

Does the use of financial incentives increase the take up rate of the human papillomavirus (HPV) vaccination in 16 - 18 year old females?

Submission date 18/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/07/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The Human Papillomavirus (HPV) is a common sexually transmitted virus responsible for most cases of cervical cancer. Immunisation against HPV requires completion of three vaccinations. Since 2008, a routine HPV vaccination programme aimed at 12-13 year-old girls has been rolled out in England and Wales, generating good uptake rates. Uptake of a catch-up HPV vaccination programme aimed at girls aged 17-18 years, however, has been significantly below the 80% target set by the NHS. One way of improving this is to offer girls money for getting vaccinated. The offer of money however, could potentially have a negative effect on the quality of girls' decisions to get vaccinated. Specifically, it is possible that the offer of money might tempt girls with negative attitudes towards the HPV vaccination and/or insufficient knowledge of the vaccination to get vaccinated. The study's aim is to find out whether offering teenage girls money for getting vaccinated against HPV could improve vaccination uptake rates. It also aims to find out whether the offer of money has a negative effect on the quality of girls' decisions to get vaccinated, as assessed by their attitudes towards the HPV vaccination and their knowledge of the HPV vaccination.

Who can participate?

One thousand girls aged 16 to 18 were invited to participate in the HPV vaccination programme: Five-hundred had received a previous invitation to get vaccinated but had failed to attend their first vaccination appointment (previous non-attenders) and 500 had never previously received a vaccination invitation (first-time invitees). Girls were randomly selected from eligible participants who i) who were registered with a GP within areas covered by the administration of the Birmingham East and North (BEN) and Heart of Birmingham Primary Care Trusts, ii) had not been previously vaccinated against HPV and iii) were eligible to receive the vaccinations through clinics. Girls were excluded from the study if they were feeling unwell at the time of presenting for the vaccinations.

What does the study involve?

The two groups of girls were randomly allocated to receive either a standard letter inviting them to attend the first HPV vaccination session or a modified invitation letter including the offer of

vouchers worth £45 for receiving the three vaccinations: £20 for receiving the first vaccination; £5 for receiving the second vaccination; and £20 for receiving the third vaccination. Girls who were sent the modified invitation letters were also sent text messages reminding them of their second and third vaccination appointments. When attending their first vaccination session, all girls were also requested to complete a questionnaire to assess the quality of their decisions to undertake the HPV vaccinations.

What are the possible benefits and risks of participating?

By participating in the study girls became immunised against HPV, thus lowering their chances of developing cervical cancer. There are no risks associated with participating in the study

Where is the study run from?

The study is run by the Birmingham East and North Primary Care Trust (BEN PCT) in association with the Young Foundation as part of the Healthy Incentives partnership between these two organisations.

When is the study starting and how long is it expected to run for?

Recruitment for the study began in February 2010 and was completed in September 2010. Evaluation of the trial began in April 2011.

Who is funding the study?

The trial is funded by the Birmingham East and North Primary Care Trust. The evaluation is funded by the Wellcome Trust, as part of a Strategic Award in Biomedical Ethics; programme title: 'The Centre for the Study of Incentives in Health'; grant number: 086031/Z/08/Z.

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

086031; Version 1

Study information

Scientific Title

Financial incentives to increase uptake of human papillomavirus (HPV) vaccination: a randomised controlled trial

Study objectives

There are two questions being addressed by this project:

1. Does the offer of financial incentives increase the uptake of human papillomavirus (HPV) vaccination in girls aged 16 - 18 years?
2. Does the offer of financial incentives to undergo HPV vaccination reduce the quality of decision-making?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Birmingham East, North and Solihull Research Ethics Committee, pending approval as of 18/02 /2010

Study design

Randomised controlled single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please contact Narinder Kular at narinder.kular@benpct.nhs.uk to request a patient information sheet

Health condition(s) or problem(s) studied

Human papillomavirus (HPV) vaccination / cervical cancer

Interventions

Those allocated to the control group are invited to attend a local community centre on three occasions to undergo HPV vaccination. Those allocated to the intervention group receive the same invitation. In addition, the intervention group is being offered shopping vouchers for attending for each of three vaccinations (sum of £45; £20 for the first vaccination; £5 for the second; and £20 for the third).

Intervention Type

Biological/Vaccine

Primary outcome measure

Proportion of participants who have the HPV vaccine when a financial incentive is offered, measured when participants attend one of the three community clinics in the trial

Secondary outcome measures

Quality of decision, assessed using a short form of the Multidimensional Measure of Informed Choice, measured when participants attend one of the three community clinics in the trial

Overall study start date

01/02/2010

Completion date

01/06/2010

Eligibility

Key inclusion criteria

1. Female, aged between 16 and 18 years
2. Living in Birmingham

Participant type(s)

Patient

Age group

Child

Lower age limit

16 Years

Upper age limit

18 Years

Sex

Female

Target number of participants

In total 1000 participants will be recruited for the trial

Key exclusion criteria

Feeling unwell at the time of presenting for vaccination

Date of first enrolment

01/02/2010

Date of final enrolment

01/06/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

King's College London

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

NHS Birmingham East and North Primary Care Trust (UK)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://benpct.nhs.uk/>

Funder(s)

Funder type

Charity

Funder Name

Healthy Incentives (UK) - covered the costs of research activities at NHS Birmingham East and North Primary Care Trust

Funder Name

The Wellcome Trust (UK) (grant ref: 086031) - covered the cost of the evaluation at Kings College London

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/09/2012		Yes	No
Results article	results	01/02/2015		Yes	No