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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

Submission date
16/08/2016

Registration date
26/09/2016

Last Edited
10/10/2023

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Type(s)
Scientific

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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
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Sponsor information

Organisation
University College London

Sponsor details
Gower Street
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England
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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?
Protocol article	protocol	06/03/2017		Yes	No
Results article	results	10/10/2017		Yes	No
Results article	results	20/03/2018		Yes	No
Results article	qualitative results	21/08/2020	10/10/2023	Yes	No