

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

Julia V Bailey, Rosie Webster, Rachael Hunter, Mark Griffin, Nicholas Freemantle, Greta Rait, Claudia Estcourt, Susan Michie, Jane Anderson, Judith Stephenson, Makeda Gerressu, Chee Siang Ang and Elizabeth Murray



**National Institute for
Health Research**

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Abstract

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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Background: This report details the development of the Men's Safer Sex website and the results of a feasibility randomised controlled trial (RCT), health economic assessment and qualitative evaluation.

Objectives: (1) Develop the Men's Safer Sex website to address barriers to condom use; (2) determine the best design for an online RCT; (3) inform the methods for collecting and analysing health economic data; (4) assess the Sexual Quality of Life (SQoL) questionnaire and European Quality of Life-5 Dimensions, three-level version (EQ-5D-3L) to calculate quality-adjusted life-years (QALYs); and (5) explore clinic staff and men's views of online research methodology.

Methods: (1) Website development: we combined evidence from research literature and the views of experts ($n = 18$) and male clinic users ($n = 43$); (2) feasibility RCT: 159 heterosexually active men were recruited from three sexual health clinics and were randomised by computer to the Men's Safer Sex website plus usual care ($n = 84$) or usual clinic care only ($n = 75$). Men were invited to complete online questionnaires at 3, 6, 9 and 12 months, and sexually transmitted infection (STI) diagnoses were recorded from clinic notes at 12 months; (3) health economic evaluation: we investigated the impact of using different questionnaires to calculate utilities and QALYs (the EQ-5D-3L and SQoL questionnaire), and compared different methods to collect resource use; and (4) qualitative evaluation: thematic analysis of interviews with 11 male trial participants and nine clinic staff, as well as free-text comments from online outcome questionnaires.

Results: (1) Software errors and clinic Wi-Fi access presented significant challenges. Response rates for online questionnaires were poor but improved with larger vouchers (from 36% with £10 to 50% with £30). Clinical records were located for 94% of participants for STI diagnoses. There were no group differences in condomless sex with female partners [incidence rate ratio (IRR) 1.01, 95% confidence interval (CI) 0.52 to 1.96]. New STI diagnoses were recorded for 8.8% (7/80) of the intervention group and 13.0% (9/69) of the control group (IRR 0.75, 95% CI 0.29 to 1.89). (2) Health-care resource data were more complete using patient files than questionnaires. The probability that the intervention is cost-effective is sensitive to the source of data used and whether or not data on intended pregnancies are included. (3) The pilot RCT fitted well around clinical activities but 37% of the intervention group did not see the Men's Safer Sex website and technical problems were frustrating. Men's views of the Men's Safer Sex website and research procedures were largely positive.

Conclusions: It would be feasible to conduct a large-scale RCT using clinic STI diagnoses as a primary outcome; however, technical errors and a poor response rate limited the collection of online self-reported outcomes. The next steps are (1) to optimise software for online trials, (2) to find the best ways to integrate digital health promotion with clinical services, (3) to develop more precise methods for collecting resource use data and (4) to work out how to overcome barriers to digital intervention testing and implementation in the NHS.

Trial registration: Current Controlled Trials ISRCTN18649610.

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List of abbreviations

BCT	behaviour change technique	IT	information technology
BCW	Behaviour Change Wheel	MSM	men who have sex with men
CEAC	cost-effectiveness acceptability curve	MSW	men who have sex with women
CI	confidence interval	NICE	National Institute for Health and Care Excellence
COM-B	capability, opportunity, motivation, behaviour	QALY	quality-adjusted life-year
EQ-5D-3L	European Quality of Life-5 Dimensions, three-level version	RCT	randomised controlled trial
GP	general practitioner	SMS	short message service
HIV	human immunodeficiency virus	SQoL	Sexual Quality of Life
HRQoL	health-related quality of life	SQoL-3D	Sexual Quality of Life 3 Dimensions
ICER	incremental cost-effectiveness ratio	STI	sexually transmitted infection
IDI	interactive digital intervention	TDF	theoretical domains framework
IRR	incidence rate ratio	UCL	University College London
		WTP	willingness to pay

Plain English summary

The Men's Safer Sex website gives advice about sexual health and how to avoid sexually transmitted infections (STIs). We wanted to find out whether or not the website is useful for men in sexual health clinics and how best to run research. Men signed up for the study on an iPad® (Apple Inc., Cupertino, CA, USA) in clinic waiting rooms and allocated to:

1. The 'no website' group: asked to complete online surveys via e-mail 3, 6 and 12 months later.
2. The 'website' group: asked to look at the Men's Safer Sex website while they were waiting and to then fill in online surveys 3, 6, 9 and 12 months later.

We checked men's clinic records after 1 year and also interviewed 11 men and nine members of staff. We found that:

- men were happy to do online research
- staff and patients felt that a sexual health website is a good idea
- staff asked men to join the study, rather men registering on iPads on their own
- there were a lot of technical problems
- one-third of the experimental group did not actually see the Men's Safer Sex website
- privacy and confidentiality is very important
- only half of the men filled in the online surveys
- we collected useful information on STIs and costs from medical records
- there were fewer infections in the group who received the Men's Safer Sex website (9% vs. 13%), but this difference might have happened by chance
- the website did not seem to cause any harm and men thought it could be helpful.

The next steps are to work out how to solve practical and technical problems before health promotion websites can be tested and used in NHS settings.

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 ≥ 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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Chapter 1 Introduction

Men's sexual health

Sexually transmitted infections (STIs) are a major public health problem as they result in high social and economic costs.^{1,2} Condoms are effective for prevention of STIs, but there are many barriers to successful condom use, for example decrease in sensation, interruption of sex, incorrect size or fit, use of alcohol/recreational drugs, anxiety affecting sexual performance and stigma associated with carrying condoms.^{3,4} Condoms may be perceived as a barrier to intimacy and trust,⁴ and their use is often lower in established relationships.⁵

As men often have the power to influence condom use for penetrative sex (because they wear condoms), efforts are needed to target the obstacles to condom use that men face.³ Although there are a variety of health promotion interventions aimed at improving sexual health for men who have sex with men (MSM), there are fewer interventions specifically for adult men who have sex with women (MSW),^{6,7} despite the fact that MSW report much less consistent condom use than MSM.⁸ Men are less likely than women to visit health professionals and generally have shorter clinic appointments,^{9,10} and so may be less likely to be offered health promotional advice or risk reduction counselling in the context of routine appointments. Furthermore, men may be reluctant to discuss their sexual health with health professionals, partners or friends.¹¹ Therefore, an online intervention offers an alternative avenue to reach out to men.¹²

Sexual health interventions

Guidance from the National Institute for Health and Care Excellence (NICE)¹ recommends that people at a high risk of acquiring STIs are offered one-to-one structured discussions to address risk-taking and this is increasingly being offered as part of routine care in genitourinary medicine and other health-care settings. Although interventions such as motivational interviewing can have an impact on sexual behaviour,¹ in practice, it is resource intensive to train and support staff and difficult to find time for structured discussions in busy clinical services. A potential alternative to such interventions is the use of interactive digital interventions (IDIs).

We define IDIs as 'computer-based programmes that provide information and one or more of decision support, behaviour-change support, or emotional support for health issues'.¹² IDIs require contributions from users to produce personally relevant tailored material and feedback, and are highly suitable for sexual health promotion because access can be private, anonymous and self-paced,¹³ which may be particularly important for men who may be reluctant to disclose a lack of knowledge or skill. Interventions can be targeted for specific groups (e.g. by age, sex or sexuality) and content can be tailored for individuals.¹⁴ IDIs can be expensive to develop, but offer the advantages of intervention fidelity¹⁵ and the potential to reach large audiences at relatively low dissemination costs.

Interactive digital interventions can improve sexual behaviour (including condom use) as well as increasing knowledge, self-efficacy and safer sex intention.^{12,16} Further evidence is needed to establish the effects on biological outcomes, such as STIs, and cost-effectiveness. Interventions are more likely to be effective if they are grounded in theory¹⁷ and involve a high level of user input in the development process.¹⁸ Therefore, this project sought to develop a theory- and evidence-based IDI, developed with a high level of user input, which was aimed at increasing condom use in MSW. This report outlines the development process of the IDI, a pilot trial of the IDI, a health economic assessment and a qualitative evaluation of the trial procedures. The overall aim was to produce a rigorously developed intervention underpinned by behaviour change theory, and recommendations for how this intervention could be assessed for clinical effectiveness and cost-effectiveness in sexual health clinic settings.

Chapter 2 Intervention development

Introduction

Understanding the exact nature and content of complex behaviour change interventions is important for understanding which intervention components are the 'active ingredients' of a behaviour change intervention;¹⁹ however, intervention designs are not often well described in publications.²⁰ As a result, replication is difficult and future intervention designers cannot learn from what is and what is not effective.^{20,21} Lack of detail in the description of the content and development process for an intervention limits the evaluation of its quality or the possibility of linking content to outcome. A further issue is that, even if one is aware that theory and user involvement should be incorporated into intervention development, it can be difficult to know exactly how to achieve this.

This paper outlines the development process of the Men's Safer Sex website and, thus, provides transparency for readers and an example of how an evidence- and theory-based IDI may be developed.

The Behaviour Change Wheel

The Behaviour Change Wheel (BCW) (Figure 1) is one method that can be used to guide this process.²³ It provides a framework for the process of developing complex interventions and it represents a synthesis of 19 theoretical frameworks of behaviour change pathways. It has the advantage of being comprehensive (i.e. it covers all the main intervention functions and policy categories), coherent (i.e. categories within it are consistent and it provides systematic steps for intervention design) and linked to an overarching model of behaviour. The BCW has been used to develop interventions that were both acceptable to users and effective in achieving their aims.^{24–26}

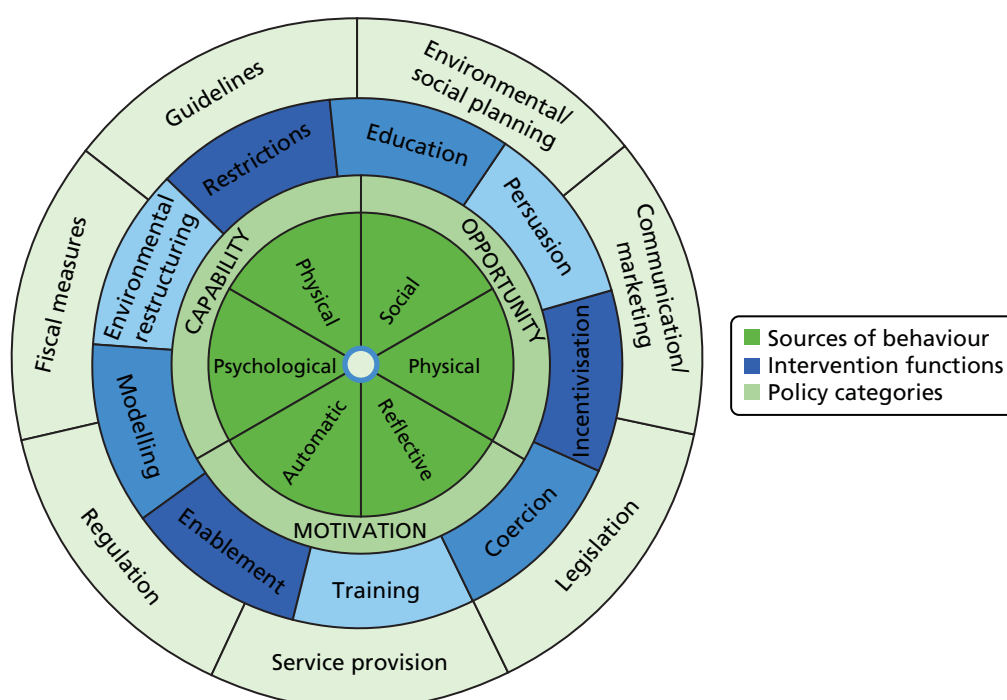


FIGURE 1 The BCW.^{22,23} © Michie *et al.*; licensee BioMed Central Ltd. 2011. This article is published under licence to BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (creativecommons.org/licenses/by/2.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

The main steps are as follows.

Step 1: specifying the target behaviour and population

This involves specifying who needs to do what, where, when and how often. Having a specific target behaviour allows for a focused development process and facilitates deciding on appropriate measurable outcomes.²² A well-defined target population enables the intervention developer to select an appropriate platform and tailor the content to the user's specific needs and preferences.

Step 2: identifying theoretical domains that explain the behaviour

At the heart of the BCW is a model in which behaviour change is conceptualised as requiring a shift in capability, opportunity and/or motivation, with these three drivers being part of an interacting system [the capability, opportunity, motivation, behaviour (COM-B) model, see *Figure 1*]. Capability may be physical or psychological, opportunity may be physical or social and motivation may be reflective or automatic. These subdivisions can be further elaborated into 14 detailed theoretical domains, specified by the theoretical domains framework (TDF) (*Table 1*).²⁷ The TDF is an amalgamation of 128 theoretical constructs from 33 theories of behaviour and behaviour change. It can be used to conduct a theoretically based assessment of the problem,^{28,29} which identifies mechanisms of action to be targeted by the intervention. The advantage of using the TDF over a single theory of health behaviour is that it delineates multiple distinct explanatory domains, which may be more appropriate for the development of a complex intervention, as a greater number of potential influences on behaviour can be considered.

Step 3: identifying how explanatory domains should be targeted

The BCW outlines nine possible 'intervention functions' that may be utilised: education, persuasion, incentivisation, coercion, training, restrictions, environmental restructuring, modelling and enablement. These delineate what 'function' the intervention will serve (i.e. to educate people, to train people, to coerce people) and appropriate functions are recommended for each of the explanatory domains identified in *Step 2: identifying theoretical domains that explain the behaviour*.^{22,23} At this point, it is important to consider which methods will be most appropriate for the intervention given its context, that is target population and setting (e.g. in terms of acceptability, affordability and practicability).²²

TABLE 1 Explanatory domains for behaviour change

COM-B component		TDF domain
Capability	Psychological	Knowledge
		Cognitive and interpersonal skills
		Memory, attention and decision processes
		Behavioural regulation
Opportunity	Physical	Skills
	Social	Social influences
	Physical	Environmental context and resources
Motivation	Reflective	Social/professional role and identity
		Beliefs about capabilities
		Optimism
		Beliefs about consequences
		Intentions
		Goals
	Automatic	Reinforcement
		Emotion

Step 4: selecting standardised behaviour change techniques

Once intervention functions have been identified, it is possible to identify the standardised behaviour change techniques (BCTs) that are relevant to each function. A BCT is an active component of an intervention designed to change behaviour³⁰ and BCTs are applicable to a range of health behaviours.³¹ One can therefore select BCTs considering the appropriateness for the population, setting and intervention format. This approach has been used successfully in a range of interventions varying in mode of delivery, content, target behaviour and context.^{21,24,32}

In addition to the steps outlined here, the BCW also includes nine 'policy' categories to select from when developing interventions on a wider scale, for example changing legislation to encourage behaviour change on a population level; however, these were not considered relevant for this (individual-level) intervention.

The development process³³ and content³⁴ of the intervention are also reported elsewhere.

Methods

Three sources of data were used to inform the intervention development process: research literature, expert consultation and interviews with the target population (men in sexual health clinics). The BCW and the TDF were used as frameworks to guide the analysis and synthesis of the evidence. Ethics approval was provided by the London City and East NHS Research Ethics Committee (reference number 13/LO/1801). The intervention website was developed by a software development company (Digital Life Sciences, Birmingham, UK).

Data collection

Research literature

A targeted literature review identified research on men's barriers to condom use. Search terms included 'men', 'heterosexual', 'condom' and 'barriers'. Databases searched included Web of Knowledge databases (including MEDLINE, EMBASE, PsycINFO) and Google Scholar (Google Inc., Mountain View, CA, USA), selecting articles on risk factors for non-condom use, theoretical correlates of condom use and men's barriers to using condoms. The full text of 27 papers was included, consisting of reviews, qualitative studies and cross-sectional, longitudinal, population-based and experimental designs.³³ These were summarised and synthesised into themes and subthemes (*Table 2*).

Expert consultation

Two expert workshops were held. Attendees at the first day-long workshop included 13 experts in the area of men's sexual health and/or behaviour change, including sexual health clinicians, health advisors and academic professors. The workshop was structured around the BCW, asking participants to give their opinions about the explanatory domains, intervention functions and the format of the intervention.

A second (half-day) workshop was held following interviews with male clinic attenders to guide final decisions regarding the intervention design and content. This workshop included five experts in the fields of sexual health, sex education and web development. Participants were presented with the findings from the development process and asked to prioritise aspects of intervention content. This informed decisions regarding resource allocation during the creative process of designing intervention features. For example, while interactive features were considered the ideal, budget constraints meant that we could not develop interactive features to target every influence on behaviour. Therefore, some 'lower priority' influences on behaviour (or those for which interactive features were deemed inappropriate, e.g. sexual pleasure) were targeted with written information.

TABLE 2 Barriers to and facilitators of condom use

Theme	Subtheme
Barriers to condom use	Pleasure
	Interruption of sexual activity
	Intimacy
	Making judgements about risk
	Saying one thing and doing another – the intention–behaviour gap
	Partner perceptions/influence
	Difficulty using condoms
	Alcohol
	Lack of perceived risk
	Condom problems (e.g. breaking, discomfort)
	Lack of awareness about risk of oral sex
Facilitators of condom use	Condoms as prevention against pregnancy
	Reflection on past behaviour as a motivator
	Awareness/close personal experience of pregnancy or STI
	Seeing condom use as an ‘essential behaviour’
	Avoidance of STI
	Dislike of visiting clinic
	Having condoms available
	Communication about condoms with partner
Theoretical/psychosocial predictors	Norms
	Attitudes
	Self-efficacy
	Perceived susceptibility/risk
	Perceived benefits and barriers
	Outcome expectancies

Interviews with the target population

Semistructured qualitative interviews were conducted with 20 men who visited sexual health clinics to gain information from the target population regarding barriers to, and facilitators of, condom use, as well as potential intervention design, content and mode of delivery.

Participants were recruited from two sexual health clinics in central London. Men attending sexual health drop-in clinics between February and April 2013, who were aged > 18 years and who had not been diagnosed with human immunodeficiency virus (HIV) or hepatitis were eligible to participate. They were given a leaflet about the study and asked to approach the researcher if they wished to take part. Participants were aged between 20 and 52 years (mean = 31 years); seven identified themselves as white British, nine as black (black African or British), two as European, one as Chinese and one as mixed ethnicity; 17 interviewees were currently sexually active with female partners and three with male partners (the decision to focus solely on MSW was made partway through the fieldwork process, hence why a small number of MSM were included in the sample).

Participants were asked about their experiences and views on using condoms and their interest in a potential sexual health website. Interviews lasted between 30 and 60 minutes and were audio-recorded. The recordings were listened to, and initial themes summarised and then analysed using qualitative thematic content analysis³⁵ and the categories provided by the BCW.^{22,23}

User testing

Focus groups ($n = 3$) were held with male sexual health clinic users ($N = 16$) to refine the Men's Safer Sex website content and design. After each focus group, themes were summarised and content and design changes were made in response to the feedback. Once an initial version of the website was ready, interviews were conducted with male sexual health clinic users ($n = 7$) to ensure acceptability, relevance and understanding, and to identify any software errors or usability issues. These findings fed into the final version of the intervention.

Intervention development: processes and outcomes

The following section outlines the methods (processes) and results (outcomes, i.e. implications for the intervention) for each step of the intervention development process.

Step 1: specifying the target behaviour and population

Process

The target behaviour and population were discussed at the initial expert workshop. Final decisions regarding this were made by the study team.

Outcome

Condom use was predefined as the specified target behaviour. MSM were identified in the expert workshop as a high-risk group for acquiring STIs; however, the research team identified a number of existing interventions for MSM but a lack of interventions for MSW;^{6,7} therefore, it was decided that the intervention would target MSW. Men in sexual health clinic settings may be at higher risk of repeat STIs,³⁶ as having had one STI is a risk factor for acquiring another, and so it was decided that the intervention would be targeted at men in clinic settings. We worded the website advice in a gender-neutral way, whenever possible, to make it relevant for men with any sex of partner(s) (e.g. how to tackle problems with condoms). However, the Men's Safer Sex website particularly targeted MSW, as they are underserved with web resources, and photographic images represented women as sexual partners and not men.

The target behaviour and population also influenced the choice of intervention format (i.e. an interactive website or a smartphone application). Technology-use data suggested that there was a high level of smartphone use in the target population; however, it was difficult to select a platform [e.g. Android™ (Google Inc., Mountain View, CA, USA), iOS (Apple Inc. Cupertino, CA, USA)] that was used by the majority of the population and the budget precluded developing the application for more than one platform. Issues of privacy or lack of motivation were also a concern for potentially preventing users from downloading an application about condoms onto their smartphone. As a result, it was decided that the intervention would take the form of an interactive website, rather than a smartphone application.

Step 2: identifying theoretical domains that explain the behaviour

Process

In order to determine which domains should be targeted within the intervention, data from the interviews, workshops and literature review were organised into the categories of the COM-B and TDF (see *Table 1*), coding the data using the TDF as a coding frame, initially for each data source, then findings were synthesised. Domains were prioritised in order of importance to guide decisions regarding what to target with the website, considering available resources. Domains were considered important if they were strongly supported by all three data sources. When evidence from the data sources was conflicting,

the research team discussed each case and made a decision regarding whether or not it should be targeted and how much of a priority it should be, drawing on their knowledge and experience of the field.

Outcome

Out of the 14 domains in the TDF, 12 were deemed to be important and were therefore targeted by the intervention: skills; knowledge; cognitive and interpersonal skills; social/professional role and identity; beliefs about capabilities; beliefs about consequences; goals; intentions; memory, attention and decision processes; emotion; environmental context and resources; and social influences (*Table 3*).

The most prominent domains were beliefs about consequences (impact on pleasure), knowledge (about risk of STIs and about condom sizes and types) and memory, attention and decision processes/emotion (difficulty using condoms in the 'heat of the moment'). Therefore, psychological capability and reflective and automatic motivation were found to be important targets for change for this population.

Some domains contained one or more subthemes. 'Beliefs about consequences' incorporated both beliefs about the impact of condoms on sexual pleasure and the belief that STIs were not serious and did not have negative long-term consequences for men. A prominent aspect of knowledge was knowledge about the risk of acquiring STIs; men often felt that they could judge the risk of a situation (e.g. by a partner's appearance or whether or not the partner was in a relationship). In addition, a lack of knowledge regarding condom sizes and types and how they might impact on sexual pleasure was identified. Some barriers to condom use fell into more than one domain, for example being caught in the 'heat of the moment' was considered to come under 'emotion' as it relates to lust; however, this emotion also interfered with memory, attention and decision processes.

For some domains, the sources of evidence were inconsistent. For example, both experts and interview participants considered that men possessed the skills in applying condoms; however, evidence from the literature suggests that rates of errors in condom use are high (e.g. putting it on the wrong way then turning it over, failing to squeeze air from the tip).³⁷ Therefore, the research team decided that it was important to target this domain.

Step 3: identifying how explanatory domains should be targeted

Process

Once appropriate domains had been selected, intervention functions were then identified by reviewing the possibilities for each domain as defined in the BCW guide²² and considering which functions were likely to be most effective given the fieldwork findings. Consideration was given to the preferences outlined by participants in the interviews as well as what would be feasible and affordable to include (in terms of software development).

