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,1* Rosie Webster,1 Rachael Hunter,2 Mark Griffin,2 Nicholas Freemantle,2 Greta Rait,2 Claudia Estcourt,3 Susan Michie,4 Jane Anderson,5 Judith Stephenson,6 Makeda Gerressu,7 Chee Siang Ang8 and Elizabeth Murray1

1E-Health unit, Research Department of Primary Care and Population Health, University College London, London, UK
2PRIMENT Clinical Trials Unit, Research Department of Primary Care and Population Health, University College London, London, UK
3Barts and The London School of Medicine and Dentistry, Barts Sexual Health Centre, Queen Mary University of London, St Bartholomew’s Hospital, London, UK
4Research Department of Clinical, Educational and Health Psychology, University College London, London, UK
5Homerton Sexual Health Services, Homerton Teaching Hospitals, London, UK
6Department of Reproductive Health, Institute for Women’s Health, University College London, London, UK
7Department of Infection and Population Health, University College London, London, UK
8Engineering and Digital Arts, University of Kent, Kent, UK

*Corresponding author

Declared competing interests of authors: Jane Anderson reports grants, personal fees and non-financial support from Gilead Sciences, personal fees from ViV, personal fees from Jansen, personal fees from Merck Sharpe & Dohme Corp., personal fees and non-financial support from Bristol-Myers Squibb outside the submitted work. Elizabeth Murray is the Managing Director of HeLP-Digital, a not-for-profit community interest company, which disseminates digital health interventions to the NHS in the UK. She does not, and will not, receive any remuneration for this work.

Published December 2016
DOI: 10.3310/hta20910
Scientific summary

The Men’s Safer Sex (MenSS) project
Health Technology Assessment 2016; Vol. 20: No. 91
DOI: 10.3310/hta20910

NIHR Journals Library www.journalslibrary.nihr.ac.uk
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.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.
Health Technology Assessment

ISSN 1366-5278 (Print)
ISSN 2046-4924 (Online)
Impact factor: 4.058

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the Health Technology Assessment journal
Reports are published in Health Technology Assessment (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in Health Technology Assessment are termed ‘systematic’ when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme
The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS.

‘Health technologies’ are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report
The research reported in this issue of the journal was funded by the HTA programme as project number 10/131/01. The contractual start date was in January 2013. The draft report began editorial review in January 2016 and was accepted for publication in July 2016. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

© Queen's Printer and Controller of HMSO 2016. This work was produced by Bailey et al. under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).
Health Technology Assessment Editor-in-Chief

Professor Hywel Williams  Director, HTA Programme, UK and Foundation Professor and Co-Director of the Centre of Evidence-Based Dermatology, University of Nottingham, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley  Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

NIHR Journals Library Editors

Professor Ken Stein  Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May  Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key  Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck  Chair in Public Sector Management and Subject Leader (Management Group), Queen’s University Management School, Queen’s University Belfast, UK

Professor Aileen Clarke  Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly  Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin  Senior Scientific Advisor, Wessex Institute, UK

Ms Tara Lamont  Scientific Advisor, NETSCC, UK

Professor William McGuire  Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads  Professor of Health Sciences Research, Health and Wellbeing Research Group, University of Winchester, UK

Professor John Norrie  Chair in Medical Statistics, University of Edinburgh, UK

Professor Jon Powell  Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery  Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma  Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts  Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Jonathan Ross  Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks  Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Jim Thornton  Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood  Director, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of members of the NIHR Journals Library Board: www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk