

# The Men's Safer Sex project: intervention development and feasibility randomised controlled trial of an interactive digital intervention to increase condom use in men

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## Scientific summary

### **The Men's Safer Sex (MenSS) project**

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# Scientific summary

## Background

Sexually transmitted infections (STIs) are a major public health problem with high social and economic costs. Condoms are effective for the prevention of STI acquisition but there are many barriers to the successful use of condoms.

Men are less likely than women to visit health professionals and can be reluctant to discuss their sexual health with practitioners, partners or friends. An online intervention offers an alternative way to reach men at risk of acquiring STIs. Digital interventions are very suitable for sexual health promotion because access can be private, anonymous and self-paced. Interventions can be targeted for specific groups (e.g. by age, sex or sexuality) and content can be tailored for individuals. Interactive digital interventions (IDIs) can be expensive to develop but offer the advantages of intervention content fidelity and the potential to reach large audiences at relatively low dissemination costs. IDIs can improve sexual behaviour as well as increasing knowledge, self-efficacy and safer sex intention, but there are few interventions for men who have sex with women and more evidence is needed to establish the effects on biological outcomes, such as STIs, as well as cost-effectiveness.

The Men's Safer Sex website is an IDI which provides information and tailored advice on sexual well-being and barriers to condom use. The website was offered to heterosexual men in the waiting rooms of NHS sexual health clinics, with the aim of increasing condom use and reducing the acquisition of STIs. This report details the development, design and content of the Men's Safer Sex website, and the results of feasibility evaluations [a pilot randomised controlled trial (RCT), a health economic assessment and a qualitative evaluation].

## Aim and objectives

### Aim

To assess the feasibility and best design of a large-scale RCT and health economic evaluation of the Men's Safer Sex website.

### Objectives

1. To develop an interactive, tailored, website that addresses men's barriers to condom use.
2. To determine the feasibility and best design for a RCT to test the effect of the Men's Safer Sex website on condom use and acquisition of STIs among men attending sexual health clinics.
3. To inform the methods for collecting and analysing cost and outcome data for a cost-effectiveness analysis alongside a Phase III trial.
4. To assess the suitability of using the Sexual Quality of Life (SQoL) questionnaire, European Quality of Life-5 Dimensions, three-level version (EQ-5D-3L) and associated utility scores to calculate quality-adjusted life-years (QALYs) for an incremental cost-utility ratio.
5. To explore the views of clinic staff and male clinic attendees regarding the online research methodology.

## Methods

### Intervention development method

We used the Behaviour Change Wheel to combine evidence from research literature with the views of sexual health and eHealth experts as well as those of male clinic users to develop a website that provided

individually tailored advice on barriers to condom use, especially on the impact of condoms on sexual pleasure. We incorporated behaviour change techniques throughout the website.

### **Feasibility randomised controlled trial method**

A total of 159 men aged  $\geq 16$  years with female sexual partners and recent condomless sex or a suspected acute STI were recruited from three English sexual health clinics. Trial procedures were online, with online eligibility, consent, registration, randomisation and data collection. Participants were randomised to receive the Men's Safer Sex website plus usual clinic care ( $n = 84$ ) or usual clinic care only ( $n = 75$ ). Men were invited via e-mail to complete online questionnaires at 3, 6, 9 and 12 months. STI diagnoses were recorded from clinic notes at 12 months and the primary outcome was retention in the trial at 3 months. Online shopping vouchers worth up to £50 were offered for completing the online questionnaires.

### **Health economic evaluation methods**

The aim of the health economic evaluation was to assess the feasibility of an economic evaluation as part of a Phase III trial and to inform the methods for future data collection. Sexual health-related resource use was collected from two sources: participants' sexual health clinical records and participant responses to questionnaires at 3, 6, 9 and 12 months. Utility scores to calculate QALYs were collected using two different questionnaires: (1) generic preference-based measure of health-related quality of life (HRQoL) – the EQ-5D-3L and (2) a sexual health-specific HRQoL measure – the SQoL questionnaire. The incremental cost per QALY was calculated to investigate the impact of using different questionnaires to calculate utilities and QALYs and using different methods to collect resource use.

