

Page 1: Homepage

Interested in sexual health? Use the internet?

We're running a research study to test a sexual health website.

We invite you to be involved.

Why?

- You could find out more about sex and sexual health
- You will help in the testing of a website, which may help people like you to avoid sexually transmitted infections
- You will receive £50 in vouchers if you complete the study!

Next

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on XXXX, email email@ucl.ac.uk ; or contact the local research staff on NNNNNNNNN.

Page 2: Eligibility

Before we start, we need to check that you are suitable for the study.

This information is completely anonymous (it won't be linked your name), and will be kept confidential.

1. What is your gender? (Male, female, transgender) (*exclude all responses except Male → p2a*)
2. Please select your age (Under 16; 16 or over) (*Exclude under 16s → p2a*)
3. How many sexual partners (male or female) have you had in the last year? (None, 1, 2, More than 2) (*Exclude none or 1 → p2a*)
4. In the last 3 months, did you use a condom every time you had penetrative sex (penis in vagina or anus)? (Yes, No, Don't know, N/A) (*Exclude Yes or N/A → p2a*)
5. Have you ever received a diagnosis of HIV or Hepatitis? (Yes/No/Don't know) (*Exclude Yes or Don't know → p2a*)

6. Are you visiting the clinic today for these reasons?

I have symptoms of a sexually transmitted infection (e.g. pain when peeing, discharge) (Yes/No/Not sure)

To get treatment for a sexually transmitted infection (Yes/No/Not sure)

To get treatment because a partner has a sexually transmitted infection (Yes/No/Not sure)

(include if: (Q3 = 2 or more than 2 AND Q4 = No or Don't know) OR 'Yes' to any Q6 item)

7. Are your sexual partners generally male or female?
 - A. Female only, never male
 - B. More often female, and at least once male
 - C. About equally often female and male
 - D. More often male, and at least once female
 - E. Male only, never female
 - F. I have not had any sexual partners
 - G. Other (please state)

(Exclude D, E, F, G)

8. Do you have an active email account? (Yes, No) (*Exclude No*)
9. Do you have access to the internet? (Yes, No) (*Exclude No*)

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on XXXXXX, email email@ucl.ac.uk ; or contact the local research staff on NNNNNNNNNN.

Page 2a: Not eligible

Thanks for your time. Unfortunately you are not suitable for the study.

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster XXXXX, email [email] ; or contact the local research staff on NNNNNNNNN.

Page 3: “Information about the research: The MenSS Study: a pilot trial to test an interactive sexual health website for men” (Include logos of all three NHS trusts, and UCL logo)

Page 2b, Eligible

Thank you, you are suitable to be in the study.

Please read this information about the research study to decide whether you'd like to sign up.

You should only take part if you want to. If you sign up, you will be free to stop at any time, and you do not have to give a reason.

If you do take part, it will make no difference to the treatment you receive from the clinic.

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on XXXX, email [email] ; or contact the local research staff on NNNNN.

The MenSS website has been designed for men in sexual health clinics (like this one). The website gives information about sexual health, sexual pleasure, and how to avoid sexually transmitted infections. It has been developed by men in sexual health clinics and a team of sexual health experts from University College London. The aim of this study is to test whether the website can help people like you to improve their sexual health.

You have been invited because you are a man who is visiting a sexual health clinic. We want to know whether the MenSS sexual health website is helpful to men like you. We hope 166 men like you will sign up to the study. Half will be asked to review the website straight away and the other half will be asked to wait until the research is over (in a year's time).

We hope that you will find the research interesting.

Page 3. What's involved?

This iPad will guide you through the steps.

This is what will happen:

1. You will be asked **whether you agree to take part** in the study

2. You will then be asked to **fill in a survey on this computer** about yourself and your sexual life. It has questions like *'How many times in the last 3 months have you had vaginal sex without a condom?'* You do not have to answer any questions that you don't want to. This survey will take about 10 minutes.

3. The computer will then put you in one of **two groups**:
 - a. The **'no website'** group. You will not be asked to do anything else today, but **we will email you in 3, 6, 9, and 12 months to ask some more questions about your sexual health**. These surveys will take between 5 and 15 minutes. If we don't hear from you, we will remind you by email, text message and telephone. We will also send you text messages and emails from time to time to remind you about the study. You will be able to view the website at the end of the study (July 2015)
 - b. The **'website'** group. **You will be asked to look at the website today** (for about 10 minutes), while you are waiting to see the doctor. After you have left the clinic, you can visit the website again at any time. We will send you text messages and emails to remind you about the website. **We will also contact you in 3, 6, 9, and 12 months to ask you to answer some more questions about your sexual health**. If we don't hear from you, we will remind you by email, text message and telephone.

Splitting people into two groups helps us to see whether there is any difference between people who look at the website and people who don't look at the website. This tells us whether the website has been helpful.

You have an equal chance of being put into each group. This will be decided by chance, by the computer, and cannot be changed.

4. After one year, we would like your permission to check your medical records at this clinic, to see how often you have visited, and whether you were diagnosed with any sexually transmitted infections

5. We will send you a £10 online shopping voucher by email if you fill in online survey questions at 3 months, 6 months and 9 months, and another £20 online shopping voucher by email if you fill in the final online survey after one year.

What will happen to my information?

- All information you give will be confidential
- All data will be stored in accordance with the Data Protection Act 1998
- No information will be given to the clinic staff. Only the research team will be able to see your information
- Regulatory authorities in the NHS trust may wish to view research data, in order to check that we are doing everything correctly
- The information that you give about sexual behaviour will not be linked to your name: we will use code numbers instead of names.
- It will not be possible to identify individual participants in research reports
- Other researchers may wish to use your anonymous questionnaire responses for future research if it has been approved by an ethics committee
- We will only use your contact details to contact you about the research study – these will NOT be given to anyone else

The small print.

- This study has been approved by the London: City and East Research Ethics Committee (REC number 13 LO 1801).
- The research will be published in a report and the results will be available online. It will not be possible to identify any individuals in these reports.
- You will receive a summary of the results by email at the end of the study.
- All information that you provide will remain confidential and will be used only for the study.
 - However, if you give us specific information which leads us to think that you or someone else is at risk of harm, we are obliged to consider discussing this with authorities such as child protection teams, or the police

- You can withdraw from the study at any time, without giving a reason. To do this, please contact Rosie Webster XXXXX [email]. We may still use your anonymous questionnaire responses.
 - Once the findings of the study have been published in a research report, you will no longer be able to withdraw from the study.
- The research team cannot offer individual sexual health advice
- We hope that you find the research interesting, but you may find some of the questions or topics embarrassing or upsetting. We will provide contact details of organisations who may be able to help you
- Please contact the researcher Rosie Webster if you have any questions or concerns about the research, on XXXXX [email]; Julia Bailey, [email]
 - You can also contact the principal investigator within your clinic:
 - Homerton Hospital: Professor Jane Anderson [email]
 - St Bartholomew's Hospital : Dr. Claudia Estcourt [email]
 - Coventry sexual health clinic: Dr. Belinda Stanley [email]

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to the Julia Bailey, [email] who is the Chief Investigator for the research and is based at University College London. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

- If you would like general advice about being involved in research, please see the INVOLVE website: www.invo.org.uk
- You can get independent advice about your care or involvement in this research from the Patient Advisory and Liaison Service (PALS):
 - Homerton:

Tel: 020 8510 7315

Email: pals@homerton.nhs.uk
 - Barts:

Tel: 020 3594 2040

Email: pals@bartshhealth.nhs.uk
 - Coventry:

Tel: 024 7653 6804

Text message: 07826 900 926

Email: pals@covwarkpt.nhs.uk

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on XXXX email [email]; or contact the local research staff on NNNNNNNN.

