ISRCTN37847119 https://doi.org/10.1186/ISRCTN37847119

Building HPV vaccine confidence in healthcare workers in Nigeria

Submission date
20/02/2025

Recruitment status
No longer recruiting

Registration date
21/02/2025

Overall study status
Completed

Last Edited
24/04/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
The HPV vaccine can effectively prevent cervical cancer, but HPV vaccine uptake is particularly low in some low-income settings, due to supply and vaccine confidence barriers. HPV vaccine confidence has also been found to be lacking among healthcare workers in some countries, including Nigeria. Nigeria has a long history of low vaccine confidence in some parts of the country. HPV vaccine rumours and concerns have been observed throughout the country, including among healthcare workers. Interventions that specifically address healthcare workers' vaccine confidence are limited, since vaccine confidence is often assumed. The aim of this pilot trial is to understand whether a full trial that tests a co-designed intervention to build healthcare workers' HPV vaccine confidence is feasible and acceptable in Nigeria.

Who can participate?
Healthcare workers who are employed within study facility will be eligible to take part. Healthcare workers are defined as those who provide direct clinical services to patients, and includes community healthcare workers and assistants.

What does the study involve?
Health facilities will be randomly assigned to receive either a digital intervention, an in-person intervention, or no intervention. For the intervention facilities, healthcare workers will either receive short information videos that contain information about HPV vaccines and demonstrate ways to handle rumours and misinformation, or attend in-person sessions where these topics are discussed amongst peers. In all facilities, healthcare workers will be asked to fill in a short survey at the end of the study.

What are the possible benefits and risks of participating?
The benefits to healthcare workers are that they will receive additional, accurate information about HPV vaccines. This could support them in their practice, and build confidence in communicating with caregivers and patients. Health care workers will also receive a small incentive for taking part in research interviews and surveys, to acknowledge the time they are giving.

Possible risks are that healthcare workers may need to take time from their clinical duties to take part in the interventions. Healthcare workers can be overburdened and so this may cause stress. Secondly, a healthcare worker may use the intervention platform to spread misinformation about HPV.

Where is the study run from?
The study is being jointly led by Karolinska Institutet, Sweden, and the Oxygen for Life Initiative, Nigeria, with primary health facilities in Jigawa and Oyo States included.

When is the study starting and how long is it expected to run for?
January 2023 to December 2025.

Who is funding the study?
The Swedish Research Council

Who is the main contact?
A/Prof Sibylle Herzig van Wee (sibylle.herzig.van.wees@ki.se)
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Contact information

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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
Building HPV vaccine confidence through co-designed interventions with and for healthcare workers in Nigeria (HCW-Trust): a pilot cluster randomized controlled trial

Acronym
HCW-Trust

Study objectives
We hypothesize that interventions co-designed with healthcare workers to address HPV vaccine confidence will be acceptable and feasible to evaluate through a cluster randomised trial design in Oyo and Jigawa States, Nigeria.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 15/05/2023, Jigawa State Ethics Committee (Ministry of Health, New Secretariat Complex, Dutse, 720101, Nigeria; -; mkainuwa@yahoo.com), ref: JGHREC/2023/151

2. approved 06/04/2023, Jigawa Ministry of Health (Ministry of Health, New Secretariat Complex, Dutse, 720101, Nigeria; -; smoh_jigawa@yahoo.com.uk), ref: MOH/PH/PHRAT/MN/23/003

3. approved 14/04/2023, Oyo State Research Ethics Committee (Ministry of Health, Department of Planning, Research and Statistics Division, Ibadan, 200285, Nigeria; -; oyosmoh@gmail.com), ref: AD/13/479/362A

4. approved 28/07/2023, University of Ibadan Research Ethics Committee (Institute for Advanced Medical Research and Training (IAMRAT), College of Medicine, University of Ibadan, Ibadan, 200285, Nigeria; +234 8033910757; imratcomui@gmail.com), ref: UI/EC/23/308

5. approved 22/10/2023, Swedish National Ethics Review Board (Box 2110, Uppsala, 750 02, Sweden; +46 104750800; registrator@etikprovning.se), ref: 2023-04772-01-471058

Study design
Unblinded three-arm pilot cluster randomized controlled trial using an embedded mixed-methods approach

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthcare worker HPV vaccine confidence

Interventions
The two interventions entail tailored and concrete strategies to build vaccine confidence among Nigerian healthcare workers - using a digital format, and an in-person format. The intervention aims to use information sharing strategies to increase Nigerian HCWs knowledge, understanding, and skills around the HPV vaccine and how to address questions and concerns from the community.

