Participant Information Sheet

Study 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)?*

Chief Investigator: Professor Cynthia Graham, Department of Psychology, University of Southampton, UK

You are being invited to take part in the above study. To help you decide whether you would like to take part, it is important that you understand why the study is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear. You may like to discuss it with others but it is up to you to decide whether or not to take part.

What is the study about?

Sexually transmitted infections (STIs) are a major public health concern in the UK and can result in serious complications, such as infertility, if left untreated. The Department of Health has recognised young men as one of the most 'at-risk' groups.

Condoms are effective in reducing the risk of STIs as long as they are used consistently (every sex act, using the condom from start to finish) and correctly (the condom is put on and removed properly). However, research has shown that condoms are often not used properly. Some men find condoms ruin the mood, make sex not feel as good, find them uncomfortable or experience erection difficulties.

HIS-UK is an education and training programme designed to help young men find condoms more enjoyable and pleasurable to use, in turn helping to reduce the risk of STIs. This study aims to find out if *HIS-UK* works. If it does, it is hoped that *HIS-UK* will help reduce costs to the NHS and have a positive impact on society as a whole.

The study is sponsored by the University of Southampton and funded by the National Institute of Health Research (NIHR) Public Health Research (PHR) Programme.

Can I take part?

Anyone with a penis can take part. You will also need to

- Be aged 16-25 years
- Have had sex without using a condom with a new or casual/non-regular partner in the last 3 months (or have experienced condom errors i.e. breakage or slippage with them)
- Not have a known latex allergy
- Commit to the trial duration (up to 12 months)
- Live within a *HIS-UK* recruitment site area
- Give informed consent
- Have internet access

What are the benefits for me if I take part?

By taking part you may

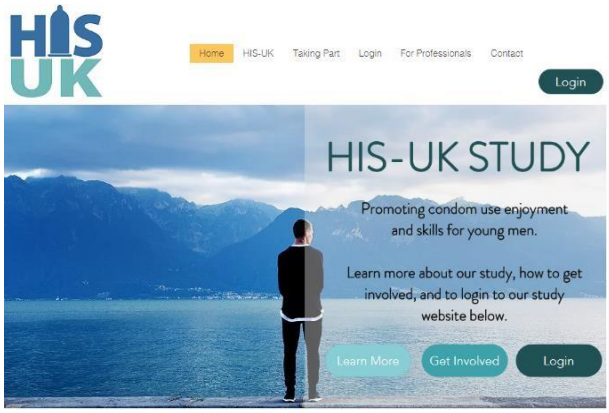
- Have a better understanding of what condoms and lubricants you prefer
- Find condom use more pleasurable
- Be able to better protect yourself from STIs

As a thank you for taking part in the study, you will receive voucher payments totalling £50 (£10 after 3 months, £15 after 6 months, and £25 after 12 months).

What can I expect if I take part?

At your clinic visit:

1. Consent
If you wish to take part in the study and are eligible, a staff member will ask you to complete an online consent form.



2. Sign Up
Once consented, you will be provided with log in details so you can sign up to the study website.

3. Questionnaire
You will then be asked to complete an online questionnaire (approx. 20 mins).

4. Study Groups
A staff member will then randomly allocate you to one of the following three study groups:

Usual in clinic NHS Condom Care
Typically involves a brief condom application demonstration and the provision of free condoms.

HIS-UK* delivered by *proHIS
proHIS provides you with additional condom and lubricant education and training delivered by a staff member. You will also receive a free kit containing 24 condoms (a minimum of eight different types, shapes and sizes) and 12 sachets of lubricant (three different types).

HIS-UK* delivered by *eHIS
eHIS provides you with access to an interactive online education and training programme (completed outside of clinic) promoting the use of condoms and lubricants. You will receive a free kit containing 24 condoms (a minimum of eight different types, shapes and sizes) and 12 sachets of lubricant (three different types).

5. Chlamydia Screening
Before the end of your clinic visit, a staff member will ask you to be screened for Chlamydia (the most common STI). This may be done in clinic or via a postal screening kit.

Chlamydia screening involves a single urine test. If you have had recent sex with another man you will be asked to be triple tested for Chlamydia (urine sample, anal and/or oral swab). If you have been tested for Chlamydia within the last 4 weeks, you may not be required to repeat the screening. A staff member will discuss this with you.

Your samples will be analysed in a laboratory and you will be told the results of your test (normally available in 7 to 10 days) and offered treatment if necessary. A staff member will be happy to answer any questions you may have about the procedure.

You can refuse Chlamydia screening if you wish and still remain in the study.

6. Condom and lubricant testing (*proHIS* and *eHIS* only)

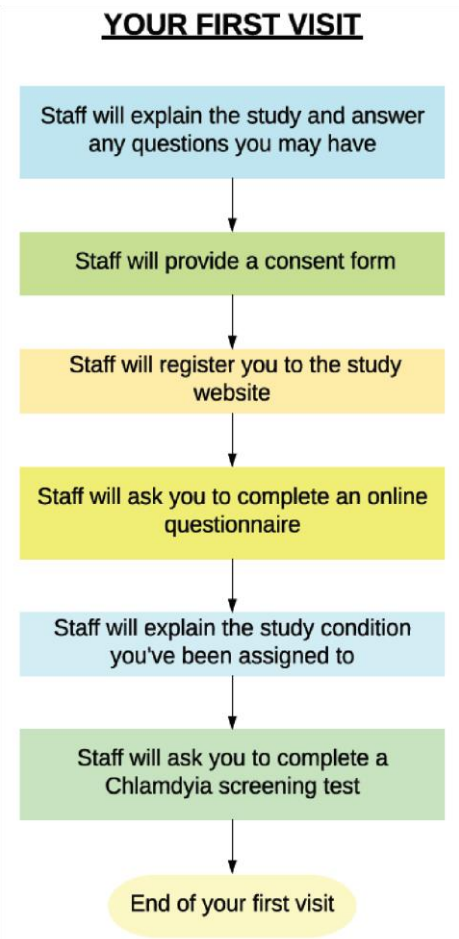
If you are allocated to the *proHIS* or *eHIS* groups we ask you to explore the contents of the kit at home and practice applying, using (masturbating with) and removing the condoms on your own to find the best ones. We also ask you to rate each condom you try using a short online form (approx. 5 minutes). You have two-weeks to complete your ratings.

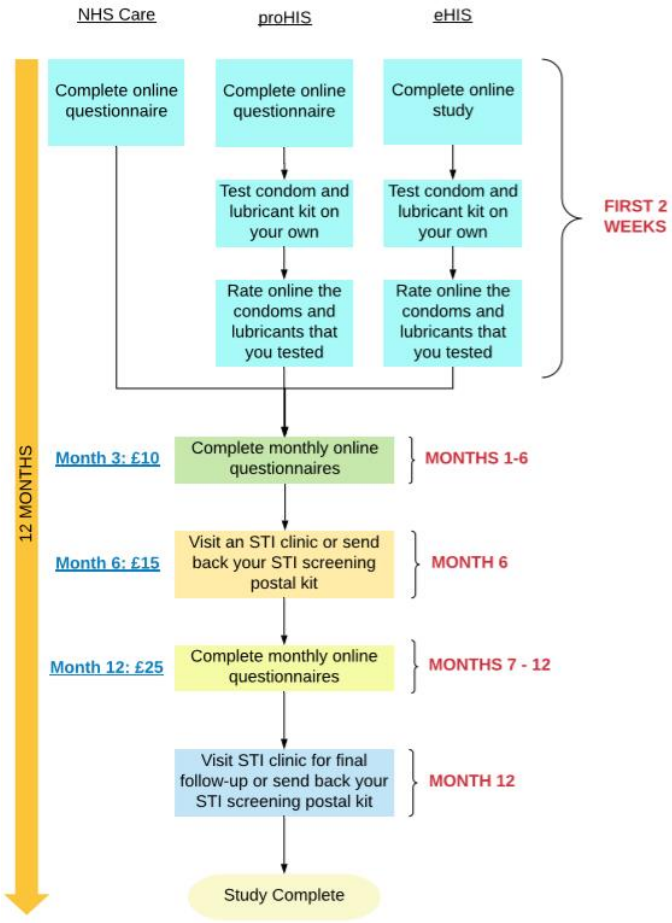
7. Follow-up (up to 12 months)

