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Evaluating HIS-UK, a condom promotion intervention to reduce chlamydia infection among young men

Submission date
18/01/2019

Recruitment status
No longer recruiting

Registration date
23/10/2019

Overall study status
Completed

Last Edited
16/04/2025

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Poor sexual health is not shared equally across the UK population. The Department of Health has identified the need to reduce sexually transmitted infection (STI) rates as a priority for reducing SH inequalities and have recognised men who have sex with men and young people as target 'at-risk' groups. The health, social, and economic costs of STIs are huge. The current cost of STI treatment to the NHS is £620 million per year. Recent guidelines from the National Institute for Health and Care Excellence include the need to teach young people to use condoms effectively and safely before providing them.

Condoms remain the main protection against STIs when used correctly and consistently, yet there are many barriers to their use such as reduced sexual pleasure, fit-and-feel problems, lubrication issues and erection difficulties. Many health promotion programmes try to improve knowledge and skills to increase condom use, but do not address the barriers. There is a need to develop effective programmes to reduce barriers and improve condom use experiences to help reduce sexual risk among young people. Furthermore, given the increasing use of the internet by young people, designing programmes using digital technology is seen as a key delivery strategy.

Researchers have developed a condom promotion programme for use among young men in the UK. The programme gives out condom kits (containing different types of condoms and lubricants) and asks men to experiment with the contents at home by themselves following condom use education and training. The education and training can either be delivered online (eHIS) or face-to-face by a health professional (proHIS). As men test each condom and lubricant they are asked to think about their own pleasure and which they like. An online rating exercise helps men to identify the 'best' condoms and lubricants for them. Men who have already tested the programme said that they have enjoyed it and would recommend it to others.

The aim of this study is to find out whether men who experiment with different types of condoms report more enjoyable, correct and consistent condom use, and are less likely to have chlamydia at follow-up than men who do not. The researchers also want to find out if it is more effective, acceptable and cost effective to deliver the programme face-to-face or online.

Who can participate?
Men aged between 16-25 years who are at risk of STIs because they do not use condoms during sex with casual and/or new partners

What does the study involve?
Young men will be recruited via adverts on social media, from young people's information and advice services, and from specialist sexual health services at selected sites across England. Men will be assigned at random to receive either the digital eHIS programme, the face-to-face proHIS programme or usual condom care and will be followed up for 12 months during which they will be asked at various times about their sexual behaviour, condom use experiences and to take Chlamydia tests, to see if Chlamydia rates and/or condom use behaviours differ between the groups of young men.

What are the possible benefits and risks of participating?
The researchers will share the findings widely to improve the health and wellbeing of young people through reducing risk to STIs. Engagement of health professionals and policy makers will support adoption of the programme into mainstream practice and help reduce public health and NHS costs. The potential benefits to participants will include:
1. Gaining knowledge regarding the many different types (sizes, shapes and textures) of condoms that are on the market
2. The opportunity to experience a broad range of lubricants
3. Gaining knowledge and skills to increase the enjoyment of condom use
4. Finding the 'best' condom for them (fit and feel)
5. Improved condom use satisfaction
6. Reduced risk of STIs
There is a small but potential risk that a young man registers for the study and is not aware that they have a latex allergy. Symptoms of latex allergy occur immediately, but some people have a delayed reaction which is more likely to be an itchy rash. Following an eligibility check participants who report that they are "unsure" if they have a latex allergy will be highlighted (via the web-based software platform Lifeguide) to the study site staff who will then further question the participant to determine level of risk. Men who report previous symptoms will be excluded from the trial. Those deemed to be at low risk with no previous allergen history will be allowed to continue but instructed to cease use of all condom products and to contact the site immediately if they experience any adverse reactions. Some participants may view having to complete routine sexual health questionnaires and being contacted by researchers (e.g. to remind participants to complete online forms) as an inconvenience. To compensate for the burden and intrusion imposed by the research all participants will receive voucher payments totalling £50 spread over the 12-month study period. As this study involves young people and is on a sensitive topic, the information sheet provided to prospective participants will highlight the risk of embarrassment/distress. Participants will be provided with a list of contacts in the information sheet if they require further support either during or after the study.

