

BMJ Open 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

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ABSTRACT

Introduction: Sexually transmitted infections (STI) are a major public health problem. Condoms provide effective protection but there are many barriers to use. Face-to-face health promotion interventions are resource-intensive and show mixed results. Interactive digital interventions may provide a suitable alternative, allowing private access to personally tailored behaviour change support. We have developed an interactive digital intervention (the Men's Safer Sex (MenSS) website) which aims to increase condom use in men. We describe the protocol for a pilot trial to assess the feasibility of a full-scale randomised controlled trial of the MenSS website in addition to usual sexual health clinical care.

Methods and analysis: Participants: Men aged 16 or over who report female sexual partners and recent unprotected sex or suspected acute STI. Participants (N=166) will be enrolled using a tablet computer in clinic waiting rooms. All trial procedures will be online, that is, eligibility checks; study consent; trial registration; automated random allocation; and data submission. At baseline and at 3, 6 and 12 months, an online questionnaire will assess condom use, self-reported STI diagnoses, and mediators of condom use (eg, knowledge, intention). Reminders will be by email and mobile phone. The primary outcome is condom use, measured at 3 months. STI rates will be recorded from sexual health clinic medical records at 12 months. The feasibility of a cost-effectiveness analysis will be assessed, to calculate incremental cost per STI prevented (Chlamydia or Gonorrhoea), from the NHS perspective.

Ethics and dissemination: Ethical approval: City and East NHS Research Ethics Committee (reference number 13 LO 1801). Findings will be made available through publication in peer-reviewed journals, and to participants and members of the public via Twitter and from the University College London eHealth Unit website. Raw data will be made available on request.

Trial registration number: Current Controlled Trials. ISRCTN18649610. Registered 15 October 2013 <http://www.controlled-trials.com/ISRCTN18649610>.

INTRODUCTION

Men's sexual health

Sexually transmitted infections (STI) are a major public health problem, with high social and economic costs.^{1 2} Condoms are effective for prevention of STI; however, there are many barriers to successful 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} The prevention of pregnancy is often a stronger motivation for condom use than prevention of STI.⁵ Condoms may be perceived as a barrier to intimacy and trust,⁴ and use is often lower in established relationships.⁶

Since it is men who primarily experience many of the disadvantages of using male condoms (eg, reduced pleasure), and have the power to influence condom use for penetrative sex (since they wear condoms), prevention efforts are needed to target the obstacles to condom use that men face.³ While 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),^{7 8} despite the fact that MSW report much less consistent condom use than MSM.⁹ Men are less likely than women to visit health

professionals and generally have shorter clinic appointments,^{10 11} so they may be less likely to be offered health promotional advice or risk reduction counselling in the context of routine appointments. Men may be reluctant to discuss their sexual health with health professionals, partners or friends.¹² An online intervention therefore offers an alternative avenue to reach men.¹³

Sexual health interventions

Guidance from the National Institute for Health and Care Excellence recommends that people at high risk of STI are offered one-to-one structured discussions to address risk-taking,¹ and this is increasingly being offered as part of routine care in genitourinary medicine and other healthcare settings. While interventions such as motivational interviewing can 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 (IDI).

We define IDI as ‘Computer-based programmes that provide information and one or more of decision support, behaviour change support, or emotional support for health issues’.¹³ IDI require contributions from users to produce personally relevant tailored material and feedback. IDI are highly suitable for sexual health promotion because access can be private, anonymous and self-paced,¹⁴ 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 (eg, by age, gender or sexuality), and content can be tailored for individuals.¹⁵ IDI can be expensive to develop but offer the advantages of intervention fidelity¹⁶ and the potential to reach large audiences at relatively low dissemination costs.

IDI can improve sexual behaviour (including condom use),^{13 17} as well as increasing knowledge, self-efficacy and safer sex intention.^{13 18} More evidence is needed to establish effects on biological outcomes (STI) and cost-effectiveness. The Men’s Safer Sex (MenSS) website is an IDI which aims to increase condom use and reduce STI in men attending sexual health clinics. The present pilot trial aims to determine the optimum parameters of a full-scale randomised controlled trial (RCT) to assess the efficacy of the MenSS website intervention.

OBJECTIVES

To establish the feasibility and optimal design of a full-scale RCT to test the effect on condom use and STI acquisition of the MenSS intervention website for men attending sexual health clinics:

- ▶ Conduct a pilot trial to optimise the parameters for a phase III RCT of usual clinical care plus the IDI compared to usual clinical care only, using the primary outcome of self-reported condom use at 3-month follow-up.

- ▶ Optimise the data collection and analysis procedures for a health economic analysis for a future Phase III RCT.

Methods and analysis

The pilot trial will be a phase II proof of concept RCT to evaluate the effect of the MenSS IDI on increasing condom use in addition to usual clinic care for men in sexual health clinics.

Setting

Participants will be recruited from three sexual health clinics: The Homerton Hospital Department of Sexual Health, St Bartholomew’s Sexual Health Centre, and City of Coventry Health Centre Integrated Sexual Health Services Department. These clinics serve a diverse range of patients in terms of age, socioeconomic status and ethnicity.

The intervention

The MenSS website content and design was developed based on evidence from the sexual health research literature and theories of behaviour change, qualitative interviews with men in sexual health clinics, and discussions with clinical and academic experts in sexual health and digital technologies.¹⁹ The development process was iterative, with a high level of user involvement. The intervention is designed to be delivered initially in clinic, to make use of the time when patients are waiting to be seen, but also providing (and encouraging) online access after patients have left the clinic.

The MenSS intervention consists of an interactive website. While in clinic, users will be presented with a tailored package of website content which addresses individual men’s barriers to condom use. The site targets a number of influences on effective condom use, such as:

- ▶ Condom knowledge (eg, about sizes and types of condoms);
- ▶ Condom use skills;
- ▶ Difficulties in negotiating condom use;
- ▶ Inaccurate beliefs about STI risk;
- ▶ Social influences, such as perceived/expected partner response;
- ▶ Sexual pleasure;
- ▶ Being caught in the ‘heat of the moment’;
- ▶ Alcohol and drug use.

While in clinic, users will be asked to select their own personal barriers to condom use. This task will produce a tailored package of information, offering solutions or counter-arguments to barriers (including interactive activities and quizzes, videos and case vignettes), which will be presented prominently on the homepage. Some content is presented to all users (eg, training in condom use skills), and all content will be available via website navigation tabs. Participants will be led through their tailored content package sequentially, and will be asked to set goals to change their behaviour. If wanted,

participants will receive emails to assess achievement of goals, and to encourage them to visit the intervention website again.

Procedure

Participant recruitment is designed to be self-directed, using a touch screen tablet computer, which will be available in the clinic waiting room. Participants will be directed to the tablet computer via brief information leaflets and posters in the waiting room, or by clinic staff. The trial software is set up to allow participants to be led through the steps of screening, consent, automatic randomisation, data collection and intervention viewing, without assistance from clinic staff (figure 1). A member of the study team or the sexual health clinic research staff will be present if needed to provide technical assistance and to answer questions about the study.

Online eligibility, consent, registration, randomisation, data collection

The tablet computer in the clinic waiting room will present information about the trial and an invitation to participate. Potential participants will then be asked to complete a screening questionnaire to determine their eligibility for the trial. Those who are ineligible at this point will be informed of this, and thanked for their time. Those who are eligible will receive detailed information regarding the study. Participants will be asked to give informed consent by agreeing to a number of statements (see online supplementary appendix 1: online participant information and consent). They will then be asked to give their contact details (email address and telephone number), in order to contact them for follow-up assessments, to send them reminders to view the website, to remind them that they are participating in the trial, and

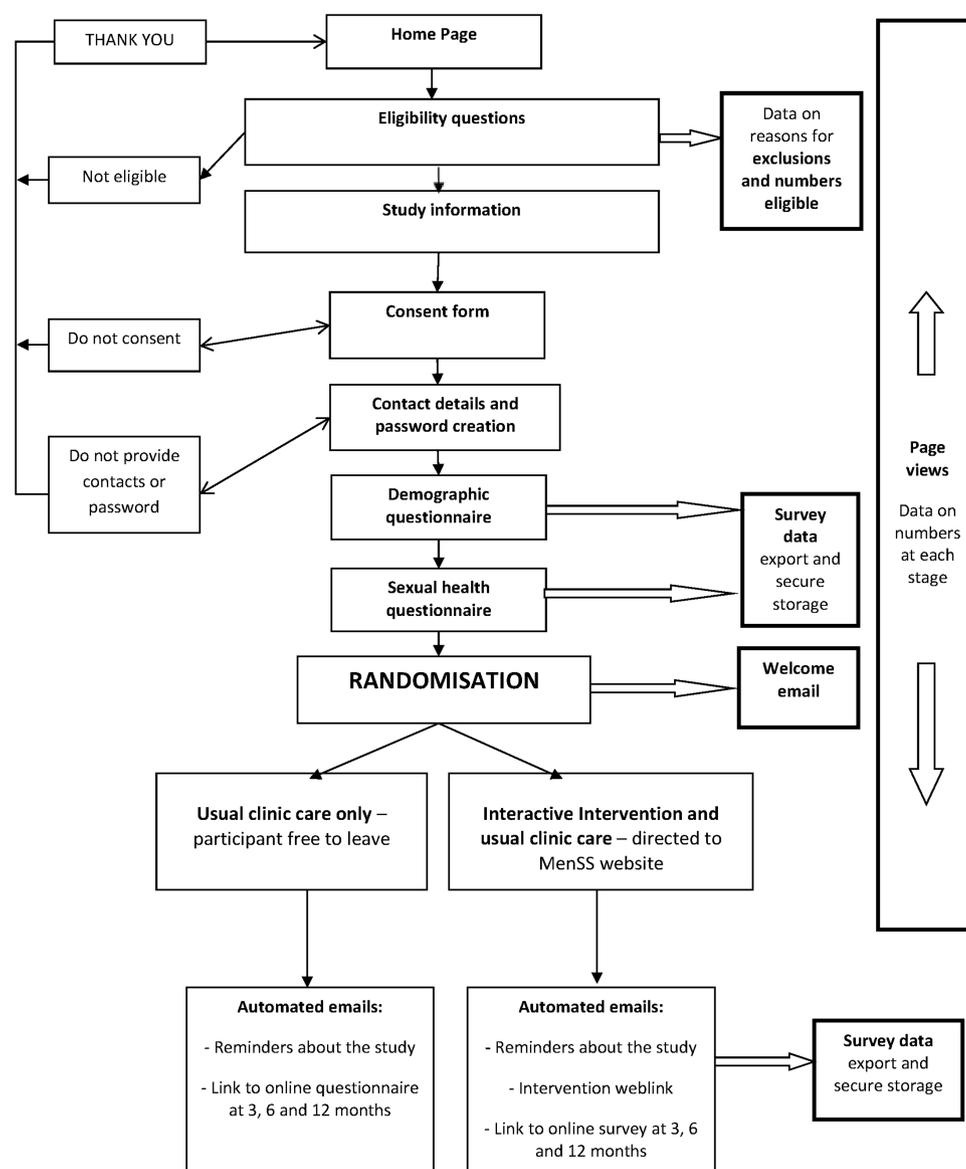


Figure 1 Men's Safer Sex trial software framework: online study information, consent, registration, data collection and randomisation.

