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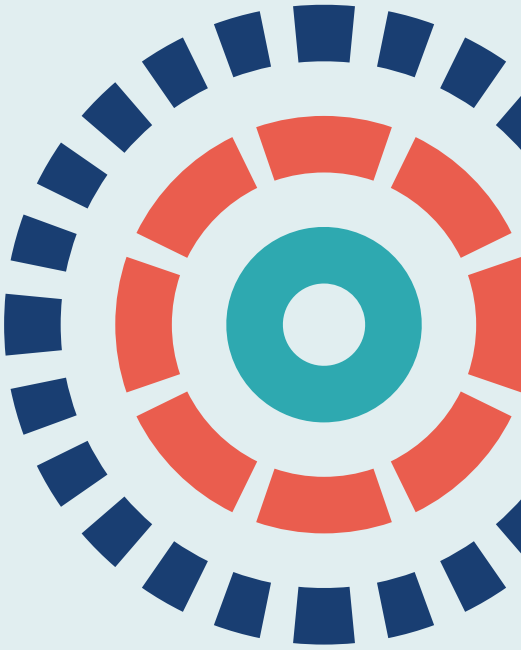

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Behavioural intervention to reduce sexually transmitted infections in people aged 16–24 years in the UK: the safetxt RCT

Caroline Free,[1*] Melissa J Palmer,[1] Kimberley Potter,[2] Ona L McCarthy,[1] Lauren Jerome,[2] Sima Berendes,[1] Anasztazia Gubijev,[1] Megan Knight,[2] Zahra Jamal,[2] Farandeep Dhaliwal,[2] James R Carpenter,[3] Tim P Morris,[4] Phil Edwards,[1] Rebecca French,[5] Louis Macgregor,[6] Katy ME Turner,[6] Paula Baraitser,[7] Ford CI Hickson,[8] Kaye Wellings,[5] Ian Roberts,[1] Julia V Bailey,[9] Graham Hart,[10] Susan Michie,[11] Tim Clayton[3] and Karen Devries[3]

[1]Clinical Trials Unit, Department of Population Health, London School of Hygiene & Tropical Medicine, London, UK
[2]Clinical Trials Unit, Department of Medical Statistics, London School of Hygiene & Tropical Medicine, London, UK
[3]Department of Medical Statistics, London School of Hygiene & Tropical Medicine, London, UK
[4]Medical Research Council Clinical Trials Unit, London, UK
[5]Department of Social and Environmental Health Research, London School of Hygiene & Tropical Medicine, London, UK
[6]Bristol Veterinary School, University of Bristol, Bristol, UK
[7]Centre for Global Health, King's College London, London, UK
[8]Sigma Research, London School of Hygiene & Tropical Medicine, London, UK
[9]eHealth Unit, Research Department of Primary Care and Population Health, University College London, London, UK
[10]Department of Infection and Population Health, University College London, London, UK
[11]Centre for Outcomes Research and Effectiveness, University College London, London, UK

*Corresponding author

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/DANE8826.

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Abstract

Behavioural intervention to reduce sexually transmitted infections in people aged 16–24 years in the UK: the safetxt RCT

Caroline Free,[1*] Melissa J Palmer,[1] Kimberley Potter,[2] Ona L McCarthy,[1] Lauren Jerome,[2] Sima Berendes,[1] Anasztazia Gubijev,[1] Megan Knight,[2] Zahra Jamal,[2] Farandeep Dhaliwal,[2] James R Carpenter,[3] Tim P Morris,[4] Phil Edwards,[1] Rebecca French,[5] Louis Macgregor,[6] Katy ME Turner,[6] Paula Baraitser,[7] Ford CI Hickson,[8] Kaye Wellings,[5] Ian Roberts,[1] Julia V Bailey,[9] Graham Hart,[10] Susan Michie,[11] Tim Clayton[3] and Karen Devries[3]

