

Using purity based messages to increase intention to receive the HPV vaccine

Submission date 10/08/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/09/2020	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

HPV is the name of a very common group of viruses. They do not cause any problems in most people, but some types can cause genital warts or cancer. HPV affects the skin. There are more than 100 different types.

High vaccination rates for human papillomavirus (HPV) are key to decreasing the burden of HPV-related 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 and include imagery 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, and then completing another survey (10-15 minutes). Participants are randomly allocated to view 1) CDC HPV description (control) or 2) CDC HPV description with HPV vaccine dose image (image control) 3) purity- and disgust-themed narrative about an HPV infection on a Tinder date 4) purity- and disgust-themed narrative about an HPV infection on a Tinder date with images. 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 Yale 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 October 2020

Who is funding the study?

Yale University (USA)

Who is the main contact?

Erin James

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRB2000027459

Study information

Scientific Title

HPV, genital warts, and purity: A 2x2 study of 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)

Approved 03/03/2020, Yale University Institutional Review Board (25 Science Park, 150 Munson St, 3rd Floor, New Haven, CT, 06511, USA; +1 203-785-4688; HRPP@yale.edu), ref: 2000027459

Study design

Interventional randomized controlled trial

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Sexually transmitted disease awareness

Interventions

Participants will be randomized using a Qualtrics algorithm. The algorithm randomly presents either the control statement, the control statement + control image, experimental statement, or experimental statement + experimental image while ensuring that group numbers are approximately balanced between the 4 groups.

This interventional study will randomize participants to receive either:

Control: An adapted CDC statement on the HPV vaccine

Control + Image: An adapted CDC statement on the HPV vaccine with an image of an HPV vaccine dose in a vial

Intervention: a message containing a brief description of a Tinder date leading to HPV infection.

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

Immediately after the intervention/control has been reviewed by the participant, intent to receive the HPV vaccine is measured once during a post-intervention survey. The method of measurement is a single question asking if the participants intend 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.

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 is a single question asking if the participants intend 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

1. Vaccine confidence as measured by the Vaccine Confidence Scale at post intervention
2. Purity/liberty measured using the moral foundations questionnaire before the intervention

Overall study start date

01/09/2019

Completion date

20/10/2020

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

2,556

Key exclusion criteria

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

Date of first enrolment

12/08/2020

Date of final enrolment

15/09/2020

Locations

Countries of recruitment

United States of America

Study participating centre**Yale School of Medicine**

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Sponsor information

Organisation

Yale School of Medicine

Sponsor details

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saad.omer@yale.edu

Sponsor type

University/education

Website

<http://medicine.yale.edu/>

Funder(s)

Funder type

University/education

Funder Name

Yale School of Medicine

Alternative Name(s)

YSM

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United States of America

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

30/09/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. 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