TABLE 3 Behaviour change mechanisms targeting barriers to condom use

Domain	Findings	Intervention functions	BCTs
Skills	High rate of errors in condom use ³⁷	Training	Instruction on how to perform the behaviour; demonstration of the behaviour
Knowledge	Men lacked knowledge about condom sizes and types and how they may improve pleasure and comfort (interviews)	Enablement	Problem-solving
	Men had incorrect knowledge about risk of acquiring STIs (interviews); knowledge about risk is related to condom use ³⁸	Education	Information about health consequences; vicarious consequences

TABLE 3 Behaviour change mechanisms targeting barriers to condom use (*continued*)

Domain	Findings	Intervention functions	BCTs
Cognitive and interpersonal skills	Communication related to use of condoms; ³⁸ difficulty knowing when to suggest condom use (interviews); fear that partner may be offended; ³⁹ difficulty negotiating if partner is reluctant (interviews)	Education, training, persuasion, enablement	Instruction on how to perform the behaviour; information about social and environmental consequences; information about others' approval; information about health consequences; verbal persuasion about capability
Memory, attention and decision processes	Being caught in the 'heat of the moment' leads to non-condom use (owing to high level of arousal and lust and competing desire for increased pleasure) (interviews) ⁴⁰	Enablement, education, training, environmental restructuring	Problem-solving; verbal persuasion about capability; information about health consequences; instruction on how to perform a behaviour; information about antecedents; restructuring the physical environment; anticipated regret; mental rehearsal of successful performance
Emotion			
Social/professional role and identity	Self-concept and values are related to condom use ^{39,41} (e.g. fostering/reinforcing being 'responsible person', who cares about others' health, may be a facilitator of condom use)	Persuasion	Information about others' approval
Beliefs about capabilities	Literature suggested this may be an important predictor of behaviour ^{38,42}	Enablement	Verbal persuasion about capability; mental rehearsal of successful performance
Beliefs about consequences	Perceptions that condoms negatively impact on pleasure and intimacy related to non-use (interviews) ^{3,43-48}	Persuasion, enablement, education, incentivisation, training, environmental restructuring	Non-specific incentive; restructuring the physical environment; instructions on how to perform the behaviour; behaviour substitution; information about health consequences; focus on past success, distraction; behavioural practice/rehearsal; anticipated regret; information about social and environmental consequences; social incentive
	Belief that STIs do not have negative consequences for men (interviews)	Education	Information about health consequences
Intentions	Literature suggested this may be an important predictor of behaviour ^{38,49}	The aim of the intervention as a whole was to increase intention. Specific intervention functions and BCTs not identified	
Goals	Goal-setting may be an important tool to implement advice in the intervention ^{50,51}	Enablement	Goal-setting; action-planning; review behaviour goals
Environmental context and resources	Intoxication owing to alcohol or recreational drugs often prevents condom use (interviews) ⁵²	Enablement, education, incentivisation	Problem-solving; verbal persuasion about capability; information about social and environmental consequences; information about antecedents; anticipated regret; non-specific incentive
Social influence	Men generally had a desire for a good reputation for sexual performance and their partner's opinions held a lot of importance (interviews) ³⁹	Persuasion, education, incentivisation	Information about others' approval; social incentive

Outcome

A full outline of the intervention functions selected for each domain can be found in *Table 3*. For the majority of domains, the intervention functions were very straightforward to select. For example, 'skills' lends itself to 'training' and 'knowledge' lends itself to 'education'. Persuasion and enablement were used in a number of sections of the website to target motivation. Coercion and restriction were deemed to be inappropriate, unfeasible and potentially unacceptable to participants.

Step 4: selecting standardised behaviour change techniques

Process

A number of potential BCTs appropriate for each intervention domain and function were identified using the BCW guide.^{22,31} These were reviewed for appropriateness to the population and intervention format, and a list of proposed BCTs for each domain was created. The selected BCTs were translated into the website intervention features and activities in a creative process involving the research team and the software development company, which also ensured that the ideas were feasible and affordable. Website content was then reviewed in comparison with the BCT taxonomy³¹ to confirm that activities and wording met the standardised criteria for each proposed BCT.

Outcome

Once BCTs were selected, they needed to be conceptualised into intervention features. The intervention website was designed to be 'interactive', whereby users can input information and get personalised feedback within the website. Resources were focused on domains which (1) were deemed most important and (2) afforded themselves to interactive features. For example, an interactive feature which addressed barriers to condom use ('problem-solving') solicited men's own problems with condoms and then provided tailored information regarding condom types to address those problems. Giving 'information about health consequences' was made more engaging by asking users to guess the answers to questions about STI risk.

Intervention content

Here we describe the content and functionality of the intervention website by providing each intervention section/topic, the rationale for it, the relevant BCTs and the subsequent content included in the intervention.

Barriers to condom use

Rationale

Interventions that are tailored to users are more likely to be effective.⁵³ The interviews and literature review identified a multitude of potential barriers to condom use.³

Behaviour change techniques

- Problem-solving.

Content

On first using the website, users were asked to select the reasons why they personally did not use condoms from 12 possible options, which were identified through our fieldwork (condoms too tight or uncomfortable, reduced pleasure, not knowing when or how to suggest it, being drunk or having taken drugs, losing erection, being in a relationship, difficulty stopping in the heat of the moment, partner not wanting to use condoms, partner might be offended, sex does not feel as good, STIs are easily treated and they often break or slip off). The homepage (*Figure 2*) was then tailored to each individual user by ensuring that the content that addressed the barriers selected was displayed prominently in the centre of the page.

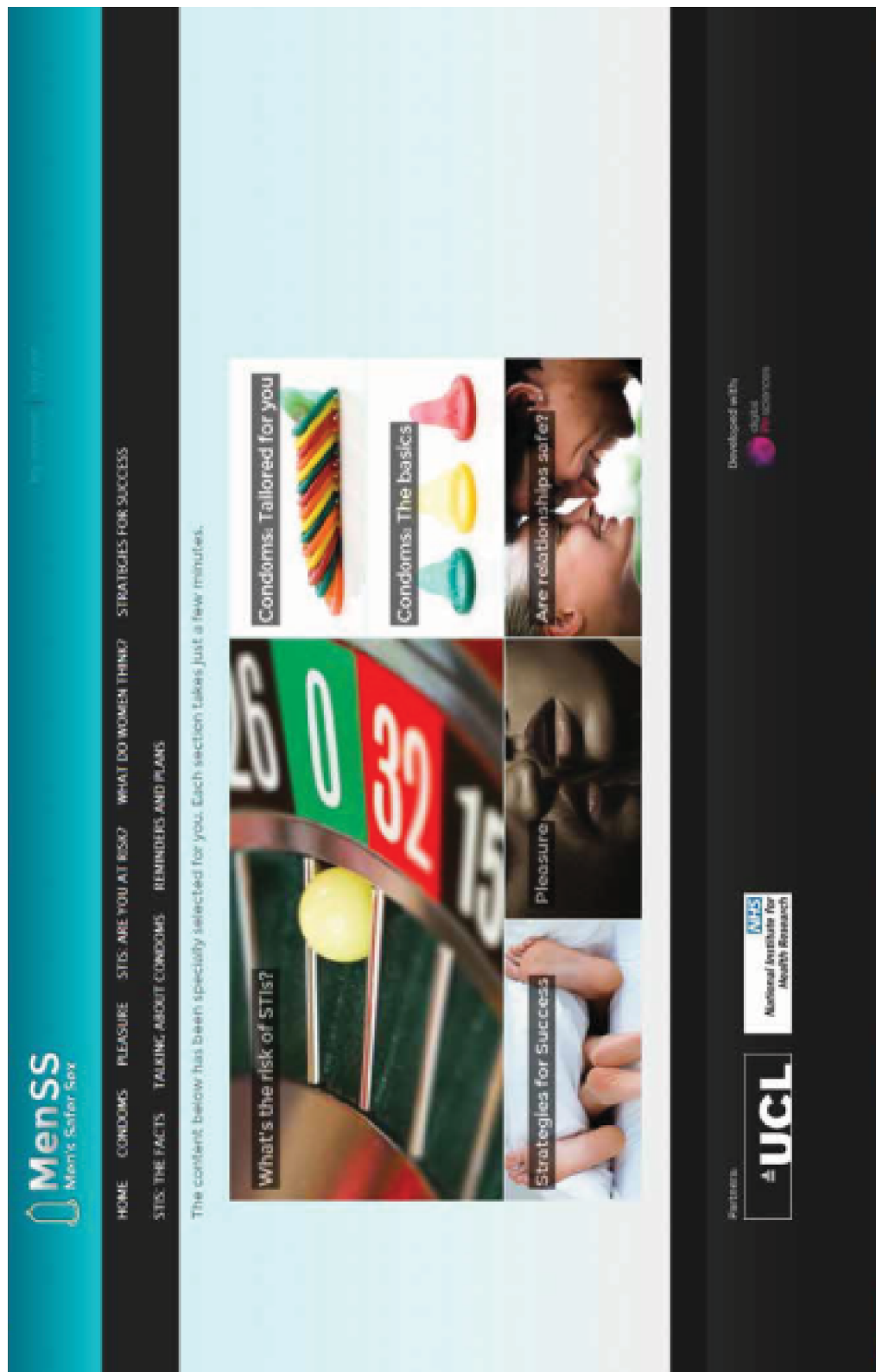


FIGURE 2 The Men's Safer Sex homepage with carousel of personalised tailored content.

Condoms: the basics

Rationale

Although data from the workshops and interviews suggested that men feel competent in applying condoms, the literature review identified high rates of errors and problems with condom use.^{37,54}

Behaviour change techniques

- Instructions for how to perform the behaviour.
- Demonstration of the behaviour.

Content

This section included a short video demonstration and a click-through slideshow, which provided advice about using condoms correctly, highlighting the key steps in condom use and the areas in which people often make mistakes (*Figure 3*).

Condoms: tailored for you

Rationale

Evidence from our qualitative work and the literature suggested that condom size and type had a strong impact on acceptability of condoms, with poorly fitting or thicker condoms being viewed more negatively. Incorrect condom size was also related to problems such as breakage.⁵⁵

Behaviour change techniques

- Problem-solving.

Content

The intervention website aimed to educate men about different sizes and types of condom, using a tailored feedback activity. In this activity, users were asked to identify problems they had with condoms and then offered tailored advice about and recommendations for condom types to help address those problems (*Figure 4*). For example, men suggesting that condoms were uncomfortable, small or problematic for breaking were offered advice about larger types of condoms. This activity was similar to the 'barriers to condom use' activity but focused on problems with the actual condom (rather than problems surrounding condom use in general), and gives specific condom-related feedback and recommendations.

Pleasure

Rationale

All data sources indicated that the belief that condoms reduce the pleasure of sex is a very important and common barrier to condom use.

Behaviour change techniques

- Non-specific incentive.
- Restructuring the physical environment.
- Instructions on how to perform the behaviour.
- Behaviour substitution.
- Information about health consequences.
- Focus on past success, distraction.
- Behavioural practice/rehearsal.
- Anticipated regret.
- Information about social and environmental consequences.
- Social incentive.

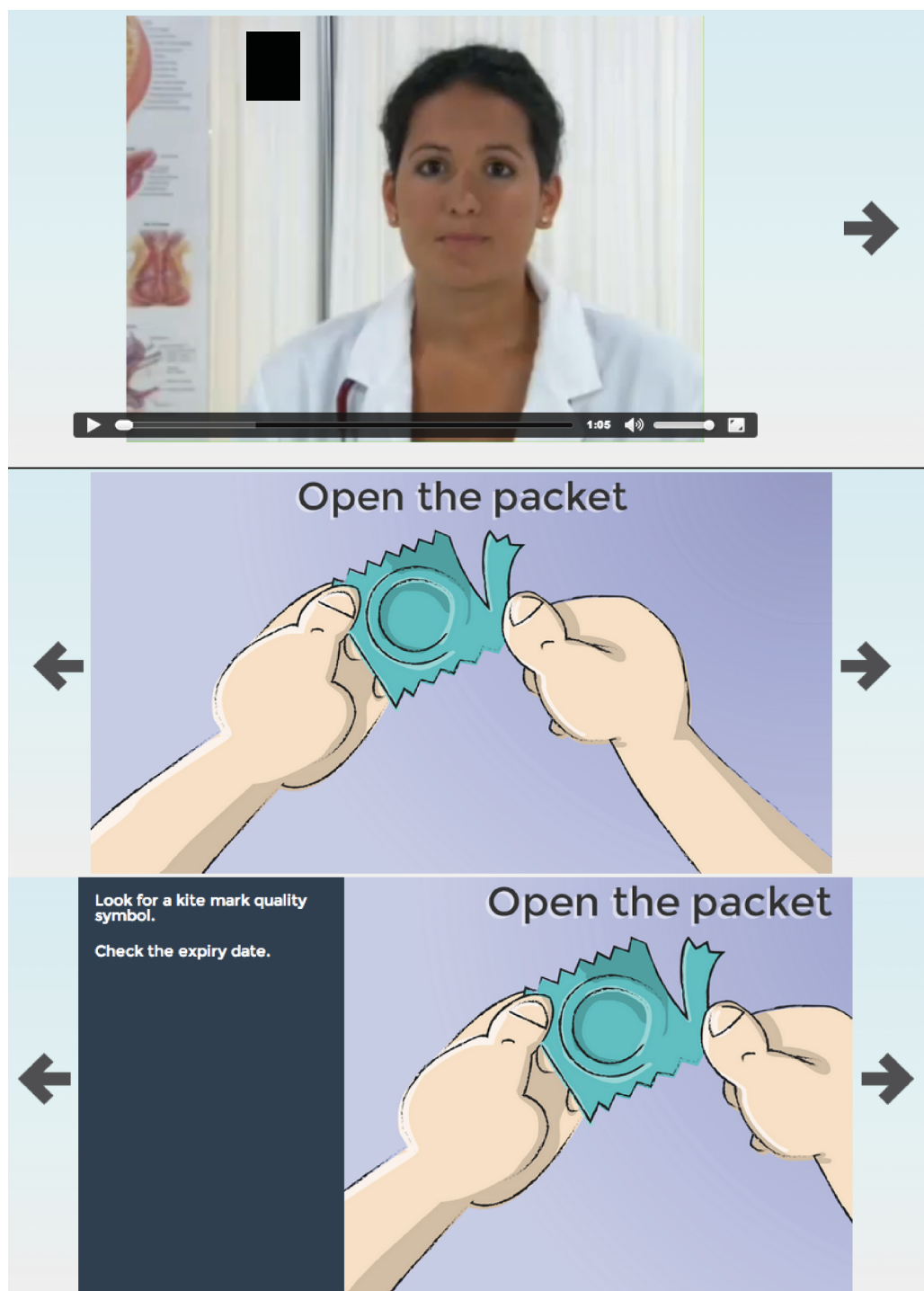


FIGURE 3 Condoms: the basics – skills in correct condom application.

Content

This section incorporated written advice and videos. It gave advice about how to improve pleasure with condoms, how sex with condoms might be preferable to sex without condoms [e.g. by reducing worry (non-specific incentive)], how there are types of condom that may be more pleasurable and how to enjoy non-penetrative sex (behavioural substitution). BCTs were conceptualised within written text; for example, the 'anticipated regret' technique encouraged users to focus on avoiding the worry and hassle that may follow an episode of condomless sex and the 'focus on past success' technique was incorporated by encouraging men who had previously had problems with loss of erection to focus on occasions when they had not lost their erection.

There are lots of reasons that people don't like condoms, but not all condoms are the same. Do you experience any of these problems? Select all that apply to you to find out which condoms can reduce these problems.

Condoms reduce pleasure	Condoms slip off	Condoms too big
Condoms break	Condoms too small	Condoms smell horrible
Lose erection	Not fun	Come too quickly
Allergy to condoms	Condoms are uncomfortable for partner	Difficult to put on

Get Your Recommendations

YOU CHOSE:

Condoms reduce pleasure, Condoms break, Difficult to put on

SIZE

It is important to use the right size of condoms - this will increase pleasure. Condoms that are too big can slip off, and condoms that are too small can break.

Theyfit condoms offer 95 different sizes. You can get a device to measure your penis and order condoms online at www.theyfit.com

You can also buy some different sized condoms in the shops:


Smaller:

Durex Close Feel, Mates Conform, Pasante Trim

Larger:

Mates Large, Mates Skyn Large, Pasante Large, Pasante King Size, Durex Comfort XL.

Condoms recommended for you



Next

FIGURE 4 Tailored feedback on selected barriers to condom use.

Sexually transmitted infections: are you at risk?

Rationale

All the data sources suggested that men were aware of the benefits of using condoms and of some of the risks of condomless sex;³⁸ however, our interviews highlighted a number of widespread incorrect beliefs about the risk of STIs (e.g. partners who are known to them or 'seem clean' are viewed as less risky).

Behaviour change techniques

- Information about health consequences.
- Vicarious consequences.

Content

The intervention included two interactive activities addressing STI risk, emphasising that the likelihood of acquiring STIs cannot be accurately judged (*Figure 5*). First, in 'What's the risk of STIs?' a quiz presented

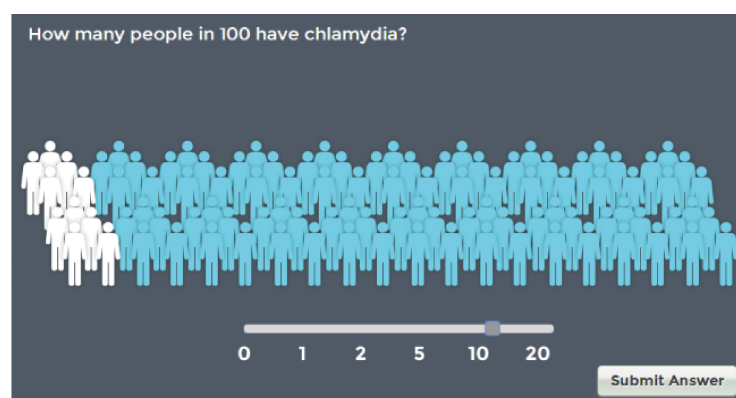


FIGURE 5 Sexually transmitted infections: are you at risk? Infographics illustrating potential risks of STIs.

facts and figures regarding STIs and their transmission (e.g. the number of people with undiagnosed HIV). This conceptualised the BCT of 'information about health consequences' in an interactive and visually appealing manner. Second, in 'Are relationships safe?' two animated diagrams demonstrated the way that STIs may spread within a network, common methods of transmission that people may not be aware of (e.g. oral sex) and how relationships may not be 'safe'. This activity encompassed the BCT of 'information about health consequences', and also used 'vicarious consequences', by demonstrating the impact of risky sexual behaviours on others.

What women think

Rationale

Both the literature³⁹ and our interviews with men identified fear of partners reacting negatively to suggestions of condom use as an important barrier to condom use. The literature also suggests that self-concept and personal values are related to carrying and using condoms;^{39,41} if a healthy behaviour is consistent with one's identity, one may be more likely to perform the behaviour.⁵⁶ Our workshops and interviews identified fostering a sense of responsibility towards others as a potentially important factor in condom use.

Behaviour change techniques

- Information about others' approval.
- Social incentive.

Content

This section included articles and videos portraying women as approving of men taking the responsibility for condom use and women not being offended by the suggestion of condoms. It also provided advice on responding to women who appeared to be offended. BCTs were conceptualised in written text and in videos, for example 'social incentive' was offered by suggesting that women would view men positively if they suggested condom use.

Slip-ups

Rationale

Pleasure or lust (being caught 'in the heat of the moment') was a widely quoted reason for non-use of condoms within the literature and our interviews with men.^{3,57} All data sources identified alcohol as a strong barrier to condom use. The importance of carrying/the availability of condoms has been related to condom use in the literature and lack of availability was identified as a barrier by experts in the workshops.

Behaviour change techniques

- Problem-solving.
- Verbal persuasion about capability.
- Information about health consequences.
- Instruction on how to perform a behaviour.
- Information about antecedents.
- Restructuring the physical environment.
- Anticipated regret.
- Mental rehearsal of successful performance.
- Information about social and environmental consequences.
- Non-specific incentive.

Content

This section included articles and videos giving specific advice about how to overcome barriers due to the 'heat of the moment' and intoxication by discussing condoms with a partner in advance (instruction on how to perform the behaviour), considering potential regret (anticipated regret) and avoiding sex when under the influence of alcohol (information about antecedents). It also provided advice regarding making condoms available (e.g. carrying them, having them near the bed) (restructuring the physical environment). Again, BCTs were conceptualised in written text (e.g. the 'verbal persuasion about capability' technique included messages that men would be able to use condoms, despite high levels of arousal or intoxication). The 'non-specific incentive' technique was incorporated by telling users that if they wait to have sex when they are not intoxicated, they may perform better, please their partner more and get a better reputation for being a good lover.

Sexually transmitted infections: the facts

Rationale

In the qualitative interviews, men showed a lack of concern for catching STIs, as they did not feel that STIs had substantial negative consequences for men.

Behaviour change techniques

- Information about health consequences.

Content

Users were presented with common misconceptions or questions about STIs and their transmission (e.g. 'STIs are easily treated, aren't they?'), which could be clicked to reveal the answer and some brief information.

Communication

Rationale

Although the literature³⁸ and the experts in our workshop suggested that difficulties in negotiating condom use was a more salient barrier for women, evidence from the interviews with men suggested that, for some, this was an issue, and for most men the opinions of their partner were important when deciding whether or not to use a condom.

Behaviour change techniques

- Instruction on how to perform the behaviour.
- Information about social and environmental consequences.
- Information about others' approval.
- Information about health consequences.
- Verbal persuasion about capability.

Content

This section offered information about specific strategies for suggesting, discussing and negotiating condom use. BCTs were conceptualised in written information, for example 'information about social and environmental consequences' included giving advice that talking about condoms before sex would mean both partners can relax and enjoy it, rather than worrying about STIs or pregnancy, and 'information about others' approval' included reassurance that most women would not be offended by the suggestion of condom use.

Reminders and plans

Rationale

Based on evidence from the literature^{50,51} and our workshops, goal-setting was identified as an important method of encouraging behaviour change.

Behaviour change techniques

- Goal-setting.
- Action-planning.
- Review behaviour goals.

Content

In each section of the website, users were offered goals to set which related to the website content (*Figure 6*). When selected, these goals populated users' own personalised 'Reminders and plans' page. Users could opt to receive a reminder by e-mail at a specific time, set time-limited goals (e.g. 'I will purchase my recommended condoms' by a selected date) or choose event-specific goals by forming an implementation intention⁵⁸ ('if-then plan'), identifying a potential situation for which condom use may be unlikely and then selecting a response to that situation.

Goals / Reminders

Setting reminders can help you to succeed in making changes. Select a change/goal that suits you. You can choose to be reminded by email.

I will get the right size condom ▾

1 week ▾

You can review and edit all your goals on the [Reminders page](#) ☐ Email opt out

Save

Plans

Making plans can help you to succeed in making changes. Here you make a plan for situations where you might be in danger of not using condoms.

Select one situation, then choose a plan for that situation from the dropdown 'THEN' menu.

☐ IF I am going out drinking/partying
 THEN

I will make sure I am carrying condoms ▾

☐ If I am drunk or high
 THEN

I will not have sex ▾

Now click 'Create Plan'. Your plan will appear in a box below. You can change it if you wish.

Create Plan

Now select a time when you would like to be reminded about this plan by email.

No reminder ▾

Now click 'Save Your Plan'. You can then create more plans if you wish.

Save Your Plan

You can review and edit all your plans on the [Reminders page](#)

FIGURE 6 'Reminders and plans' feature.

Strategies for engagement

Rationale

Increased engagement with an IDIs can lead to increased effectiveness.⁵⁹ Encouraging users to engage in IDIs, particularly over a long period of time, is notoriously difficult.⁶⁰ E-mail prompts can be used to increase engagement with the intervention.⁶¹

Behaviour change techniques

- Prompts and cues.
- Information about health consequences.
- Review behaviour goals.

Content

Users were sent monthly e-mails prompting them to visit the intervention website. These contained 'teasers' regarding website information and links to the website (e.g. 'Do you know how many people have chlamydia? Find out here'). In addition, if users set goals or implementation intentions within the website, they could select the option of being reminded via e-mail. These e-mails asked users if they had achieved their goal and prompted them to return to the website to review their goals.

Discussion

Triangulation between a targeted literature review, expert workshops and interviews with the target population, all led by a multidisciplinary team, ensured that a range of potential influences on condom use were captured and that feedback to men on barriers to condom use were relevant to them. The resulting intervention is extensive, tailored to individual needs and targets a wide set of influences on sexual health. This is in line with recommendations that sexual health interventions should use a holistic approach to sexual health and well-being.¹²

As with many complex interventions, the Men's Safer Sex website contains multiple components, targeting a number of influences on behaviour. Therefore, it can be difficult to determine which part(s) of the intervention are effective and via which mechanisms. Online interventions offer the possibility of easily monitoring patterns of intervention use, which can facilitate the analysis the mechanisms of action of an intervention. Furthermore, clearly describing the intervention aims and content assists in this analysis. BCTs provide a standardised method for this process of describing intervention content.

The utility of the Behaviour Change Wheel

The BCW provided a useful and manageable framework for integrating information from multiple sources to design an intervention, especially for organising the information conceptually, for guiding the process of identifying influences on behaviour, and for selecting and delineating standardised methods for targeting those influences.

The advantage of using an integrative theoretical framework, such as the TDF, over a single theory of health behaviour is that they encompass multiple explanatory domains and, therefore, provide a more comprehensive assessment of factors which are important to the target population.²³ This is illustrated in a recent review of theories of behaviour change which found that only 3 out of 83 theories were integrative and set out to be comprehensive.^{62,63} Models such as the Theory of Planned Behaviour⁶⁴ present a cognitive model of behaviour (attitudes, perceived norms and perceived behavioural control predict intentions which, in turn, predict behaviour), downplaying impulsive factors in decision-making, which may influence motivation (an important influence on behaviour). Beyond identifying potential influences on behaviour, the BCW also provides structured guidance for determining the content and format of interventions.

