ISRCTN81591000 https://doi.org/10.1186/ISRCTN81591000

Purity, disgust, and intent to receive the HPV vaccine

Submission date 11/02/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/03/2020	**Overall study status** Completed	
Last Edited 09/03/2020	**Condition category** Other	

Plain English summary of protocol

Background and study aims
High human papillomavirus (HPV) vaccination rates 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 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 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 September 2020

Who is funding the study?
Yale University (USA)

Who is the main contact?
Erin James
erin.james@yale.edu

Contact information

Type(s)
Public

Contact name
Dr Erin James

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

Contact details
1 Church St
Suite 340
New Haven
United States of America
06510
+1 2023658826
erin.james@yale.edu

Additional identifiers

Protocol serial number
IRB2000027459

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)
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
Intent to receive HP 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.

Immediately after the visual message 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 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.

Key secondary outcome(s)
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.

Completion date
01/09/2020

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
10/03/2020

Date of final enrolment
01/04/2020

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
Data will be available upon request from Erin James 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