[1]Clinical Trials Unit, Department of Population Health, London School of Hygiene & Tropical Medicine, London, UK
[2]Clinical Trials Unit, Department of Medical Statistics, London School of Hygiene & Tropical Medicine, London, UK
[3]Department of Medical Statistics, London School of Hygiene & Tropical Medicine, London, UK
[4]Medical Research Council Clinical Trials Unit, London, UK
[5]Department of Social and Environmental Health Research, London School of Hygiene & Tropical Medicine, London, UK
[6]Bristol Veterinary School, University of Bristol, Bristol, UK
[7]Centre for Global Health, King's College London, London, UK
[8]Sigma Research, London School of Hygiene & Tropical Medicine, London, UK
[9]eHealth Unit, Research Department of Primary Care and Population Health, University College London, London, UK
[10]Department of Infection and Population Health, University College London, London, UK
[11]Centre for Outcomes Research and Effectiveness, University College London, London, UK

*Corresponding author caroline.free@lshtm.ac.uk

Background: The prevalence of genital chlamydia and gonorrhoea is higher in the 16–24 years age group than those in other age group. With users, we developed the theory-based safetxt intervention to reduce sexually transmitted infections.

Objectives: To establish the effect of the safetxt intervention on the incidence of chlamydia/gonorrhoea infection at 1 year.

Design: A parallel-group, individual-level, randomised superiority trial in which care providers and outcome assessors were blinded to allocation.

Setting: Recruitment was from 92 UK sexual health clinics.

Participants: Inclusion criteria were a positive chlamydia or gonorrhoea test result, diagnosis of non-specific urethritis or treatment started for chlamydia/gonorrhoea/non-specific urethritis in the last 2 weeks; owning a personal mobile phone; and being aged 16–24 years.

Allocation: Remote computer-based randomisation with an automated link to the messaging system delivering intervention or control group messages.

Intervention: The safetxt intervention was designed to reduce sexually transmitted infection by increasing partner notification, condom use and sexually transmitted infection testing before sex with new partners. It employed educational, enabling and incentivising content delivered by 42–79 text messages over 1 year, tailored according to type of infection, gender and sexuality.

Comparator: A monthly message regarding trial participation.

Main outcomes: The primary outcome was the incidence of chlamydia and gonorrhoea infection at 12 months, assessed using nucleic acid amplification tests. Secondary outcomes at 1 and 12 months included self-reported partner notification, condom use and sexually transmitted infection testing prior to sex with new partner(s).

Results: Between 1 April 2016 and 23 November 2018, we assessed 20,476 people for eligibility and consented and randomised 6248 participants, allocating 3123 to the safetxt intervention and 3125 to the control. Primary outcome data were available for 4675 (74.8%) participants. The incidence of chlamydia/gonorrhoea infection was 22.2% (693/3123) in the intervention group and 20.3% (633/3125) in the control group (odds ratio 1.13, 95% confidence interval 0.98 to 1.31). There was no evidence of heterogeneity in any of the prespecified subgroups. Partner notification was 85.6% in the intervention group and 84.0% in the control group (odds ratio 1.14, 95% confidence interval 0.99 to 1.33). At 12 months, condom use at last sex was 33.8% in the intervention group and 31.2% in the control group (odds ratio 1.14, 95% confidence interval 1.01 to 1.28) and condom use at first sex with most recent new partner was 54.4% in the intervention group and 48.7% in the control group (odds ratio 1.27, 95% confidence interval 1.11 to 1.45). Testing before sex with a new partner was 39.5% in the intervention group and 40.9% in the control group (odds ratio 0.95, 95% confidence interval 0.82 to 1.10). Having two or more partners since joining the trial was 56.9% in the intervention group and 54.8% in the control group (odds ratio 1.11, 95% confidence interval 1.00 to 1.24) and having sex with someone new since joining the trial was 69.7% in the intervention group and 67.4% in the control group (odds ratio 1.13, 95% confidence interval 1.00 to 1.28). There were no differences in safety outcomes. Additional sensitivity and per-protocol analyses showed similar results.