### **Qualitative evaluation method**

Semistructured interviews were conducted with 11 men who had participated in the pilot RCT and with nine clinic staff. We also collated free-text comments taken from the online outcome questionnaires. Interviews were audio-recorded and transcribed, and a thematic analysis of these three data sources was conducted to identify themes.

## **Results**

### **Feasibility randomised controlled trial results**

Recruitment via a tablet computer in the waiting rooms of sexual health clinics was successful. Retention within the trial was a significant problem owing to software technical problems and low response rates to the online questionnaire (36% at 3 and 6 months, and 50% at 12 months). Clinical records were located for 94% of participants (for STI diagnoses  $> 12$  months). There was no detectable difference between the intervention and control in condomless sex with female partners between groups, but the numbers were very small owing to the low survey response rate [incidence rate ratio (IRR) 1.01, 95% confidence interval (CI) 0.52 to 1.96]. There were fewer clinical diagnoses of STIs over 1 year in the intervention group who were offered the Men's Safer Sex website but the differences were non-significant (IRR 0.75, 95% CI 0.29 to 1.89). No harmful effects or adverse events were identified.

### **Health economic assessment results**

The probability that the Men's Safer Sex website was cost-effective compared with current practice differed by whether data from questionnaires or clinical records were used. Resource use for sexual health clinics taken from questionnaire responses accounted for 84–87% of costs, capturing the majority of cost data. There was a significant decrease in QALYs calculated using the EQ-5D-3L for patients with a STI at baseline but no change detected by the SQoL questionnaire.

### **Qualitative evaluation results**

Male clinic users felt that the Men's Safer Sex website could be useful, especially for men who do not want to discuss their sex lives, but both staff and clinic users did not want a website to replace face-to-face health care. The pilot RCT fitted well around clinical activities, but men did not self-direct to the iPads®

(Apple Inc., Cupertino, CA, USA) and technical problems hampered website access and data collection. Staff were more concerned about consent and confidentiality than clinic users. Experiences of the sexual health questionnaire and follow-up procedures were widely positive. The outcome questionnaire was sometimes thought-provoking and could constitute an intervention in itself.

## Conclusions

The Men's Safer Sex website was broadly well-received by male patients and clinic staff, and we were able to measure the impact of the website on the acquisition of STIs by checking clinical notes. It is likely to be feasible to conduct a future large-scale RCT to assess the impact of an online intervention using clinic STI diagnoses as a primary outcome; however, technical errors and low response rates limited the collection of online self-reported outcomes. There were challenges with unreliable research software and lengthy research procedures, which hampered online self-reported data collection and access to the Men's Safer Sex intervention. Response rates were boosted following a higher-value incentive, but remained poor (50%) at 6 months. There were no reported harmful effects from the Men's Safer Sex website and it has the potential to be cost-effective. Qualitative evaluation indicates that the Men's Safer Sex website can prompt useful changes in attitudes and behaviour for some men. We need to know more about how the digital intervention might work, for whom and when, and how to ensure that participants engage with a digital intervention for long enough to effect change. Practical and technical challenges need to be addressed before a large-scale RCT is warranted.

## The next steps

1. To refine the Men's Safer Sex website in the light of suggestions made by men and by clinic staff.
2. To draw on our experiences and the latest software security protocols to develop a reliable and secure software framework for online trials.
3. To optimise online research procedures (e.g. information formats suitable for reading online, efficient registration procedures and minimal baseline outcome measurement).
4. To conduct qualitative work with patients, clinic staff and other stakeholders to investigate the best ways to incorporate digital health promotion into NHS clinic pathways, to benefit both patients and clinic staff.
5. To explore potential mechanisms of action of the Men's Safer Sex digital interventions, including the best ways to enhance engagement with the website.
6. To develop more precise estimations of the costs of service use and resources through capturing better data on clinic staff costs, time and resources allocated to each patient.

Public health policy advocates the use of digital interventions for health and these interventions have the potential to offer cost-effective sexual health promotion. However, we encountered significant obstacles to online research and to engagement with the Men's Safer Sex website in NHS clinic settings. Interactive digital interventions show exciting potential for health promotion but, first, we need to overcome barriers to digital intervention testing and implementation in NHS clinical settings.

## Trial registration

This trial is registered as ISRCTN18649610.

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