

Purity, disgust, and intent to receive the HPV vaccine

Submission date 11/02/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/03/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/03/2020	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 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

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: 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

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 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

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1,672

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

Sponsor details

1 Church St

Suite 340

New Haven

United States of America

06510

+1 2023658826

erin.james@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

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