Limitations: Our understanding of the mechanism of action for the unanticipated effects is limited.

Conclusions: The safetxt intervention did not reduce chlamydia and gonorrhoea infections, with slightly more infections in the intervention group. The intervention increased condom use but also increased the number of partners and new partners. Randomised controlled trials are essential for evaluating health communication interventions, which can have unanticipated effects.

Future work: Randomised controlled trials evaluating novel interventions in this complex area are needed.

Trial registration: This trial is registered as ISRCTN64390461.

Funding: This project was funded by the National Institute for Health and Care Research (NIHR) Public Health Research programme and will be published in full in *Public Health Research*; Vol. 11, No. 1. See the NIHR Journals Library website for further project information.

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/DANE8826).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

AI	artificial intelligence
CI	confidence interval
CoE	certainty of evidence
COM-B	capability, opportunity and motivation model of behaviour
HIV	human immunodeficiency virus
ICER	incremental cost-effectiveness ratio
IMD	Index of Multiple Deprivation
MAR	missing at random
MICE	multiple imputation by chained equations
MSM	men who have sex with men only
MSMW	men who have sex with men and women
MSW	men who have sex with women
NAAT	nucleic acid amplification test
NBSM	non-binary people who have sex with men only
NIHR	National Institute for Health and Care Research
NSU	non-specific urethritis
OR	odds ratio
PEP	post-exposure prophylaxis
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SMS	short message service
SRH	sexual and reproductive health
STI	sexually transmitted infection
TSC	Trial Steering Committee
WSM	women who have sex with men only
WSMW	women who have sex with men and women
WSW	women who have sex with women only

Plain English summary

Sexually transmitted infections are common in young people and can cause significant health problems. People are less likely to get an infection if they use condoms and get tested before they have sex with a new partner, and people with an infection are less likely to get another infection if they tell their partner, but these things can be hard to do.

In previous research, we developed educational and supportive text messages for and with young people. The messages were intended to help young people use condoms, get tested, tell a partner about an infection and reduce infections. Young people liked the messages. They said that the messages increased knowledge, helped them to talk to partners about infections and helped them to use condoms.

Randomised controlled trials are the best way of testing if a new approach works. We conducted a randomised controlled trial to tell us if this form of health education reduces sexually transmitted infections. We recruited 6248 people. We randomly (i.e. by chance) sent 3123 people the educational messages and 3125 people the control messages about taking part in the trial.

The educational messages did not reduce infections over 12 months. There were slightly more infections in the intervention group. The educational messages increased condom use and slightly increased the number of people telling their partner about an infection but did not change the number of people testing for infections before sex with a new partner. The messages slightly increased the number of people with a new sexual partner or with two or more sexual partners.

The safetxt text messages about partner notification should not be used in the NHS as they may cause people to get more infections. The messages about condom use can help people use condoms and could be used. Sexual behaviour is complex, so the effects of new interventions must be tested in trials.

Scientific summary

Background

Young people aged 16–24 years bear the heaviest burden of sexually transmitted infections (STIs), such as chlamydia and gonorrhoea, and the long-term adverse health effects, including ectopic pregnancy and subfertility. The risk of adverse health effects increases with repeated infections, and reinfection rates following treatment are high: up to 30% for chlamydia and 12% for gonorrhoea at 1 year. Those with a STI are more likely to acquire further STIs and HIV (human immunodeficiency virus) if exposed. Inequalities in sexual health persist: STIs are positively associated with having a lower education level and living in a more deprived area.

High STI rates among young people also reflect broader aspects of poor sexual well-being, such as a lack of knowledge, skills or confidence in how to carry out safer sex behaviours and how to communicate with partners about sex or safer sex.

