Purity, disgust, and intent to receive the HPV vaccine

Submission date 09/01/2019	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 18/01/2019	Overall study status Completed	 Statistical analysis plan Results
Last Edited 03/09/2019	Condition category Urological and Genital Diseases	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

High human papillomavirus (HPV) vaccination rates are key to decreasing the burden of HPVrelated diseases. Most messages that promote HPV vaccination to college-aged individuals focus on the long-term consequences of HPV infection. Messages that focus more on short-term consequences of HPV infection may be more effective in this age group. The aim of this study is to see if a message focusing more on the short-term consequences of HPV infection, like genital warts, might increase a person's intent to receive the HPV vaccine.

Who can participate?

Anyone who is between 18 and 23 years of age, lives in the United States, and has not completed the HPV vaccine series

What does the study involve?

Participation involves completing a short survey (5-10 minutes), viewing of a message with some pictures, and then completing another survey (15-20 minutes). Participants are randomly allocated to view either a message containing an image of a bird on a feeder and a brief description of birdfeeding, or a message containing images of genital warts and a brief description of a Tinder date leading to HPV infection. Intent to receive the HPV vaccine is measured using a survey immediately after the message has been reviewed by the participant.

What are the possible benefits and risks of participating?

The study is not intended to directly benefit participants. The risks in the study are likely to be small. There is a possibility of viewing images of a graphic nature, which some people may find disturbing. There is always a small chance that confidentiality will be broken despite extensive procedures to preserve confidentiality.

Where is the study run from?

The study is being run from Emory University (USA), but all study procedures (questionnaires and messages) take place online.

When is the study starting and how long is it expected to run for? June 2017 to September 2019 (updated 20/06/2019, previously: June 2019) Who is funding the study? Emory University (USA)

Who is the main contact? Avnika Amin

Contact information

Type(s) Public

Contact name Ms Avnika Amin

Contact details 1518 Clifton Rd Atlanta United States of America 30322

Type(s) Scientific

Contact name Dr Saad Omer

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers IRB00104624

Study information

Scientific Title

HPV, genital warts, and purity: college-aged individuals' perceptions of HPV and intention to receive the HPV vaccine

Study objectives

Participants who read the interventional message will have a higher intent to receive HPV vaccine than participants who read the control message.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Emory University Institutional Review Board, 1599 Clifton Road NE, 5th Floor, Atlanta, GA 30322, USA, Tel: +1 (0)404 712 0720, Email: IRB@emory.edu, 11/12/2018, ref: IRB00104624

Study design

This interventional study will randomize participants to receive either a visual message related to birdfeeding (control) or a visual message describing the consequences of HPV infection.

Primary study design

Interventional

Secondary study design Randomised controlled trial

Study setting(s) Internet/virtual

Study type(s) Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Intent to receive HPV vaccine

Interventions

Participants will be randomized using a Qualtrics algorithm. The algorithm randomly presents either the control or experimental visual message while ensuring that control and experimental group numbers are approximately balanced.

This interventional study will randomize participants to receive either:

Control: a visual message containing an image of a bird on a feeder and a brief description of birdfeeding.

Intervention: a visual message containing images of genital warts and a brief description of a Tinder date leading to HPV infection.

Intervention Type

Behavioural

Primary outcome measure

Intent to receive the HPV vaccine, measured once during a post-intervention survey administered immediately after the visual message has been reviewed by the participant. The method of measurement for the primary outcome is a single question asking if the participants intends to initiate (if they have received 0 HPV vaccine doses) or continue (if they have received 1-2 HPV vaccine doses) the HPV vaccine series.

Secondary outcome measures

Clicks on a link helping to locate the nearest vaccine clinic, measured using embedded data in the online survey administered immediately after the visual message has been reviewed by the participant.

Overall study start date

01/06/2017

Completion date

15/09/2019

Eligibility

Key inclusion criteria

- 1. Between 18 and 23 years of age (inclusive)
- 2. Resident of the United States
- 3. Has received no more than 2 doses of the HPV vaccine

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants 5,049

Key exclusion criteria

Has completed the HPV vaccine series (3 or more doses)
 Has already completed the survey

Date of first enrolment 15/01/2019

Date of final enrolment 15/08/2019

Locations

Countries of recruitment United States of America

Study participating centre Emory University Rollins School of Public Health 1518 Clifton Rd Atlanta United States of America 30322

Sponsor information

Organisation Emory University Rollins School of Public Health

Sponsor details 1518 Clifton Rd Atlanta United States of America 30322

Sponsor type University/education

Website https://www.sph.emory.edu/

ROR https://ror.org/03czfpz43

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The study protocol, which contains a brief analysis plan, will be made available. Planned publication of the study results in a high-impact, peer-reviewed journal.

Intention to publish date

15/09/2020

Individual participant data (IPD) sharing plan

Data will be available upon request from Avnika Amin to legitimate researchers with a brief, methodologically sound proposal. This includes de-identified individual participant data used to generate the results reported. The data will be available within one month of publication of the manuscript. After approval, data will be shared via a link (to be provided) and should only be used for the aims detailed in the approved proposals.

IPD sharing plan summary

Available on request