Page 4: Consent form

(Include logos of all three NHS trusts, and UCL logo)

Please read the following statements and tick the boxes if you agree with them.

1. I have read the study information and understand what the study involves
2. I understand that I can withdraw from the study at any time
3. I agree for the research team to record all contact details, questionnaire responses, and information about my use of the MenSS website
4. I understand that my information will be treated as confidential and handled in accordance with the Data Protection Act 1998
5. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from UCL, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
6. I agree that my anonymous questionnaire answers may be used by others for future research which has been approved by an ethics committee
7. I agree for the research team to access my clinic records to get information about sexually transmitted infection diagnoses
8. I agree to take part in this study
(All Yes/No responses, if any 'No' responses direct to page 4b)

Please press the back button if you would like to read the study information again

Submit

Back (to p3)

I'd like more time to think about whether I'd like to be involved (- leads to page 4a)

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on XXXXX, email V[email] ; or contact the local research staff on NNNNNNN.

Back

Page 4a:

If you would like some more time to think about whether you want to sign up, please leave the tablet for the next person to use. You can come back to the tablet and sign up for the study at any time during your clinic visit.

Page 4b: Not consented

Thanks for your interest. Unfortunately if you do not agree to all the statements, you cannot be in the study.

If you would like to reconsider, please press 'back'. You may enter your responses again.

Thank you for your time.

Back

Page 5: Registration details (contact details and password)

We need **your contact details** for the following reasons:

- To email and text you information about the study, reminders about the website, and links to questionnaires
- To send you your £10 and £20 vouchers

Your contact details will remain completely confidential. We will not use them for anything other than the research study.

Note: If you do not give your contact details, or give incorrect contact details, you will not be able to complete the study, and you will not receive the £10 and £20 vouchers.

Name:

Email:

Re-type email:

Mobile phone number:

(We will now send you a verification code by text message. This is to confirm that you have typed your mobile number in correctly. Once you have received it, please enter it into the box below)

Verification code:

Please **create a password**. You will be asked for this every time you access the website, or complete a questionnaire. This is so that we know who has answered the questions or looked at the MenSS website, without you having to give your name. Please try and make your password memorable.

Password:

Retype password:

(Reject participants without an email address and mobile phone number– if not, direct to page 5a)

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on XXXXX, email **[email]** ; or contact the local research staff on NNNNNNN.

Page 5a: Did not supply contacts or password

You have not entered a valid email address, mobile number or password.

Please press back to re-enter.

Back

If you do not want to give this information, please click this button to exit the study registration.

Home

Page 6: Demographic questionnaire

Thank you and welcome to the MenSS research study.

The next step is to fill in an **online survey**. This will include some questions about you, and some questions about your sexual behaviour.

The survey takes less than 10 minutes

Please answer as honestly as you can. All answers are confidential.

(Demographic questionnaire leading straight into sexual health questionnaire.)

Page 7: Sexual health questionnaire

(Randomisation)

Page 8a: Intervention group – informed and directed to intervention

Thank you for completing the survey. You have been put into the ‘website’ group. Please look at the MenSS website now, while you are waiting in the clinic.

If you no longer want to look at it, or are called in by the doctor, please click one of the ‘quit’ buttons that are on each page:

Want to quit the website

Called in to doctor or nurse

You will also have access to the website (link to MenSS website) over the next 12 months. We will email and text you the link to it, with a reminder about your password.

Page 8b: Control group – informed and free to leave

Thank you for completing the online survey. You have been put in the ‘no website’ group. You are not required to do anything else today. We will email you in 3, 6, 9, and 12 months to ask you about your sexual health, and then show you the MenSS website.

Thank you for your time.

Page 9: End of intervention viewing

(Shown after hitting one of the quit buttons, or after completing all designated in-clinic activities)

Thank you for looking at the website.

You will now have access to the new website (URL) over the next 12 months. We will email and text you the link to this, so you do not have to remember it.

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on XXXXX, email [email]; or contact the local research staff on NNNNNN.