There is some evidence that existing interventions delivered face to face that target condom use and safer sex can reduce STI infection or reinfection. However, the interventions that have been effective in young people have involved multiple sessions over a number of weeks, which has proven too intensive and costly for widespread application in the NHS.

Mobile phones have the potential to provide effective, low-cost and highly cost-effective health behaviour support. In the UK, almost all 16- to 24-year-olds are mobile phone users, and mobile phone ownership is high across all socioeconomic groups. Thus, mobile phones have the potential to provide information and support across sociodemographic groups.

Our systematic review shows that evidence of the effect of mobile phone support on long-term condom use, partner notification and STIs is equivocal.

We developed a novel mobile phone-based programme to increase partner notification, condom use with new partners and STI testing before sex with a new partner. A description of the intervention development and its theoretical rationale has been published. The messages were developed based on behaviour change theory; evidence-based behaviour change techniques; the content of effective face-to-face safer sex interventions; the factors known to influence safer sex behaviours; the views of 82 young people collected in focus groups; and a questionnaire completed by 100 people aged 16–24 years. The intervention was informed by the capability, opportunity and motivation model of behaviour (COM-B). It aimed to influence the knowledge, beliefs, self-efficacy, skills, and social and interpersonal factors that have important effects on motivation, capability and opportunity to reduce sexual risk behaviour.

In a qualitative study with young people, recipients reported that the tone, language, content and frequency of messages were appropriate. Messages reportedly increased knowledge about STIs and confidence in how to use condoms. Recipients reported that the messages were reassuring and reduced stigma, enabling them to tell a partner about a STI more calmly and with greater confidence. Some reported that they would not have otherwise told their partner. Sharing messages with their partner enabled some participants to negotiate condom use. Based on the young people's feedback, the programme was further refined for the main trial. We ensured that messages were relevant to men who have sex with men and women who have sex with women by seeking their views on the programme in further interviews and a focus group.

Objectives

The primary objective of this trial was to quantify the effects of the novel safetxt intervention compared with a control group receiving usual care and messages about trial participation on chlamydia or gonorrhoea infection at 1 year.

The secondary objectives were to determine the effects of safetxt on:

- partner notification and condom use at 4 weeks
- condom use and condom use with new partners
- STI testing before unprotected sex with a new partner at 1 year.

To explore which programme components were effective, we collected data on the constructs on the pathway to behaviour change. According to the intervention theory of change these constructs would be influenced by the intervention components. We planned to establish the cost-effectiveness of the programme.

Methods

Safetxt was a parallel-group, individual-level, randomised controlled superiority trial to establish the effects of a safer sex intervention delivered by text message on the incidence of chlamydia and gonorrhoea infection. Care providers and outcome assessors were blinded to allocation.

Potential participants testing positive for chlamydia or gonorrhoea or diagnosed with non-specific urethritis (NSU) were identified from 92 STI testing services across the UK. Research nurses in clinics and researchers based in the trial co-ordinating centre provided study information on paper or online, answered any questions and obtained informed consent in writing or via the trial website. Participants' details were manually entered into the web-based data entry form and were randomised by remote computer-based randomisation in a 1 : 1 allocation ratio. A link to the message delivery system resulted in young people successfully recruited to the trial being automatically sent intervention or control group messages according to their allocation.

The inclusion criteria were having received a positive chlamydia or gonorrhoea test result, having been diagnosed with NSU in the last 2 weeks or having started treatment for chlamydia, gonorrhoea or NSU in the last 2 weeks; owning a personal mobile phone; being aged 16–24 years; and being able to provide informed consent. The single exclusion criterion was known to be a sexual partner of someone already recruited to the trial, assessed by potential participants' report or clinic attendance with a sexual partner.