to send an electronic shopping voucher to recompense participants for their time. Participants will also be asked to create a password. The password will give the intervention group access to the intervention website, which will also enable collection of website usage data. It will also be needed to access the follow-up questionnaires. Demographic and baseline sexual health data will then be collected. At this point, the software program will use a computer algorithm to randomly allocate participants to either the intervention or control conditions. This allocation will be unalterable.

Follow-up data collection

At 3, 6 and 12 months after their initial clinic visit, participants will receive an automated email asking them to complete a follow-up questionnaire (see Outcome assessment section), by clicking on a weblink to an online questionnaire. If they do not complete the questionnaire, they will receive three further email prompts, at 1-week intervals, as well as two text messages to their mobile phone (again including the weblink) alongside the latter two emails. If participants still do not respond, the researcher will telephone participants a week after the final email to remind them to fill in the study questionnaire. Information about STI diagnoses will be collected at all time points via self-report, and at 12 months by recording diagnoses or suspected diagnoses over the past year recorded in the clinical notes at the sexual health clinics participants are recruited from.

Inclusion and exclusion criteria

Inclusion criteria

Men aged 16 years and above (with no upper age limit); able to read English; with access to the internet; and at high risk of future STI (ie, two or more partners in the past year (male or female) and some non-condom use in the past 3 months; or symptoms of acute STI; or seeking treatment for an STI); and for whom at least half of their sexual partners are female.

Exclusion criteria

HIV-positive men and men with hepatitis B or C will be excluded, since patients with these diagnoses are likely to receive risk reduction advice in the course of routine clinical care. We will exclude men who have had sexual experience only ever with males, more often with males but at least once with a female, or no sexual experience at all.²⁰

Randomisation

Once participants have been checked for eligibility, given informed consent, and submitted baseline data, they will be allocated by the computer algorithm randomisation system to either the intervention or control group. The participant will be informed with an automated message on the tablet computer, and this allocation will be unalterable.

Allocation concealment

Allocation will be undertaken using a concealed automated computer-based algorithm, which will be immediate.

Participants allocated to the control condition will be notified that they have not been selected to view the intervention and told that they will be contacted again in 3, 6 and 12 months to gather follow-up data. Those allocated to the intervention condition will be directed to the intervention website where they will be presented with a tailored package of health promotion/behaviour change content. Website usage (page views) will be automatically recorded.

Outcome assessment

Development of the online measurement instrument

We adapted the Sexunzipped online sexual health questionnaire²¹ 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. We conducted interviews with men in sexual health clinics (N=11) to gain feedback on successive versions of the outcome questionnaire. Interviews with men checked their understanding of questions, the clarity of questions, and content suitability for the selected measures of behavioural outcomes and mediators of those outcomes. On the basis of feedback, we modified the structure and content of the outcome questionnaire.

Mediators of behaviour change (eg, beliefs about pleasure, motivation, knowledge, self-efficacy), behavioural outcomes (including condom use, STI testing, communication with partner/s) and cumulative STI incidence (self-reported and from clinical notes) will be measured. Service use and quality of life will be measured for the cost-effectiveness analysis. The primary outcome will be self-reported condom use at 3-month follow-up.

Measures

In the light of evidence that measurement alone may prompt behaviour change,²² we will measure a limited number of outcomes (condom use and the main mediators, and self-reported STI diagnoses) at baseline; we will also assess a full range of outcomes at 3, 6 and 12 months (table 1). All assessments have a recall period of the previous 3 months, which is the time between follow-up assessments.

Outcome measures

The online outcome measurement instrument is detailed in full in online supplementary appendix 2.

Demographics

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

Table 1 Variables assessed at each time point

Baseline measures	3-month, 6-month and 12-month follow-up assessments
Demographic details (age, occupation, ethnicity)	
Sexual health outcomes	
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
Health-related quality of life	Health-related quality of life
	Service use
Mediators of condom use	
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 due to intoxication	Non-condom use due to intoxication
	Evaluation of condom use
	Communication
	Identity
	Self-efficacy
	Condom problems
	Knowledge

Condom use

The objective of the study is to promote condom use with female partners, so the primary outcome is the number of episodes of unprotected vaginal sex (without a condom) over the previous 3 months, assessed at the 3-month follow-up. We expect the majority of change in behaviour to occur shortly after recruitment, as we expect users will be most likely to engage with the intervention during the clinic visit.

Sexual partners

Participants will be asked to report the number and type of sexual partners over the past 3 months (both female and male). We will also assess the number of partners participants have had unprotected sex with over the previous 3 months: female (vaginal and anal sex) and male (anal sex).

Contraception use and pregnancy

Participants will be asked to indicate which types of contraception (if any) they are using with current partners. Participants will be asked whether a female partner has been pregnant in the past 3 months, and the outcome of that pregnancy (if known).

STI diagnoses

Participants will be asked to report STI diagnoses over the past 3 months at every follow-up point. We will also assess whether participants have received treatment due to a partner being diagnosed with an STI. In order to assess laboratory diagnoses, all STI diagnoses recorded in sexual health clinic records (in the participating sites) over the study period will be noted at 12 months.

Health-related quality of life

Health-related quality of life (HRQoL) will be assessed using the EQ-5D,^{23 24} which is a 5-item, 3-level questionnaire covering self-care, usual activity, anxiety and depression, and pain and mobility. We will also use a newly developed sexual health Quality of Life Scale,²⁵ and compare its performance with the EQ-5D, to assess its suitability for outcome assessment in a sexual health context.

Service use

Use of a variety of sexual health services over the period of the study will be assessed (eg, sexual health clinics, general practice, outreach services).

Measuring mediators of condom use

While it is important to assess changes in behaviour, it is also important to assess the mediators of behaviour change. This provides information about the mechanisms by which behaviour might have changed. The mediators measured were identified following consultation with experts, a review of the literature, interviews with the target population, and using the theoretical frameworks of the COM-B model²⁶ and the PRIME theory of motivation.²⁷

Condom use errors and problems

To ensure that condom use is 'correct', and to assess any impact on condom use skills, we will assess condom use problems at all time points, using a measure defined by Crosby *et al*,²⁸ 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 clarity.

Knowledge

Knowledge (of risk of STIs and condom sizes) will be assessed using an 11-item measure, devised based on gaps in men's knowledge identified in the literature and in interviews with the target population. A number of 'true or false' statements regarding misconceptions about condoms and risk will be given (eg, 'You would know if you had an STI, without needing a test'; 'Standard sized condoms are suitable for all men').

Communication with partners

To assess communication with partners over a 3-month period, we adapted the six-item Partner Communication Scale.²⁹ The scale was adapted in the light of qualitative fieldwork, and the recall period was modified from 6 to 3 months, as follow-up assessments will be 3 months apart.

Identity

To assess potential links between identity (self-perception) and condom use,²⁷ we created a seven-item scale, derived from issues relating to condom use identity that had been identified during the fieldwork.

Beliefs about pleasure

Beliefs about pleasure will be assessed using an eight-item scale, adapted from the 'Effect of sexual experience' subscale of the Condom Perceived Barriers Scale.³⁰ The scale was adapted in the light of qualitative fieldwork, to improve relevance and clarity.

Self-efficacy

Self-efficacy will be assessed using a 14-item measure, adapted from the widely validated Brafford and Beck Scale.³¹ The scale was adapted in the light of qualitative fieldwork, to improve relevance and clarity.

Motivation, intention and evaluation of condom use

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

Alcohol and drug use

Alcohol and drug use were found in our fieldwork to be important factors in non-condom use. We therefore included a single item assessing the number of times in the past 3 months that participants had unprotected sex when intoxicated.

Engagement with the intervention (patterns of website use)

We will record website usage in order to assess engagement with the intervention (and whether this appears to be related to outcomes). The software used will record the number of times each user visits the site, the pages visited and the time spent on each topic section.

Adverse effects

We will record any adverse impacts on sexual health outcomes at 3, 6 and 12 months. Participants will be asked to report whether they have experienced any adverse impacts as a result of the study, recording this in a free text box on each of the follow-up questionnaires. Adverse impacts may also be identified when the research team liaise directly with participants (eg, participant emails or follow-up telephone calls to non-responders to questionnaires).

Intervention development costs and trial feasibility indicators

Intervention development costs and recruitment and retention rates will be reported.

Methods to protect against sources of bias

Participants will use the tablet computer without assistance, providing baseline data that will be submitted directly online. A study researcher will be available in the clinic and via telephone, solely to clarify research procedures and assist with technical problems. Baseline data will be collected prior to randomisation. Once eligibility for the study is established and baseline data are collected, allocation to the intervention or control group will be automatically randomly assigned by computer algorithm, and this will not be changeable by participants or researchers. Subsequent outcome data will be collected online using an emailed link to the online outcome questionnaire. Data will be exported and analysed using ID numbers only. Participants will be aware of their allocation to the intervention or control group, but the automated data collection procedures protect from researcher bias during data collection.

Maximising retention

We will follow up participants by email, texts and by telephone.^{32 33}

1. Automated emails, with three further follow-up emails at weekly intervals;
2. Two text messages—at the same time as the last two emails;
3. Contact via telephone a week after the final email.

We will offer participants a £10 online shopping voucher for filling in the online questionnaires at 3 and 6 months, with a £20 voucher for the final 12-month follow-up questionnaire. Vouchers will be sent by email.

STATISTICAL ANALYSIS PLAN

Sample size and power calculations

This is 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. We will also calculate the effect sizes of key outcomes including condom use over the past 3 months, to inform power calculations for a future phase III RCT.

The study is powered to allow estimates of the effect of the intervention on episodes of unprotected vaginal sex over the past 3 months. A sample size of 166 participants (83 intervention, 83 comparator, randomised 1:1 between experimental and control conditions) is adequate to detect a reduction of 1.35 episodes of unprotected 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, a sample size of 122 participants (61 intervention, 61 comparator) is adequate to find a reduction of 1.35 episodes of unprotected 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 one-point difference in self-efficacy on Likert scales, with a conventional two-sided α of 0.05 and 90% power ($1-\beta$).

Data analysis

Analysis of outcomes

Analysis of sexual health outcomes will be based on all participants according to their initial experimental allocation (on an intention-to-treat analysis). Analysis for the primary outcome will use a generalised mixed model, with log link and Poisson/mixed error. The response variable will be the number of episodes of unprotected vaginal sex for each subject. Explanatory variables will be the baseline ($\log_e(x)$) number of episodes of unprotected vaginal sex and the experimental condition. The analysis will include a generalised (random effects) overdispersion parameter. Comparisons of sexual health between intervention and control groups will include the baseline value of each outcome as subject level explanatory variables, so that analysis is of the difference in end point conditional on the within-subject baseline measure. For sexual health outcomes measured only at follow-up, we will compare effect sizes between intervention and control groups alone using all available data and describe loss to follow-up for each treatment condition. For other outcomes, analyses will be based on generalised linear models with appropriate link functions and error structures. Statistical analyses will be described a priori in a Statistical Analysis Plan, and the principal analyses will be implemented independently by two statisticians.

Mediation analyses

We will conduct a prognostic model in order to determine whether change in any of the mediating variables (eg, beliefs about pleasure, self-efficacy) is associated with any intervention effects. This will help to identify which elements of the website seem to be most influential.

Cost-effectiveness analysis

The principal aim of the economic data collection will be to determine the feasibility and validity of collecting cost and outcome data for a cost-effectiveness analysis within a phase III trial. We will conduct an initial cost-effectiveness analysis (CEA) of incremental cost per gain

in outcome, looking at the cost per STI prevented (*Chlamydia* or *Gonorrhoea*), comparing intervention participants with controls from the NHS perspective. This will include one-way, two-way and parametric sensitivity tests.

The aim of the analysis will primarily be to evaluate whether information collected is fit for the purpose, and to inform information collection in a future trial. We will examine the feasibility of collecting cost data for intervention and control participants including costs associated with STI tests and treatments, and contract tracing, testing and treatment. Trial subjects may access sexual health services from a range of providers, so information from sexual health clinic notes alone may prove unreliable. We will therefore ask participants about sexual health-related health service contacts over the past 12 months as part of the self-reported outcomes. Information collected from sexual health clinic notes will be used to assess the reliability of the self-reported information collected. Personal Social Services Research Unit (PSSRU) reference costs,³⁴ British National Formulary³⁵ and other national sources of costing information will be used to calculate unit costs. Costs associated with the maintenance of the intervention website and updating the website will also be included.

STIs prevented will be calculated by taking account of diagnoses recorded from clinical records at 12-month follow-up as well as self-reported episodes for the previous year. We will calculate the cost per episode of *Chlamydia* or *Gonorrhoea* prevented for the intervention group versus controls. The National Institute of Health and Care Excellence (NICE) recommends that quality-adjusted life years (QALYs) are used as the outcome in CEA, to allow for the comparison of results for different CEA across disease areas. QALYs are calculated by multiplying HRQoL by the amount of time spent in the HRQoL state. The EQ-5D is the questionnaire recommended by NICE to calculate HRQoL;²⁴ it has been recognised, however, that the EQ-5D may not be suitable for economic evaluations of public health interventions as it may not capture the relevant information on the full psychosocial impact of public health interventions or be sufficiently sensitive for that purpose.^{36 37} We will therefore also collect data on the performance of the Sexual QoL questionnaire²⁵ to assess its suitability for use in a future large-scale RCT.

Acquisition of STI may have cost and QALYs impacts that occur beyond the end of the trial, so it is important that this information is accounted for as part of the model. This is commonly achieved by a decision analytical model that has a time horizon beyond the end of the trial and combines cost and outcome data from a range of published sources in addition to trial information. As a result, we will design a decision analytical model that will take account of costs and QALYs for the lifetime of the service users. The values in the decision analytical model will come from a comprehensive review of the literature including the efficacy of condoms, research to increase condom use and the incidence and

prevalence of STIs. The quality of each type of evidence and relevance to the UK context will be assessed to determine the best coefficients to use in the cost-effectiveness model.³⁶ We will also aim to determine utility values for the long-term QALYs outcomes associated with STIs. The final model will compare the incremental cost per QALYs gained and cost per STI prevented of the internet based intervention versus the control group. It will be subject to one-way, two-way and probabilistic sensitivity analyses and a cost-effectiveness acceptability curve calculated to determine the probability that the internet based intervention is cost-effective for a range of values of willingness to pay for an outcome gained.

ETHICAL ISSUES

Potential ethical issues

This project aims to encourage behaviour change to reduce morbidity and the social and emotional costs of STI acquisition, with the aim of benefiting trial participants as well as wider society. There is a risk that the study may unintentionally exacerbate the stigma of STI and risky behaviour for participants. We strive to be non-judgemental about choices of lifestyle or behaviour, respecting others' autonomy. It could be that participants' partners or others see the intervention website, texts to participants' mobile phones or email messages. Study information makes clear to participants the nature of study-related communications and possible risks. However, there is a danger that this may be accessed by others and that this leads to embarrassment or relationship difficulties in some way. A component of the intervention will focus on communication with partners, so it is hoped that the intervention will improve the quality of relationships rather than cause harm. Participants will receive detailed information about the study including risks and benefits while being led through the consent process on the trial software. Participants will be offered the opportunity to ask the researcher any further questions.