Where is the study run from?
1. University of Southampton (UK)
2. Brighton and Sussex Clinical Trials Unit, Brighton and Sussex Medical School (UK)

When is the study starting and how long is it expected to run for?
February 2019 to December 2023

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
255684

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PHR: 17/54/06; CPMS: 41155; IRAS: 255684

Study information

Scientific Title
Evaluating the Home-based Intervention Strategy (HIS-UK) to reduce new chlamydia infection among young men aged 16-25 years by promoting correct and consistent condom use: What is the cost effectiveness of two different delivery models (face-to-face and digital delivery)?

Acronym
HIS-UK evaluation

Study objectives
1. Does the UK Home-based Intervention Strategy (HIS-UK) delivered face-to-face by health professionals (proHIS) and digitally delivered by an interactive website (eHIS) reduce Chlamydia test positivity among young men aged 16-25 years by enhancing condom use experiences and improving correct and consistent condom use as compared to usual condom distribution care?
2. What is the cost-effectiveness of the two different delivery models of HIS-UK (face-to-face (proHIS) and digital delivery (eHIS)) as compared to usual condom distribution care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/11/2019, South Central Oxford B REC (Whitefriars, Level 3, Block B, Bristol Research Ethics Committee Centre, BS1 2NT, UK;+44 (0)207 104 8253; nrescommittee.southcentral-oxfordb@nhs.net), ref: 19/SC/0486

Study design
Multi-centre randomised controlled superiority trial with three parallel groups

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Sexually transmitted infections

Interventions

On submission of baseline questionnaire data, participants are randomised by way of a computer algorithm within each recruitment setting, with stratification by ethnicity and sexual orientation. Participants will be allocated to one of the three trial arms at a ratio of 1:1:1.

Face-to-Face Delivery: proHIS

Young men allocated to the proHIS intervention arm will receive a brief face-to-face consultation with the trained research nurse (RN) at the registration visit (10 mins), during which each participant will receive:

1. A verbal introduction to HIS-UK
2. A comprehensive condom application demonstration using a penile demonstrator to teach correct condom use competency
3. Information about lubricants, their benefits, and how to use them
4. An overview of the condom information and self-practice instruction guide containing details of the home-based exercises and how to rate the condoms and lubricants tested
5. A condom kit containing a variety of condoms and lubricants
6. Login details to the Lifeguide on-line delivery platform with access to the condom/lubricant rating forms and follow-up questionnaires

Digital Delivery: eHIS

Young men allocated to the eHIS intervention arm will receive the following from the RN:

1. A condom kit containing a variety of condoms and lubricants
2. Login details to the Lifeguide platform with full access rights to the eHIS website, the condom /lubricant rating forms and follow-up questionnaires

Lifeguide is an interactive web-based intervention software platform and secure validated data management system designed to collect participant information and deliver digital interventions (DI) to support health behaviour change. Participants who are allocated to eHIS will be granted access to the eHIS web-pages when logging into Lifeguide. The eHIS pages will remain hidden to all other participants.

Using interactive digital media (information, videos and serious gaming) the eHIS website will provide:

1. An introduction to HIS-UK
2. Teaching on correct condom use
3. Information about lubricants, their benefits, and how to use them
4. Advice on condom self-practice and details of condom use exercises to try out at home
5. Details on how to test and rate the condoms and lubricants provided in the condom kit

Following education and training all young men in the two intervention arms (proHIS and eHIS) then begin a two-week condom/lubricant experimentation and self-practice period using the contents of the condom kits and following the home-based exercises. The aim is for participants to practice applying, using (masturbating with) and removing each of the condoms provided in the condom kit in “low pressure” situations (i.e., not in the presence of a sexual partner) and to try out and experiment with the different lubricants.

After experimentation with each condom/lubricant, participants are requested to complete an online rating and feedback form using the Lifeguide platform. Automated texts and e-mails will prompt intervention arm participants to complete the required ratings. Protocol compliance is defined as a minimum of three submitted rating forms and full compliance as the submission of eight.