Facilities will be selected for participation with the Ministry of Health, and consent for the study will be obtained from the facility in-charge. All the healthcare workers within the intervention arm facilities will be approached by study staff, and asked if they want to take part in: arm a) receiving digital materials to their phone; arm b) in person facilitated sessions within the health facility. The content and implementation approach for both arms is being co-designed with healthcare workers in Jigawa and Oyo states, with the final materials expected to be finalised by May 2025.

In arm A, healthcare workers will receive a series of short digital interventions sent to their personal phone number, over a three month period. In arm B, healthcare workers will be invited to a series of in-person workshops that take place in their health facility, with the other members of staff, over a three month period. The content of both digital and in-person interventions will include HPV vaccine information, behavioural change strategies to tackle misinformation and rumours, and effective communication with caregivers and patients.

At the end of three months, all healthcare workers (regardless of whether they took part in the intervention activities) within the study facilities (intervention and control), will be invited to complete a short survey as part of the evaluation. The survey is expected to take 15 minutes, and there is no further follow-up planned.

Intervention Type
Behavioural

Primary outcome(s)
Proportion of healthcare workers who self-report engaging with the intervention content – either receiving information through digital channels or taking part in face-to-face sessions measured using qualitative interviews at endline

Key secondary outcome(s))

1. Acceptability of the intervention:
1.1 Proportion of healthcare workers employed in intervention facilities who have viewed at least one digital message is measured using endline survey at endline
1.2 Proportion of healthcare workers employed in intervention facilities who have taken part in an in-person session is measured using endline survey at endline
1.3 Mean number of digital messages that healthcare workers employed at intervention facilities have viewed is measured using endline survey at endline
1.4 Mean number of in-person sessions attended by healthcare workers employed at intervention facilities is measured using endline survey at endline
1.5 Number of views/likes that individual digital messages receive is measured using implementation monitoring at endline
1.6 Number and content of messages sent in digital discussions is measured using implementation monitoring at endline
1.7 Participatory engagement with the in-person intervention sessions is measured using implementation monitoring at endline
1.8 Content of in-person intervention sessions is measured using implementation monitoring at endline
1.9 Reasons for not engaging with the intervention is measured using qualitative interviews at endline
1.10 Perceptions of the intervention is measured using qualitative interviews at endline

2. Feasibility of intervention:
2.1 Proportion of healthcare workers that own a phone that can support the digital intervention is measured using endline survey at endline
2.2 Proportion of healthcare workers in intervention and control facilities that have the digital delivery platform installed on their phone is measured using endline survey at endline
2.3 Extra healthcare worker time needed to engage in the intervention is measured using endline survey at endline
2.4 Perception of the intervention burden, including network cost, compensation and task shifting is measured using qualitative interviews at endline

3. Feasibility of cRCT design:
3.1 Proportion of facilities that consent to the randomisation process is measured using study records at endline
3.2 Vaccine availability is measured using baseline facility survey at baseline
3.3 Proportion of healthcare workers who are employed in study facilities for a minimum duration of 3 months is measured using endline survey at endline
3.4 Social desirability in reporting the outcome of vaccine confidence is measured using qualitative interviews at endline

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Healthcare workers who are employed within study facilities
2. Provide direct clinical services and includes community healthcare workers and assistants.
3. Aged 18 years and older
4. Able to provide informed consent

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Temporary staff who are not employed at the facility
2. <18 years old
3. Unable to provide consent

Date of first enrolment
01/05/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Nigeria

Study participating centre
Oxygen for Life Initiative
Department of Pediatrics, College of Medicine, University of Ibadan
Ibadan
Nigeria
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Sponsor information

Organisation

Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Not defined

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. These data will include quantitative intervention monitoring data, and healthcare worker survey data. These will be made available at the time of publication of the main pilot trial results, as supplementary materials. All data will be collected and shared in an anonymised way. Qualitative data from interviews with healthcare workers and facility managers will not be made publicly available, and requests for sharing will be considered on a case by case basis, and with approval from the research ethics committee.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/04/2025	24/04/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes