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The Men's Safer Sex (MenSS) Trial: a website to increase condom use

Submission date
19/09/2013

Recruitment status
No longer recruiting

Registration date
15/10/2013

Overall study status
Completed

Last Edited
16/03/2020

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
Sexually transmitted infections (STI) and unwanted pregnancy are major public health problems. Condoms are effective for prevention, but there are many barriers to successful use such as decrease in sensation, interruption of sex, incorrect size or fit, use of alcohol/recreational drugs, anxiety, and stigma. Face-to-face condom-use interventions are expensive and not very effective. Interactive digital interventions (IDI) such as websites are highly suitable for sexual health issues: access can be private and self-paced, and programmes can be tailored for individuals. Evidence shows that IDI can improve sexual behaviour (condom use) as well as increasing knowledge. Men who are engaging in unprotected sex are at high risk of future infection, so targeting this measure at these men will increase the impact of IDI. This initial study aims to find out how we should plan a future larger study regarding an interactive, theory-based website to increase condom use.

Who can participate?
We will recruit men, aged 18 years and over who are at risk of sexually transmitted infection, from three sexual health clinics.

What does the study involve?
Men will be invited to register for the study using a laptop which will be available in clinic waiting rooms. Study information and consent will be offered on the laptop, with participants submitting contact details and demographic details and answering sexual health questions online, directly onto the laptop. A programme on the laptop will automatically allocate eligible men either to usual sexual health clinic care plus the website, or to usual care only, and measuring any changes in outcomes such as knowledge, confidence and condom use at 12 months. We will collect data online at 3, 6, 9 and 12 months, and ask participants for permission to check their clinic notes after one year. We will also collect data on costs and possible benefits of this method. We will interview some participants to understand how the method was used, and to work out the best design for a future large scale study.

What are the possible benefits and risks of participating?
This project aims to encourage behaviour change (i.e. safer sex) to reduce the incidence of sexually transmitted infections. This will benefit the participants as well as wider society. The

tone of the intervention website is non-judgemental about choices of lifestyle or behaviour, however, there is a risk that the study may unintentionally aggravate the stigma of STI or of particular sexual behaviours. It could be that the content embarrasses or upsets some participants. The website itself will provide links to helpful resources, for example regarding domestic violence, HIV, sexual problems etc. We will also refer on to support organisations any participants who contact the research team directly with any concerns. It could be that participants partners or others see the intervention website, texts or email messages (which will be sent as prompts to complete the follow-up assessments and to re-visit the website) and that this leads to embarrassment or relationship difficulties in some way. A component of the intervention will focus on communication with partners, so it is hoped that the intervention will improve the quality of relationships rather than cause harm.

Where is the study run from?
We will recruit from three sexual health clinics in England: Homerton Department of Sexual Health in East London, Barts Sexual Health Centre at St. Bartholomew's hospital, and Coventry Integrated Sexual Health Services at the City of Coventry Health Centre.

When is the study starting and how long is it expected to run for?
The study runs between January 2014 to September 2015, recruiting men from January 2014 to June 2014.

Who is funding the study?
The National Institute for Health Research (NIHR), UK.

Who is the main contact?
Dr Julia Bailey
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number

HTA 10/131/01

Study information

Scientific Title
An interactive digital intervention to increase condom use in heterosexual men in sexual health clinics: a pilot trial and qualitative evaluation of trial procedures

Acronym
MenSS

Study objectives
That an interactive, theory-based website plus usual sexual health clinic care will be more effective in increasing men's condom use than usual care only.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1013101
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/81138/PRO-10-131-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - City & East, 14/02/2014, REC ref: 13/LO/1801

Study design
Randomised controlled trial with linked qualitative process evaluation

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of sexually transmitted infections

Interventions
Participants will be allocated by computer algorithm to either usual care (the control condition) or usual care plus the interactive digital intervention (intervention condition). Those in the intervention condition will be asked to spend time interacting with the intervention whilst in the clinic waiting room, and will then have access to the intervention for the next 12 months. The intervention is an interactive, theory-based website to promote condom use in men. Sexual health outcomes (e.g., condom use, STI diagnoses) will be assessed at baseline (before randomisation), and 3, 6, 9, and 12 months later.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
The primary outcome is self-reported condom use for penetrative sex over the previous three months. This is a small-scale pilot trial to test the procedures for a future full-scale trial, so we will also assess the success of recruitment, trial procedures and retention over one year.

Key secondary outcome(s))
Pilot trial:
1. We will measure outcomes such as knowledge, confidence in ability, and motivation, which contribute to behaviour change (increased condom use). We will also measure self-reported sexually transmitted infection (STI) and record STI diagnoses from sexual health clinic notes.
2. Qualitative process evaluation:
2.1. Men's experiences and views of participating in the pilot trial, and views of the website to increase condom use
2.2. Sexual health clinic staff members' views of the trial procedures and the role of interactive digital interventions (e.g. websites) in sexual health clinical care
3. We will also work out the best methods of data collection and analysis for a cost effectiveness analysis analysis for a future full scale randomised controlled trial

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Male
2. Aged 18 years and over (with no upper age limit)
3. Able to read English
4. Heterosexual and sexually active
5. Possession of an active email account and access to the internet
6. Reporting 2 or more sexual partners in the last year, and unprotected sex in the last 3 months
7. Predominantly female partners, or an equal number of male and female partners

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Male

Key exclusion criteria

1. HIV positive men
2. Men with hepatitis B or C
3. We will exclude men who have had sexual experience only ever with males, more often with males and at least once with a female or no sexual experience at all

Date of first enrolment
06/01/2014

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
e-Health Unit
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
University College London (UCL) (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/11/2016		Yes	No
Results article	results	01/12/2016		Yes	No
Protocol article	protocol	16/02/2015		Yes	No
HRA research summary			28/06/2023	No	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