Usual care is the comparator control condition. Young men randomly allocated to the control arm receive:
1. Standard condom distribution care offered in the sexual health/GUM recruitment setting
2. Login details to the Lifeguide platform (to complete the follow-up questionnaires)

Intervention Type
Behavioural

Primary outcome(s)
Chlamydia test positivity rate, measured through biomarker testing and treatment at baseline, 6 and 12 months, and through self-reporting at other times. The primary health endpoint will be test positivity rate at 6 months. To examine longevity of intervention effect, test positivity will be assessed up until 12 months post randomisation

Key secondary outcome(s))
To assess the effectiveness of HIS-UK to improve correct and consistent condom use as compared to usual condom distribution care, the following validated online questionnaires obtained at baseline (T0), and at monthly intervals to 12 months (T1-T12) will be used:
1. Condom Barriers Scale
2. Condom Use Errors and Problems Survey
3. Condom Use Self-Efficacy Scale
4. Multidimensional Condom Attitude Scale
5. Sexual behaviour and contraceptive use survey (sexual partner history, relationship status /type, frequency of intercourse, use of contraception/condoms)
6. Health-related quality of life indicators (SF-12 and EQ5D-5L)

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/07/2023:
Young men in the UK who are ‘at-risk’ of STIs, defined as:
1. Men and people with attributes of a biological male (i.e. penis)
2. Aged 16-25 years
3. Self-reported residency in England
4. At risk of STIs through reporting of condom use errors (i.e. breakage/slippage) or condomless penile-vaginal or penile-anal intercourse with casual/non-regular or new sexual partners during the previous 3 months
5.. Willingness to commit to the trial duration
6. Capable of giving informed consent

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Previous inclusion criteria:
Young men in the UK who are ‘at-risk’ of STIs, defined as:
1. Men and people with attributes of a biological male (i.e. penis)
2. Aged 16-25 years
3. Current resident of England

4. At risk of STIs through reporting of condomless penile-vaginal or penile-anal intercourse with casual/non-regular or new sexual partners during the previous three months
5. Able to commit to the 12-month duration of the study.
6. Capable of giving informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
25 years

Sex
Male

Total final enrolment
725

Key exclusion criteria
1. People without attributes of a biological male (i.e. a penis)
2. A recognised latex allergy
3. No access to the internet
4. Limited written and spoken English proficiency

Date of first enrolment
10/12/2019

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Solent NHS Trust
Highpoint Venue
Bursledon Road

Southampton
United Kingdom
SO19 8BR

Study participating centre
University Hospitals Sussex NHS Foundation Trust
Elton John Centre HIV GUM Research Dept
2nd Floor Sussex House
1, Abbey Rd
Brighton
United Kingdom
BN2 1ES

Study participating centre
Dorset Healthcare University NHS Foundation Trust
Sexual Health (East and West Hubs)
66-68 Palmerston Road
Bournemouth
United Kingdom
BH1 4JT

Study participating centre
Nottingham University Health Service (Cripps Health Centre)
Cripps Health Centre
Nottingham University Health Centre
University Park
Nottingham
United Kingdom
NG7 2QW

Study participating centre
Central London Community Healthcare NHS Trust
Westgate House Floor 2
Edgware Community Hospital
Burnt Oak Broadway
Edgware
London
United Kingdom
HA8 0AD

Study participating centre

iCaSH, (Integrated Contraception and Sexual Health)
Cambridgeshire Community Services NHS Trust
Units 7/8, Meadow Lane
St Ives
United Kingdom
PE27 4LG

Study participating centre
Liverpool University Hospitals NHS Foundation Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Berkshire Healthcare NHS Foundation Trust
Fitzwilliam House
Skimped Hill Lane
Bracknell
United Kingdom
RG12 1BQ

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Standard metadata procedures (e.g. Datacite) will be followed to ensure others are able to find, access and ultimately reuse data generated as part of this trial, with DOIs being issued for the dataset and data subsets as per the University of Southampton's DOI policy. Metadata records for the data (and published outputs) will also be maintained on the University of Southampton Institutional Research Repository. In accordance with the University's Data policy, the data will be archived in an appropriate repository (UK Data Service, eprints and Dspace, for example) for a minimum of 10 years after publication or last access, whichever is longer, to ensure long term access and safeguarding of the data and resulting outputs. Future users of the data will be bound by data-sharing agreements. Where suitable, a licence (currently Creative Commons) can be applied to data deposited in the repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/12/2024	19/12/2024	Yes	No
Protocol article		10/08/2022	12/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Assessing participants' experiences in the study through qualitative semi-structured interviews	01/08/2024	16/04/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes