ISRCTN51541314 https://doi.org/10.1186/ISRCTN51541314

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

Submission date
10/08/2020

Recruitment status
No longer recruiting

Registration date
12/08/2020

Overall study status
Completed

Last Edited
18/09/2020

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
erin.james@yale.edu

Contact information

Type(s)
Scientific

Contact name
Dr Erin James

ORCID ID
https://orcid.org/0000-0003-0172-5292

Contact details
One Church St
Suite 340
New Haven
United States of America
06510
+1 (203) 432-5015
erin.james@yale.edu

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Prevention

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(s)
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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
One Church St
Suite 340

New Haven
United States of America
06510

Sponsor information

Organisation
Yale School of Medicine

Funder(s)

Funder type
University/education

Funder Name
Yale School of Medicine

Alternative Name(s)
Medical Institution of Yale College, Yale School of Medicine - Yale University, YSM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

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