

Appendix 1 - MenSS Trial online study information and consent form

Information about the research: The MenSS Study: a pilot trial to test an interactive sexual health website for men

V5 6th May 2014

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 07768100384, email rosemary.webster@ucl.ac.uk.

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.

What's involved?

This tablet computer will guide you through the steps.

This is what will happen:

1. You will be asked to **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. We will send you emails about the study:
 - a. To welcome you to the study
 - b. To ask you to complete questionnaires
 - c. To remind you about the study, or to visit the website
 - d. If you choose to set reminders on the website. You do not have to set reminders, and you can choose not to receive reminder emails

Please note – Email communication is not 100% secure, so there is a very small risk that email could be seen by someone else. If someone you know has access to your email account (e.g. family member, partner), they may see the emails that we send to you. Our emails will not contain any information about you unless you have chosen to set reminders.

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 *each time* you fill in the 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 City and East National 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 (020 7794 0500 ext.31429, rosemary.webster@ucl.ac.uk). 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 020 7794 0500 (ext.31429) rosemary.webster@ucl.ac.uk; Julia Bailey, Julia.bailey@ucl.ac.uk
 - You can also contact the principal investigator within your clinic:
 - Homerton Hospital: Professor Jane Anderson janderson@nhs.net
 - St Bartholomew's Hospital : Dr. Claudia Estcourt c.s.estcourt@qmul.ac.uk
 - Coventry sexual health clinic: Dr. Belinda Stanley Belinda.Stanley@covwarkpt.nhs.uk

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, Julia.bailey@ucl.ac.uk 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@bartshealth.nhs.uk
 - Coventry:

Tel: 024 7653 6804

Text message: 07826 900 926

Email: pals@covwarkpt.nhs.uk

- This research has been approved by the City and East London NHS Research Ethics Committee.

Advice and help organisations

Health services near you: NHS Choices

<http://www.nhs.uk/servicedirectories/Pages/ServiceSearch.aspx>

Advice about sexual health and HIV: Terrence Higgins Trust

<http://www.tht.org.uk>

Contraception and sexually transmitted infection: Family Planning Association <http://www.fpa.org.uk/home>

Help after sexual assault: The Havens <http://www.thehavens.org.uk>

Sort out stress <http://www.sortoutstress.co.uk/site>

The Samaritans <http://www.samaritans.org>

Gay, bisexual and transgender health: PACE <http://www.pacehealth.org.uk>

The MenSS Study: a pilot trial to test an interactive sexual health website for men: Consent form

V3 6th May 2014

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 agree for the research team to use my contact details to contact me about the study
5. I understand that my information will be treated as confidential and handled in accordance with the Data Protection Act 1998
6. 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.
7. I agree that my anonymous questionnaire answers may be used by others for future research which has been approved by an ethics committee
8. I agree for the research team to access my clinic records to get information about sexually transmitted infection diagnoses
9. I agree to take part in this study

(All Yes/No responses, if any 'No' responses, directed to a page where they are thanked for their time (plus given the option to return to the consent form to reconsider))

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

Submit *(agrees consent)*

Back *(returns to study information page)*

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 07768100384, email rosemary.webster@ucl.ac.uk ; or contact the local research staff on NNNNNNNNN.