Evaluation of a sex education lesson on chlamydia to see whether it increases the likelihood that young adults will use condoms to protect against this sexually transmitted infection (STI)

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
22/11/2012		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/12/2012	Completed	Results		
Last Edited	Condition category	Individual participant data		
14/12/2017	Infections and Infestations	Record updated in last year		

Plain English summary of protocol

Background and study aims

Young people may underestimate their risk of getting a sexually transmitted infection (STI) called chlamydia. This infection can be serious if untreated, leading to conditions such as infertility. Increasing young peoples' knowledge and understanding of this STI may increase their motivation to use condoms to protect themselves against it. The study aims to find out if after having a sex education lesson on chlamydia, young peoples' beliefs about the risk of chalmydia have changed and whether they are then more likely to use condoms during sexual intercourse.

Who can participate?

Pupils aged 13-16 from selected secondary schools across England

What does the study involve?

Schools are selected at random to give either just their usual teaching on STIs, or their usual teaching on STIs plus a specially designed lesson on chlamydia. All pupils are asked to complete three short questionnaires: one before the lessons, one straight after, and one three months later.

What are the possible benefits and risks of participating?

Pupils get the opportunity to be involved in shaping future sex education on STIs. Schools receive a £60 Amazon voucher in recognition of the time and support they have given to the study. There are not thought to be any risks involved with taking part.

Where is the study run from?

Coventry University (Applied research Centre in Heath and Lifestyle Interventions (ARC-HLI)) and the Health Protection Agency (Primary Care Unit) are running this study. Coventry University is the lead organisation.

When is the study starting and how long is it expected to run for? January 2013 to December 2013

Who is funding the study?

The study has no funding. Researchers' time and overheads are being funded by their respective organisations.

Who is the main contact? Katie Newby k.newby@coventry.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Increasing young adults' condom use intentions and behaviour through changing chlamydia risk and coping appraisals: a cluster randomised controlled trial of efficacy

Study objectives

Primary research question

1. Is the lesson effective in increasing young people's intentions to use condoms during vaginal sex with casual sexual partners?

Secondary research questions

- 2. Is the lesson effective in increasing young people's condom use during vaginal sex with casual sexual partners?
- 3. If the lesson is effective, are changes in young people's condom use intentions or behaviour due to changes in their chlamydia risk appraisals (perceived likelihood and severity) and/or coping appraisals (condom use response efficacy and self-efficacy)?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Coventry University Ethics Committee - approval pending

Study design

Two-arm cluster randomised controlled trial with a waiting-list control

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Chlamydia trachomatis

Interventions

In the experimental group, participants will receive the school's standard teaching on STIs plus a theory- and evidence-based lesson on chlamydia.

In the control group participants will receive just their school's usual teaching on STIs.

The teaching will last 40 minutes. The duration of follow-up is three months.

Intervention Type

Behavioural

Primary outcome measure

Intention to use condoms during vaginal sex with casual sexual partners over the next three months

Secondary outcome measures

- 1. Use of condoms during vaginal sex with casual sexual partners over three months post delivery
- 2. Perceived likelihood of chlamydia
- 3. Perceived severity of chlamydia
- 4. Response efficacy for condom use
- 5. Self-efficacy for using condoms during vaginal sex with casual sexual partners over the next three months

Overall study start date

01/01/2013

Completion date

31/12/2013

Eligibility

Key inclusion criteria

- 1. Aged 13-16 years old
- 2. Attending a secondary school in England which has a Sex and Relationships Education (SRE) protocol and curriculum
- 3. Have not received any previous formal education on STIs through school

Participant type(s)

Other

Age group

Child

Lower age limit

13 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

770

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/01/2013

Date of final enrolment

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Coventry University

Coventry United Kingdom CV1 5FB

Sponsor information

Organisation

Coventry University (UK)

Sponsor details

Priory Street Coventry England United Kingdom CV1 5FB +44 (0)24 7688 7688 geneng.hls@coventry.ac.uk

Sponsor type

University/education

Website

http://www.coventry.ac.uk

ROR

https://ror.org/01tgmhj36

Funder(s)

Funder type

University/education

Funder Name

Coventry University (UK)

Alternative Name(s)

CU

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

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	30/05/2013		Yes	No