

Sexunzipped pilot online trial

Submission date 12/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/01/2014	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.sexunzipped.co.uk>

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

Study information

Scientific Title

An interactive computer-based intervention for sexual behaviour change: Sexunzipped pilot online trial

Study objectives

That an interactive, tailored online intervention for sexual health promotion will be more effective in promoting sexual health in young people than an information-only website.

Ethics approval required

Old ethics approval format

Ethics approval(s)

UCL Ethics Committee approved on the 4th August 2010 (ref: 1023/002)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Supplied online via www.sexunzipped.co.uk ('sign up')

Health condition(s) or problem(s) studied

Sexual Health

Interventions

1. Interactive website containing sexual health information and activities based on psychological theories of behaviour change and a holistic conception of sexual wellbeing which includes a focus on pleasure
2. Quizzes and decision-making activities with tailored feedback
3. Control - brief, information-only website with content which focuses mainly on sexually transmitted infection and contraception
4. No interactive activities

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. This pilot study will help to determine which outcome should be the primary outcome for a substantive trial. We will report on all measured outcomes including:

- 1.1. Knowledge
- 1.2. Self-efficacy
- 1.3. Intention
- 1.4. Affective outcomes
- 1.5. Communication in relationships
- 1.6. Sexual behaviour (especially condom use for vaginal or anal sex)
- 1.7. Genital chlamydia (postal sample)

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/11/2010

Completion date

30/09/2011

Eligibility**Key inclusion criteria**

1. Young people aged 16 - 20 years, either sex
2. Living in the UK
3. Able to read English

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

2000

Key exclusion criteria

People aged under 16 or over 21

Date of first enrolment

01/11/2010

Date of final enrolment

30/09/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

e-Health Unit

London

United Kingdom

NW3 2PF

Sponsor information

Organisation

University College London (UCL) (UK)

Sponsor details

Joint UCL, UCLH and Royal Free Biomedical Research Unit

1st Floor, Maple House

149 Tottenham Court Road

London

England

United Kingdom

W1T 7NF

Sponsor type

University/education

Website

<http://www.ucl.ac.uk/joint-rd-unit/>

ROR

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

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) (ref: G0701749)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

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?
Results article	results	11/12/2013		Yes	No
Results article	results	12/12/2013		Yes	No