Although the TDF is helpful in that it offers an extensive list of potential influences on behaviour, some domains were difficult to conceptualise within this context. 'Goals' was included as an important domain, but largely as a method of encouraging people to implement the advice given in the website and to target other domains (such as memory, attention and decision processes). Although the aim of the intervention was to improve intention, this was approached by targeting other domains. The TDF is a framework, rather than a theoretical model, and so does not specify causal pathways between variables. The intervention developer must draw on other evidence and theories to decide and elaborate on potential relationships between variables.

The use of standardised BCTs to specify the intervention content provided two advantages. First, the BCTs provided ideas for website features and health promotion messages (so the authors did not start with a 'blank canvas'). Second, the BCTs were used to specify the content in standardised terms to facilitate replication, judgements regarding quality and comparisons with other interventions.³⁰ Translating BCTs into interactive website features can be a difficult process and requires a certain level of creativity. Given that the content of complex interventions is often not described in detail,²⁰ building a repository of examples of such features would be a valuable resource for intervention designers.

The study had some limitations. For example, although we collected detailed data to specify intervention content, the literature review was targeted, rather than fully systematic, owing to time and resource constraints. This means some relevant evidence may have been missed; however, the inclusion of a number of reviews in the literature review mitigates this concern. A second limitation is that all men interviewed during the development process were sampled from sexual health clinics within inner London, thus potentially limiting the transferability to other populations and settings. However, the findings from our literature review confirmed the importance of the emergent themes from the interviews.

This chapter has provided a detailed description of an evidence-based IDI for sexual health, including how BCTs were translated into practice within the design of the Men's Safer Sex website. It is hoped that this will assist intervention developers in their development work and reporting in terms of BCTs.

Chapter 3 Feasibility randomised controlled trial of the Men's Safer Sex website

Introduction

Interactive digital interventions are effective for improving knowledge^{12,16} and can improve sexual behaviour (including condom use),^{12,16} but more evidence is needed to establish effects on biological outcomes, such as STIs, and cost-effectiveness. We planned to conduct an online randomised controlled trial (RCT) in sexual health clinic settings, offering the Men's Safer Sex website on an iPad® (Apple Inc., Cupertino, CA, USA) to men in clinic waiting rooms. However, it can be difficult to recruit people to trials in clinical settings and to retain participants in online trials.¹⁴ This feasibility trial was designed to evaluate retention rates and methods of outcome measurement for costs and sexual health outcomes (self-reported online and using clinic records).

Aims

To establish the feasibility and optimal design of a full-scale RCT to test the effect of the Men's Safer Sex intervention website on condom use and STI acquisition in men attending sexual health clinics.

Methods

Design

This study is a feasibility RCT with random allocation to the Men's Safer Sex website plus usual sexual health clinical care compared with usual sexual health clinical care only.

Participants and setting

Participants were recruited from three English sexual health clinics, two in central London and one in the Midlands. These clinics were selected as they serve a diverse range of patients in terms of age, socioeconomic status and ethnicity.

Inclusion criteria

- Men aged ≥ 16 years (with no upper age limit).
- Able to read English.
- Have access to the internet.
- At a high risk of future STI [i.e. two or more partners in the past year (male or female) *and* non-condom use in the past 3 months, *or* symptoms of suspected acute STI, *or* seeking treatment for a STI].
- For whom at least half of their sexual partners are female.

Exclusion criteria

Men who were HIV positive and men with hepatitis B or C were excluded, as patients with these diagnoses are likely to receive more intensive input in the course of routine clinical care. Men who had ever had sexual experiences only with other men, men who had sexual experiences more often with males but at least once with a female, or men with no sexual experience at all⁶⁵ were also excluded.

Procedure

Research procedures were conducted online: a tablet computer (iPad) was positioned in the sexual health clinic waiting rooms or a side room. Leaflets and posters advertised the study and invited potential participants to approach the iPad (see *Appendix 7*); research and clinic staff also directed patients towards the iPad. Enrolment was self-directed, with staff available to help with technical problems. Trial software on the iPad guided participants through eligibility questions, informed consent and baseline demographic and outcome questions (see *Appendices 8–10*). Most online questions were compulsory and free-text comment boxes were offered at the end of groups of questions. All participant data were stored online using secure external servers. Following completion of baseline questionnaires, an automated computer algorithm allocated participants randomly either to the control group (at which point they were thanked for their time and asked to log out) or the intervention group (at which point they were directed to the intervention website). Those allocated to the intervention group were asked to engage with the Men's Safer Sex website for as long as they wished (usually until the point at which they were called in to see health professionals). They also had access to the website by logging in after leaving the clinic.

Intervention

Participants in the intervention group were invited to interact with the Men's Safer Sex intervention website while in the clinic waiting room. The time available for this varied by participant but we expected that participants would have an average of 10 minutes to interact with the intervention. Participants in the intervention group were also able to access the intervention website after leaving the clinic, for the duration of the follow-up period (12 months), using a username and login that they had chosen. Monthly e-mails were sent to participants in the intervention group, reminding them to visit the website, giving 'teaser' web links to intervention content. In addition, participants received e-mails reminding them about goals they had set on the website (see *Chapter 2*).

At 3, 6, 9 and 12 months after their initial clinic visit, participants were invited via e-mail to complete an online follow-up questionnaire. If they did not initially complete the questionnaire, they received three further e-mail prompts, at 1-week intervals, as well as two short message service (SMS) messages to their mobile phone (again, including the web link) at 1-week intervals alongside the previous two e-mails. If participants still did not respond, the researcher telephoned them 1 week after the final e-mail and SMS, reminding them about the questionnaire. Participants were given a 7-week window to complete their questionnaire. This window was extended at 3 months (until the 6-month questionnaire was due) in order to maximise responses, as technical issues had caused participants some difficulty in logging in. Information about STI diagnoses were collected at all time points via self-report and at 12 months by recording diagnoses or suspected diagnoses over the past 18 months (to control for pre-baseline service usage) recorded in the clinical notes at the sexual health clinics that participants were recruited from.

Outcomes

We adapted the Sexunzipped online sexual health questionnaire⁶⁶ to measure outcomes and mediators of condom use. We selected items for inclusion based on a literature search for established measures and consultation with experts. Interviews were conducted with men in sexual health clinics ($n = 11$) to gain feedback on successive versions of the outcome questionnaire.

In the light of evidence that measurement alone may prompt behaviour change,^{67,68} a limited number of outcomes were measured at baseline (condom use and the main mediators, and self-reported STI diagnoses) and a full range of outcomes were assessed at 3, 6 and 12 months (*Table 4*). The primary feasibility outcome was retention in the study at 3 months, which was measured by response to the 3-month online questionnaire. The main behavioural outcome of interest was self-reported number of episodes of condomless sex at the 3-month follow-up. All self-assessments had a recall period of the previous 3 months. A full copy of the follow-up questionnaire (which assessed all outcomes) can be found in *Appendix 7*.

TABLE 4 Variables assessed at each time point

Baseline measures	3-, 6- and 12-month follow-up assessments
Demographic details (age, occupation, ethnicity)	
<i>Sexual health outcomes</i>	
Sexual partners	Sexual partners
Condom use: episodes and partners	Condom use: episodes and partners
Self-reported STI diagnoses	Self-reported STI diagnoses
Contraception use and pregnancy	Contraception use and pregnancy
HRQoL (EQ-5D-3L)	HRQoL (EQ-5D-3L)
	Service use
SQoL	SQoL
<i>Mediators of condom use</i>	
Motivation to use condoms	Motivation to use condoms
Intentions to use condoms	Intentions to use condoms
Beliefs about pleasure	Beliefs about pleasure
Non-condom use owing to intoxication	Non-condom use owing to intoxication
	Evaluation of condoms
	Communication
	Identity
	Self-efficacy
	Condom problems
	Knowledge
EQ-5D-3L, European Quality of Life-5 Dimensions, three-level version; HRQoL, health-related quality of life; SQoL, Sexual Quality of Life.	

Outcome measures

Demographics

Questions at baseline included demographic information including age, employment status and ethnicity.

Condom use

The objective of the study was to promote condom use with female partners and so the primary outcome was the number of episodes of condomless vaginal or anal sex over the previous 3 months, assessed at the 3-month follow-up. It was expected that the majority of change in behaviour would occur shortly after recruitment, as it was expected that users would be most likely to engage with the intervention during the clinic visit. The published protocol⁶⁹ stated that the primary outcome was episodes of condomless vaginal sex only; however, during revisions to the questionnaire (to reduce the length in response to user feedback) questions regarding episodes of vaginal and anal sex were combined into one question. This combined item was therefore used as the main outcome of interest. The number of partners that participants had condomless sex with over the previous 3 months was also assessed – female (vaginal and anal sex) and male (anal sex).

Sexual partners

Participants were asked to report the number of sexual partners over the past 3 months (both female and male).

Contraception use and pregnancy

Participants were asked to indicate which types of contraception (if any) they were using with current partners. Participants were asked whether or not a female partner had been pregnant in the past 3 months and the outcome of that pregnancy.

Sexually transmitted infection diagnoses

Participants were asked to report acute STI diagnoses over the past 3 months at every follow-up point. Participants were also asked whether or not they had received treatment owing to a partner being diagnosed with a STI. In order to assess laboratory diagnoses, all STI diagnoses recorded in sexual health clinic records (in the participating sites) over the study period were noted at 12 months.

Health-related quality of Life

Health-related quality of life (HRQoL) was assessed using the European Quality of Life-5 Dimensions, three-level version (EQ-5D-3L)^{70,71} which is a 5-item, 3-level questionnaire covering self-care, usual activity, anxiety and depression, pain and mobility. A newly developed SQoL questionnaire⁷² was also used, in order to compare its performance with the EQ-5D-3L to assess its suitability for outcome assessment in a sexual health context.

Service use

Use of various sexual health services (e.g. sexual health clinics, general practice, outreach services) over the study period was assessed by self-report.

Engagement with the intervention (patterns of website use)

Website usage (times the website was visited, pages visited) was recorded in order to assess engagement with the intervention.

Adverse effects

Participants were asked to report whether or not they experienced any adverse effects as a result of the study, recording this in a free-text box on each of the follow-up questionnaires (at 3, 6, 9 and 12 months).

Mediators of condom use

Although it is important to assess changes in behaviour, it is also important to assess the mediators of behaviour change to provide information about the mechanisms by which behaviour might have changed. The mediators measured determinants of condom use that were specifically targeted within the intervention, identified using the theoretical frameworks of the COM-B model²³ and the Plans, Responses, Impulses, Motives and Evaluations (PRIME) theory of motivation.⁵⁶

Condom-use errors and problems

To assess any impact on condom-use skills, condom-use problems were assessed at all time points, using a measure defined by Crosby *et al.*,³⁷ which assesses the occurrence of 15 condom errors and problems within the past 3 months. The scale was adapted in the light of qualitative fieldwork to improve relevance and understanding.

Knowledge

Knowledge (of risk of STIs and condom sizes) was assessed using an 11-item measure, devised based on gaps in men's knowledge identified in the literature⁶⁹ and in interviews with the target population during the development of the intervention. A number of 'true or false' statements regarding misconceptions about condoms and risk were given (e.g. 'You would know if you had a STI, without needing a test').

Communication with partners

To assess communication with partners over a 3-month period, the 6-item Partner Communication Scale was used.⁷³ The scale was adapted in the light of qualitative fieldwork and the recall period was modified from 6 months to 3 months in line with all other assessments.

Identity

To assess potential links between identity (self-perception) and condom use,⁵⁶ a 7-item scale was created, derived from issues relating to condom-use identity that had arisen during the fieldwork.

Beliefs about pleasure

Beliefs about pleasure were assessed using an 8-item scale, adapted from the 'Effect of sexual experience' subscale of the Condom Perceived Barriers Scale.⁷⁴ The scale was adapted in the light of qualitative fieldwork to improve relevance and understanding.

Self-efficacy

Self-efficacy was assessed using a 14-item measure, adapted from the widely validated Brafford and Beck scale.⁷⁵ The scale was adapted in the light of qualitative fieldwork to improve relevance and understanding.

Motivation, intention and evaluation of condom use

Motivation (want) and intention to use condoms, and evaluation of condom use, were assessed using single-item measures (Robert West, University College London, 12 September 2013, personal communication).

Alcohol and drug use

A single item assessing the number of times in the past 3 months participants had condomless sex when intoxicated was included.

Data from medical records

Participants were asked to provide consent to access their medical records held at the sexual health clinic from which they were recruited from the study. A study researcher located files from patient records, collecting information for sexual health clinic attendances 6 months prior to participants' date of recruitment to the trial and for the duration of the trial. Data were recorded on a Microsoft Excel® 2010 (Microsoft Corporation, Redmond, WA, USA) spreadsheet with no participant identifiable information included; the unique participant identifier linked the clinic data to participant questionnaire data.

Sample size

This was a pilot RCT with a primary aim of assessing the success of recruitment and retention, engagement with the intervention and the acceptability of trial procedures to participants and clinic staff. The possible effect size of key outcomes, including condom use over the past 3 months, were assessed to inform power calculations for a future Phase III RCT.

Power calculations were performed based on data from the Sexunzipped online trial.⁶⁶ The study was powered to allow estimates of the effect of the intervention on episodes of condomless vaginal sex over the past 3 months. A sample size of 166 (intervention, $n = 83$; comparator, $n = 83$) randomised 1 : 1 between experimental and control conditions is adequate to detect a reduction of 1.35 episodes of condomless sex with a conventional two-sided α of 0.05 and 90% power ($1 - \beta$). Allowing for potential loss to follow-up at 3 months, 122 participants (intervention, $n = 61$; comparator, $n = 61$) is adequate to find a reduction of 1.35 episodes of condomless sex with a conventional two-sided α of 0.05 and 80% power ($1 - \beta$). In addition, this sample size is also sufficient to detect a 1.65 difference in safer sex intention and a 1-point difference in self-efficacy on Likert scales, with a conventional two-sided α of 0.05 and 90% power ($1 - \beta$). A total of 176 participants were randomised and, after later exclusions and withdrawals, 159 remained.

Randomisation

Once participants had been checked for eligibility, given informed consent and submitted baseline data, they were allocated 1 : 1 using a computer algorithm randomisation system to either the intervention or control group. The allocation was automated and instant and, therefore, was concealed until the point of allocation. Participants were informed with an automated message on the iPad and this allocation was unalterable.

Blinding

It was not possible to blind participants to their allocation, as those in the control condition did not receive access to any website. Research staff (including those conducting the analysis) were blind to allocation condition, as allocation was performed using the software on the iPad; however, the researcher performing recruitment may have been aware of allocation owing to the amount of time participants spent on the iPad. Allocation was revealed only once statistical analyses were complete.

Statistical methods

We present descriptive statistics by group at baseline and follow-up for main and secondary outcomes. The treatment effect at follow-up was estimated using generalised linear models with a \log_e link and Poisson error. The \log_e of the baseline values were included in each model as explanatory variables to account for baseline differences. Standard errors were estimated using variance components to account for overdispersion in the models. Incidence rate ratios (IRRs) comparing the control with intervention groups were estimated from these models along with their 95% confidence intervals (CIs) and *p*-values.

Results

Recruitment

Participants were recruited between 28 April 2014 and 7 July 2014. Follow-up data were collected between 28 July 2014 and 2 July 2015. Recruitment ceased once target numbers were reached. Participant flow is outlined in *Figure 7*. Owing to a technical error in the online recruitment software, reasons for exclusion were available only for 20 participants.

One hundred and seventy-six participants were randomised, of whom seven withdrew from the study, one was a duplicate account and nine were withdrawn owing to being later found to be ineligible (they had been erroneously classed as eligible because of a technical error in the eligibility screening questionnaire). Fifty-five responded to the baseline questionnaire and the 3-month follow-up questionnaire (the principal outcome point) (22 in the control group, 33 in the intervention group). Forty-six participants responded to the baseline questionnaire and to all three follow-up questionnaires (27 in the control group, 19 in the intervention group). Data on STIs from clinic records were available for 149 (93.7%) participants. We monitored free-text comments on the online outcome questionnaires and found no reason to terminate the trial early. We did not conduct interim data analyses as the primary aim was to assess retention at follow-up.

Participants

Characteristics of participants are shown in *Table 5*. The mean age of participants is in line with data that suggest people in the 25–34 years age bracket are more likely to attend STI testing⁷⁶ and employment status and ethnicity were comparable with the general population.^{77,78}

Website usage

Thirty-seven per cent of participants in the intervention group visited the Men's Safer Sex website once ($n = 31/84$), 26% more than once ($n = 22/84$) and 37% did not see the Men's Safer Sex website at all ($n = 31/84$). Twenty-two participants (26%) returned to the website after leaving the clinic, with most of these participants logging into the website twice in total ($n = 13/22$). The maximum number of return visits was eight. Participants visited a median number of 15 pages out of a maximum of 35 main topic or activity pages.

Descriptive statistics

Distributions of outcomes for condom use, self-reported STI and mediators of behaviour change are reported in *Tables 6* and *7*.

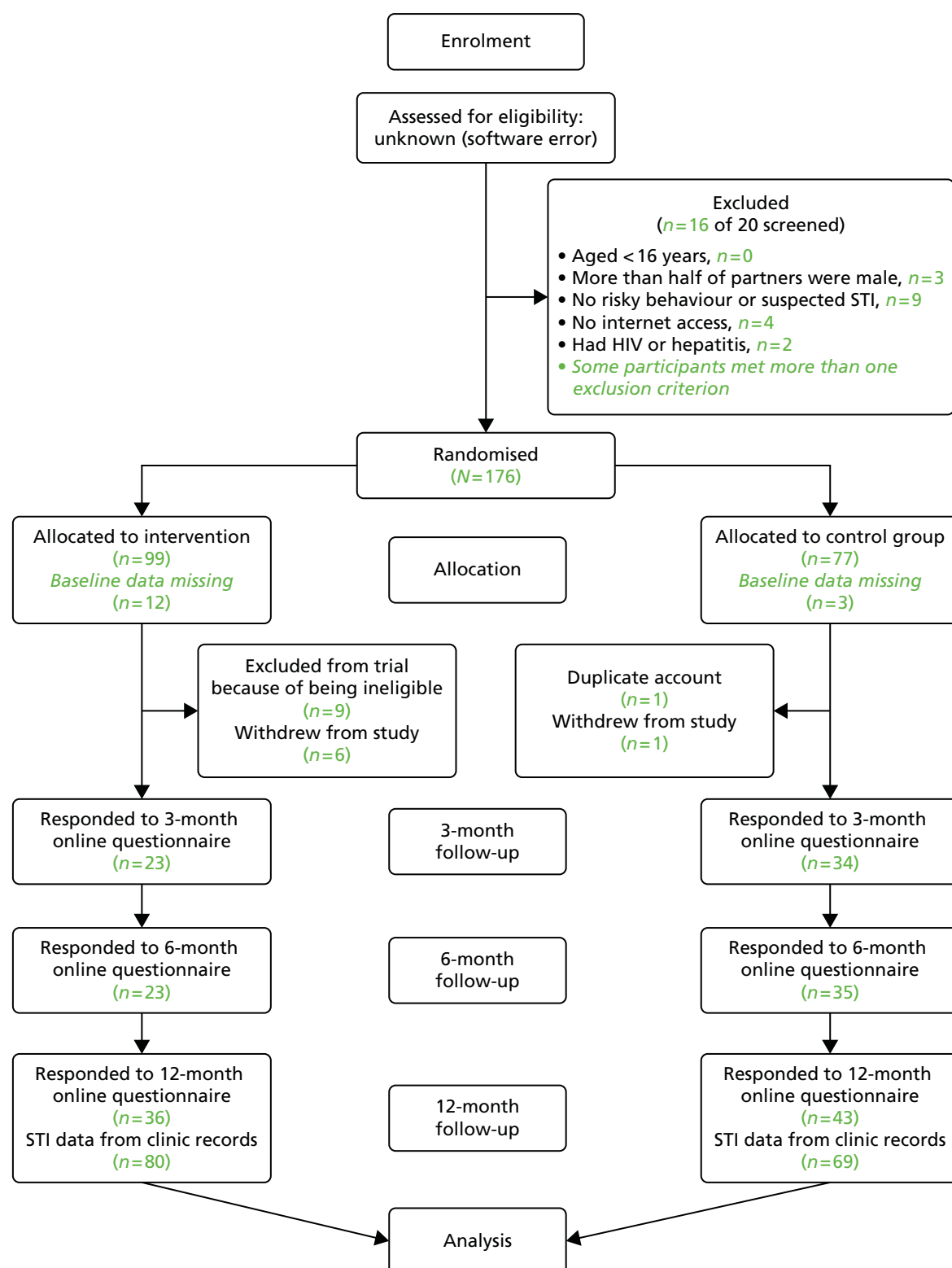


FIGURE 7 The Consolidated Standards of Reporting Trials diagram showing flow of participants.

TABLE 5 Baseline demographic characteristics of participants

Demographic characteristic	Intervention, <i>n</i> (%) (<i>N</i> = 84)	Control, <i>n</i> (%) (<i>N</i> = 75)
Age (years), mean (SD)	29.3 (8.8)	29.5 (8.4)
<i>Employment status</i>		
School/college/training	10 (11.9)	19 (25.3)
Working	61 (72.6)	49 (65.3)
Unemployed	11 (13.1)	5 (6.7)
Long-term sick or disabled	1 (1.2)	0 (0)
Other	1 (1.2)	2 (2.7)
<i>Ethnicity</i>		
White British/Irish/other	60 (71.4)	50 (66.7)
Black British/Caribbean/African/other	11 (13.1)	12 (16.0)
Asian British/Indian/Pakistani/Bengali	4 (4.8)	4 (5.3)
Chinese/other Asian	2 (2.4)	2 (2.7)
Mixed cultural background	4 (4.8)	4 (5.3)
Other	3 (3.6)	2 (2.7)
Prefer not to say	0 (0)	1 (1.3)
SD, standard deviation.		

TABLE 6 Condomless sex and STI diagnoses at baseline and follow-up

Sexual health outcome	Control (<i>n</i> = 75)					Intervention (<i>n</i> = 84)				
	Q1	Med	Q3	Maximum	<i>n</i>	Q1	Med	Q3	Maximum	<i>n</i>
<i>Episodes of condomless vaginal or anal sex with a woman in past 3 months</i>										
Baseline	2	6	20	50	72	1	4	20	155	72
3 months	3	12	30	100	34	2	10	40	100	23
<i>Number of female condomless sex partners in 3 months</i>										
Baseline	1	1	2	15	72	1	1	2	20	72
3 months	1	1	2	6	34	1	1	2	15	23
<i>Number of male condomless anal sex partners</i>										
Baseline	0	0	0	0	72	0	0	0	3	72
3 months	0	0	0	1	34	0	0	1	3	23
<i>STIs (clinic notes)</i>										
Baseline	0	0	1	3	69	0	0	1	2	80
12 months	0	0	0	4	69	0	0	0	2	80
<i>Self-reported STI (online)</i>										
Baseline	0	0	0	2	72	0	0	0	1	72
3 months	0	0	0	1	34	0	0	0	1	23
Med, median; Q1, lower quartile; Q3, upper quartile. Data are presented as medians and interquartile ranges, as the data were highly skewed.										

TABLE 7 Sexual health outcomes at baseline and follow-up

Sexual health outcome	Control (<i>n</i> = 75)					Intervention (<i>n</i> = 84)				
	Q1	Med	Q3	Maximum	<i>n</i>	Q1	Med	Q3	Maximum	<i>n</i>
Number of female partners in 3 months										
Baseline	1	3	4	179	72	1	2	4	55	72
3 months	1	2	3	18	34	1	1	4	23	23
Number of male partners in 3 months										
Baseline	0	0	0	5	72	0	0	0	15	72
3 months	0	0	0	0	34	0	0	0	4	23
Episodes of condomless sex owing to being drunk/having taken recreational drugs in 3 months										
Baseline	0	0	2	20	72	0	0	1	30	72
3 months	0	0	3	25	34	0	0	1	5	23
Self-efficacy score										
3 months	36	40	45	50 (range 10–50)	33	40	44	46	50	21
Pleasure score										
Baseline	21	25	29	38 (range 9–45)	72	19	24	31	41	72
3 months	20	24	27	32 (range 9–45)	34	21	25	30	36	23
Number of condom problems in the past 3 months										
3 months	1	2	4	8 (range 0–14)	34	1	2	3	5	23
Motivation										
Baseline	2	3	4	4 (range 1–4)	71	2	3	4	4	69
3 months	2	3	4	4 (range 1–4)	32	1	3	3	4	21
Intention										
Baseline	2	3	3	4 (range 1–4)	68	2	3	4	4	67
3 months	2	3	3	4 (range 1–4)	32	1	3	3	4	21
Evaluation of condom use										
3 months	3	4	4	4 (range 1–4)	34	4	4	4	4	22
Knowledge score										
3 months	8	9	10	11 (range 0–11)	34	9	10	11	11	23
Communication score										
3 months	0	2	4	5 (range 0–5)	34	1	2	4	5	23
Identity score										
3 months	25	27	29	35 (range 7–35)	34	25	28	30	35	23
Med, median; Q1, lower quartile; Q3, upper quartile. Data are presented as medians and interquartile ranges, as the data were highly skewed.										

