

# Does offering girls a reward increase the number of vaccination consent forms that are returned? A study to look at whether a future larger study of rewards is feasible

<b>Submission date</b> 16/08/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/10/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-how-to-increase-the-number-of-young-women-having-the-hpv-vaccine>

## Contact information

### Type(s)

Public

### Contact name

Ms Lauren Rockcliffe

### Contact details

Health Behaviour Research Centre  
UCL, Gower Street  
London  
United Kingdom  
WC1E 6BT

### Type(s)

Scientific

### Contact name

Dr Alice Forster

### ORCID ID

<http://orcid.org/0000-0002-9933-7919>

**Contact details**

Health Behaviour Research Centre  
UCL, Gower Street  
London  
United Kingdom  
WC1E 6BT

**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

**Study information****Scientific Title**

A cluster randomised feasibility study of an adolescent incentive intervention to increase uptake of HPV vaccination among girls

**Acronym**

reWARD off HPV

**Study objectives**

The aim is to establish the feasibility of conducting a cluster RCT of an adolescent incentive intervention to increase uptake of HPV vaccination among girls.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

UCL Research Ethics Committee, 09/06/2016, ref: 6615/002

**Study design**

Two-arm single-blind cluster randomized feasibility trial

**Primary study design**

Interventional

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

School

## **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**

Human papillomavirus (HPV)

## **Interventions**

Standard invitation arm:

The standard invitation arm comprises adolescents being provided with an information leaflet about the HPV vaccine and a consent form by their school, which they are asked to give to their parents (delivered by hand) and return to the school before a prescribed date. Immunisation nurses may engage in additional promotional activities with schools to improve uptake of the vaccine and this information about these activities will be collected informally.

Incentive intervention arm:

Participants in the incentive intervention arm will receive the standard invitation. They will also be advised by their school form tutor and in a letter that they will be entered into a prize draw to win a £50 'Love2Shop' voucher if they return their consent form, with a 1 in 10 chance of winning. It will be made clear that adolescents are eligible for prize draw entry regardless of whether consent is given, so long as the consent form is returned. The voucher can be exchanged at a large number of retailers.

Blocked randomisation will be performed by the statistical advisor using computer generated random numbers.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

There is no primary outcome as this is a feasibility study. The first outcome that will be assessed is schools' and parents' willingness to participate in the study and schools' willingness to be randomised. Measured by recording number of schools contacted, number who express initial interest and number who participate. Measured at baseline.

## **Secondary outcome measures**

1. Response rates to questionnaires by parents and girls (assessed by recording number of completed questionnaires returned)
2. Data completeness regarding the proportion of missing data: whether consent form was returned, whether consent was given (reported by schools and reported by parents in brief questionnaire), socio-demographic characteristics (ascertained through brief questionnaire completed and index of multiple deprivation (IMD) score, ascertained through girls' postcode provided by schools) and all other questionnaire items.
3. Girls' attitudes towards the incentive offered (assessed through brief questionnaire).
4. Parents'/guardians' attitudes towards the incentive offered (assessed through brief questionnaire).
5. School staff experiences of participating (ascertained through brief interviews)

6. School staff fidelity to the intervention (ascertained through brief interviews)
7. Detailed description of immunisation processes performed in each school (i.e. what additions to the standard invitation were performed) by the immunisation teams and school staff (ascertained through brief interviews with school staff and informal information provided by immunisation teams)
8. Unintended consequences of the intervention:
  - 8.1. Girls' perceptions of why incentive was offered (assessed through brief questionnaire)
  - 8.2. Parents'/guardians' informed decision making (assessed through brief questionnaire, using measure described by Mantzari et al. 2015)
  - 8.3. Girls' attitudes towards returning future consent forms (assessed through brief questionnaire)
9. Mechanisms of action (assessed through brief girls' questionnaire)
10. Cost per returned consent form and cost per consent form that is agreeing to vaccination.

All information will be collected after vaccination day

Researchers will also estimate intervention effect on:

11. Initiation of the vaccination series (whether consent was given to vaccination reported by schools and self-reported by parents in a brief questionnaire after vaccination day)
12. Consent form return rates (reported by schools)

### **Overall study start date**

01/07/2016

### **Completion date**

31/01/2017

## **Eligibility**

### **Key inclusion criteria**

Inclusion criteria at the cluster-level:

1. Secondary schools based in the London boroughs of Enfield, Lambeth and Southwark and who participate in the HPV immunisation programme

Inclusion criteria at the individual-level:

2. Adolescent girls attending participating schools
3. Adolescent girls who enter Year 8 in the autumn academic term
4. School staff employed at participating schools
5. Parent/guardians of adolescent girls participating in the trial

### **Participant type(s)**

Learner/student

### **Age group**

Mixed

### **Sex**

Both

### **Target number of participants**

At least 6 clusters (schools), with approximately 100 adolescent girls per cluster. Questionnaire data is collected from parents/guardians of participating adolescent girls. Interviews are conducted with 18 members of school staff.

### **Key exclusion criteria**

Exclusion criteria at the cluster-level:

1. Secondary schools based outside of the London boroughs of Enfield, Lambeth and Southwark
2. Secondary schools not participating in the HPV immunisation programme

Exclusion criteria at the individual-level:

3. Adolescent girls not attending participating schools
4. Adolescent girls not in year 8 in the autumn academic term
5. School staff employed at schools not participating in the trial
6. Parents/guardians of adolescent girls not participating in the trial

### **Date of first enrolment**

01/07/2016

### **Date of final enrolment**

20/01/2017

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

**University College London**

Health Behaviour Research Centre

Gower Street

London

United Kingdom

WC1E 6BT

## **Sponsor information**

### **Organisation**

University College London

### **Sponsor details**

Gower Street

London

England  
United Kingdom  
WC1E 6BT

**Sponsor type**  
University/education

**ROR**  
<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Cancer Research UK

**Alternative Name(s)**  
CR\_UK, Cancer Research UK - London, CRUK

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

## Results and Publications

### Publication and dissemination plan

1. Study protocol (September 2016)
2. Full results paper (March 2017)
3. Dissemination to stakeholders: Findings will be disseminated to all participating schools by means of a copy of the final report in March 2017
4. Social media and online: Findings will be written about in online blogs and referred to on social media, such as Twitter (March 2017)

**Intention to publish date**  
31/03/2017

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Alice Forster (alice.forster@ucl.ac.uk).

## IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	06/03/2017		Yes	No
<a href="#">Results article</a>	results	10/10/2017		Yes	No
<a href="#">Results article</a>	results	20/03/2018		Yes	No
<a href="#">Results article</a>	qualitative results	21/08/2020	10/10/2023	Yes	No