Informed consent form and information sheet

Informed consent will be obtained using a standardised Participant Information Sheet and consent form (both integrated into the trial software), which have been approved by the London City and East ethics committee and local NHS Research and Development offices (see online supplementary appendix 1).

All participants included in the trial will be asked for their consent to take part and for their contact details to be used to communicate with them (eg, for follow-up questionnaires, and reminders to use the website), and for data obtained as a result of their use of the NHS services (ie, medical records) to be used for research purposes. Users will not be able to register for the study unless they consent to all statements. We will ensure that all research procedures meet the highest standards for

data protection and confidentiality, storing data on an encrypted server. We will give participants the contact details for support organisations in case they are needed, and follow protocols to ensure the safety and well-being of participants under the age of 18 who may be at risk of harm.

Protocol amendments

Protocol amendments will be communicated to the funder (NIHR Health Technology Assessment programme), the Trial Steering Committee, the Trial Management Group, the research sponsor and to the research ethics committee.

Ancillary and post-trial care

Trial participants who request help will be advised to contact appropriate healthcare organisations (eg, their general practitioner) and offered the details of appropriate telephone helplines or online resources. All trial participants (including those allocated to the control group) will be offered access to the MenSS website at the end of the trial, for a period of 3 months.

DISSEMINATION

The following papers will be prepared and submitted for publication in peer-reviewed journals:

- ▶ Description of the development process of the MenSS intervention website;
- ▶ Description of the content of the MenSS intervention website;
- ▶ Main findings of the pilot trial;
- ▶ Findings of a qualitative process evaluation of trial procedures;
- ▶ Exploration of the relationship between mediators of condom use behaviour and outcome measures.

Findings will also be made available to participants and members of the public via Twitter and via a weblink from the University College London eHealth Unit website.

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Contributors All co-authors except SD contributed to the design of the pilot trial. SD conducted interviews with men to refine the online outcome measure. RW, JVB, GR, SM, CE, JA, MG, JS, CSA, GH and EM contributed to the conceptual

design of the MenSS intervention website. NF designed the statistical analysis plan and RH designed the health economic analysis plan. JVB and RW wrote the first draft of the paper and all coauthors were involved in revising the paper, and have given final approval of the version to be published.

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Competing interests None.

Patient consent Obtained.

Ethics approval The study was approved by the City and East NHS Research Ethics Committee (Study reference number 13 LO 1801).

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

Data sharing statement Anonymised data will be available on request once the study is complete and data have been analysed by the research team.

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Appendix 1 - MenSS Trial online study information and consent form

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

V5 6th May 2014

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

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

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

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on 07768100384, email rosemary.webster@ucl.ac.uk.

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

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

We hope that you will find the research interesting.

What's involved?

This tablet computer will guide you through the steps.

This is what will happen:

1. You will be asked to **whether you agree to take part** in the study
2. You will then be asked to **fill in a survey on this computer** about yourself and your sexual life. It has questions like *'How many times in the last 3 months have you had vaginal sex without a condom?'* You do not have to answer any questions that you don't want to. This survey will take about 10 minutes.
3. The computer will then put you in one of **two groups**:
 - a. The **'no website'** group. You will not be asked to do anything else today, but **we will email you in 3, 6, 9, and 12 months to ask some more questions about your sexual health**. These surveys will take between 5 and 15 minutes. If we don't hear from

you, we will remind you by email, text message and telephone. We will also send you text messages and emails from time to time to remind you about the study. You will be able to view the website at the end of the study (July 2015)

- b. The '**website**' group. **You will be asked to look at the website today** (for about 10 minutes), while you are waiting to see the doctor. After you have left the clinic, you can visit the website again at any time. We will send you text messages and emails to remind you about the website. **We will also contact you in 3, 6, 9, and 12 months to ask you to answer some more questions about your sexual health.** If we don't hear from you, we will remind you by email, text message and telephone.

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

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

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

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

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

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

What will happen to my information?

- All information you give will be confidential

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

The small print.

- This study has been approved by the City and East National Research Ethics Committee (REC number 13/LO/1801).
- The research will be published in a report and the results will be available online. It will not be possible to identify any individuals in these reports.
- You will receive a summary of the results by email at the end of the study.
- All information that you provide will remain confidential and will be used only for the study.
 - However, if you give us specific information which leads us to think that you or someone else is at risk of harm, we are obliged to consider discussing this with authorities such as child protection teams, or the police
- You can withdraw from the study at any time, without giving a reason. To do this, please contact Rosie Webster (020 7794 0500 ext.31429, rosemary.webster@ucl.ac.uk). We may still use your anonymous questionnaire responses.
 - Once the findings of the study have been published in a research report, you will no longer be able to withdraw from the study.
- The research team cannot offer individual sexual health advice

- We hope that you find the research interesting, but you may find some of the questions or topics embarrassing or upsetting. We will provide contact details of organisations who may be able to help you
- Please contact the researcher Rosie Webster if you have any questions or concerns about the research, on 020 7794 0500 (ext.31429) rosemary.webster@ucl.ac.uk; Julia Bailey, Julia.bailey@ucl.ac.uk
 - You can also contact the principal investigator within your clinic:
 - Homerton Hospital: Professor Jane Anderson janderson@nhs.net
 - St Bartholomew's Hospital : Dr. Claudia Estcourt c.s.estcourt@qmul.ac.uk
 - Coventry sexual health clinic: Dr. Belinda Stanley Belinda.Stanley@covwarkpt.nhs.uk