Safetxt intervention group

The programme aimed to increase safer sex in three ways: (1) encouraging participants to correctly follow STI treatment instructions, including informing partner(s) about infection; (2) promoting condom use with new or casual partners; and (3) encouraging participants to obtain testing for STIs prior to unprotected sex. Participants in the intervention group received regular messages delivered by text message to personal mobile phones in the community in accordance with a predetermined schedule. The programme was informed by COM-B. It aimed to influence the knowledge, beliefs, self-efficacy, skills, and social and interpersonal factors that have important effects on motivation, capability and opportunity to reduce sexual risk behaviour. Participants in the control group received a monthly untailored text message asking for information about any changes in postal or e-mail addresses. All participants received usual care and were free to seek any other existing service or support that they wanted to.

The primary outcome was the incidence of chlamydia and gonorrhoea infection at 12 months, assessed using nucleic acid amplification tests. Self-reported secondary outcomes were collected in a survey, with self-reported testing before sex with new partners checked against clinic data to confirm that testing had occurred. Secondary outcomes collected by postal paper questionnaire or online questionnaire at the trial website included, at 1 month, partner notification, correct treatment, condom use at last sex and data regarding the theoretical constructs underlying the components of the intervention (behaviour change mediators); and, at 12 months, condom use at last sex, condom use at last sex with someone new, STI (confirmed by clinic record), testing for self prior to sex with someone new (confirmed by clinic record), whether or not the participant had a new partner, and number of sexual partners since joining the trial. Safety outcomes included partner violence and car accidents. Partner violence can be a consequence of partner notification and in some contexts where mobile phone privacy is not assured, receiving messages by mobile phone on sensitive topics has been shown to increase risk of partner violence among those at risk. Car accidents are a demonstrated harm of text messaging. An open feedback question asked whether or not anything good or bad had happened as a result of taking part in the research.

We describe and discuss the details of our recruitment and follow-up approaches and methods in *Chapter 3* of the main report.

Results

Between 1 April 2016 and 23 November 2018, we assessed 20,476 people for eligibility and consented and randomised 6248 participants, with 3123 allocated to the safetxt intervention and 3125 allocated to the control. Follow-up was conducted from 1 May 2016 to 28 February 2020. Primary outcome data were available for 4675 (74.8%) participants. The incidence of chlamydia/gonorrhoea infection was 22.2% (693/3123) in the intervention group and 20.3% (633/3125) in the control group [odds ratio (OR) 1.13, 95% confidence interval (CI) 0.98 to 1.31; $p = 0.085$]. There was no evidence of heterogeneity in any of the prespecified subgroups. There were similar findings in the complete-case analysis.

For secondary outcomes, partner notification was 85.6% in the intervention group and 84.0% in the control group (OR 1.14, 95% CI 0.99 to 1.33; $p = 0.08$), correct treatment for STI was 89.6% in the intervention group and 88.6% in the control group (OR 1.11, 95% CI 0.94 to 1.32; $p = 0.22$), and partner attendance for treatment according to data from clinics that routinely collect this was 11.7% in the intervention group and 13.0% in the control group (OR 0.88, 95% CI 0.75 to 1.02; $p = 0.10$). At 4 weeks, condom use at last sex was 42.0% in the intervention group and 39.6% in the control group (OR 1.12, 95% CI 1.00 to 1.25; $p = 0.045$). At 12 months, condom use at last sex was 33.8% in the intervention group and 31.2% in the control group (OR 1.14, 95% CI 1.01 to 1.28; $p = 0.038$) and condom use at first sex with most recent new partner was 54.4% in the intervention group and 48.7% in the control group (OR 1.27, 95% CI 1.11 to 1.45; $p = 0.001$). Testing before sex with a new partner was 39.5% in the intervention group and 40.9% in the control group (OR 0.95, 95% CI 0.82 to 1.10; $p = 0.48$) and the self-reported effect on partners being tested prior to sex with the participant was 31.3% in the intervention group and 28.2% in the control group (OR 1.15, 95% CI 0.88 to 1.51; $p = 0.28$). Those with two or more partners since joining the trial was 56.9% in the intervention group and 54.8% in the control group (OR 1.11, 95% CI 1.00 to 1.24; $p = 0.061$) and having sex with someone new since joining the trial was 69.7% in the intervention group and 67.4% in the control group (OR 1.13, 95% CI 1.00 to 1.28; $p = 0.06$). There were no differences in safety outcomes.