Group comparisons for condomless sex and sexually transmitted infections

Measures of condomless sex with female and male partners were not significantly different between the intervention and control groups at 3 months (Table 8). Twenty-three diagnoses of acute STI (one or more over 12 months) were recorded in the clinical notes of 15 trial participants (non-specific urethritis, *n* = 7; *Chlamydia trachomatis*, *n* = 7; *Neisseria gonorrhoeae*, *n* = 3; epididymitis, *n* = 2; molluscum contagiosum, *n* = 2; and people treated as contacts of someone with chlamydia, *n* = 2). New acute STI diagnoses were

TABLE 8 Group comparisons for condomless sex and STI diagnoses

Outcome	Baseline		Follow-up		IRR	95% CI	p-value	n
	Control median (n); Q1,Q3	Intervention median (n); Q1,Q3	Control median (n); Q1,Q3	Intervention median (n); Q1,Q3				
Number of times had condomless sex with a woman (in 3 months, at 3-month follow-up)	6 (72); 2,20	4 (72); 1,20	12 (34); 3,30	10 (23); 2,40	1.01	0.52 to 1.96	0.975	55
Number of women had condomless sex with (in 3 months, at 3-month follow-up)	1 (72); 1,2	1 (72); 1,2	1 (34); 1,2	1 (23); 1,2	1.09	0.69 to 1.71	0.712	55
Number of men had condomless sex with (in 3 months, at 3-month follow-up)	0 (72); 0,0	0 (72); 0,0	0 (34); 0,0	0 (23); 0,1	1.72	0.60 to 4.93	0.318	55
Number of STI diagnoses from clinic notes (over 1 year, at 12-month follow-up)	0 (69); 0,1	0 (80); 0,1	0 (69); 0,0	0 (80); 0,0	0.75	0.29 to 1.90	0.543	149

recorded for 8.8% (7/80) of men in the intervention group and 13.0% (9/69) in the control group over the course of 12 months. The IRR indicated a 25% lower cumulative incidence in the intervention group than the control group, but this was not a significant difference (IRR 0.75, 95% CI 0.29 to 1.90).

Discussion

In this pilot trial we explored the feasibility of a full-scale online RCT (in sexual health clinic settings) of the Men's Safer Sex website for MSW. Recruitment into the trial was a success: the target sample size was achieved within 2 months, with the highest rates of recruitment on days when a researcher was present to remind staff and patients about the study. Retrieval of clinic records for clinical STI diagnoses was excellent (94%); however, response rates for online outcome measurement were poor (36–50%) despite a number of strategies to improve follow-up, including offers of incentives, repeated e-mail prompts, text messages and telephone calls. There were no reported harmful effects from the Men's Safer Sex website or online trial. We discuss the implications of this feasibility trial for the conduct of online trials of digital interventions in sexual health clinic settings.

Problems with software and patient Wi-Fi access

We encountered technical issues at all time points which hampered recruitment and registration, participant access to the Men's Safer Sex website, online data collection and retention of men in the trial at 3-, 6- and 12-month follow-up points. The NHS lags behind many other institutions in terms of patient access to digital services;⁷⁹ therefore, it was difficult to set up and maintain access to Wi-Fi for patients in clinic waiting rooms because the process for permission and set up was complicated, connections were often poor and staff were not always confident about remedying internet access problems.⁸⁰

There were substantial software development errors that had an impact on recruitment of eligible participants as well as data collection and access to the intervention (e.g. errors with links to the outcome questionnaire, login and password reset functions). Despite careful specification of requirements for the project, there were delays to intervention development, there was a faulty algorithm for participant selection, user experience of the website was not always positive, there was failure of automated analytic data collection, and the login/website access was occasionally faulty. Despite careful specification of requirements, and extensive manual testing by the research staff, the time available for automated testing

and user testing was severely reduced and the extent of these problems was realised only after patients had been recruited. Reliable software frameworks for online RCTs are needed, which are customisable, user-friendly and which meet requirements for secure data protection and data storage.

Ethical issues

It is essential that participants in research are given the information that they need to give informed consent and that confidentiality and data security are ensured.⁸¹ However, we encountered are several tensions between these principles and the practical realities of (online) research.

Informed consent and the online environment

We required potential participants to establish their eligibility (through responses to nine online questions), to read study information online (see *Appendix 6*), indicate agreement on the consent form, create a unique account with a secure password and then respond to demographic and sexual health questions before being offered access to the intervention website. Ethics committees require careful explanation, in writing, to participants regarding what is involved in the research; however, we found that research participants might not read this in detail⁸² and, instead, make judgements based on their trust in the researchers, for example.⁶⁸ Users do not like large amounts of text online^{79,83} and we found that research participants did not read the information pages in detail. Furthermore, some participants appeared to be annoyed by the online research procedures (see *Chapter 5*).

Privacy and data security

The online environment opens up the potential for irreversible breaches of privacy and data security.⁸¹ University College London (UCL) information governance protocols required users to select passwords that are hard to guess, but this also makes passwords harder for participants to remember. The software security protocol also led to frustrating problems, for example a password would be rejected as 'not matching' if participants had entered a space at the end of the password on one occasion and not another.

Most e-mail accounts are not secure (i.e. can be hacked) and it is also a risk that someone's e-mails or texts may be read by another person on a mobile phone or on computer. Other people would be able to see a participant's website browsing history unless they had chosen to delete or hide this. There were concerns that this type of breach of privacy could reveal that a participant had been to a sexual health clinic.

We met the requirements for informed consent and data security, but one-third of the intervention group did not actually see the Men's Safer Sex website (37%), which may have been because of the time taken on enrolment and research procedures and/or being called in for appointments (see *Chapter 5*).

We found that participants were not particularly concerned about consent and confidentiality, and there were no adverse events reported which related to consent or confidentiality (see *Chapter 5*). Participants' trust was enhanced by the fact that this research was conducted by a university (UCL) in partnership with the NHS and participants did not necessarily wish to have detailed information regarding the research.

It may be feasible to reduce burden on research participants through solutions such as offering bullet point summaries of study information online, with links to full information for those who would like it, and making clear the nature of the potential risks of online research. The online research environment is relatively novel and protocols for secure data handling are evolving. It would be useful for stakeholders, including researchers, funders and ethics committees, to consider the particular context of a digital environment on the ethical principles of respect for individual autonomy and dignity, to maximise benefits and minimise harm.⁸¹ When there are risks, the nature of these risks can be outlined for participants, allowing participants to judge for themselves whether or not these are acceptable.

Engagement with the Men's Safer Sex website

Engagement with digital interventions for health promotion can be a major challenge.⁸⁴ We placed the intervention in clinic waiting rooms to take advantage of the waiting time that is common in drop-in sexual health clinics; however, this depended on flow of patients into the clinic. One-third of the intervention group did not see the Men's Safer Sex intervention website, which may have been a result of lack of available time. We shortened the length of the outcome questionnaire by capturing only key outcomes at baseline, but the research procedures still took time (especially if participants were affected by the technical problems described in *Problems with software and patient Wi-Fi access*).⁸⁰

We sent e-mails at 1-month intervals to prompt men to access the intervention and one-third of participants did visit the website after their initial clinic visit. We expected that the main opportunity for intervention would be at the time of a clinic visit but, as discussed above, the time available for this was limited. We offered financial incentives for follow-up data collection but not for engagement with the intervention itself. The best methods for engagement need to be established, for example integrating the Men's Safer Sex website as a step in the patient pathway through the clinic.⁷⁹

Sexually transmitted infection diagnoses in clinic records

We located clinic records with usable data on STI diagnoses for 94% of participants, searching by names given, date attended, e-mail address or telephone number. The location of data from clinic records could be improved by requesting additional information from participants (e.g. date of birth, address, clinic number); however, soliciting additional identifiable data may discourage some people from participating in research.⁸⁰ Almost half of the sample (72/159) returned to the same clinic within 1 year; however, rates of STI acquisition and service use may have been underestimated as participants are free to attend other sexual health clinics and/or their general practitioner (GP) and records are not shared between clinics. This would undermine the validity of clinically recorded STI diagnosis as an outcome if patients in different experimental conditions returned to the original clinic at different rates. It might be possible to capture STI diagnoses made at other sites by using Hospital Episode Statistics and GP data. However, patients in sexual health clinics can choose pseudonyms and may be wary about confidentiality.⁸⁰

Recording STI diagnoses from clinical notes has several advantages over self-reported online outcome measurement: clinic record data are not subject to recall bias or social desirability bias, and data collection from records is cheaper in terms of researcher time and costs of participant incentives. In addition, filling in a sexual health questionnaire may prompt participants to reflect on their behaviour (for both control and intervention participants),^{68,80} potentially reducing the apparent effect of an intervention. Recording diagnoses from clinic records allows collection of cumulative incidence of STI over time, which is likely to be more accurate than self-reported outcomes. The cumulative incidence of acute STIs over 1 year was 9.4%, which compares with an annual recorded rate of 0.85% for new STI diagnoses for men attending sexual health services in England.⁸⁵ We were therefore successful in recruiting men at substantial risk of STI.

Online outcome measurement

Online trials have a number of potential advantages including automated enrolment, randomisation, data entry and reminders.⁷⁹ Online questionnaires can capture internally valid data on a range of outcomes including sexual well-being outcomes, which reflect participants' priorities.^{68,86}

However, although online recruitment can be good, there can be high drop-out rates which limit validity.^{79,87} The response rates for Men's Safer Sex online questionnaires sent by e-mail were poor (maximum of 50%), despite an increased level of incentive for the final questionnaire (£30 vouchers). We used evidence-based methods to enhance retention, that is contacting participants multiple times via different routes (by personalised e-mail, text message and telephone calls).^{66,87,88} However, we do not know whether or not e-mails ended up in junk mail or how many participants were put off by the initial technical problems with password access and malfunctioning links to the outcome questionnaire. The larger incentive offered at 12 months appeared to have a positive influence on the response rate (an increase from 36% to 50%), which is in line with studies which tested the effect of larger incentives.^{66,89}

Conclusion

There are particular challenges for online trials of digital interventions which include ensuring the reliability of software, data security, patient access to information technology (IT) in clinical settings and patient engagement with digital interventions. We have shown that using STI diagnoses from clinical records as a biological outcome is feasible, but that it is challenging capturing self-reported outcomes, which limits exploration of the mechanism of action of an intervention and measurement of sexual well-being. An implementation study is needed to work out how best to maximise engagement with the Men's Safer Sex intervention (e.g. integrating it into routine clinic pathways and procedures). In conclusion, it is feasible to conduct a future large-scale RCT to assess the impact of the Men's Safer Sex website on STI acquisition (recording clinic diagnoses as a primary outcome), but is not feasible at present to collect reliable online self-reported data to analyse intervention mechanism of action.

Chapter 4 Economic evaluation

Aim of Men's Safer Sex economic evaluation

1. To inform the methods for collecting and analysing cost and outcome data for a cost-effectiveness analysis alongside a Phase III trial.
2. To indicate whether or not the intervention seems promising with regard to cost-effectiveness.

Analyses

A cost-utility analysis is the analysis preferred by NICE for the economic evaluation of new technologies [calculating the incremental cost per quality-adjusted life-year (QALY) gained for intervention compared with control]. Using standardised methods to calculate QALYs is recommended to facilitate the comparison of the results of health economic evaluations across disease areas and programmes of work.⁹⁰ Recent guidance from NICE and other experts has recognised that some interventions, particularly those aimed at the primary prevention of disease, may not be suitable for cost per QALY analysis and have recommended other methods, such as reporting of costs alongside outcomes, also known as cost-consequences analysis.^{91,92} This increases the ability to show the impact of an intervention on a wider range of outcomes compared with impact on costs. The feasibility and suitability of using QALYs in digital media interventions of sexual health promotion has not been tested in previous studies.⁷⁹ The Men's Safer Sex study presented an opportunity to assess the implications of the calculation of QALYs as part of an economic evaluation of a digital intervention for STI prevention and improved condom use.

Because health economic evaluations that calculate cost-utility in the area of STI prevention are rare, there is little known about the best way to collect QALYs.⁷⁹ As a result, utility scores to calculate QALYs were collected using two different questionnaires: (1) a generic preference-based measure of HRQoL, the EQ-5D-3L,⁹³ and (2) a sexual health-specific HRQoL measure – the Sexual Quality of Life (SQoL questionnaire).⁷² Specifically, a simplified version of the SQoL questionnaire, the Sexual Quality of Life 3 Dimensions (SQoL-3D), was used in the study. The SQoL-3D was chosen as a measure of sexual quality of life because it has an associated preference-based tariff that can be used to calculate QALYs for economic evaluations. Sexual quality of life was evaluated on the premise that the improvement of sexual knowledge and behaviour may also improve sexual quality of life, something that is not specifically measured as part of the EQ-5D-3L.

Sexual health-related health-care resource use and a health-care cost perspective were also collected from two sources: (1) self-reported questionnaires completed at 3, 6, 9 and 12 months and (2) data collected from participant sexual health clinic medical records (see *Chapter 4*). To investigate the impact on the results of a cost-utility analysis of using different questionnaires to calculate utilities and QALYs, and using different methods to collect resource use, five cost-effectiveness analyses have been conducted:

1. EQ-5D-3L and self-completed questionnaires for resource use
2. SQoL-3D and self-completed questionnaires for resource use
3. disutility of a STI and resource use from participant sexual health clinic medical records
4. cost per STI prevented using self-completed questionnaire responses for resource use
5. cost per STI prevented using participant sexual health clinic medical records for resource use.

Calculating quality-adjusted life-years

For analyses 1 and 2 described above, individual-level utility scores were calculated from individual responses to the EQ-5D-3L and the SQoL-3D at baseline and at 3, 6, 9 and 12 months. EQ-5D-3L utility scores are calculated using the algorithm published by Dolan⁹⁴ and the SQoL-3D using the rescaled utility algorithm, for which death equals zero, published by Ratcliffe *et al.*⁷² Patient-level QALYs were calculated as the area under the curve using the methodology described in Hunter *et al.*⁹⁵ for complete case analysis, adjusting for baseline values. CIs were constructed using bootstrapping and 1000 iterations.

To assess the suitability of the EQ-5D-3L and SQoL-3D for calculating QALYs in sexual health digital interventions, linear regression models were fitted to evaluate whether or not there is a significant relationship at $p < 0.05$ between individual-level utility scores and QALYs compared with any instances of condomless sex and STI diagnosis.

Analysis 3 (disutility of a STI and resource use from participant sexual health clinic medical records), evaluated the feasibility and impact of calculating the cost-effectiveness of the Men's Safer Sex intervention using patient files. Data from the trial were used to calculate the 1-year disutility of having a STI using simple linear regression fitted to complete case QALYs calculated from the EQ-5D-3L. A coefficient was included for STI at baseline compared with no STI at baseline to calculate the disutility. Owing to the small number of participants diagnosed with a STI and who had complete EQ-5D-3L data, STI-specific disutility could not be calculated.

Participant clinical files were used to identify participants with STIs over the 12 months' follow-up. It was assumed that all participants have the mean utility score except for participants who have a STI. A 12-month disutility for having a STI is then applied to any patients diagnosed with a STI during the 12-month follow-up.

Sexually transmitted infection-related health-care resource use and costs

Participants completed questionnaires on sexual health-related resource use at 3, 6 and 12 months. Differences in resource use at each follow-up point between groups have been tested using the chi-squared test and any significant differences at an $\alpha < 0.05$ reported. Unit costs applied to resource use and their sources are reported in *Table 9*. It was not possible to tell whether or not STI tests and treatment occurred in the same or different appointments, so it was assumed that a blood test, urine test and swab would all occur in the same appointment and then additional appointments were counted for each subsequent time

TABLE 9 Unit costs

Resource	Cost (£)	Reference
Condom pick-up (assumed three condoms per pack)	2	Boots (Nottingham, UK) ⁹⁶
Self-test kit for STIs	16.50 (test kit), 2 (postage)	NICE ²
GP appointment	46 (including qualifications)	Curtis ⁹⁷
Sexual health clinic appointment (half of appointment with the nurse and half with the consultant)	105	Department of Health ⁹⁸
Urine test	16	NICE ²
Blood test	2	Department of Health ⁹⁹
Treatment (weighted for prevalence of chlamydia and warts in files)	11	BNF ¹⁰⁰
Sexual health advice: primary care or sexual health clinic	20	NICE ²
Sexual health counselling sessions	47	NICE ¹⁰¹

they had had the same test. Furthermore, the assumption was made that treatment happened in an additional appointment. For example, if a participant had two urine tests and one blood test but received treatment once, it was assumed that they had attended three appointments – two for the tests (one for each test type) and one for the treatment. For sexual health advice, this was added on as an additional £20 per instance in line with the NICE costing template for sexual health services.¹

Mean total cost per patient at each follow-up point has been calculated and reported for complete cases (questionnaire completion at all follow-up points). In addition, 95% CIs have been calculated using bootstrapping and 1000 iterations.¹⁰² No baseline resource use data were collected via patient questionnaires so as to maximise the amount of time participants in the intervention group could spend on the intervention. As a result, sexual health-care resource use collected using questionnaires could not be adjusted for baseline differences between groups.

Data from participant clinical records were used to calculate (1) the cost of the appointment that directly followed recruitment to the trial and (2) the cost of any follow-up appointments that occurred between recruitment and follow-up. Information on appointments that occurred during the 6 months prior to recruitment was used to adjust for differences in resource use using regression analysis. Costing was carried out using a bottom-up approach costing for clinician time (including on-costs and overheads),⁹⁷ diagnostic tests^{2,99} and medication.¹⁰⁰

All costs are reported as 2014 values. Costs prior to 2014 were inflated to 2014 values using the hospital and community health services index.⁹⁷

Cost of the intervention

The total cost of developing and maintaining the intervention website was collected as part of the project management of the trial. There is no definitive way to incorporate the cost of a digital intervention into an economic evaluation.⁷⁹ The complications with doing so are the result of a number of factors, including (1) the intervention has now been developed and, hence, could be considered a 'sunk cost' as no further costs are required to develop it, (2) it is free to patients and providers at the point of access, (3) it is unclear how many people will go on to use the site therefore the cost per patient is hard to calculate and (4) it may be hard to disentangle costs associated with the trial (e.g. developing questionnaires and databases to store trial-related data) from the costs of developing the intervention and day-to-day maintenance if it were to be made widely available. As a result, we report the different costs associated with developing the website and the number of individuals that accessed the website to give some estimation of cost per individual.

If QALY gains are seen in the intervention group compared with the control group, we can also report the number of patients that would need to access the website for it to be cost-effective at the lower end of the willingness-to-pay (WTP) threshold of £20,000 per QALY, which is the threshold generally deemed likely for NICE to approve the implementation of an intervention.¹⁰³

Incremental cost-effectiveness ratio

The mean costs and QALYs calculated above will be used to calculate the mean incremental cost per QALY gained, known as the incremental cost-effectiveness ratio (ICER), of the website intervention compared with control over the 12-month duration of the trial for all analyses specified above. The number of infections prevented has been taken from the statistical analysis reported in *Chapter 4* and used to calculate the mean incremental cost per infection prevented.

Cost-effectiveness acceptability curve

A cost-effectiveness acceptability curve (CEAC) reports the probability that an intervention is cost-effective compared with the control. This is based on running the analysis a number of times, in this case 1000 times using bootstrap sampling from the data collected and recalculating the statistic of interest, and counting the number of times that the ICER is below the WTP threshold. This is divided by the number of times the analysis has been run to give the probability. The results of the bootstrap were used to construct

CEACs for a range of values of WTP for a QALY gained. The probability that the website is cost-effective compared with the control at a WTP for a QALY gained of £20,000 is reported in *Results*.

Sensitivity analyses

The number of pregnancies (in female sexual partners) was also reported in the patient questionnaires. These are rare and expensive events that may be hard to capture and could skew the results; therefore, they have been included in the sensitivity analysis only. Only pregnancies after baseline were included given no other cost information is available at baseline. All pregnancies after baseline were reported as miscarriages which have an average cost of £551 per miscarriage.⁹⁹ The sensitivity analysis was run using the same methodology as above but including the cost of pregnancy.

Results

Completion of questionnaires

There was a large proportion of missing data owing to poor follow-up rates. Analyses have been conducted on complete cases (follow-up data at 3, 6 and 12 months for costs and also including information baseline for QALYs) in line with the statistical analysis plan and assuming that cases are missing at random. The number of participants completing questionnaires at each time point and complete cases are reported in *Tables 10* and *11*. From 72 participants in each group at baseline, there were 27 (37.5%) complete cases in the control group and 19 (26.4%) in the website intervention group.

TABLE 10 Questionnaire completion rates, utilities and QALYs using EQ-5D-3L

Utilities	Control group <i>n</i> , mean (SD)	Intervention group <i>n</i> , mean (SD)
Baseline	72, 0.881 (0.160)	72, 0.868 (0.226)
3 months	34, 0.912 (0.129)	23, 0.900 (0.146)
6 months	35, 0.870 (0.205)	23, 0.884 (0.175)
12 months	43, 0.862 (0.248)	36, 0.905 (0.195)
Area under the curve	Complete cases <i>n</i> , mean (SD)	Complete cases <i>n</i> , mean (SD)
QALYs	27, 0.904 (0.113)	19, 0.902 (0.112)
QALYs (adjusted)	27, 0.886	19, 0.918
SD, standard deviation.		

TABLE 11 Questionnaire completion rates, utilities and QALYs using SQuL

Utilities	Control group <i>n</i> , mean (SD)	Website group <i>n</i> , mean (SD)
Baseline	72, 0.932 (0.043)	72, 0.935 (0.044)
3 months	34, 0.945 (0.037)	23, 0.941 (0.039)
6 months	35, 0.939 (0.046)	23, 0.928 (0.053)
12 months	43, 0.937 (0.047)	36, 0.939 (0.042)
Area under the curve	Complete cases <i>n</i> , mean (SD)	Complete cases <i>n</i> , mean (SD)
QALYs	27, 0.940 (0.032)	19, 0.936 (0.034)
QALYs (adjusted)	0.937	0.938
SD, standard deviation.		

Quality-adjusted life-years

Utility scores and QALYs calculated from responses to the EQ-5D-3L and the tariff developed by Dolan⁹⁴ are reported in *Table 10*. There was no significant difference in QALYs between the two groups with an adjusted difference of 0.03 for intervention minus control group (95% CI –0.02 to 0.08).

Utility scores and QALYs calculated from response to the SQoL questionnaire and the tariff developed by Radcliffe *et al.*⁷² are reported in *Table 11*. There was no significant difference in QALYs between the two groups with an adjusted difference of 0.001 for intervention minus control group (95% CI –0.02 to 0.02).

Table 12 reports the linear regression relationship between the EQ-5D-3L (index and QALY), any condomless sex and STIs. *Table 13* reports the linear regression relationship between the SQoL-3D (index and QALY), any condomless sex and STIs. The only statistically significant relationship at $p < 0.05$ is between QALYs and STIs at baseline using the EQ-5D-3L.

TABLE 12 Linear regression coefficient for the relationship patient-level utilities, QALYs calculated using the EQ-5D-3L and condomless sex and STIs

Any instance of condomless sex	Patient-level utility baseline (n = 144)	Patient-level utility at 3 months (n = 57)	Patient-level utility at 6 months (n = 58)	Patient-level utility at 12 months (n = 79)	QALYs (n = 46)
Baseline	0.007				–0.015
3 months		–0.015			0.051
6 months			–0.024		–0.0002
9 months				–0.020	0.076
STI at baseline (clinic notes)	–0.047	–0.049	–0.077	–0.026	–0.083*
STI at 9 months (clinic notes)				0.089	–0.052
* $p < 0.05$.					

TABLE 13 Linear regression coefficient for the relationship patient-level utilities, QALYs calculated using the SQoL-3D and condomless sex and STIs

Any instance of condomless sex	Patient-level utility baseline (n = 144)	Patient-level utility at 3 months (n = 57)	Patient-level utility at 6 months (n = 58)	Patient-level utility at 12 months (n = 79)	QALYs (n = 46)
Baseline	–0.005				–0.028
3 months		–0.029			–0.027
6 months			0.014		0.015
9 months				–0.002	–0.009
STI at baseline (clinic notes)	–0.006	0.004	0.003	–0.011	–0.001
STI at 9 months (clinic notes)				–0.029	0.0005

Sexual health-care resource use and costs: from questionnaires

Sexual health-related resource use and costs are reported in *Tables 14* and *15*, respectively. There was no significant difference in resource use between the two groups and there were only minor differences in costs between the two groups. At $p < 0.05$, the intervention group had significantly higher costs of self-tests for STIs: £1.85 (95% CI £0.00 to £7.45) versus £0.00. The control group had significantly higher sexual health clinic costs at the 6-month follow-up: £48 (95% CI £0.00 to £143) versus £12.70 (95% CI £0.00 to £54.70).

