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Testing the Super Protegidas approach to improve HPV vaccine uptake in Colombian girls

Submission date
18/01/2025

Recruitment status
No longer recruiting

Registration date
21/01/2025

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Human Papillomavirus (HPV) vaccination is crucial for cervical cancer prevention, which is the third most common type of cancer among women in Colombia, with approximately 4570 new cases and 2435 deaths annually. Despite vaccine availability, with a vaccine that is administered free of charge to girls and adolescents between 9 and 17 years of age. Current vaccination coverage is far below what is recommended by the World Health Organization to reduce the burden of disease in the country, highlighting the need for effective interventional strategies among vaccine-eligible girls aged 9-14 and their caregivers. This study aims to determine the effectiveness of a behavioral intervention to increase the HPV vaccination uptake in girls between 9 and 14 years old, students at public schools in Colombia.

Who can participate?
Girls aged between 9 and 14 years old, students at public schools in the municipality of Envigado (Colombia) with their respective parents or caregivers. Girls should not have started the HPV vaccination.

What does the study involve?
The interventions compared are Super Protegidas and conventional intervention. Participants were identified by the Envigado Department of Health as candidates to receive the HPV vaccine and were assigned to the intervention group or control group. The girls in the intervention group received a one-hour playful-pedagogical workshop in which information was provided through two stories, a 3-D model of the female reproductive system, brief training on how to fill out the informed consent form when they were going to be vaccinated and an infographic. The parents of this group received a letter, 5 text messages with information about cervical cancer and a reminder message the day before the vaccination date. The control group received the conventional intervention, which consisted of information on the HPV vaccine, provided by the staff of the vaccination team of the Department of Health to girls and adolescents in their schools. The study involved two measures at the following time points: baseline before intervention about behavior factors and retesting after the immunization day at the schools (only for parents in the intervention group). Both groups completed a sociodemographic survey. The outcome variable was the vaccination status, which was obtained through the Vaccination Registry of the Health Department of the Municipality of Envigado.

What are the possible benefits and risks of participating?
As a benefit, participants received information about cervical cancer prevention and resolved concerns about HPV vaccines. The only risk of participation was the temporary feeling of discomfort or embarrassment when receiving information about cervical cancer. To deal with this risk, the psychologist who carried out the intervention was trained to provide emotional support to the participants.

Where is the study run from?
Universidad de San Buenaventura, Medellín (Colombia)

When is the study starting and how long is it expected to run for?
August 2022 to November 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
449011- D24.04.07

Study information

Scientific Title
Implementation of the Super Protected protocol to increase HPV vaccination in girls and adolescents aged 9 to 14 years in the municipality of Envigado: a behavioral randomized controlled trial

Study objectives
Implementation of the Super Protegidas protocol, a COM-B model-based behavioral intervention, will lead to significantly higher HPV vaccine uptake among girls aged 9-14 in Colombia compared to those receiving standard vaccination outreach

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/11/2023, Comite de Bioetica de la Universidad de San Buenaventura Seccional Medellin (Carrera 56C No. 51-110, Medellin, 050010, Colombia; +5745145600; secretaria.cideh@usbmed.edu.co), ref: 449011- D24.04.07

Study design
Single-centre outcome assessor-blinded interventional two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Prevention of cervical cancer in girls who where unvaccinated against HPV

Interventions

Cluster randomization was implemented at the school level using SPSS v.24 software. From the eligible 12 urban public schools in Envigado municipality (excluding one school from a previous feasibility study), 11 institutions were considered. Four schools were randomly selected and then randomly assigned to either intervention (n=2) or control (n=2) groups. This cluster randomization approach was chosen to minimize contamination between groups due to potential spillover effects. The study was assessor-blinded, as the Health Department was unaware of school group assignments.

In the intervention arm girls received a one-hour playful-pedagogical workshop in which information was provided through two stories, a 3-D model of the female reproductive system, a brief training on how to fill out the informed consent form when they were going to be vaccinated and an infographic. The parents of the intervention group received a letter, 5 text messages with information about cervical cancer and a reminder message the day before the vaccination date. The control group received the traditional intervention, which consists of providing information on the HPV vaccine, provided by the staff of the vaccination team of the Department of Health to girls and adolescents in their schools. There were no other follow-up activities besides the outcome assessment.

Intervention Type
Behavioural

Primary outcome(s)
Vaccine status was measured using data collected in the Municipal Vaccine Registry at follow-up, one week after the “Vaccine day” in each school. This information was provided by the Health Department with parental consent from each participant (the vaccine was a single dose).

Key secondary outcome(s))
Capability, motivation, opportunity, and self-efficacy were measured using an ad hoc online questionnaire of 11 items. Each item used a 5-point Likert scale (1=strongly disagree to 5=strongly agree). The questionnaire was administered one week after the "Vaccine day" in each school.

Completion date
30/11/2024

Eligibility

Key inclusion criteria
For girls:
1. Be at least 9 years old and no more than 14 years old
2. Be enrolled in an official institution in the municipality of Envigado
3. Have not started the HPV vaccination schedule
4. Know how to read and write

For parents/caregivers:
1. To know how to read and write
2. To have a smartphone with a multimedia instant messaging application (Whatsapp)

Participant type(s)
Carer, Learner/student

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
9 years

Upper age limit
65 years

Sex
All

Total final enrolment
154

Key exclusion criteria
For girls:
Having some cognitive disability (according to the School record)

For parents:
Not having a smartphone

Date of first enrolment
12/03/2024

Date of final enrolment
02/08/2024

Locations

Countries of recruitment
Colombia

Study participating centre
Secretaria de Educacion de Envigado
Calle 38 sur No 45A Sur 67
Envigado
Colombia
055421

Sponsor information

Organisation
Universidad de San Buenaventura, Medellin

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a publicly available repository (https://osf.io/) and will become available upon publication in a peer-reviewed journal. Consent forms from the participants were obtained and their data will be anonymized by dissociating their personal data from their measurements.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan			21/01/2025	No	No