Every month you will receive a text and/or email asking you to complete an online questionnaire, similar to the one you completed in clinic (approx. 20 mins). At 6 and 12 months you may be asked to complete another Chlamydia screening. You can choose to either attend a clinic or request a postal screening kit.

Finally, during the 12 month follow-up you may be asked for your consent to be interviewed about your involvement in the study by one of the *HIS-UK* research team. You do not have to agree to take part in these interviews.

Please see the images below summarising what to expect during and after your first visit:





Are there any risks involved?

As this study is on a sensitive topic, you may feel slightly embarrassed while taking part (in our experience with similar research, this risk is very small and most participants benefit from being

involved). If you require further support either during or after the study, we have included a list of contacts for your information (see ***Useful Contacts***).

If you are unsure if you have a latex allergy you will be asked by a staff member about your previous use of rubber products. Symptoms of latex allergy typically occur immediately; however, some people have a delayed reaction which is more likely to be an itchy rash. If you have ever displayed symptoms you will be unable to take part.

For any problems related to any of the condoms and/or lubricants supplied in the *HIS-UK* kit such as breakage, slippage, or irritation, further information on who to contact can be found in the kit provided. If you are worried or concerned about your health, please contact your GP or local sexual health service.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. You are also free to change your mind and withdraw from the study at any time.

What data will be collected?

We will make sure all aspects of the study will protect your data and keep it confidential.

The study will collect **personal data,** including name, email /phone number, postal address, ethnicity, sexual orientation, age, education/employment, sexual history, sexual activity, relationship status, contraceptive use, experiences with condoms. We will also collect your Chlamydia screening result data.

In order for us to send out regular reminders via email and text to complete our questionnaires and condom rating forms, **your contact information will be stored securely** throughout the study on University based servers.

Your Chlamydia samples will be analysed within a laboratory and your screening results will be securely shared between the laboratory, NHS clinical care team and the research team. Your samples will not be stored for this study and will be destroyed after screening. Samples will be tested for Chlamydia, analysed and then destroyed, all following NHS procedure.

What happens if I change my mind?

You have the right to change your mind and no longer take part at any time without giving a reason. Your participant rights or NHS care will not be affected. Please let the research team know (see ***Where can I get more Information?***) if you no longer want to take part.

If you do leave the study, the research team will retain any data collected up to the point of withdrawal, unless you inform the research team otherwise.

What will happen to the results of the research?

You will be informed by the research team when the results will be made available on the study website.

The anonymised results will also be published in scientific journals and presented at conferences to other researchers, policy makers and health professionals. Anonymised quotes from recordings may be used in publications; however, we will ensure that you are not personally identifiable as a participant.

The information collected from this study will be used to support other research in the future. We will follow standard procedures to ensure others are able to find, access and reuse data generated as part of the study (digital audio-recordings, anonymised data). Records of the data will be maintained on the University of Southampton Institutional Research Repository. In accordance with the University of Southampton Data Policy, the anonymised data will be archived in an appropriate repository for a minimum of ten years after publication or last access, to ensure long term access and safeguarding of the data. Future users of the data will be bound by data sharing agreements.

Will my participation be confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

Only the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the study is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. For the purposes of Chlamydia screening and treatment selected personal data (i.e. name, address, mobile/email, ID number, screening result) will need to be shared between the research team, the clinical care team and the laboratory. All of these people have a duty to keep your information, as a NHS patient and research participant, strictly confidential.