There was no significant difference in costs between the two groups with a total mean incremental cost of –£24 (95% CI –£145 to £97) for the intervention minus the control group if pregnancy costs are excluded, and –£65 (95% CI –£193 to £63) if the cost of pregnancy is included. Sexual health clinic costs accounted for 88% of the cost in the control group and 84% of the cost in the intervention group.

Sexual health-care resource use and costs: from clinical files

Clinical files could be located for the sexual health clinic appointment directly after recruitment for 69 (92%) participants in the control group and 80 (95%) of participants in the intervention group. Thirty-five participants (47%) in the control group had clinical records for appointments up to 12 months after recruitment and 39 (46%) in the intervention group. Participants who attended the same sexual health clinic after recruitment and whose clinical files could be located had an average of 2.3 appointments over the 12 months for the control group and 2.5 appointments in the intervention group. This is compared with the questionnaire data for which 40% of participants report a blood, swab or urine test at a sexual health clinic in the control group at 12 months and 55% in the intervention group, with an average number of attendances of two in the control group and 1.3 in the intervention group. The proportion with appointments combined with the number of appointments results in a significantly higher average number of appointments recorded in clinical files than in questionnaires for the intervention group ($p = 0.04$) but does not differ significantly for the control group ($p = 0.45$).

TABLE 14 Number of participants and percentage that used each type of resource and average number of times

Resource ^a	Control group, <i>n</i> (%), mean (if > 0)			Intervention group, <i>n</i> (%), mean (if > 0)		
	3 months (<i>N</i> = 34)	6 months (<i>N</i> = 35)	12 months (<i>N</i> = 43)	3 months (<i>N</i> = 23)	6 months (<i>N</i> = 23)	12 months (<i>N</i> = 36)
Condom pick-up	9 (27), 1.3	7 (20), 1	4 (9), 1	7 (13), 1.3	2 (9), 1	6 (8), 1
Self-test kit for STIs	0	1 (3), 1	0	2 (9), 1	1 (4), 1	3 (8), 1
GP resource use						
Urine test/swab	6 (18), 1.2	0	2 (5), 1	3 (13), 1	1 (4), 1	1 (3), 1
Blood test	2 (6), 1	2 (6), 1	2 (6), 1	4 (17), 1	2 (9), 1	1 (3), 1
Treatment	1 (3), 1	1 (3), 1	0	2 (9), 1	0	0
Sexual Health Advice	2 (6), 1	4 (12), 1	0	2 (9), 1	0	0
Sexual Health Services						
Urine test/swab	13 (38), 1.4	8 (23), 1.1	5 (12), 1.2	12 (52), 1.2	2 (9), 1	3 (8), 1
Blood test	10 (29), 1.5	6 (17), 1.2	5 (12), 1.2	11 (48), 1.2	2 (9), 1	4 (11), 1
Treatment	8 (24), 2	4 (11), 1	1 (2), 1	6 (26), 1	0	0
Sexual health advice	9 (26), 1.6	4 (11), 1.3	1 (2), 1	9 (39), 1.3	2 (9), 1	2 (6), 1
Sexual health counselling	0	0	0	1 (4), 1	0	0
Pregnancy (miscarriage)	1 (3), 1	0	1 (2), 1	0	0	0

^a Calculated only for those using the resource.

TABLE 15 Sexual health resource use: average cost (£) per participant (complete case analysis)

Resource	Control, mean (SD)				Intervention, mean (SD)			
	3 months (n = 34)	6 months (n = 35)	12 months (n = 43)	Total (complete case) (n = 27)	3 months (n = 23)	6 months (n = 23)	12 months (n = 36)	Total (complete case) (n = 20)
Condom pick-up	0.71 (1.38)	0.4 (0.81)	0.19 (0.59)	1.18 (1.78)	0.35 (0.98)	0.17 (0.58)	0.11 (0.46)	0.60 (1.14)
Self-test kit for STIs	0	0.53 (3.12)	0*	0*	1.61 (5.32)	0.80 (3.86)	1.54 (5.19)*	1.85 (5.6)*
GP resource use (including tests and treatment)	15.91 (37.58)	6.83 (19.17)	3.12 (14.27)	24.33 (49.43)	19.65 (39.21)	5.13 (17.17)	1.89 (11.17)	25.9 (46.10)
Sexual Health Services (including tests and treatment)	147 (241)	48 (95)*	20.63 (55)	188 (240)	121 (106)	12.70 (42)*	17.58 (43)	159 (131)
Sexual health counselling sessions	0	0	0	0	2.04 (9.8)	0	0	2.35 (10.5)
Pregnancy (miscarriage)	7.35 (64)	0	7.35(64)	14.69 (89)	0	0	0	0
Total cost (excluding pregnancy)	164 (257)	56 (110)	24 (62)	214 (264)	145 (129)	19 (53)	21 (49)	189 (159)
Total cost (including pregnancy)	180 (264)	56 (110)	37 (101)	254 (280)	145 (129)	19 (53)	21 (49)	189 (159)

* $p < 0.05$.

SD, standard deviation.

Costs using a bottom-up costing approach and number of appointments attended pre-recruitment, directly after recruitment and post recruitment using data only from participant clinical files are reported in *Table 16*. If no record is available, it is assumed that there was no appointment and, hence, the cost was zero. There was no significant difference in costs between the intervention and the control group. Adjusting for baseline differences the incremental mean cost per participant of the intervention group compared with the control group was £12 (95% CI –£8 to £32).

Quality-adjusted life-years decrement from sexually transmitted infections and resource use from clinical records

Out of the 42 participants with complete QALY data and data available from clinical records, 10 participants had a STI diagnosis at recruitment: genital warts, $n = 6$; genital chlamydia, $n = 2$; genital herpes, $n = 1$; and urethritis, $n = 1$. Patients with a STI diagnosis at baseline had significantly lower QALYs of 0.843 over the 12 months than 0.926 for participants with no diagnosis of STIs at baseline ($p = 0.03$).

To calculate QALYs for patients using the clinical files, a QALY decrement of 0.083 was applied to any patient with a STI at baseline or who had a new STI diagnosis during the 12 months after recruitment. All other patients had QALYs of 0.926 during the 12 months of the study.

There was no significant difference in QALYs between the control and the intervention group, with a mean difference in QALYs for the intervention minus control of 0.004 (95% CI –0.011 to 0.020).

TABLE 16 Cost of sexual health clinical attendance per recruitment, following recruitment and post recruitment

Analysis	Control ($n = 75$)			Intervention ($n = 84$)		
	Pre recruitment (6 months)	Recruitment	Post recruitment (12 months)	Pre recruitment (6 months)	Recruitment	Post recruitment (12 months)
Number with clinical records (%)	29 (39)	69 (93)	35 (47)	30 (35)	80 (95)	39 (46)
Average (SD) number of appointments (all participants)	0.69 (1.2)	0.93	1.05 (2.25)	0.56 (0.92)	0.95	1.17 (1.7)
Average (SD) number of appointments (participants with records)	1.79 (1.45)	1	2.26 (2.9)	1.57 (0.90)	1	2.54 (1.69)
Average (SD) cost (£) of clinicians (participants with records)	34 (37)	20 (4.5)	45 (58)	31 (29)	21 (8.8)	49 (34)
Average (SD) cost (£) of tests (participants with records)	57 (51)	37 (23)	41 (52)	41 (24)	34 (24)	47 (49)
Average (SD) cost (£) of medications (participants with records)	8.21 (24)	4.40 (15.1)	4.40 (15)	6.18 (12)	4.57 (14.93)	4.57 (15)
Average (SD) total cost (£) (participants with records)	115 (92)	63 (26)	95	81 (32)	60 (28)	107 (74)
Average (SD) total cost (£) (all participants)	38 (76)	57 (31)	44 (86)	28 (43)	56 (31)	50 (74)
SD, standard deviation.						

Incremental cost-effectiveness ratios and cost-effectiveness acceptability curves

In analyses 1, 2 and 4, the intervention dominates the control in that it results in more QALYs and lower costs. In analyses 3 and 5, in which patient files are used to calculate costs, the intervention results in an additional adjusted cost of £12 and is more effective (but not by a significant margin).

In analysis 3, in which QALYs are calculated based on the disutility of having a STI, the intervention results in an additional 0.004 QALYs per participant for an additional cost of £12. This translates to a mean incremental cost per QALY gained of £3000.

In analysis 5, in which costs are calculated from patient files, the intervention prevents four infections per 100 patient-years for an additional cost of £12 per patient. This translates to a mean incremental cost per STI prevented of £291.

The CEACs are depicted in *Figures 8* [for results calculated using the EQ-5D-3L (analysis 1) and those derived from patient files (analysis 3)] and *9* [for results calculated using the SQoL questionnaire (analysis 2)]. Using data from questionnaire responses and calculating QALYs from the EQ-5D-3L, in 88% of instances the intervention is cost-effective compared with control at the WTP for a QALY threshold of £20,000. This is the same regardless of whether the cost of pregnancies is excluded or included. Using patient files for resource use and calculating QALYs from the disutility of STIs, there is a 68% probability that the intervention is cost-effective compared with control. If QALYs are calculated using the SQoL questionnaire, there is a 61% probability the intervention is cost-effective if pregnancy costs are excluded and 69% if they are included.

Cost of the website

The total cost of the developing the website was £101,515 (*Table 17*). Activities and costs not associated with the intervention aspect of the website have already been excluded from the costs. In the trial, 84 participants in the intervention group accessed the website, resulting in a cost per patient of £1209 for the website.

Using the results of analysis 1, QALYs calculated from the EQ-5D-3L tariff and using responses to patient questionnaires to calculate costs, the intervention resulted in an average cost saving of £24 per participant in sexual health service use. Taking away the cost savings from the cost of the website leaves a total mean cost per participant for the intervention group compared with the control group of £1185. There was an adjusted QALY gain of 0.03 in the intervention group compared with the control group. This equates to an incremental mean cost per QALY of £39,466.

There is no reason why access to the website should be limited to the 84 participants who accessed it as part of the trial. Assuming that there is an average cost saving per participant accessing the intervention of £24 and an average QALY gain per participant of 0.003, given there is no additional cost per participant to access the website as the costs have already occurred, an additional 26 participants would need to access the website for an ICER of £30,000, which is the upper end of the NICE threshold for cost-effectiveness. Using the results from the clinical files, that is assuming that the intervention costs an average adjusted cost of £12 more than no intervention and results in 0.004 QALYs, the current ICER is £305,128 per QALY gained. An additional 856 participants would need to access the website for the ICER to be below £30,000 with a cost per participant for the website of £108.

Discussion

This is the first cost-utility (cost per QALY gained) analysis of a digital intervention for sexual health that we are aware of. As a result, the focus of this work has been to evaluate the different methods of cost-utility and cost-effectiveness analysis and their impact on the results. Across the different analyses

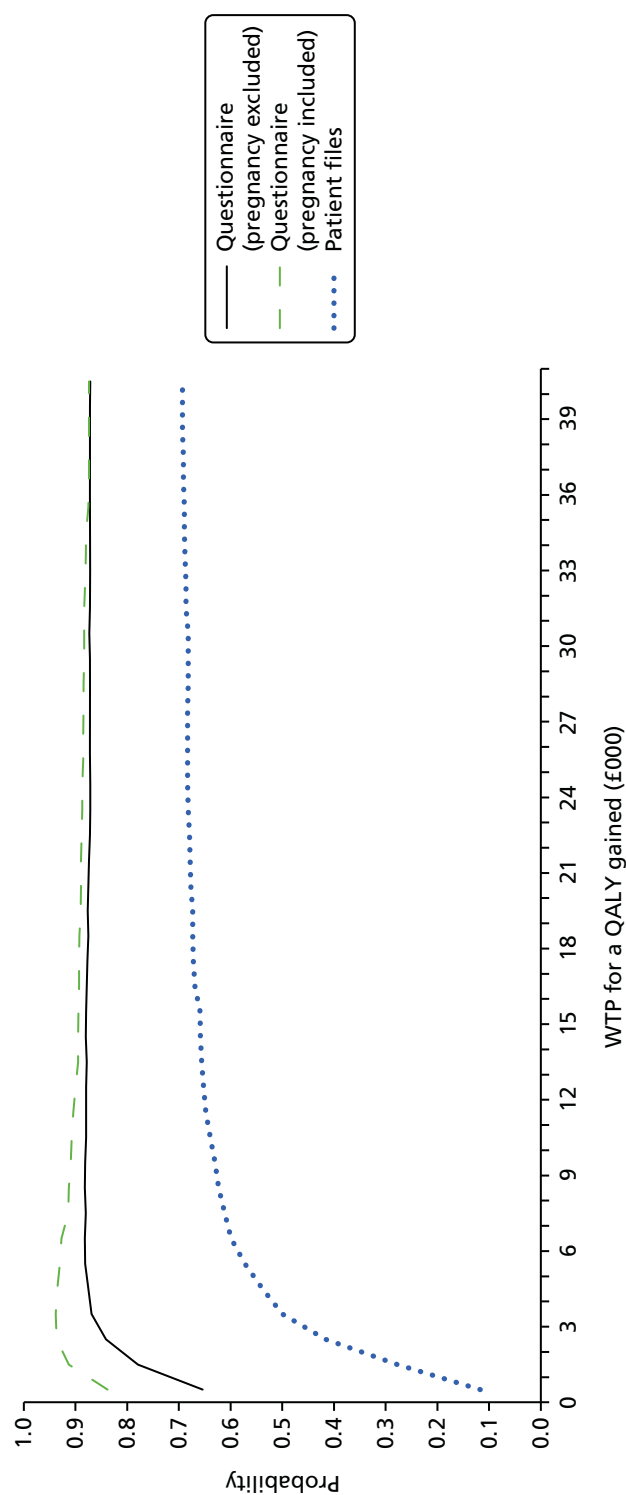


FIGURE 8 Cost-effectiveness acceptability curve of intervention compared with control: QALYs calculated from EQ-5D-3L and questionnaires (with or without pregnancy) or patient files.

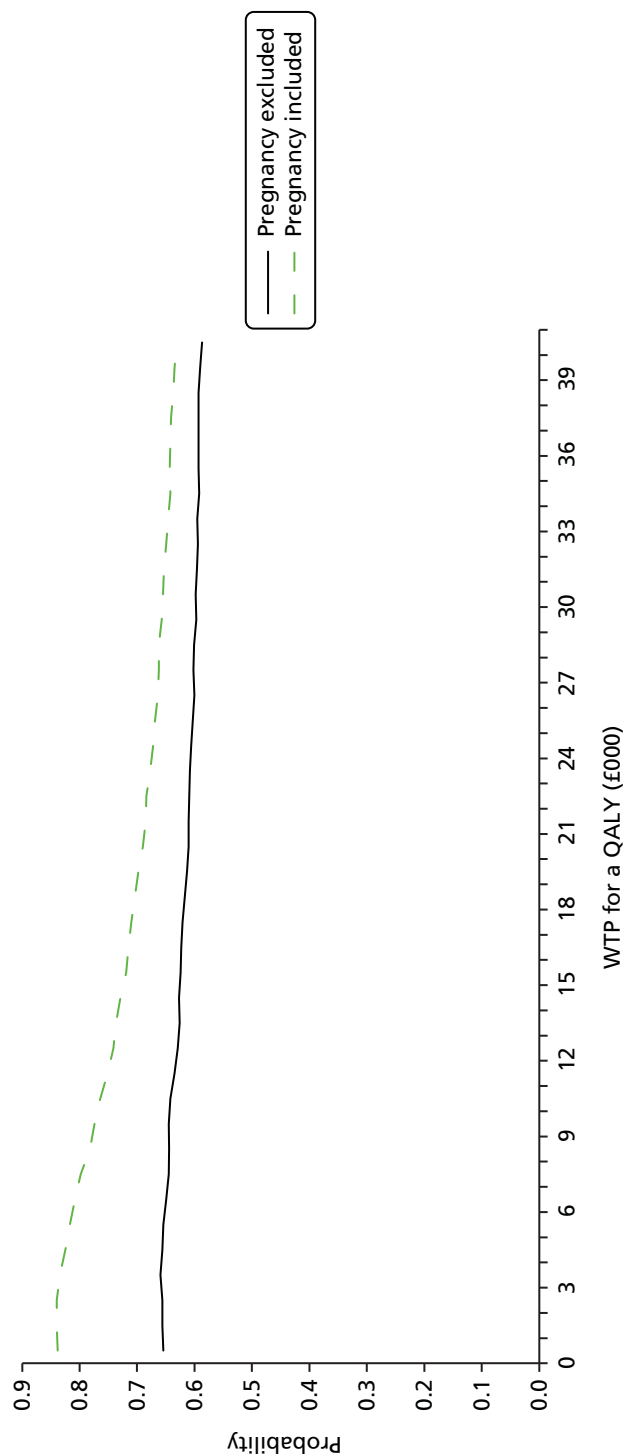


FIGURE 9 Cost-effectiveness acceptability curve of intervention compared with control: QALYs calculated from SQoL.

TABLE 17 Cost components of the development of the intervention website

Cost component	Activity	Cost (£)
Preliminary intervention design	£15 incentive for interviews with 27 participants	405
Focus groups for intervention development	£20 incentive for 16 participants	320
Coding and development of website		
	Draft plan for website	5625
	Outline of intervention	8438
	Final draft of website	25,313
	Testing and completion	16,875
	Total website cost (intervention only)	56,250
Research associate full time for 1 year	75% of their time working on the intervention	34,543
Senior researcher 0.2 FTE 1 year	75% of their time working on the intervention	9996
Total cost		101,515
FTE, full-time equivalent.		

conducted, there is a 61–88% probability that the website is cost-effective compared with current practice at a cost-effectiveness threshold of £20,000 per QALY gained. The impact of the cost of the website on these results varies depending on assumptions made about how many people will access the intervention in the future. It should be noted that this was an analysis of a feasibility trial with the aim of informing methods for a Phase III trial. The design of any future trials should take into account the impact that different methods of data collection (patient-completed data collection vs. data collection from clinical files) have on the results of the cost-effectiveness analysis. If patient files are used, methods for capturing impact on quality of life and the cost of unintended pregnancies will need to be considered.

As discussed, there were challenges following up participants to obtain responses to online questionnaires. Follow-up using clinical files was feasible but did not yield significantly different results to questionnaire data in the control group, and captured more appointments and costs in the intervention group than would be expected based on completed trial outcome questionnaires. There was some concern that clinical files would be less sensitive given that patients can choose any clinic to go to and, therefore, not all clinic attendances may be captured. Although clinical files may miss some of the attendances, they captured more costs than questionnaires and, hence, appear to be more valid.

In the clinical files analysis, an average QALY decrement was applied to a STI diagnosis in patient files based on calculations using complete trial data. Although this provides a methodology for calculating QALYs from clinical files that does not require patient follow-up, further work is required to obtain better estimates of QALY decrements associated with STIs. This could be done by administering the EQ-5D-3L to a large number of STI clinic attendees and collecting detailed data on their current and past sexual health status. Alternatively, a new method for assessing the value people place on sexual health may need to be developed. The utility decrement for STIs calculated using QALYs and the EQ-5D-3L utility score is statistically significant at $p < 0.05$. Given the number of analyses run, this result could have occurred by chance and should be interpreted with caution. The small sample size of 46 participants meant that STI-specific decrements could not be calculated.

The majority of STIs were genital warts which, owing to their visible and symptomatic nature, are likely to have a greater QALY decrement than STIs that can be present with no symptoms, such as chlamydia and gonorrhoea. It is possible that a diagnosis of chlamydia or gonorrhoea may have an impact on quality of life through having a negative impact on relationships or through anxiety over long-term health implications. Further investigation is required as to what the EQ-5D-3L is measuring and if it is the most appropriate outcome to use in sexual health promotion interventions, digital or otherwise.

An additional concern with using clinical files from STI clinics is that they do not capture the cost of other STI-related services. Questionnaire responses collected as part of the trial would suggest that, for this patient group, most patients access STI services through sexual health clinics rather than their GP or community-based services. Resource use for sexual health clinics accounted for 84–87% of costs, capturing the majority of cost data.

Costs differed for cost per sexual health clinic appointment using the NHS payment tariff¹⁰⁴ compared with bottom-up costing. The bottom-up costing may, in some ways, be imprecise as there were data available on which type of clinician the patient saw but not on duration of the contact. It was assumed that the average appointment duration was 20 minutes, unless a diagnostic test was being conducted in which case the appointment length was increased to 30 minutes. There is also limited information available on the costs of diagnostic tests. STI clinics are likely to have bulk contracts with the laboratories that process the diagnostic tests and, hence, are unlikely to know the cost per test. Even assuming appointments are longer, the £63 calculated as the average cost per appointment using bottom-up costing is significantly lower than the £105 value for the NHS tariff.

Website running costs were not included in the analyses, as there was no information available on ongoing running costs. There were no requests from participants for technical assistance in using the Men's Safer Sex intervention website and any maintenance to the website during the trial was research-related only. Based on the QALY gain of 0.003 per participant, an average cost saving of £24 and a WTP for a QALY of £20,000, the website would need to cost £94 per person to be above the threshold for cost-effectiveness. A larger, longer-running trial may provide additional information on what the ongoing maintenance costs for a website of this sort may include.

Further work including decision-modelling may provide additional preliminary evidence of the potential cost-effectiveness of the website intervention by incorporating additional evidence from the literature into the model and extrapolating the findings over a longer time horizon. It may also yield information on where further research is important if evidence is lacking and has implications for the cost or effectiveness of the intervention.

Recommendations

- A future RCT should collect health economic data from clinic patient files rather than self-completed questionnaires. Consideration still needs to be given as to if, and how, QALYs will be calculated and how to collect costs on unintended pregnancies.
- Further research on the suitability of the EQ-5D-3L to calculate QALYs in sexual health-related interventions.
- Further research is needed on the cost of STI clinic visits including staff salaries, time dedicated by each staff member to a patient (including administrative time) and the cost of diagnostic tests.
- Development of a method to allocate per patient costs for digital interventions with unpredictable or variable running costs.

Chapter 5 Clinic staff and user views of the Men's Safer Sex website and online randomised controlled trial

This chapter reports on a qualitative evaluation of the RCT research procedures, exploring the views of clinic staff and male clinic users regarding online trial procedures and the potential of a sexual health website for men in a sexual health clinic setting.

Aims

The main aim of this qualitative evaluation was to provide patient and clinic staff perspectives on online trial procedures, to inform the optimum design of a future full-scale RCT.

Methods

Qualitative study design

The study was a qualitative interview study, using semistructured interviews. We used three qualitative data sources to assess the acceptability and validity of the pilot RCT methodology: (1) individual interviews with 11 male RCT participants, (2) individual interviews with nine clinic staff who assisted with the study recruitment in each of the sexual health clinic research sites and (3) comments made in free-text boxes on the 3-, 6- and 12-month online outcome questionnaires.

Data source 1: male sexual health clinic user interviews

Male study participants were recruited in the same way as participants in the Men's Safer Sex pilot RCT, registering on a tablet computer (iPad) placed in the waiting rooms of sexual health clinics. Forty-eight men were invited to participate in interviews. Their experience of the RCT study procedures were the same, except that e-mail follow-up was at 2 weeks only instead of at 3, 6, 9 and 12 months (to enhance recall of trial procedures). An additional question in the online recruitment process asked permission to contact the men for a post-study interview. Their quantitative outcome data were not included in the pilot RCT data analysis. Ethics committee permission was provided by the City and East NHS Research Ethics Committee (study reference number 13/LO/1801).

We interviewed 11 male sexual health clinic users who had enrolled for the Men's Safer Sex pilot trial. In order to recruit a diverse sample, as the recruitment proceeded we undertook theoretical sampling on the basis of age, trial allocation condition (i.e. intervention or control) and response to follow-up (positive/negative responses to requests for follow-up data).

Interview procedures

Participants were interviewed face to face or by telephone. The topic guide included questions regarding methods of recruitment, online registration and consent, the receipt of incentives, online questionnaires, contact/follow-up via e-mail and men's views of the Men's Safer Sex intervention website (i.e. preference for access point, relevance and usefulness of website, etc.) (see *Appendix 10*). All participants were offered £20 as a thank you for their participation. The interviews were conducted in a variety of settings including sexual health centre side rooms, university offices or via skype™ (Microsoft Corporation, Redmond, WA, USA) video link, and all participants were interviewed alone.