The intervention increased knowledge and self-efficacy regarding how to use condoms but did not increase self-efficacy in communicating with partners about condom use or partner notification.

Post hoc analyses

Our primary analysis assumed that data were missing at random. We conducted non-prespecified sensitivity analyses with a range of different assumptions regarding missing data. We conducted an analysis adjusting for baseline differences in the number of sexual partners between groups. These showed similar results to the primary outcome. We also conducted a post hoc per-protocol analysis comparing a subgroup of intervention participants who (1) did not stop the messages, (2) were not among the few participants who did not receive any messages and (3) reported that they had read all or most messages with control group participants who did not stop the messages. The per-protocol analysis showed slightly higher odds of the incidence of chlamydia and gonorrhoea in the intervention group (OR 1.17, 95% CI 0.99 to 1.38; $p = 0.06$).

A total of 2412 out of 3123 (77%) intervention participants responded to the question regarding reading messages. Of these, 1506 (65.5%) read all of the messages, 661 (27.4%) read most of the messages, 229 (9.5%) read few of the messages and 16 (0.7%) participants read no messages.

A total of 3525 (56.4%) participants provided open feedback comments. In the open feedback, there were several areas in which participants reported an impact on their attitudes and behaviour that reflected previous qualitative research findings regarding partner notification, reassurance and reduction of stigma, condom use and STI testing. New areas emerged, including reports of a general sense of awareness about sexual health with greater caution about who they had sex with; increased agency and confidence and reduced embarrassment, resulting in more discussions about sexual health; and a reduced sense of isolation in being diagnosed with a STI. Overall, according to recipients' views as expressed in open feedback comments, the safetxt intervention had a positive impact on many aspects of broader definitions of positive sexual health. A few people reported that the messages were too frequent or annoying. Open feedback comments suggested having an STI and trial participation impacted on behaviour for people in both groups.

We developed a costing model that could be adapted for other interventions, but we did not use it as the main outcome did not show a benefit.

Conclusions

The safetxt intervention did not reduce the incidence of chlamydia and gonorrhoea at 12 months. Instead, there was the suggestion of a slight increase in the incidence of chlamydia and gonorrhoea.

The intervention modestly increased condom use with new partners and condom use at last sex at 4 weeks and 1 year, but it also increased the odds of having a new partner or having two or more partners. There was no difference in STI testing before sex with new partners or partners attending for treatment based on clinic records and self-report. There was increased participant report of partners testing for STI prior to sex with the participant. There was a suggestion of slightly increased self-reported partner notification. The CIs for other outcomes encompassed no effect but were in the direction of benefit, except for the outcome 'any STI', whose CI was in the direction of an increase.

The results of the additional and sensitivity analyses were similar to those of the primary analysis, and the per-protocol analysis found slightly higher odds of the incidence of chlamydia and gonorrhoea than the primary analysis. The consistency and direction of effect of these findings add to the weight of evidence suggesting that the slight increase in chlamydia and gonorrhoea was not due to bias.

The trial data, previous qualitative research and open feedback provided little direct evidence for the unanticipated mechanism by which the safetxt intervention may have increased chlamydia/gonorrhoea infections and the proportion of participants in the intervention group having two or more partners

over 12 months compared with the control group. Further qualitative research to explore the unanticipated effect has been undertaken and will be reported separately. Overall, according to recipients' views expressed in open feedback comments, the safetxt intervention had a positive impact on many aspects of broader definitions of positive sexual health.