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

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

Tel: 020 8510 7315

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

Tel: 020 3594 2040

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

Tel: 024 7653 6804

Text message: 07826 900 926

Email: pals@covwarkpt.nhs.uk

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

Advice and help organisations

Health services near you: NHS Choices

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

Advice about sexual health and HIV: Terrence Higgins Trust

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

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

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

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

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

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

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

V3 6th May 2014

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

1. I have read the study information and understand what the study involves
2. I understand that I can withdraw from the study at any time
3. I agree for the research team to record all contact details, questionnaire responses, and information about my use of the MenSS website
4. I agree for the research team to use my contact details to contact me about the study
5. I understand that my information will be treated as confidential and handled in accordance with the Data Protection Act 1998
6. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from UCL, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
7. I agree that my anonymous questionnaire answers may be used by others for future research which has been approved by an ethics committee
8. I agree for the research team to access my clinic records to get information about sexually transmitted infection diagnoses
9. I agree to take part in this study

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

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

Submit *(agrees consent)*

Back *(returns to study information page)*

If you have any questions, please ask the research staff in the clinic (the receptionist will be able to tell you where to find them) or contact Rosie Webster on 07768100384, email rosemary.webster@ucl.ac.uk ; or contact the local research staff on NNNNNNNNN.

The Men's Safer Sex (MenSS) Trial: protocol for a pilot randomized controlled trial of an interactive digital intervention to increase condom use in men

Appendix 2: Full outcome questionnaire

1. In the last 3 months how many of these types of female partners have you had sex with?

Regular partner

Occasional partner, e.g. friends with benefits

One off partner (e.g. one night stand)

Sex worker (paid for)

Other

(please specify):

(Text boxes restricted to 3 digit number for each option; free text box for 'please specify')

2. In the last 3 months how many of these types of male partners have you had sex with?

Regular partner

Occasional partner, e.g. friends with benefits

One off partner (e.g. one night stand)

Sex worker (paid for)

Other

(please specify):

(Text boxes restricted to 3 digit number for each option; free text box for 'please specify')

3. In the last 3 months, how many **women** have you had **unprotected vaginal or anal sex** with (without a condom)?

(Free text response, restricted to 3 digits numeric)

4. In the last 3 months, how many **TIMES** have you had **unprotected vaginal or anal sex** with a **woman** (without a condom)? (Please answer as accurately as you can)

(Free text response, restricted to 3 digits numeric)

5. In the last 3 months, how many **men** have you had **unprotected anal sex** with (without a condom)?

(Free text response, restricted to 3 digits numeric)

6. In the last 3 months, how many times have you experienced any of the following problems?

Condoms not available when needed 0 1 2 3 or more

Using condoms stored in wallet more than 1 month 0 1 2 3 or more

Using condoms that were not lubricated 0 1 2 3 or more

Applied condom after sex had begun 0 1 2 3 or more

Removed condom before sex ended 0 1 2 3 or more

Did not change condoms when switching from one form of sex to another 0 1 2 3 or more

Erection lost when putting on a condom 0 1 2 3 or more

Erection lost during sex 0 1 2 3 or more

Condom broke 0 1 2 3 or more

Condom slipped off during sex 0 1 2 3 or more

Condom slipped off during withdrawal 0 1 2 3 or more

Ejaculate dripped onto partner's genitals 0 1 2 3 or more

Condom put on penis the wrong way, then turned and put on the right way 0 1 2 3 or more

Did not change condoms when switching from one partner to another 0 1 2 3 or more

7. In the last 3 months, how many times have you had **unprotected sex** (without a condom) because you were **drunk or high**? (Please answer as accurately as you can)

(Free text response, restricted to 3 digits numeric)

8. In the last 3 months, have you used these types of contraception with female partners ?

Tick all that apply

- Don't know
- None
- None –trying for a baby
- The Pill, contraceptive patch, or contraceptive vaginal ring
- Condoms (including female condoms)
- Emergency contraceptive pill (morning after pill)
- Injection
- Contraceptive implant
- Withdrawal (pulling out)
- Intrauterine device (coil/IUD/IUS)
- Diaphragm or cap or spermicide
- Natural family planning (safe period/rhythm method)

- Don't know name of the contraception
- Other (please state).....

9. In the last 3 months, have you had any of the following sexually transmitted infections (tick all that apply)?

- Warts
- Herpes
- Chlamydia
- Gonorrhoea
- Pubic lice (Crabs)
- Trichomonas (TV)
- Non-specific urethritis (NSU)
- Syphilis
- HIV
- Hepatitis
- Can't remember the name
- Other (please write in name)
.....
- No sexually transmitted infections

10. In the last 3 months have you had antibiotic treatment because a partner had an STI?

Yes

No

11. Has a female partner been pregnant in the last 3 months?

Yes

No

Don't know

(If yes) What happened with the pregnancy?

Still pregnant

Miscarriage or stillbirth

An abortion

A baby

Don't know

12. 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)

(Text boxes restricted to 3 digit number for each option; free text box for 'please state')

*STIs = Sexually Transmitted Infections

* GP = General practitioner, family doctor

13. I feel confident that I could:

Get hold of condoms (eg buying from a shop) strongly disagree disagree undecided agree strongly agree

Use a condom on correctly strongly disagree disagree undecided agree strongly agree

Put a condom on without losing my erection strongly disagree disagree undecided agree strongly agree

Remove and dispose of a condom after sex strongly disagree disagree undecided agree strongly agree

Choose the correct size/type of condom strongly disagree disagree undecided agree strongly agree

Discuss using condoms with any partner I might have strongly disagree disagree undecided agree strongly agree

Suggest using a condom with a new partner strongly disagree disagree undecided agree strongly agree

Suggest using a condom without my partner feeling 'diseased' strongly disagree disagree undecided agree strongly agree

Remember to use a condom even if I am drunk or high strongly disagree disagree undecided agree strongly agree

Stop to put a condom on myself or my partner even in the heat of the moment strongly disagree disagree undecided agree strongly agree

14. True or false?

Whether or not people get sexually transmitted infections (STIs) is just luck.