Data source 2: staff interviews

Participant recruitment: clinic staff

We interviewed nine members of staff from the three clinic research sites. All staff members involved in the recruitment to the trial were eligible to participate and we interviewed all staff who were directly involved in the conduct of the trial. Staff were at different grades, with different levels of involvement in the research (e.g. clinical staff who identified patients, research nurses who assisted in recruitment and consent and receptionists who gave out leaflets to potential participants).

Interview procedures

All staff were interviewed face to face by a researcher from UCL who had not been involved in the trial in any way. The topic guide included questions regarding their views on recruitment procedures and the feasibility and usefulness of providing access to an IDI in a sexual health setting. The interviews were all conducted in sexual health centres in clinic rooms and all participants were interviewed alone.

Analysis of qualitative interview data

ATLAS.ti software (version 7.5.11, Cincom Systems Inc., Berlin, Germany) was used to facilitate data retrieval, coding and linkage, and to record analytic notes. Thematic analysis was used to identify patterns and themes within the data. One researcher independently coded text from the transcripts, categorised data by theme and identified relationships between different elements of the text. A data meeting was held to discuss the coding schema and coding decisions were reviewed by a second researcher.

Data source 3: free-text questionnaire comments

Space was offered for voluntary free-text comments after each cluster of questions on the quantitative online outcome questionnaires. At the end of each follow-up survey, participants were also asked whether or not being in the study had any good or bad effects on their lives.

Quantitative survey data were available for 159 men after excluding men who withdrew from the study and those later found to be ineligible. A total of 281 free-text comments on outcome questionnaires for these 159 men were analysed. Forty-six men out of the 159 eligible participants commented on the good or bad effects of the study at the end of at least one of the 3-, 6- or 12-month outcome questionnaires. Comments were exported in a Microsoft Excel file and coded thematically in situ.

Results

Reasons for participating in the research

Participants commonly cited boredom and a desire to help the researchers as their main reasons for participating. The promise of a voucher was described by many as an added bonus but most participants said they would have taken part without this incentive. Features of the study which made it more appealing were anonymity, the flexibility to fit around patients' consultations and that it was short. For most men, the particulars of the study were unimportant, but many were reassured by the academic nature of the study and would have been less keen to participate had it been a marketing questionnaire for a private company.

Participants' understanding of the purpose of the research

Participants' understanding of the research was often incomplete. Many felt it was purely an exercise in data collection and did not realise that the website was intended as an intervention to change behaviours. However, participants were happy to proceed without full understanding of the purpose of the research. By virtue of the study's affiliation with a university (UCL) and with the NHS, men trusted that the study would be trying to do something good and that the details were not particularly important. Two participants had initial concerns that the study may have been sponsored by condom manufacturers,

which led them to feel cynical. Others agreed that they would have felt uncomfortable about participating in a marketing questionnaire.

Experience of completing the research in the clinic

All three of the clinics offer sexual health appointments on a drop-in basis and the waiting time varies by time of day and day of the week. The iPads were positioned so that men could access them while waiting to see clinical staff but the placement of the iPads varied. In one clinic, the research was conducted in the waiting room and in two clinics, participants were taken to a side room to complete research procedures and see the Men's Safer Sex website in private. Staff described the tensions between making the iPad accessible in the main waiting room (and, thus, increasing access) and offering participants privacy. Some felt uncomfortable approaching potential participants and explaining the study in a public waiting room, especially as the study focused on MSW and staff sometimes knew that men were MSM who would not be eligible. Male participants agreed that privacy was important and most felt happy with the location of the iPad that they had experienced.

The staff who were interviewed had been concerned that patients might be worried about missing their appointments and one of their important roles was to ensure that this did not happen. Participants' worries about missing appointments were pre-empted by the staff who explained the study.

Attitudes towards online consent

Staff expressed mixed opinions of the self-directed online consent. Although it lessened paperwork and, in theory, should have saved staff time and effort, many felt duty-bound to obtain verbal consent as well, worried that participants may skim read or fail to understand. Participant interviews confirmed some of these fears, with several male interviewees admitting to scanning the consent pages and many others unable recall specific details (although this may also reflect difficulties recalling details ≥ 2 weeks after enrolment):

Interviewer: . . . any other problems at all with the consent process?

Staff member 09, clinic 1: . . . it seemed like, I don't know whether quite a long information sheet on there . . . and, I think, a lot of people were sort of . . . you felt like they were whizzing through it; and you're thinking, you can't possibly be reading this . . . and, obviously you've got to have all the information in there . . . and I don't know how you get around that; but some people seemed a bit, you know, huffing and puffing because they were reading through it all, and then they'd scroll up and they'd realise there's another [unclear]. And I could see people being, oh, for God's sake, but I didn't stop them obviously, they've got to read it. So I don't know how you get around that because you've got to have all the information in there. You have to have graphics don't you, but I'm sure there must be a way that you can bullet point it. I wonder if bullet points would be better?

The study materials featured UCL and NHS logos and participants trusted that researchers would protect their anonymity and safety and were not interested in knowing the details of this.

Problems with software and Wi-Fi access

As discussed in *Chapter 3*, patient Wi-Fi access was problematic in all three clinics and there were multiple problems with the research software. These problems were frustrating for potential research participants and had an impact on recruitment and retention:

The Wi-Fi, we had a nightmare with that, and that genuinely like was a problem because, you know, you'd get people in, they'd sit down and they wouldn't be able to do it, and it was just so infuriating because they could have been eligible, they could have been, you know, and I had one guy who was so desperate to do it but the Wi-Fi wasn't working, and it's just things like that.

Staff member 09, clinic 1

I mean, the only bad thing about the trial was, the follow up questionnaire, when you had to click the link, it didn't work . . . from the website, so I had to e-mail in, saying I can't get in . . . and it turned out the problem was, that if you already logged in, instead of taking you to the questionnaire, it took you to your account page . . . I was bothered enough to . . . having already done the first thing, I was kind of like, well, if they're not aware of the issue, then no-one's going to complete it, and the whole thing is going to be a waste of everyone's time.

Participant 340 (interviewee)

Online outcome questionnaire

The questionnaire content was acceptable to interviewees and men said that they were honest in their questionnaire responses. Some commented that it was easier to be honest online than in person.

Interviewer: it's just good for us to know, but were you honest in the answers that you gave in the questionnaire?

Participant 355: Yes . . . You know, I don't see the point in saying, oh, I'm not talking about that, because it, at the end of the day, it can potentially harm the research, because you're not getting the true picture, and it doesn't . . . you know, it's very unlikely that I'm ever, you know, going to knowingly meet any of the actual research team, you know, so . . .

Some interviewees did not realise the distinction between the Men's Safer Sex intervention website and the outcome questionnaire (and so were not clear about whether they were in the intervention or control group).

Engagement with the Men's Safer Sex website

There were eight sections of research-related information and procedures to complete as well as the baseline questionnaire before intervention group participants could access the Men's Safer Sex website (see Appendix 6), which was a barrier to engagement as it took some time to complete the research procedures.

. . . it's hard to get people to interact with it, I think, because of the . . . but that's because of the way the research is done. [. . .] So for example when I was . . . so when the patients are doing this it can often take quite a while to get through all the data that you require. So, things like demographic data, and there's stuff about, I don't know, sexual preferences, sexual performance, all that kind of stuff, it takes a while to get through. And then by the time they do actually get to the website they aren't really engaged to use it for that long. Like, a lot of patients would, kind of, just say, I don't know. Can I go?

Staff member 01, clinic 1

Potential impact of the study on sexual well-being

Our quantitative results showed no significant differences in measured outcomes (although, as a feasibility RCT, the sample size was intentionally small). It was difficult for interviewees to unpick the influence of the research (outcome measurements with or without viewing the Men's Safer Sex website) from the influence of visiting the clinic and the subsequent invitation for interview. However, participating in the study did seem to change some men's attitudes and sexual health behaviours.

For some, the act of filling in survey questions prompted some changes:

. . . when I had to do the test and the questions are put in front of you then I started to realise how much I wasn't being honest in my head . . . that's what made me realise I had to change my life. That's when the study helped me so much.

Participant 372 (interviewee)

I think it has been a positive experience. I found being submitted the same questions over and over and having to answer them, offered me the chance to ponder over this topic that often I might have overlooked. It has made me feel more conscious about my sex life.

Participant 332, control group, final comment on 12-month questionnaire

Made me think about protection and prevention before embarking on new relationship.

Participant 181, control group, final comment on 12-month questionnaire

It's been good because it's a little reminder to be careful if I were to cheat and it reminds me of going to get tested at the hospital and how much I hated it and it's much easier just to wear a condom.

Participant 215, control group, final comment on 12-month questionnaire

Good. I am more responsible in the fact I'm more open to talking about contraception and protection.

Participant 199, control group, final comment on 12-month questionnaire

Good effects. Nice to reflect on this aspect of life. I also spent the first £10 voucher on a new yoga mat. Thanks for that!

Participant 254, control group, free text comment on 6-month questionnaire

The outcome questions had no reported impact on other men, but the voucher incentives were valued.

I am not learning anything new, so it is not having any effect on my life beyond taking up some time and providing me with amazon vouchers . . .

Participant 167, control group, final comment on 3-month questionnaire

Among the intervention group participants, it is difficult to separate the potential impact of outcome measurement from impacts of viewing the Men's Safer Sex website. Some participants learned new information as a consequence of participating in the study (presumably from the Men's Safer Sex website, which contained multimedia features addressing STI transmission):

It has helped me understand more about the way that STI can be transmitted.

Participant 207, intervention group, free-text comment on 3-month questionnaire

There were differing views of the website's promotion of condom use:

It has been helpful to revise good practice for safer sex. The study has reminded me of risk but not necessarily offered any new solution. I can't help but feel you are trying to promote condoms, an old message. Everything on the website comes back to 'use a condom' People, including me take absurd risks because sex with a condom is not the same thing as sex without. There are condoms that work a little better. Your website hedges around actually recommending a brand or type on the grounds of pleasure. That's what people want to know. Is there a condom that I can forget that I'm wearing?

Participant 208, intervention group, final comment on 12-month questionnaire

. . . in a good way I feel that this study has really challenged my sexual habits and made me question why I put my health at risk for a few seconds of intense pleasure when using condoms is not a chore and could save my life.

Participant 218, intervention group, final comment on 3-month questionnaire

However, some men felt that condom use/safer sex was not relevant to them:

I appreciate the study and fully support it, but as I am in a long-term relationship with a single partner, I find that a large amount of questions do not apply to me.

Participant 137, intervention group, comment on 6-month questionnaire

Some felt that participating in the study had no effect on their sexual health.

Final comment box: has being a part of this study had any good or bad effects on your life?

[N]ot really to be honest. I feel that generally speaking it was very obvious the advice that was given, although I do think it is very important to make people aware of some things that perhaps some people do not see as being obvious. Personally I found it obvious and I do not feel that it has had any affect on my sexual practice or my well being. However i am grateful to have taken part and I wish you all the success with your study:)

Participant 304, intervention group, comment on 12-month questionnaire

Potential adverse impacts of the study

Although most comments on the effect of participating in the study were neutral or positive, one man described an adverse impact of participating:

Final comment box: has being a part of this study had any good or bad effects on your life?

Not really, i mean, it reminds me of the sadness of losing my long term girlfriend and also imagining her having sex with other people, which is quite painful to think about but, in terms of my own sexual psychology i think i am fine . . . Honest answer . . . you did ask! ;)

Participant 304, intervention group, final comment on 3-month questionnaire

The place of digital interventions in sexual health care

Male clinic users and clinic staff were positive about the role that digital interventions could play in terms of being a useful resource for sexual health information either before or after clinic appointments. Offering a web-based resource in sexual health waiting rooms was felt to be appropriate.

I think the ideal time to do it would be the waiting room beforehand because you've almost got a captive audience. You've got like, a marketeer's dream, haven't you, because you've got people who can't go anywhere, who are already actually by virtue of being there, a little bit engaged with the subject you want to talk to them about. So, it's a little bit easier to talk to them about sexual health than just wondering up to them at Liverpool Street station and saying, I'm going to talk to you about sexual health.

Participant 353 (interviewee)

Clinic staff felt that the website could have a useful role in providing access to additional information for patients, at their convenience, but felt that a digital intervention could not and should not replace their role in communicating directly with clinic users.

I think anybody who comes to the clinic has . . . we should be promoting it. It's not there to substitute any health education that we provide, it's not there to substitute CBT [cognitive-behavioural therapy] that the psychologist might want to give to the patient, or motivational interviewing that the health advisor might want to do. It's there as an additional tool to . . . that is accessible 24 hours a day to the patient. And there's nothing wrong with us making an advert of it in the clinic or having a computer where patients can go and interact with in the waiting room, or having it as an app that they can access on their phones from home. [. . .] I don't think it changes . . . you are what you are. We cannot be replaced by robots; this can only provide information but it almost ends up being almost one way because it's quite a rigid system. It can only give you information based on the questions that are already set on the system. It doesn't have the ability to pick up behaviour, it doesn't have the ability to pick up any verbal cues that young people might be asking or be uncomfortable with so it can't prompt, so it doesn't replace human beings in any way, shape or form. [. . .] I think it has a role and we can use it as a tool. I don't think it should be there to replace what we do.

Staff member 08 (clinic 2)

Clinic users agreed that face-to-face communication can offer advantages over digital interventions.

I don't like the idea of it being used in a consultation because I, kind of, want to speak to the clinician then who's the expert. You know, sometimes clinicians ask a second question, which actually prompts an outpouring of something that proves to be really useful and really, kind of, helps pinpoint a problem.

Participant 353 (interviewee)

Discussion

In summary, male clinic users felt that the Men's Safer Sex website could be thought-provoking, especially for men who do not want to discuss their sex lives. Both clinic staff and clinic users felt that web-based resources could play a useful role in sexual health care, but were concerned that a website should supplement, but not replace, face-to-face health care. The pilot RCT fitted well around clinical activities but men did not self-direct to the iPads and technical problems hampered access and engagement with the website and data collection. The location of the iPads – either in the waiting room or in a side room – meant a trade-off between accessibility and privacy. Staff were more concerned about consent and confidentiality than clinic users. The experiences of the sexual health questionnaire and follow-up procedures were widely positive and the outcome questionnaire was sometimes thought-provoking and could constitute an intervention in itself.

Qualitative study limitations

We interviewed all staff who were directly involved in the conduct of the Men's Safer Sex trial at the three sexual health clinics. However, we interviewed only 11 male pilot trial participants (staff sickness meant that it was not possible to conduct more participant interviews) and their views may not be representative of other trial participants (particularly of men who dropped out of the trial). However, the qualitative analysis gives useful insight into our research procedures and of the Men's Safer Sex website and its design, content and potential usefulness to male sexual health clinic users. Participants in the qualitative study were interviewed 2 weeks after they had registered for the study to enhance recall. This means that we do not have information about user views of follow-up procedures (e-mails, texts and telephone calls) or men's reactions to e-mail prompts to use the website after clinic visits.

Conclusions

The main message from our qualitative field work is that digital interventions can be a useful supplement to NHS clinical care, but that technical problems must be ironed out before the benefits can be enjoyed. Frameworks for assessing the ethical issues and potential risks of digital research (such as those developed by the British Psychological Society⁸¹) would help researchers and ethical committee members to assess any potential risks of online research, and robust protocols for data protection and secure data storage are needed. Engagement with a health promotion website is a challenge in a setting in which digital health care is not routinely provided and online research procedures need to be efficient, with minimal outcome measurement to ensure that participants have time to engage with an intervention.

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 clinical settings. Off-the-shelf software frameworks for online trials and universal access to Wi-Fi in clinics for patients are needed to facilitate smooth conduct of online RCTs. Researcher effort was needed to guide men to the intervention and in order to facilitate routine implementation, IDIs should be offered as components of standardised pathways for sexual health care (e.g. offering online health promotion alongside clinic procedures such as online appointment booking and/or sexual history data collection).

Chapter 6 Next steps

The Men's Safer Sex website was broadly well received by male patients and clinic staff and we were able to measure the impact on the rate of STI acquisition 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 poor response limited collection of online self-reported outcomes. There were challenges with unreliable 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 by a larger level of incentive but remained poor (50%) at 12 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 it might work, as well as when and how, to ensure that participants engage with a digital intervention for long enough to effect change. Important challenges within the NHS are staff resistance to digital interventions⁷⁹ and patient access to IT (Wi-Fi) in clinic settings. These practical and technical challenges need to be addressed before a large-scale RCT is warranted. There are still uncertainties related to how best to evaluate the cost-effectiveness of websites that promote sexual health. This trial provided evidence of the feasibility of collecting data from clinical files to calculate costs. Further work is required on how to incorporate the costs of the website into the cost-effectiveness analysis, methods for calculating QALYs or other measures of effectiveness in sexual health and obtaining more precise costs of a patient visit to sexual health clinics.

The next steps are to:

- refine the Men's Safer Sex website in the light of suggestions made by men and by clinic staff
- draw on our experiences and the latest software security protocols to develop a reliable, secure software framework for online trials
- optimise online research procedures (e.g. information formats suitable for reading online, efficient registration procedures, minimal baseline outcome measurement)
- 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
- explore potential mechanisms of action of the Men's Safer Sex digital interventions, including the best ways to enhance engagement with the website, to make best use of opportunities for intervention
- develop more precise methods for estimation of the costs of service use and resources in sexual health clinics
- conduct further research on outcome measures to use in evaluating the cost-effectiveness of Men's Safer Sex digital interventions
- conduct additional research and publish clearer guidance on how to incorporate the costs of website development, maintenance and running costs into cost-effectiveness analyses.

Interactive digital interventions show exciting potential for health promotion;¹⁰⁵ however, we first need to know more about how to overcome barriers to digital intervention testing and implementation in NHS clinical settings.

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Contributions of authors

Julia V Bailey was the principal investigator.

Rosie Webster conducted qualitative field work and was the trial co-ordinator.

Rachael Hunter conducted the health economic analyses.

Mark Griffin and **Nicholas Freemantle** conducted the statistical analyses.

Greta Rait, Claudia Estcourt, Susan Michie, Jane Anderson, Judith Stephenson, Makeda Gerressu, Chee Siang Ang and **Elizabeth Murray** guided the design and conduct of the qualitative field work, the Men's Safer Sex intervention content and the feasibility trial.

All authors commented on project publications.

Contributions of others

Lorna Hobbs conducted interviews for the qualitative process evaluation and Naomi Tomlinson conducted qualitative data analysis.

Publications

Webster R, Michie S, Estcourt C, Gerressu M, Bailey JV, on behalf of the MenSS Trial Group. Increasing condom use in heterosexual men: development of a theory-based interactive digital intervention. *Translational Behav Med* 2016;**6**:418–27.

Webster R, Gerressu M, Michie S, Estcourt C, Anderson J, Ang CS, *et al.* Defining the content of an online sexual health intervention: the MenSS website. *JMIR Res Protoc* 2015;**4**:e82.

Bailey JV, Webster R, Hunter R, Freemantle N, Rait G, Michie S, *et al.* The Men's Safer Sex (MenSS) trial: protocol for a pilot randomised controlled trial of an interactive digital intervention to increase condom use in men. *BMJ Open* 2015;**5**:e00755.

Bailey JV, Webster R, Griffin M, Freemantle N, Hunter R, Rait G, *et al.* The Men's Safer Sex (MenSS Trial): a feasibility randomised controlled trial of an interactive digital intervention to increase condom use in men. *Digital Health* 2016;**2**:1–12.

Bailey JV, Tomlinson N, Hobbs LJ, Webster R, on behalf of the MenSS Trial Group. Challenges and opportunities in evaluating a digital sexual health intervention in a clinical setting: staff and patient views. *Digital Health* 2016; submitted.

Data sharing statement

Anonymised qualitative interview data transcripts and quantitative pilot trial outcome data can be obtained from the authors.

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Appendix 1 Worksheet from expert workshop 1

Intervention template

Name:

Please complete this template throughout the day, as we complete each task. Start by listing the intervention functions, in order of importance. Please use green for the essential targets and blue for 'nice to have' targets. Please don't feel that this template has to match the group consensus – we want to know what each individual thinks.

Task 1: What behaviour should we be targeting?

When?

.....

Where?

.....

How often?

.....

With whom?

.....

In what context?

.....

Task 2: Who should the intervention target?

.....

Task 3		Task 4		Task 5	Task 6
Intervention target domains (theoretical domains)	Rationale	Intervention functions	Rationale	Potential interactive digital features	Mode of delivery
<i>Write one target (e.g., knowledge, intentions, emotion) per line. Include more specific examples if possible</i>	<i>Indicate why you think this domain is important</i>	<i>List the intervention functions that you feel are appropriate for each target domain</i>	<i>Indicate why you think this function suits this domain</i>	<i>e.g., quizzes, virtual environments (also include how these might be tailored if possible)</i>	<i>e.g., website, app, text messages</i>
<i>Example: Physical skills</i>	<i>Many people make errors when using condoms due to a lack of physical skills</i>	<i>Training</i>	<i>Training is a good way to improve physical skills, and can allow people to practice to behaviour</i>	<i>Videos (of how to put a condom on) Quizzes about knowledge/skills in condom use, with feedback to highlight errors</i>	<i>Website</i>

Appendix 2 Information sheets for interview study

University College London e-Health Unit,
Research Department of Primary Care and
Population Health,
Royal Free Hospital, Upper Third Floor,
Rowland Hill Street,
London NW3 2PF

Information Sheet for Participants in Research Studies

You will be given a copy of this information sheet.

Title of Project: **Men's views on a computer-based intervention for sexual health**

This study has been approved by the NHS Research Ethics Committee (Project ID Number): 12/LO/1643

Name Dr Julia Bailey

Work Address e-Health Unit,
Research Department of Primary Care and Population Health
University College London,
Upper third floor, Royal Free Hospital,
Rowland Hill Street,
London NW3 2PF

Contact Details [email] Telephone: XXXXX

We invite you to participate in this research project. You should only take part if you want to: choosing not to take part will not disadvantage you in any way. If you do decide to take part you are still free to withdraw at any time without giving a reason. Please read the following information and discuss with the researcher if you want to. Please ask if there is anything that is unclear, or if you need more information.

Why are we doing this study?

A research team at University College London are developing a **website and mobile phone application** for men who have attended a sexual health clinic.

The new website and mobile phone app is likely to include **advice about sexually transmitted infections, avoiding future infections, and advice on sexual problems**. We would like to know whether a website or mobile phone app could be a good way for men to get advice and help for sexual health problems.

Why have I been chosen?

You have been invited to take part in this research because you are male, and have visited a sexual health clinic.

What will happen to me if I take part?

We would like to **interview you** to ask your views on:

- * Whether you think a sexual health website or mobile phone app could be useful
- * What kind of sexual health advice you might find helpful

- * Your experiences and views on using condoms to prevent sexually transmitted infections
- * Your views on the design of a new website or mobile phone app (e.g. interactive features)
- * Your views on our future research plans (to test a new website or app)

We would like to tape-record the interview with your permission. We will then summarise the things that different people say in interviews, and use the results to help design the new website and mobile phone app.

Will I benefit from taking part?

We hope that you will enjoy participating in this study and discussing sexual health issues. We hope that it will feel satisfying to have contributed to the design and content of a new website and mobile phone app which could help men in future. You will be offered £15 as a token of appreciation for your time

Are there any risks involved?

There is a risk that some subjects could be embarrassing or upsetting to discuss. We hope that it will still feel helpful to discuss these topics. You are free to stop an interview at any time. At the bottom of this information sheet there are the contact details for organisations which can help with a variety of issues.

What if there is a problem?

If you have a concern about any aspect of this study, please contact the principal investigator, Dr Julia Bailey [email] Telephone: XXXX, or Dr Elizabeth Murray [email]

What happens if something goes wrong?

Every care will be taken in the course of this study. In the unlikely event that you are injured by taking part, compensation may be available. If you suspect that the injury is the result of negligence by the Sponsor (University College London) or the hospital then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Julia Bailey 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.

Regardless of this, 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 or about any side effects (adverse events) you may have experienced due to your participation in the research, the normal National Health Service complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. Details can be obtained from the Department of Health Website: <http://www.dh.gov.uk>

What happens when the study stops?

The computer-based intervention will be tested in another research study, to see whether it is useful to men who have had a sexually transmitted infection.

Can I withdraw from the study once I'm in it?

It is your decision whether to take part in the study or not. You are free to withdraw at any point without giving a reason. You may also choose to withdraw what you said after the group takes place.

What will happen to the information I provide?

Interviews will be tape-recorded and written down with your permission. The information you give and the results from the project will be kept confidential and anonymous. University College London finance department will need your name, address and signature to confirm that you received

the £15 payment. The researchers for this study and the finance department will be the only people who can access your information. All data will be collected and stored in accordance with the Data Protection Act 1998. Any quotations in publications or reports will be anonymous so that you cannot be identified.