Owing to the slight increase in STIs, we do not recommend implementing the safetxt intervention as evaluated in this trial. The safetxt intervention content promoting condom use was similar to the content of face-to-face interventions that have increased condom use and reduced STIs. Based on a cost of 5 pence per message, the condom promotion content costs £1.80 per person. This content could be considered for implementation. Our research highlights the importance of randomised evaluations of health communication interventions, especially in the complex area of sexual behaviour, to reliably establish their effects.

Patient and public involvement

Patient advisory focus groups informed the study question, intervention design, design of data collection materials and procedures, and dissemination of the trial results, and there was one patient and public involvement member of the Trial Steering Committee.

Ethics statement

Ethics approval was provided by the NHS Health Research Authority – London – Riverside Research Ethics Committee (REC reference 15/LO/1665) and the London School of Hygiene & Tropical Medicine (reference 10464).

Trial registration

This trial is registered as ISRCTN64390461.

Funding

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Chapter 1 Introduction

Scientific background

Young people aged 16–24 years bear the heaviest burden of sexually transmitted infections (STIs) such as chlamydia and gonorrhoea and their long-term adverse health effects, including ectopic pregnancy and subfertility.[2,3] The risk of adverse health effects increases with repeated infections and reinfection rates following treatment are high, at up to 30% for chlamydia and 12% for gonorrhoea at 1 year.[4] Those with a STI are more likely to acquire further STIs and HIV (human immunodeficiency virus), if exposed. Inequalities in sexual health persist; STIs are positively associated with lower educational levels[5] and living in more deprived areas.[3,6,7]

Sexual and reproductive health (SRH) is defined as 'a state of physical, emotional, mental and social wellbeing in relation to all aspects of sexuality and reproduction, not merely absence of disease, dysfunction or infirmity' [© Copyright World Health Organization (WHO), reproduced with permission].[8] High STI rates among young people also reflect broader aspects of poor sexual health, such as a lack of knowledge, skills or confidence in how to carry out safer sex behaviours and how to communicate with partners about sex or safer sex behaviours.[9]

Current treatment and management of chlamydia, gonorrhoea and non-specific urethritis in primary care

Chlamydia and gonorrhoea infections are diagnosed in community SRH clinics, genitourinary clinics and general practice, via some community outreach testing and, increasingly, via online services in the UK. Treatment for chlamydia and non-specific urethritis (NSU) occurs in all of these settings, but people with gonorrhoea infections are usually referred to either community SRH or genitourinary clinics for swabs for culture and antimicrobial sensitivity testing.[10] The British Association for Sexual Health and HIV (BASHH) has issued guidance on the advice that health-care providers should give to those testing positive. In community and SRH services and genitourinary clinics, there has been the opportunity to see a health advisor for counselling regarding risk and precautionary behaviours, but cuts to services have reduced the availability of such services.[11]

What kind of interventions, if shown to be effective, could be implemented in the NHS?

There is some evidence that existing interventions delivered face to face that target condom use and safer sex can reduce STI infection or reinfection. However, the interventions that have been effective among young people have involved multiple sessions over 4–12 weeks, which has proven too intensive and costly for widespread application in the NHS.[12–17]

If proven effective, remote or digital information and support could be an approach that is feasible to implement in the NHS. However, although one trial of a video-based intervention shown in clinics was effective in reducing STI,[18] trials of telephone and interactive web-based support have, to date, not shown benefits in reducing STI, unless these are combined with intensive face-to-face interventions.[15,19–23] Brief videos could be implemented in SRH or genitourinary clinics but may not be feasible to implement in general practice. Expedited partner therapy offers a promising approach to partner notification; however, other novel and effective ways to increase partner notification in specialist and primary care settings are needed.[24–27]

Mobile phones have the potential to provide effective, low-cost and highly cost-effective health behaviour support.[28,29] In the UK, 98% of 16- to 24 -year-olds are mobile phone users and mobile phone ownership is high across all socioeconomic groups.[30] Thus, mobile phones have the potential to provide information and support across sociodemographic groups. Effective and cost-effective smoking cessation support delivered by text message was implemented and made available across England within 12 months of publication of randomised controlled trial (RCT) results.[28] There are a number of SMS (short message service) services accredited by the NHS that allow messages sent to be automatically recorded in patient notes [e.g. Accurx (London, UK) and MJOG (London, UK)] and these are increasingly used in the NHS to remind patients of appointments and convey information. Thus, a texting intervention, if shown to be effective, would be scalable for delivery across NHS services.

