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers DRIC/UCC/18

Study information

Scientific Title

Impact of health education intervention on cervical cancer and screening for women in Ghana: a community-based trial

Acronym IHEICCSWG

Study objectives

The study hypothesised that there will be an increase in knowledge about cervical cancer, knowledge about cervical cancer screening, perceived susceptibility, perceived seriousness,

perceived benefits, and self-efficacy in the intervention group compared to the control group. It also hypothesised that perceived barriers about cervical cancer screening will decrease for women in the intervention group compared to the control group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by 08/06/2017, Institutional Review Board of the University of Cape Coast, University of Cape Coast, Institutional Review Board, Private Mail Bag, Cape Coast, Ghana, Tel: +233 (0) 558093143/ +233 (0)508878309/ +233 (0)244207814, Email: irb@ucc.edu.gh, ref: UCCIRB/CHAS /2017/24

Study design Non-equivalent control-group design

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Community

Study type(s) Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Cervical cancer and screening beliefs and perceptions

Interventions

Six weeks health education was given to women in the selected churches in the intervention group. These women were grouped in their respective churches and baseline data collected before offering the health education on cervical cancer and screening using a standardised tool. The health education intervention took approximately six weeks, variety of teaching methodologies were employed. Also, each participating church had the opportunity of being educated once a week for six weeks. The education was given by a qualified registered nurse, and each session took approximately 1 hour. Participants were reassessed after the intervention

For the control group, initial data was collected from eligible women in the churches constituting the control group who volunteered to participate in the study. Participants from the selected churches were conveniently sampled based on their consent to participate in the study. Data were collected from the same group six weeks after the initial data collection.

Official permission was sought from the leadership of the various churches. Written informed consent was obtained from each participant and with assurance of confidentiality and anonymity. Privacy was also ensured at the data collection stage of the research. Additionally, no personal identifying information was found on the instrument. Persons suspected of having the

disease were referred to an obstetrician gynaecologist at the Cape Coast Teaching Hospital for further investigation and management. This intervention would have been expanded to cover all the women in the district, but due to the limited funding available for this project, only the selected women benefited. It is hoped that future interventions would be upscaled to cover other women in the district and beyond.

Intervention Type

Behavioural

Primary outcome measure

- 1. Knowledge of cervical cancer
- 2. Knowledge of cervical cancer screening
- 3. Perceived susceptibility
- 4. Perceived seriousness
- 5. Perceived benefits
- 6. Perceived barriers
- 7. Self-efficacy

All measured using a questionnaire adapted from Ebu, Mupepi, Siakwa, and Sampselle (2015) and Mupepi, Sampselle and Johnson (2011) at baseline and 6 weeks

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

08/08/2017

Completion date

07/11/2018

Eligibility

Key inclusion criteria

Women aged 11 to 70 years residing in the K.E.E.A District were included in this study. It was assumed that if women as young as 11 years obtain information about cervical cancer and screening, they will be well informed about the risks and prevention strategies

Participant type(s)

Healthy volunteer

Age group Other

Other

Sex Female

Target number of participants

418 women were recruited for the intervention group and another 418 for the control group

Total final enrolment

782

Key exclusion criteria

1. Women who failed to volunteer for the study

2. Those under 11 years and above 70

3. Those with dementia or mental health problems

4. Those who were not residing in the study area

Date of first enrolment 07/08/2018

Date of final enrolment 30/08/2018

Locations

Countries of recruitment Ghana

Study participating centre Elmina and Kissi in the Central Region of Ghana School of Nursing and Midwifery University of Cape Coast Cape Coast Ghana

Sponsor information

Organisation University of Cape Coast

Sponsor details University of Cape Coast Cape Coast Ghana -+233 (03321) 32480/32483

registrar@ucc.edu.gh

Sponsor type Government

Website www.ucc.edu.gh

ROR

Funder(s)

Funder type University/education

Funder Name University of Cape Coast

Results and Publications

Publication and dissemination plan

A manuscript has been prepared for submission to BMC Public Health. The findings will be shared with the participants and stakeholders interested in cervical cancer at the local and international level.

Intention to publish date

08/10/2019

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.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	11/11/2019	15/11/2019	Yes	No