There are some legal limits to confidentiality which are important to know. We are obliged under the 'Working Together to Safeguard Children' legislation to consider informing social services or other agencies if we find out that the health, safety or welfare of a person under 18 is at grave risk. Similarly, if it becomes clear that you or someone else is at risk of domestic abuse or other harm, we will consider referring to a local Multi-Agency Risk Assessment Conference meeting, or the police.

Who is organising and funding the study?

The research is being run by Dr Julia Bailey from the University College London e-Health Unit, and is funded by the National Institute for Health Research Health Technology Assessment programme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been approved by the East London and City Research Ethics Committee.

Can I get general advice about taking part in research?

Yes. INVOLVE is a national advisory group that supports greater public involvement in NHS, public health and social care research. You can find out more from www.invo.org.uk or telephone 023 8065 1088

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>

Julia Bailey

University College London e-Health Unit

Appendix 3 Consent form for interviews

Informed Consent Form for Participants in Research Studies

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Project: **Men's views on a computer-based intervention for sexual health**

This study has been approved by the NHS Research Ethics Committee (Project ID Number):

12/LO/1643

Thank you for your interest in taking part in this research. Before you agree to take part, the person organising the research must explain the project to you.

If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you to decide whether to join in. You will be given a copy of this Consent Form to keep.

Participant's Statement

I (Name)

Have read the notes written above and the Information Sheet, and understand what the study involves.	
Agree that the research project named above has been explained to me to my satisfaction.	
Understand that if I decide at any time that I no longer wish to take part in this project, I can notify the researchers involved and withdraw immediately.	
Consent to the processing of my personal information for the purposes of this research study.	
Understand that such information will be treated as strictly confidential and handled in	

accordance with the provisions of the Data Protection Act 1998.	
Agree to the audio-recording of interviews or focus groups, and agree to the use of this material to fulfil the aims of the project.	
Agree that transcripts and audio-recordings may be used by others for future research once it has been made anonymous (e.g. using code numbers instead of names), providing ethical committee permission has been granted for any such future research.	
I agree to take part in this study	

Signature of participant:

Date:

Signature of researcher:

Date

Appendix 4 Topic guide for individual interviews

Men's views on a computer-based intervention for sexual health

What is this research for?

We are developing a website and mobile phone application for men who have attended a sexual health clinic for treatment or advice on sexually transmitted infections.

The new website and mobile phone app could include information such as advice about sexually transmitted infections, and advice on sexual problems.

Aim of the interview:

We would like your views on the design of the new website and mobile phone app - to help to decide which sexual health topics to include, and your views on programme designs.

We would like your views on:

* Whether you think a sexual health website or mobile phone app could be useful

* What kind of sexual health advice you might find helpful

* Your experiences and views on using condoms to prevent sexually transmitted infections

* Your views on the design of a new website or mobile phone app

Confidentiality:

We will keep everything confidential unless you or someone else is in danger of harm

We will use fake names in the report

No information disclosed during the interview will be reported back to the clinic staff

Interview: 1 hour. Free to stop at any time

CONSENT FORM – Sign, and keep information sheet

Your opinions: design and content of a computer-based intervention for men

Could you tell me a little bit about your internet usage?
e.g., how much time you spend on the internet, and what devices you use to access it?

Do you access the Internet for sexual health advice or information?
What advice? Why via Internet or mobile phone? How helpful was the advice?

Clinic visit, health promotion, condom use

Why did you come to the clinic today?
Did you receive a diagnosis or any treatment?
How did you feel about this?
Have you received any sexual health diagnosis in the past?

If you have visited a sexual health clinic recently, what information or advice were you given?
What do you think of the advice you were given?
What information or advice would you have liked (but didn't get) from the clinic?
Were you encouraged to use condoms by clinic staff?
By whom? What did they say? How did you feel about any advice you were given?
I'd like to talk to you a bit about your personal use of condoms now. So I can put this in context, could you tell me a bit about what your situations is in terms of partners/relationships?
What are your experiences and views on using condoms to prevent sexually transmitted infections?
Do you use condoms?
When? All the time? With who?
How do you make the decision to use/not use condoms?
If not, why not?
Is there anything that you think might make you more inclined to use condoms more often?
Do you use condoms for oral sex?
Have you ever had any problems with condoms?
Are you aware of different types of condoms?
E.g., different sizes?

Would you personally find a website useful after visiting a sexual health clinic?
If yes, why? For which topics in particular?

Would it interest you if the website contained information about:
Sexual problems, e.g. (give list)
Sexual pleasure, e.g., 'sex tips', ways to please a girl/woman, ways to make condoms sexy
Might this make you more likely to look at the website?

What do you think is the most important topic to include in a sexual health website?
And the next? And the next?

Here are some suggestions for topics which we might include in a new website and mobile phone app – which of these might you find useful?
e.g. information on sexually transmitted infections, sexual problems, sexual pleasure
– prioritise these with reasons

Which interactive and multi-media features would interest you? (if any)

(Give participant the list and give a brief outline of all components)

For example:

Quizzes with feedback on answers

Games

Chat rooms

Online diaries

Videos

Others' stories

Branching scenarios

Virtual characters

Virtual worlds

Animations, music

For which topics? Why?

Do you think you might access the programme in the following ways?

Touch-screen module on a laptop in clinic

Website to be freely accessible at any time

Mobile phone components (text-messages, and a smart phone 'app')

Do you think an app would be useful in addition to or instead of a website?

(Present pros and cons – accessible offline, stores information onto the phone, may not be accessible to all devices, would need to be downloaded and stored on desktop)

Any other comments?

Please fill in demographic questionnaire

£15 and signature to confirm receipt of cash

Appendix 5 Advertisement poster/leaflet for pilot trial

Interested in research about men's sexual health?

Male?

Over 16?

Heterosexual?

Never been diagnosed with HIV or Hepatitis?



We would like to ask you to take part in an online study to test a **new website** which is designed to **improve men's sexual health**

Receive up to £50 in vouchers as a token of appreciation

(£10 to £20 each time you complete a questionnaire)

If you'd like to be involved, please **go to the iPad in the waiting room.**

The computer will tell you what to do.

You can also ask the research staff for more information (the reception staff will tell you where they are)

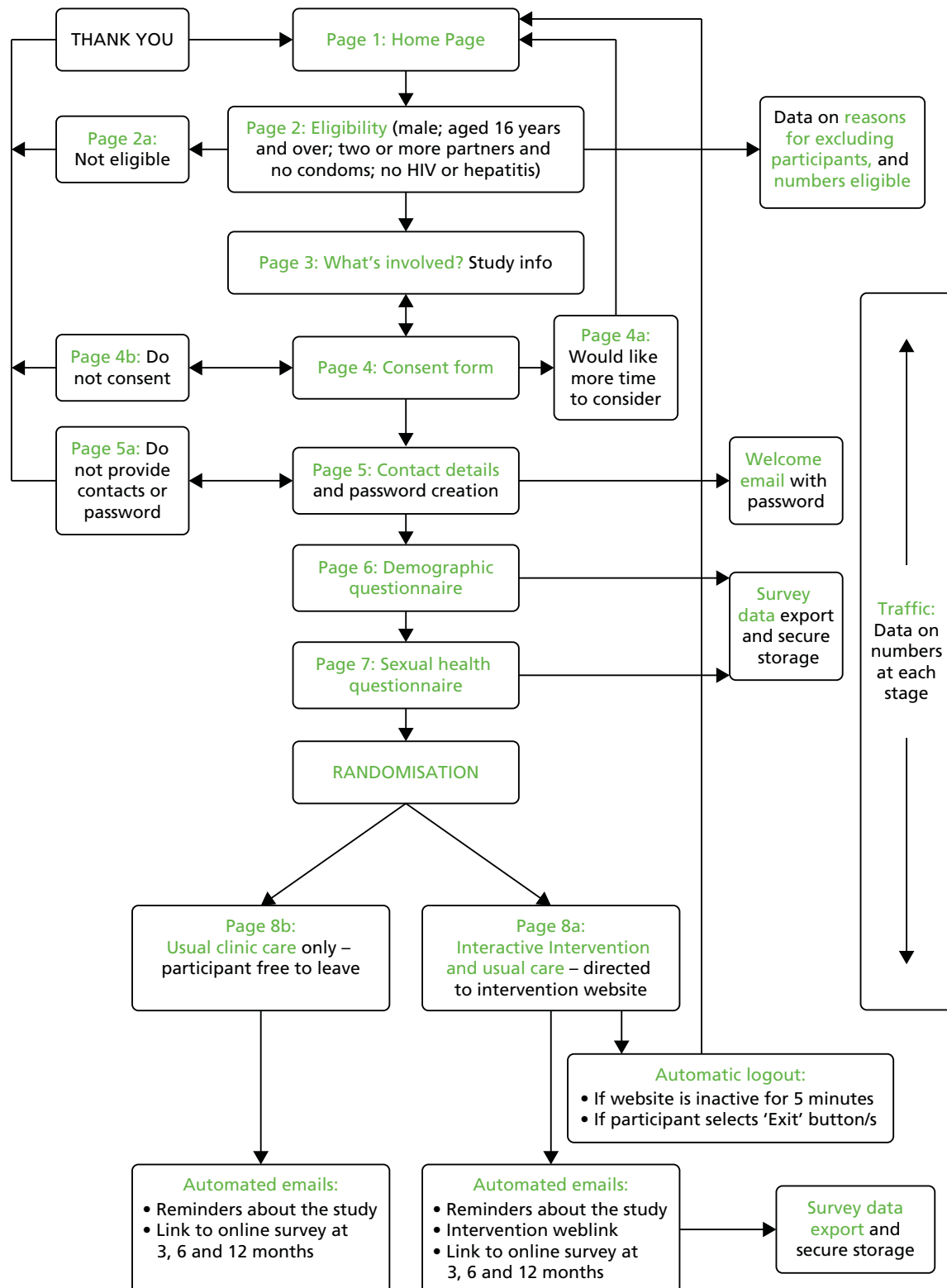
Rosie Webster: [email]

University College London e-Health Unit. Telephone: XXX



Appendix 6 Trial software framework

The trial software framework



Wording of online registration software

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

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 NNNNNNNNNN.

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@bartshealth.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 NNNNNNN.

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.

Appendix 7 Questionnaire for pilot trial

Questions
Your behaviour
<p>1. In the last 3 months how many of these types of female partners have you had sex with?</p> <p>Regular partner</p> <p>Occasional partner, e.g. friends with benefits</p> <p>One off partner (e.g. one night stand)</p> <p>Sex worker (paid for)</p> <p>Other</p> <p>(please specify):</p> <p><i>(Text boxes restricted to 3 digit number for each option; free text box for 'please specify')</i></p>
<p>2. In the last 3 months how many of these types of male partners have you had sex with?</p> <p>Regular partner</p> <p>Occasional partner, e.g. friends with benefits</p> <p>One off partner (e.g. one night stand)</p> <p>Sex worker (paid for)</p> <p>Other</p> <p>(please specify):</p> <p><i>(Text boxes restricted to 3 digit number for each option; free text box for 'please specify')</i></p>
Condom use
<p>3. In the last 3 months, how many women have you had condomless vaginal or anal sex with (without a condom)?</p> <p><i>(Free text response, restricted to 3 digits numeric)</i></p>
<p>4. In the last 3 months, how many TIMES have you had condomless vaginal or anal sex with a woman (without a condom)? (Please answer as accurately as you can)</p> <p><i>(Free text response, restricted to 3 digits numeric)</i></p>
<p>5. In the last 3 months, how many men have you had condomless anal sex with (without a condom)?</p> <p><i>(Free text response, restricted to 3 digits numeric)</i></p>
<p>6. In the last 3 months, how many times have you experienced any of the following problems?</p> <p>Condoms not available when needed <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more</p> <p>Using condoms stored in wallet more than 1 <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more</p> <p>month</p> <p>Using condoms that were not lubricated <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more</p> <p>Applied condom after sex had begun <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more</p> <p>Removed condom before sex ended <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more</p> <p>Did not change condoms when switching <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more</p> <p>from one form of sex to another</p> <p>Erection lost when putting on a condom <input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more</p>

Erection lost during sex	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more
Condom broke	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more
Condom slipped off during sex	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more
Condom slipped off during withdrawal	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more
Ejaculate dripped onto partner's genitals	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more
Condom put on penis the wrong way, then turned and put on the right way	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more
Did not change condoms when switching from one partner to another	<input type="radio"/> 0 <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 or more
<p>7. In the last 3 months, how many times have you had condomless sex (without a condom) because you were drunk or high? (Please answer as accurately as you can)</p> <p><i>(Free text response, restricted to 3 digits numeric)</i></p>	
<p>8. In the last 3 months, have you used these types of contraception with female partners ?</p> <p>Tick all that apply</p> <p><input type="radio"/> Don't know</p> <p><input type="radio"/> None</p> <p><input type="radio"/> None –trying for a baby</p> <p><input type="radio"/> The Pill, contraceptive patch, or contraceptive vaginal ring</p> <p><input type="radio"/> Condoms (including female condoms)</p> <p><input type="radio"/> Emergency contraceptive pill (morning after pill)</p> <p><input type="radio"/> Injection</p> <p><input type="radio"/> Contraceptive implant</p> <p><input type="radio"/> Withdrawal (pulling out)</p> <p><input type="radio"/> Intrauterine device (coil/IUD/IUS)</p> <p><input type="radio"/> Diaphragm or cap or spermicide</p> <p><input type="radio"/> Natural family planning (safe period/rhythm method)</p> <p><input type="radio"/> Don't know name of the contraception</p> <p><input type="radio"/> Other (please state).....</p>	
STI diagnoses	
<p>9. In the last 3 months, have you had any of the following sexually transmitted infections (tick all that apply)?</p> <p><input type="radio"/> Warts</p> <p><input type="radio"/> Herpes</p> <p><input type="radio"/> Chlamydia</p> <p><input type="radio"/> Gonorrhoea</p> <p><input type="radio"/> Pubic lice (Crabs)</p> <p><input type="radio"/> Trichomonas (TV)</p> <p><input type="radio"/> Non-specific urethritis (NSU)</p> <p><input type="radio"/> Syphilis</p>	


<input type="radio"/> HIV <input type="radio"/> Hepatitis <input type="radio"/> Can't remember the name <input type="radio"/> Other (please write in name) <input type="radio"/> No sexually transmitted infections	
10. In the last 3 months have you had antibiotic treatment because a partner had an STI? <input type="radio"/> Yes <input type="radio"/> No	
1. Has a female partner been pregnant in the last 3 months? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know (If yes) What happened with the pregnancy? <input type="radio"/> Still pregnant <input type="radio"/> Miscarriage or stillbirth <input type="radio"/> An abortion <input type="radio"/> A baby <input type="radio"/> Don't know	
2. In the last 3 months, how many times have you used each of these sexual health services? Condom pick-up Self-test kit for STIs* (e.g. postal Chlamydia test kit) Urine tests/swabs at the GP Urine tests/swabs at a sexual health clinic Blood tests for STIs at the GP Blood tests for STIs at a sexual health clinic Treatment of an STI at the GP Treatment of an STI at a sexual health clinic Sexual health advice from the GP Sexual health advice from a sexual health clinic Outreach contraception and sexual service (CASH) Sexual health counselling or therapy Other sexual health services (please state) <i>(Text boxes restricted to 3 digit number for each option; free text box for 'please state')</i> *STIs = Sexually Transmitted Infections * GP = General practitioner, family doctor	
Self-efficacy	
3. I feel confident that I could:	
Get hold of condoms (eg buying from a shop)	<input type="radio"/> Strongly disagree <input type="radio"/> Disagree <input type="radio"/> Undecided <input type="radio"/> Agree <input type="radio"/> Strongly agree
Use a condom on correctly	<input type="radio"/> Strongly disagree <input type="radio"/> Disagree <input type="radio"/> Undecided <input type="radio"/> Agree <input type="radio"/> Strongly agree

Put a condom on without losing my erection	<input type="radio"/> strongly agree <input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree
Remove and dispose of a condom after sex	<input type="radio"/> strongly agree <input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree
Choose the correct size/type of condom	<input type="radio"/> strongly agree <input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree
Discuss using condoms with any partner I might have	<input type="radio"/> strongly agree <input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree
Suggest using a condom with a new partner	<input type="radio"/> strongly agree <input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree
Suggest using a condom without my partner feeling 'diseased'	<input type="radio"/> strongly agree <input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree
Remember to use a condom even if I am drunk or high	<input type="radio"/> strongly agree <input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree
Stop to put a condom on myself or my partner even in the heat of the moment	<input type="radio"/> strongly agree <input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree
Knowledge	
4. True or false?	
Whether or not people get sexually transmitted infections (STIs) is just luck.	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
You would know if you had an STI, without needing a test	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
You can tell who is likely to have an STI	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
You can have HIV and not know	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
You can catch STIs from oral sex	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
If you are in a relationship, you are safe from catching STIs	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
You are less likely to catch an STI from someone you know	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
Some STIs can't be treated	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
With a condom on, the man should wait until the penis is soft before withdrawing after sex	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer
Baby oil or Vaseline is a good lubricant to use on a condom	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer

Standard sized condoms are suitable for all men	<input type="radio"/> True <input type="radio"/> False <input type="radio"/> Unsure of answer Levels: True = 1 False = 0 Unsure = 2
Motivation	
5. Thinking about situations when you will have sex in the future, which of the following best applies to you? <input type="radio"/> I do not want to wear a condom <input type="radio"/> I am not sure if I will want to wear a condom <input type="radio"/> I might want to wear a condom <input type="radio"/> I very much want to wear a condom	
Intention	
6. Which of the following best applies to you: <input type="radio"/> I plan not to use condoms when I have sex <input type="radio"/> I don't have any particular plans to use condoms when I have sex <input type="radio"/> From now on I will try to use a condom as often as possible whenever I have sex <input type="radio"/> From now on I will make sure I always use a condom whenever I have sex	
Evaluation	
7. Which of the following best applies to you? <input type="radio"/> I think the disadvantages of using a condom are greater than the advantages <input type="radio"/> I think there is little to choose between the advantages and disadvantages of using a condom <input type="radio"/> I think the advantages of using a condom are a bit greater than the disadvantages <input type="radio"/> I think the advantages of using a condom (e.g., protection against STIs and pregnancy) are always much greater than any disadvantages (e.g., reduced pleasure)	
<input type="radio"/> I think the disadvantages of using a condom are greater than the advantages	
8. Do you agree or disagree with the following statements?	
Condoms feel unnatural	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Condoms interrupt the mood	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Condoms don't feel good	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Condoms reduce the quality of the climax or orgasm	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Condoms are uncomfortable	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Condoms don't fit right	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
I feel closer to my partner without a condom	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree

Using a condom helps me worry less during sex	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Using a condom helps my partner/s worry less during sex	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree Levels: strongly disagree = 1 disagree = 2 undecided = 3 agree = 4 strongly agree = 5
Communication	
9. During the last 3 months, have you discussed the following things with partner(s)?	
How to prevent pregnancy	<input type="radio"/> Yes <input type="radio"/> No
How to use condoms	<input type="radio"/> Yes <input type="radio"/> No
How to prevent STIs and HIV	<input type="radio"/> Yes <input type="radio"/> No
Your sex history	<input type="radio"/> Yes <input type="radio"/> No
Their sex history	<input type="radio"/> Yes <input type="radio"/> No
Identity	
10. Do you agree or disagree with the following statements?	
I feel I am a responsible person, which is why I use condoms	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
I feel I am a spontaneous person, which is why I don't use condoms	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Using condoms is the woman's responsibility	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Condoms make me feel less of a man	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
I use condoms because I am concerned about my health	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
I use condoms because I am concerned about my partners health	<input type="radio"/> strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree

Getting a girl pregnant proves that I am a real man	<input type="radio"/> Strongly disagree <input type="radio"/> disagree <input type="radio"/> undecided <input type="radio"/> agree <input type="radio"/> strongly agree
Your health	
<p>11. We'd like to know about your sexual well-being over the last 3 months. Please select the statements that best apply to you.</p> <p>1. Sexual performance</p> <p><input type="checkbox"/> Your sexual performance is good</p> <p><input type="checkbox"/> Your sexual performance is adequate</p> <p><input type="checkbox"/> Your sexual performance is sometimes inadequate</p> <p><input type="checkbox"/> Your sexual performance is inadequate</p> <p>2. Sexual relationship</p> <p><input type="checkbox"/> Your sexual relationship is never poor</p> <p><input type="checkbox"/> Your sexual relationship is rarely poor</p> <p><input type="checkbox"/> Your sexual relationship is sometimes poor</p> <p><input type="checkbox"/> Your sexual relationship is always poor</p> <p>3. Sexual anxiety</p> <p><input type="checkbox"/> Thinking about your sex life you never feel anxious</p> <p><input type="checkbox"/> Thinking about your sex life you rarely feel anxious</p> <p><input type="checkbox"/> Thinking about your sex life you sometimes feel anxious</p> <p><input type="checkbox"/> Thinking about your sex life you always feel anxious</p>	
<p>Under each heading, please tick the ONE box that best describes your health TODAY</p> <p>12. <u>Mobility (walking about)</u></p> <p><input type="radio"/> I have no problems walking about</p> <p><input type="radio"/> I have some problems walking about</p> <p><input type="radio"/> I have a lot of problems walking about</p> <p>13. <u>Looking after myself</u></p> <p><input type="radio"/> I have no problems washing or dressing myself</p> <p><input type="radio"/> I have some problems washing or dressing myself</p> <p><input type="radio"/> I have a lot of problems washing or dressing myself</p> <p>14. <u>Doing usual activities (for example, going to school, hobbies, sports, playing, doing things with family or friends)</u></p> <p><input type="radio"/> I have no problems doing my usual activities</p> <p><input type="radio"/> I have some problems doing my usual activities</p> <p><input type="radio"/> I have a lot of problems doing my usual activities</p> <p>15. <u>Having pain or discomfort</u></p> <p><input type="radio"/> I have no pain or discomfort</p> <p><input type="radio"/> I have some pain or discomfort</p> <p><input type="radio"/> I have a lot of pain or discomfort</p> <p>16. <u>Feeling worried, sad or unhappy</u></p> <p><input type="radio"/> I am not worried, sad or unhappy</p> <p><input type="radio"/> I am a bit worried, sad or unhappy</p> <p><input type="radio"/> I am very worried, sad or unhappy</p>	

<p>17. We would like to know how good or bad your health is TODAY.</p> <p>This line is numbered from 0 to 100.</p> <p>100 means the best health you can imagine.</p> <p>0 means the worst health you can imagine.</p> <p>Please mark an X on the line that shows how good or bad your health is TODAY.</p> <p>How good is your health TODAY</p>	<p>The best health you can imagine</p> <p>100</p>  <p>0</p> <p>The worst health you can imagine</p>
<p>18. Has being a part of this study had any good or bad effects on your life? Please explain how:</p> <p><i>(Free text box)</i></p>	

Appendix 8 Information sheet for qualitative evaluation of trial procedures interviews: participants

Information Sheet for Participants in Research Studies

You will be given a copy of this information sheet.

Title of Project: **The MenSS Study: a pilot trial to test an interactive sexual health website for men**

This study has been approved by the NHS Research Ethics Committee: 13 LO 1801

Name Dr Julia Bailey

Work Address e-Health Unit,
Research Department of Primary Care and Population Health
University College London,
Upper third floor, Royal Free Hospital,
Rowland Hill Street,
London NW3 2PF

Contact Details [email] Telephone: XXXXX

We invite you to participate in this research project. You should only take part if you want to: choosing not to take part will not disadvantage you in any way. If you do decide to take part you are still free to withdraw at any time without giving a reason. Please read the following information and discuss with the researcher if you want to. Please ask if there is anything that is unclear, or if you need more information.

Why are we doing this study?

You recently took part in a study to test the MenSS website. We'd really like to interview you now to ask you what you thought of being in the research study, and to ask your opinion of the usefulness of websites for sexual health for men.

We hope that you will find the research interesting. What you say might help us to work out the best ways to run research in sexual health clinics and online.

What's involved?

This study involves an interview with a member of our research team. They will ask you questions about what you thought about being in the research study, and your opinions on the usefulness of sexual health websites for men. Do not worry if you have not seen the website, we will show it to you again. The interview will be in the clinic that you attended, or in central London. We can also do it over the phone or using Skype. The interview will take about an hour. We'll pay you £20 for helping us out.

The interview will include questions like:

- Why did you sign up for the research trial?
- Do you think that doing the survey made you think about your sexual health differently?
- Do you think the website would be useful to you?

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 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 interview 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, XXXXX [email]; Julia Bailey, XXXXX [email]
 - o 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):
 - o Homerton:
 - Tel: 020 8510 7315
 - Email: pals@homerton.nhs.uk
 - o Barts:
 - Tel: 020 3594 2040
 - Email: pals@bartshealth.nhs.uk
 - o Coventry:
 - Tel: 024 7653 6804
 - Text message: 07826 900 926
 - Email: pals@covwarkpt.nhs.uk
- This research has been approved by the London – City and East 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>

Julia Bailey

University College London e-Health Unit

Appendix 9 Consent form for qualitative evaluation interviews

Informed Consent Form for Participants in Research Studies

Please complete this form after you have read the Information Sheet about the research.