All data generated as part of the study (electronic and hard copy) will be securely stored (in pseudo- anonymised format) in line with procedures approved by the Faculty of Environmental and Life Sciences at the University of Southampton. Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Hard-copy data will be securely stored in lockable filing cabinets. All personalised data will be stored separately (in separate filing cabinets) from hard-copy and transcripts.

All electronic data (including media files from digital audio recordings) will be transferred and stored in the University of Southampton iSolutions secure research data storage service. Only authorised users can access data stored within these facilities and it is managed under the governance of the University of Southampton's Research Data Management Policy.

Anonymised transcripts and any personalised data collected will also be stored on the University managed storage in separate password protected folders. The transfer of data between researchers involved in the study will be encrypted and comply with the General Data Protection regulation (GDPR). Digital audio-recordings will be held securely and destroyed once the anonymised transcripts (anonymised at the point of transcription) have been validated (checked for accuracy by the researchers). Transcription of audio-recordings will be completed internally by members of the University of Southampton.

Only the clinical care team will have access to your medical records. However, the research team will be told of your Chlamydia test result via secure data transfer.

Safeguarding

Safeguarding means protecting a person's right to live in safety, free from abuse and neglect.

If you reveal information to clinic staff when signing up to the study that suggests you are at risk of significant harm (physical harm, emotion and psychological harm, sexual harm and exploitation, neglect), the NHS safeguarding policy will be followed in order to support you.

If any worries or concerns are revealed to a member of the research team related to the study, you will be provided with contacts that offer advice and support. For information that is believed to suggest an immediate risk, such as the intention to harm yourself, then any confidentiality agreement will be stopped and the information passed on as per the University of Southampton safeguarding policy. You cannot refuse this referral process.

Where can I get more information?

If you have any questions, please contact our research team or visit our study website: www.his-uk.net

Professor Cynthia Graham	Dr Nicole Stone	Rowena Bedford
C.A.Graham@soton.ac.uk	ncs@soton.ac.uk	r.d.bedford@soton.ac.uk
(023) 8059 3091	(023) 8059 7770	(023) 8059 7770

What happens if there is a problem?

If you have a concern about any part of the study, please speak to the research team who will do their best to answer your questions.

If you remain unhappy or have a complaint about any part of the study, please contact the University of Southampton Research Integrity and Governance Manager: (023) 8059 5058, rgoinfo@soton.ac.uk

Study Sponsor:
University of Southampton (UK)
Main Switchboard: (023) 8059 5000

NHS Complaints:
Patient Advice and Liaison Services (PALS): https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

Useful Contacts

• Your GP. To register with a GP Practice visit: www.nhs.uk/using-the-nhs/nhs-services/gps/how-to-register-with-a-gp-practice

• Sexual health services. To find your local services visit: www.nhs.uk/Service-Search/Sexual-health-services/LocationSearch/1847

• Brook Advisory: Provides free and confidential expert sexual health and wellbeing support for under 25s: www.brook.org.uk

• NHS Choices Sexual Health: www.nhs.uk/common-health-questions/sexual-health

• Health Talk: Provides free, reliable information about health issues, by sharing people's real- life experiences: https://healthtalk.org/sexual-health/overview

• Terrence Higgins Trust: the UK's leading HIV and sexual health charity: www.tht.org.uk

Please also see the contact card attached to this information sheet for further support services local to you.

Thank you for taking the time to read this information sheet and considering taking part in this study

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research study. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website: (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this study and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research studies and can be found at: http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our study and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose. Appropriate insurance arrangements have been put in place to cover the activities within this study to meet the legal liabilities of the University of Southampton as sponsor.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

All trial data will be retained for a period of ten years in a pseudo-anonymised format. Only the researchers of the study will be able to access this anonymised data to enable an individual to be identified.