True False Unsure of answer

You would know if you had an STI, without needing a test

True False Unsure of answer

You can tell who is likely to have an STI

True False Unsure of answer

You can have HIV and not know

True False Unsure of answer

You can catch STIs from oral sex

True False Unsure of answer

If you are in a relationship, you are safe from catching STIs

True False Unsure of answer

You are less likely to catch an STI from someone you know

True False Unsure of answer

Some STIs can't be treated

True False Unsure of answer

With a condom on, the man should wait until the penis is soft before withdrawing after sex

True False Unsure of answer

Baby oil or Vaseline is a good lubricant to use on a condom

True False Unsure of answer

Standard sized condoms are suitable for all men

True False Unsure of answer

15. Thinking about situations when you will have sex in the future, which of the following best applies to you?

- I do not want to wear a condom
- I am not sure if I will want to wear a condom
- I might want to wear a condom
- I very much want to wear a condom

16. Which of the following best applies to you:

- I plan not to use condoms when I have sex
- I don't have any particular plans to use condoms when I have sex
- From now on I will try to use a condom as often as possible whenever I have sex
- From now on I will make sure I always use a condom whenever I have sex

17. Which of the following best applies to you?

- I think the disadvantages of using a condom are greater than the advantages
- I think there is little to choose between the advantages and disadvantages of using a condom
- I think the advantages of using a condom are a bit greater than the disadvantages
- 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)

18. Do you agree or disagree with the following statements?

Condoms feel unnatural strongly disagree disagree undecided agree strongly agree

Condoms interrupt the mood strongly disagree disagree undecided agree strongly agree

Condoms don't feel good strongly disagree disagree undecided agree strongly agree

Condoms reduce the quality of the climax or orgasm strongly disagree disagree undecided agree strongly agree

Condoms are uncomfortable strongly disagree disagree undecided agree strongly agree

Condoms don't fit right strongly disagree disagree undecided agree strongly agree

I feel closer to my partner without a condom strongly disagree disagree undecided agree strongly agree

Using a condom helps me worry less during sex strongly disagree disagree undecided agree strongly agree

Using a condom helps my partner/s worry less during sex strongly disagree disagree undecided agree strongly agree

19. During the last 3 months, have you discussed the following things with partner(s)?

How to prevent pregnancy Yes No

How to use condoms Yes No

How to prevent STIs and HIV Yes No

Your sex history Yes No

Their sex history Yes No

20. Do you agree or disagree with the following statements?

I feel I am a responsible person, which is why I use condoms strongly disagree disagree undecided agree strongly agree

I feel I am a spontaneous person, which is why I don't use condoms strongly disagree disagree undecided agree strongly agree

Using condoms is the woman's responsibility strongly disagree disagree undecided agree strongly agree

Condoms make me feel less of a man strongly disagree disagree undecided agree strongly agree

I use condoms because I am concerned about my health strongly disagree disagree undecided agree strongly agree

I use condoms because I am concerned about my partners health strongly disagree disagree undecided agree strongly agree

Getting a girl pregnant proves that I am a real man strongly disagree disagree undecided agree strongly agree

21. We'd like to know about your sexual well-being over the last 3 months. Please select the statements that best apply to you.

1. Sexual performance

_ Your sexual performance is good

_ Your sexual performance is adequate

_ Your sexual performance is sometimes inadequate

Your sexual performance is inadequate

2. Sexual relationship

Your sexual relationship is never poor

Your sexual relationship is rarely poor

Your sexual relationship is sometimes poor

Your sexual relationship is always poor

3. Sexual anxiety

Thinking about your sex life you never feel anxious

Thinking about your sex life you rarely feel anxious

Thinking about your sex life you sometimes feel anxious

Thinking about your sex life you always feel anxious

Under each heading, please tick the ONE box that best describes your health TODAY

22. Mobility (walking about)

I have no problems walking about

I have some problems walking about

I have a lot of problems walking about

23. Looking after myself

I have no problems washing or dressing myself

- I have some problems washing or dressing myself
- I have a lot of problems washing or dressing myself

24. Doing usual activities (for example, going to school, hobbies, sports, playing, doing things with family or friends)

- I have no problems doing my usual activities
- I have some problems doing my usual activities
- I have a lot of problems doing my usual activities

25. Having pain or discomfort

- I have no pain or discomfort
- I have some pain or discomfort
- I have a lot of pain or discomfort

26. Feeling worried, sad or unhappy

- I am not worried, sad or unhappy
- I am a bit worried, sad or unhappy
- I am very worried, sad or unhappy

We would like to know how good or bad your health is TODAY.

This line is numbered from 0 to 100.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Please mark an X on the line that shows how good or bad your health is TODAY.

How good is your health TODAY

The best health you can imagine

100



0

The worst health you can imagine

Has being a part of this study had any good or bad effects on your life? Please explain how:

[Free text comment box]