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

This study has been approved by the NHS Research Ethics Committee: 13 LO 1801

Thank you for your interest in taking part in this research. Before you agree to take part, the person organising the research must explain the project to you. If you have any questions, please ask the researcher before you decide whether to join in.

You will be given a copy of this Consent Form to keep and refer to at any time.

(Please write your name)

(Please initial boxes)

I have read Information Sheet and/or discussed the study with the researcher/s

I understand what the study involves.

I understand that if I change my mind and no longer want to take part in this project, I can tell the researchers and withdraw immediately.

I agree that researchers can use and store my personal information (e.g. my name and contact details) for the purposes of this research study only

I understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.

I understand that my interview will be audio recorded and that what I say may be quoted anonymously

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.

I understand that the research findings will be posted online and published as reports or papers, but that it will not be possible to identify me in any publications.

The research project named above has been explained to me to my satisfaction and I agree to take part in this study.

I agree that my interview may be used by others for future research once it has been made anonymous (e.g. by using code numbers instead of names)

Signature of participant:

Date:

Signature of researcher:

Date:

Appendix 10 Topic guide for interviews with trial participants

Topic guide: MenSS Study

Date

Interviewer.....

Participant ID number

Location

Allocation to intervention or control?

Age

No of days since final follow-up

Completed follow-up questionnaire?

Resources needed:

Mobile phone, panic alarm, security notification (someone who knows ID of participant and time and location of interview), digital audio-recorder, wording of automated emails, paper copy of questionnaire, Website on laptop with Internet access.

Introduction

Thank the participant and introduce yourself

“You recently took part in our research trial, and agreed to be interviewed afterwards.

The purpose of this interview is to find out what you thought about being in the MenSS research trial, and your opinions of the MenSS website that was on the iPad in the clinic. It doesn't matter if you didn't look at the website, I'll show it to you again.

We're interested in your opinions, not testing your knowledge.

What you say might help us to work out the best ways to run research in sexual health clinics and online.

You're free to stop at any point, or to miss out questions if you like

Go through info and consent form

Any questions?

What was it like taking part in the MenSS sexual health research?

[Research questions: are the procedures acceptable, how might they be improved]

Being in our research project

- Why did you sign up for the research trial?
- Do you remember what the research involved? [what did you have to do to get the voucher?]
 - [Reminder: the research involved- Registering on the tablet computer in clinic; a questionnaire about sexual health and relationships; access to the website; follow-up questionnaires via email]
- What did you think of the research project? [Prompt: what was positive, what was negative, did you feel worried about it....?]
- What did you think the research was for? [Did this matter to you?]
- Would you do it again? Why or why not?
- Were you aware of who was running the research? [e.g. university, a company, Rosie?.....Did this matter to you?]

Registration and consent process

(Have registration screen available to prompt recall)

- Do you remember registering for the study?
 - [Reminder – you registered on a tablet computer, which showed you the study information and took your details]
- Did you understand the process of registering for the study on the tablet computer?
 - [Prompt – was any of it confusing?]
- Did you understand the study information that was given on the tablet computer?
 - [Prompt – was it clear to you what the study was? Did you understand what you were agreeing to?]
- Did you ask the researchers any questions when you were registering on the tablet computer?
 - (If yes) Did you speak to them in person or over the phone?
 - Can you remember who you spoke to?
 - Were you happy with the answer that you got?
 - (If no) Were there any questions that you wanted to ask, but didn't?
 - If so, why didn't you ask?
- How did you feel about entering your contact details into the tablet computer?
 - [Prompt – reluctant? Privacy concerns? Prompt separately about phone, email, and home address]
- How did you feel about completing the surveys on the tablet computer in the clinic?
 - [Prompt – any embarrassment or privacy concerns, trouble with questions or software]

- What did you understand about who has access to your medical records and why?

Emails and online surveys

‘The following questions are about the survey questionnaires you filled out online’...

- What did you think of being contacted by email?
 - [Prompt: frequency?]
- What did you think of filling in the surveys online?
 - Were you worried about anyone seeing your answers?
- Do you remember what the surveys were about?
- Did you mind being asked about sex and relationships?
- Did you feel that your answers were important for the research?
- Were you honest in your answers?
 - If not, please can you say why not?
 - What questions were easy to be honest about? Which were harder?
- Do you think that doing the survey made you think about your sexual health differently?
 - [check participant realises that the survey is different to the website]
- Do you think that doing the survey led you to change your sexual behaviour?
 - [choices about sexual partners, contraception, condom use....]
- Did you know which group you were allocated to (Int or Cntrl)? And was this ok with you?

The voucher

- Did you receive your voucher?
- How important was the voucher as a reward? Would you have done the research anyway?

Intervention website

- Views of the MenSS website intervention - *Intervention group*:
 - Did you find looking at the website in clinic useful? Why/why not?
 - Did you feel you had enough time in clinic to look at the website?
 - Did you look at the website again after visiting clinic?
 - If yes:
 - Why? What for? How often? What did you look at?
 - If no:
 - Why not? What might have made you more likely to go back and look at it?
 - Did you think the website was relevant to you, as a man who accesses sexual health clinics?
 - Why? Why not?
 - Was the website useful to you?
 - Why? Why not?
 - Where there any particular sections that were useful/not useful?
 - What could make it more useful?

- Who might it be useful for? (Age, type of behaviour)
 - Do you have any suggestions for changes to the website?
 - E.g., things you'd take out or put in
- Views of the MenSS website intervention - control group:
 - (Offer them the website to look over)
 - Would you be interested in using a website like this, either in or after clinic?
 - Why? Why not?
 - How often?
 - When?
 - What would you look at?
 - Did you think the website is relevant to you, as a man who accesses sexual health clinics?
 - Why? Why not?
 - Do you think the website would be useful to you?
 - Why? Why not?
 - Where there any particular sections that could be useful/not useful?
 - What could make it more useful?
 - Do you have any suggestions for changes to the website?
 - E.g., things you'd take out, other information that could be put in
- Views of the usefulness of online interventions before/during or after a visit to a sexual health clinic
 - How useful do you think it is to have a website like this, in clinic?
 - How do you think it could be made more useful?
 - When do you think the website is/could be most useful? (Before, during, after clinic)

THANK YOU!

Signature on the finance form

£20 including travel costs

Appendix 11 Statistical analysis plan

An interactive digital intervention to increase condom use in heterosexual men in sexual health clinics: a pilot trial (MenSS)

Statistical Analysis Plan (SAP)

Introduction

The following analysis plan covers the statistical analyses of the predetermined outcome measures (primary and secondary and other) from the MenSS pilot trial.

All analyses will be conducted in accordance with the University College London (UCL) Primary Care and Mental Health (PRIMENT) clinical trials unit (CTU) standard operating procedures (SOPs) in addition to conforming to the CONSORT statement.

Trial overview

Trial design

A phase 2 pilot multi-centre RCT of adult males who have sex with women, with a recent history of risky sexual behaviour comparing an interactive digital intervention (IDI) plus usual care with usual care alone on condom use.

Aim

To establish the feasibility and best design of a full scale trial of the IDI comparing usual clinical care plus the intervention to usual care alone.

Objectives

Optimise the parameters for a phase 3 randomised controlled trial (RCT) of usual care plus the IDI compared to usual care alone, using the primary outcome of self-reported condom use at the 3 month follow-up.

Optimise the data collection and analysis procedures for a health economic analysis for a future phase 3 RCT.

Setting

Participants will be recruited from three Genitourinary Medicine (GUM) clinics: The Homerton Hospital Department of Sexual Health; Barts Sexual Health Centre; and City of Coventry Integrated Sexual Health Services Department.

Inclusion criteria

Clinic attendee

Male

Age 16 years and over

Able to read English

Internet access with an active e-mail account

Report of recent sexual risk behaviour:

Symptoms of acute STI or

Seeking treatment for an STI or

Two or more partners in the last year AND Non-condom use in the last 3 months

Exclusion criteria

HIV positive

Hepatitis B or C

Men who have sex with men (MSM):

Men who only have sex with men
 Men who more often have sex with men
 Men with no sexual experience

Intervention

Participants will work through a structured, individually tailored website whilst they are in clinic. Participants will receive access to the entire website; however, tailored information based on their individual responses regarding barriers to condom use will be presented most prominently on the homepage. They will be asked to set goals to change their behaviour. They will be sent text messages and/or e-mails to encourage them to visit the intervention website after leaving the clinic.

The intervention group will also receive usual clinical care.

Control

Usual clinical care.

Trial procedure

Clinic staff or researchers, flyers and posters will inform potential participants about the trial and direct them to the trial website available on an iPad in the clinic waiting room or side room. The software will take them through eligibility screening and consent. Eligible, consenting participants who provide contact details including at least an e-mail address and mobile number will be asked to create a password which will instigate a unique participant identifier (ID). Demographic and baseline questionnaire data will be collected electronically by the software. Participants will then be randomly allocated, by the software, to the intervention or control group. They will be informed of their allocation. The ID will give access to the intervention website for only those randomised as such. Automated e-mail reminders, including a link to the questionnaires, will be sent to all participants for the 3, 6 and 12 month follow-ups.

Sample size

Power calculations were performed based on data from the Sexunzipped online trial. The study is sufficiently powered to allow estimates of the effect of the intervention on episodes of condomless vaginal sex over the last 3 months. A sample size of 166 (83 intervention, 83 comparator, randomised 1:1 between experimental and control conditions) is adequate to find a reduction of 1.35 episodes of condomless sex with a conventional two sided alpha of .05 and 90% power. Even when accounting for potential loss to follow-up at 3 months (which is the primary outcome point), 122 participants (61 intervention, 61 comparator) is adequate to find a reduction of 1.35 episodes of condomless sex with a conventional two sided alpha of .05 and 80% power. In addition, this sample size is also sufficient to detect a 1.65 difference in safer sex intention, and a one-point difference in self-efficacy on Likert scales, with a conventional two sided alpha of .05 and 90% power.

Randomisation

The trial software will randomly allocate participants to the intervention or control groups in a ratio of 1:1 using a computer algorithm.

Blinding

Data collection is automated and trial personnel will be blind to allocation. Participants will be informed whether they have been allocated to the intervention immediately post automated randomisation.

Data entry

The majority of the study data will be entered directly by participants using the online questionnaires integral to the tailored software. Baseline data will be collected before randomisation and then participants will be prompted to complete follow-up questionnaires at 3, 6 and 12 months. Data will be saved and exported using ID numbers only.

Additional data will be collected by study personnel from clinical notes with regard to visits to the recruiting clinics, and diagnoses of STIs. Data for the period covering 6 months prior to the date of recruitment of the first patient up to 12 months from date of recruitment of the last patient will be collected for ALL patients.

Data collection

Baseline data collected with further follow-up data at 3, 6 and 12 months post initial clinic visit (point of randomisation).

Demographic (baseline) data

Age (in years)

Employment status (choice of 1 of 6 categories or “other” with free text)

Ethnicity (choice of 1 of 15 categories plus “other” with free text or “prefer not to say”)

Baseline data (over last 3 months)

Number of female partners:

Regular

Occasional

One off

Sex worker

Other (plus free text)

Number of male partners:

Regular

Occasional

One off

Sex worker

Other (plus free text)

Number of women had condomless sex (vaginal or anal) with

Number of times had condomless sex (vaginal or anal) with a woman

Number of men had condomless anal sex

Number of times had condomless sex because drunk or high

Any STIs (tick all that apply of 10 options, plus “can’t remember name”, “other” with free text and “none”)

Antibiotic treatment for STI (Yes/No)

Female partner pregnant (Yes/No/Don’t Know)

Outcome (4 categories plus “Don’t Know”)

Motivation to use condoms (4 options plus ‘does not apply for me’ with free text)

Intention to use condoms (4 options plus ‘does not apply for me’ with free text)

Impact of condom use on sexual pleasure (each likert rating scale: strongly disagree, disagree, undecided, agree, strongly agree):

Feel unnatural

Interrupt mood

Don’t feel good

Reduce quality of climax/orgasm
 Uncomfortable
 Don't fit right
 Feel closer to partner without
 Worry less if use
 Partners worry less if use
 Sexual health Quality of Life (each likert rating scale with 4 categories):
 Sexual performance
 Sexual relationship
 Sexual anxiety
 General health **today** (EQ5D – each likert rating scale with 3 categories):
 Mobility
 Looking after myself
 Usual activities
 Pain or discomfort
 Feeling worried, sad or unhappy
 General Health (EQ5D):
 Mark thermometer (0-100)

Three, six, nine and twelve month data (each over previous 3 months)
(Red text indicates data NOT collected at baseline)

Number of female partners:

Regular
 Occasional
 One off
 Sex worker
 Other (plus free text)

Number of male partners:

Regular
 Occasional
 One off
 Sex worker
 Other (plus free text)

Number of women had condomless sex (vaginal or anal) with

Number of times had condomless sex (vaginal or anal) with a woman

Number of men had condomless anal sex

Number of times problems experienced (0, 1, 2, 3 or more):

Condoms not available
 Using condoms stored in wallet more than 1 month
 Using condoms not lubricated
 Applying condom after sex begun
 Removed condom before sex finished
 Not changing condom between different forms of sex
 Erection lost when putting on condom
 Erection lost during sex
 Condom broke
 Condom slipped off during sex
 Condom slipped off during withdrawal
 Ejaculate dripped on partner's genitals
 Condom put on wrong way then turned around
 Not changing condom between different partners

Number of times had condomless sex because drunk or high

Types of contraception used (tick all that apply of 9 options, plus "don't know", "none", "none – trying for baby", "don't know name" and "other" with free text)

Any STIs (tick all that apply of 10 options, plus “can’t remember name”, “other” with free text and “none”)

Antibiotic treatment for STI (Yes/No)

Female partner pregnant (Yes/No/Don’t Know)

Outcome (4 categories plus “Don’t Know”)

Number of times used each sexual health service:

Condom pick-up

Self-test kit

Urine test/swabs (GP)

Urine test/swabs (clinic)

Blood test (GP)

Blood test (clinic)

STI treatment (GP)

STI treatment (clinic)

Sexual health advice (GP)

Sexual health advice (clinic)

Outreach

Counselling or therapy

Other (specify)

Self-efficacy (each likert rating scale: strongly disagree, disagree, undecided, agree, strongly agree):

Get hold of condoms

Use condom correctly

Put condom on without erection loss

Remove and dispose of condom

Choose correct condom

Discuss condom use with partner

Suggest condom use with new partner

Suggest condom use with new partner without them feeling diseased

Remember to use even if drunk/high

Stop to put condom on in heat of the moment

Knowledge (True/false/unsure):

Getting STIs is just luck

Would know you have STI without test

Can tell who has an STI

Can have HIV and not know

Can Catch STIs from oral sex

Safe from catching STIs if in a relationship

Less likely to catch an STI from someone you know

Some STIs can’t be treated

With condom on only withdraw after penis soft

Baby oil or Vaseline is a good lubricant

Standard sized condoms are suitable for all

Motivation to use condoms (4 options plus ‘does not apply for me’ with free text)

Intention to use condoms (4 options plus ‘does not apply for me’ with free text)

Evaluation of condom use (choice of 1 of 4 categories)

Impact of condom use on sexual pleasure (each likert rating scale: strongly disagree, disagree, undecided, agree, strongly agree):

Feel unnatural

Interrupt mood

Don’t feel good

Reduce quality of climax/orgasm

Uncomfortable

Don’t fit right

Feel closer to partner without

Worry less if use

Partners worry less if use

Communication, discussed following with partner(s) (Yes/No):

How to prevent pregnancy

How to use condoms

How to prevent STIs/HIV

Your sex history

Their sex history

Identity (each likert rating scale: strongly disagree, disagree, undecided, agree, strongly agree):

Feel like a responsible person so use condoms

Feel like a spontaneous person so don't use condoms

Using condoms is the woman's responsibility

Condoms make me feel less of a man

Use condoms due to health concerns

Use condoms due to concerns about partner's health

Getting a girl pregnant proves I'm a real man

Sexual health Quality of Life (each likert rating scale with 4 categories):

Sexual performance

Sexual relationship

Sexual anxiety

General health **today** (EQ5D – each likert rating scale with 3 categories):

Mobility

Looking after myself

Usual activities

Pain or discomfort

Feeling worried, sad or unhappy

General Health (EQ5D):

Mark thermometer (0-100)

Has being part of the study had any good or bad effects on your life (explain)? (free text)

Additional data

Website usage data (number of times site visited, number of times pages visited, number of pages visited).

Intervention development costs.

Recruitment and retention rates.

Primary outcome

Number of episodes of condomless vaginal or anal sex with a woman (without a condom) over the previous 3 months at the three months follow-up.

Secondary outcome

STI diagnoses **from clinic notes**: total number of new STI diagnoses in the last twelve months.

Other outcomes (each collected baseline at 3, 6 and 12 months except where indicated)

STI diagnoses **from self-report**: total number of STIs* in previous 3 months at each follow-up (3, 6 and 12 months).

*(exclude possible recurring conditions: i.e. include only Chlamydia, gonorrhoea, pubic lice, trichomoniasis, NSU)

Problems with condom use (score calculated from 14 questions each with frequency category: 0, 1, 2, 3 or more times). **Not collected at baseline.**

Number of times condomless sex because drunk or high.

Condom use self-efficacy (score calculated from 10 questions each with Likert scale: 1 of 5 options). **Not collected at baseline.**

Knowledge (score calculated from 11 questions each with yes/no/unsure response). **Not collected at baseline.**

Motivation to use condoms (single question: 1 of 4 options).

Intention to use condoms (single question: 1 of 4 options).

Evaluation of condom use (single question: 1 of 4 options). **Not collected at baseline.**

Impact of condom use on pleasure (score calculated from 9 questions each with likert scale: 1 of 5 options).

Communication (score calculated from 5 questions each with yes/no response). **Not collected at baseline.**

Identity (score calculated from 7 questions each with likert scale: 1 of 5 options). **Not collected at baseline.**

Analysis population

Individuals who have both baseline (where appropriate) and follow-up data available will be included in the analyses.

Data analysis

All analyses will be undertaken on an intention to treat (ITT) basis using available data.

Missing data

Missing data is likely to be not missing at random. However, under the assumption that there is no interaction between treatment group and “missingness” a complete case analysis will provide unbiased estimates.

CONSORT diagram

A consort diagram will be produced summarising:

Numbers of individuals initially interested in participating in the trial;

Numbers meeting the eligibility criteria;

Numbers consenting to be randomised;

Numbers randomised to each group;

Numbers completing follow-up questionnaires at each time point (by group).

Descriptive analysis

Descriptive data for all variables will be presented by group and overall for each follow-up: baseline, 3, 6 and 12 months.

Continuous data that are approximately normally distributed will be summarised in terms of the mean, standard deviation and number of observations. Skewed data will be presented in terms of the median, lower quartile, upper quartile and number of observations. Categorical data will be summarised in terms of frequency counts and percentages. No statistical inference will be used (i.e. there will be no significance testing or use of confidence intervals).

Analysis of primary outcome

Comparison between the intervention and control group of the number of episodes of condomless vaginal or anal sex with a woman (without a condom) over the previous 3 months at the three months follow-up will be undertaken using Poisson regression.

The baseline value for this outcome will be used as an explanatory variable. The ratio of the number of events over the three month period, between the intervention and control group with an associated 95% CI and p-value will be estimated from this model.

The model will be assessed for the presence of over dispersion (extra Poisson variability). If there is evidence of over dispersion a random intercepts term will be included to model the over dispersion.

Sensitivity analyses

Additional analyses, as per the model described above, will be undertaken in order to assess the robustness of the results. This will include:

- (i) The assumption that individuals with missing outcome data in the intervention group had a poorer outcome than individuals with missing data in the control group
- (ii) The assumption that individuals with missing outcome data in the control group had a poorer outcome than individuals with missing data in the intervention group

Analysis of secondary outcome

Comparison between the intervention and control group for the secondary outcome will be based on generalised linear models with appropriate link function and error structure. Baseline data for the outcome has will be included as an explanatory variable in the model.

Analysis of other outcomes

Descriptive data for all variables will be presented by group and overall for each follow-up: baseline, 3, 6 and 12 months (where collected).

No formal statistical comparisons will be undertaken.

Economic Analyses

Aim of analysis

There are two key aims of the analysis:

- 1) Assess the feasibility of collecting QoL and health care resource use to do a cost-effectiveness analysis of a digital sexual health intervention; and
- 2) Assess the suitability of using the SQoL and EQ-5D and associated utility scores to calculate quality adjusted life years (QALYs) for an incremental cost-utility ratio.

Calculating utility scores

Individual level utility scores will be calculated from individual responses to the EQ-5D and the SQoL at baseline, 3, 6 and 12 months. The EQ-5D utility scores will be calculated using the algorithm published by Dolan and the SQoL using the re-scaled utility algorithm where death equals zero published by Ratcliffe et al (2009).

Agreement of QoL measures

Descriptive statistics including mean, standard deviation, data completeness and box plots to assess ceiling and floor effects will be reported for the utility scores for the EQ-5D and SQoL. Pairwise agreement between the two different QoL instruments will be assessed using the Bland and Altman approach. The Pearson's correlation coefficient for the correlation between the EQ-5D and SQoL will be reported in addition to the correlation the two questionnaires and: the primary outcome, other measures of instances of condomless sex, total number of times problems are experienced with condoms, self-efficacy, impact of condom use on sexual pleasure and communication. We will use appropriate regression models to see if there is any significant relationship with STI diagnosis and antibiotic treatment. 95% confidence intervals will be constructed from bootstrapping.

Suitability of Sexual health care resource use questionnaire

Descriptive statistics for the different types of sexual health resource use at each follow up point will be reported, along with data completeness. Sexual Health resource use collected via individual questionnaire will be compared with resource use collected from patient records.

Cost of the intervention

We will calculate the total cost of developing and maintaining the MenSS website. There is no clear way to incorporate these costs into an economic evaluation given (a) the intervention has now been developed and hence could be considered a "sunk cost" as no further costs are required to develop it; (b) it is free to patients and providers at the point of access; (c) it is unclear how many people will go on to use the site hence the cost per patient is hard to calculate; and (d) it may be hard to disentangle costs associated with the trial (e.g. developing questionnaires and databases to store trial related data) with the costs of developing the intervention and day to day maintenance if it were to be made widely available. An estimation of the cost of the website being implemented in practice is also potentially relevant. As a result we will report the different costs associated with developing the website, and the number of individuals that accessed the website to give some estimation of cost per individual. This will be subject to extensive sensitivity testing of the different assumptions though as part of the analysis.

Cost of 12 month health and social care service use

Sexual health service use for the intervention and control group will be calculated from patient completed questionnaires at baseline, 3, 6 and 12 months. These will be costed for each patient using unit costs from the most recent Unit Costs of Health and Social

Care published by the Personal Social Services Research Unit, Department of Health reference costs, sexual health commissioning guidance and other published sources. Mean cost per patient for intervention and control groups will be reported by type of service use for each follow up point and the total 12 months. Total 12 month costs and CIs will be calculated from bootstrapping and adjusted by baseline service use from patient records.

QALYs

We will calculate the mean quality adjusted life year (QALY) of the MenSS website compared to control over 12 months. QALYs will be calculated using the EQ-5D and the formula developed by Dolan and colleagues. We will calculate the mean area under the curve for each group from baseline to 12 months, controlling for any baseline differences using regression analysis.

We will also calculate the mean QALYs of the MenSS website compared to control over 12 months calculating QALYs from utility scores obtained from the SQoL.

Confidence Intervals and Missing data

Confidence intervals will be constructed using bootstrapping. Missing data will be handled in line with the rest of the statistical analysis plan (complete case).

Incremental cost-effectiveness ratio (ICER)

The mean costs and QALYs calculated above will be used to calculate the mean incremental cost per QALY gained of MenSS compared to control.

The incremental cost per infection avoided and per change in primary outcome will also be reported.

Cost-effectiveness plane (CEP) and cost-effectiveness acceptability curve (CEAC)

The results of the non-parametric bootstrap will be presented on a CEP. A CEAC will also be constructed using the bootstrap data from a range of values of willingness to pay for a QALY gained. The probability that the website is cost-effective compared to control at a willingness to pay for a QALY gained of £30,000 will be reported.

Sensitivity Analyses

If any key assumptions become apparent during the analysis these will also be tested for as part of the sensitivity analyses – in particular in relation to the cost of the intervention and the impact it has on the results and cost estimations from different methods of collecting resource use.

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and flow.

EME
HS&DR
HTA
PGfAR
PHR

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