

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

Submission date 18/01/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/10/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/04/2025	Condition category Infections and Infestations	<input type="checkbox"/> 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?

1. Prof. Cynthia Graham
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2. Dr Nicole Stone
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Study website

<https://www.his-uk.net>

Contact information

Type(s)

Scientific

Contact name

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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

255684

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised parallel trial

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

Available at <https://www.his-uk.net>

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/02/2019

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

Age group

Mixed

Lower age limit

16 Years

Upper age limit

25 Years

Sex

Male

Target number of participants

2231

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

England

United Kingdom

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
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RG12 1BQ

Sponsor information**Organisation**

University of Southampton

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Sponsor type

University/education

Website

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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

Publication and dissemination plan

Current publication and dissemination plan as of 21/07/2023:

In light of the early closure of the HIS-UK study and the impact COVID had on recruitment the study dissemination plan has been revised as follows:

The research will generate important outputs for dissemination, including:

1. An evidence-based digital condom promotion intervention tailored for young men
2. Manual and best practice protocol for delivering the intervention in face-to-face contexts
3. Estimates of costs of the intervention
4. Stakeholder database for future research and implementation
5. Scientific synthesis report for funders and lay summary findings
6. Conference presentations and peer-reviewed articles

All descriptions or documentation of the intervention (e.g., in write-ups, reports) will be informed by the TIDieR framework. The researchers will set up a university-based project website and social media pages to disseminate research updates, working papers/reports, links to online resources, media-friendly summaries, key findings, and recommendations. Findings will be posted on Twitter and other social networking sites which link to these sites.

The researchers will disseminate findings through the Office for Health Improvement and Disparities (OHID) sexual health facilitators (SHF). The researchers will ensure findings are shared with NICE to inform any future revision of the NICE Guideline (NG68; Sexually transmitted infections: Condom distribution schemes, which includes recommendations for LAs). A lay executive summary and associated podcasts and animated explainer videos and presentations (i.e. Powtoon) will be shared with all identified stakeholders and to all those who participated in the research activities and they will be encouraged to further distribute to interested parties. The University media relations offices will issue press releases about the study via local/national media and the public engagement units will enhance the profile of this work in the public domain. The researchers shall work with the Teenage Pregnancy Knowledge Exchange to share our findings which has a database of all teenage pregnancy leads in Local Authorities and the FSRH sexual health and HIV e-bulletin which reaches large numbers of commissioners. Findings will also be disseminated to the academic and healthcare community through the more traditional academic routes of conference presentations (e.g., Sexual Health Advisors National Conference, British Association for Sexual Health and HIV, International clinical trials methodology conference) and peer-reviewed, open-access journal articles.

Other pathways to dissemination will include engagement with the following networks; CRN, UK clinical research collaboration, Trials Managers network.

In December 2023 we will publish our synopsis report with the NIHR journal library which will link to our three identified output papers: A qualitative process paper, quantitative outcome paper, and a lessons learned paper.

Previous publication and dissemination plan:

The research will generate important outputs for dissemination, including:

1. An evidence-based digital condom promotion intervention tailored for young men
2. Manual and best practice protocol for delivering the intervention in face-to-face contexts
3. Estimates of costs of the intervention
4. Stakeholder database for future research and implementation
5. Scientific report for funders and lay summary report
6. Conference presentations and peer-reviewed articles

All descriptions or documentation of the intervention (e.g., in write-ups, reports) will be informed by the TIDieR framework. The researchers will set up a university-based project website and Facebook page to disseminate research updates, working papers/reports, links to

online resources, media-friendly summaries, key findings, and recommendations. Updates will be posted on Twitter and other social networking sites which link to these websites. The study will have an online discussion forum to invite and encourage discussion among all of the stakeholders. Relevant social networking sites (Facebook, Twitter etc.) will be created for user group communication activities. The researchers will also establish early channels of communication with NICE and PHE to ensure that their findings feedback into any future recommendations.

The researchers will disseminate findings through the PHE sexual health facilitators (SHF). One SHF is based in each of the PHE centres and works closely with local authority (LA) sexual health commissioners through regional networks and individual support. The researchers will present findings and recommendations at a meeting of the English Sexual Health and HIV Commissioners Group. Funded by PHE, this group brings together commissioners from all LAs, through four meetings per year and also has a website for sharing information. The researchers will ensure findings are shared with NICE to inform any future revision of the NICE Guideline (NG68; Sexually transmitted infections: Condom distribution schemes, which includes recommendations for LAs). They will host a dissemination event to bring together stakeholders and end-users and provide an open forum for the research to be discussed, for stakeholders to provide fresh perspectives, to encourage positive exchange, and to facilitate impact. A lay executive summary will be distributed to all identified stakeholders and to all those who participated in the research activities and they will be encouraged to further distribute to interested parties. The University media relations offices will issue press releases about the study via local/national media and the public engagement units will enhance the profile of this work in the public domain. The researchers shall work with the Teenage Pregnancy Knowledge Exchange to share our findings which has a database of all teenage pregnancy leads in Local Authorities and the FSRH sexual health and HIV e-bulletin which reaches large numbers of commissioners. Findings will also be disseminated to the academic and healthcare community through the more traditional academic routes of conference presentations (e.g., Sexual Health Advisors National Conference, British Association for Sexual Health and HIV) and peer-reviewed, open-access journal articles.

Intention to publish date

31/12/2024

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

Date Date Peer Patient-

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