Evidence of the effectiveness of mobile phone sexual health support

Evidence of the effectiveness of mobile phone support for safer sex behaviours and STI outcomes at the outset of the trial in 2016 was equivocal,[31–33] and in 2020, prior to our trial, the results remained equivocal for the effects on long-term condom use, partner notification and STIs.

We completed a systematic review of targeted client communication via mobile devices for improving SRH (search conducted in July/August 2017),[34] which led to the conclusion that the effects of interventions on condom use, STI occurrence and unintended consequences were uncertain owing to very low certainty of evidence (CoE), as assessed using GRADE (Grading of Recommendations, Assessment, Development and Evaluations) ratings.[35,36] The findings suggested that interventions may increase STI testing rates, but the CoE was low.

We also completed a systematic review of sexual health interventions delivered to participants by mobile technologies, with a more recent literature search conducted in February 2020.[37,38] After double screening 6683 titles/abstracts and 535 full-text articles, we identified a total of 22 eligible RCTs that reported on mobile interventions delivered to participants aged $\geq$ 10 years to prevent the sexual transmission of STIs/HIV. Eighteen of these trials used text messaging interventions.

Among the interventions employing text messages, seven trials targeted testing behaviour only (high-income countries, $n = 1$, low- and middle-income countries, $n = 6$), mostly sending unidirectional text messages over short time periods (< 4 weeks) to remind people to (re-)test for HIV/STIs. One trial included reminders to notify partners. Six trials targeted precautionary behaviour only, and nine targeted both precautionary and testing behaviour; 15 educated and reminded participants about condom use, and seven also taught condom use (negotiation) skills. A few interventions also discussed contraception, illegal drug use and/or delaying first sex/abstinence. Only two trials included treatment-related messages to educate and remind people about taking STI medications and abstaining from sex until treatment completion.

The CoE for long-term STI/HIV-testing [odds ratio (OR) 0.86, 95% confidence interval (CI) 0.25 to 2.95], assessed in only two trials,[32,39] was very low as a result of inconsistency and imprecision, but it was moderate for short-/medium-term STI/HIV testing, assessed in seven trials (three in Australia,[39–41] two in Africa,[42,43] one in the USA[44] and one in the UK[32]) showing that text message reminders probably increase STI testing in general populations (OR 1.83, 95% CI 1.41 to 2.36).

Only three trials examined the long-term effects ($\geq$ 12 months) on condom use: a RCT among music festival visitors in Australia,[39] a cluster RCT among secondary school students in Ghana[45] and the safetxt pilot RCT.[32] A meta-analysis of these trials suggests that we are uncertain of the effects of interventions on condom use at $\geq$ 12 months (OR 1.10, 95% CI 0.77 to 1.56), but the CoE was low. The interventions varied in content, and the effect estimate of the safetxt pilot RCT was larger than that of the other trials.

Nine trials examined short-/medium-term effects (i.e. < 12 months) on condom use, comprising four RCTs conducted in the USA [two among men who have sex with men only (MSM)[44,46] and two among young female patients[47,48]], two RCTs in Australia (both among 16- to 29-year-old people[39,41]), one RCT in Ireland (among young clinic clients[49]), one RCT in Africa (among key populations in South Africa, Zimbabwe and Mozambique[42]) and one RCT in the UK (the pilot safetxt RCT[32]). Most of the trials were small, and none showed any statistically significant effects. Many of the interventions addressed few of the factors influencing safer sex; for example, only three targeted condom use skills.[32,44,48] The pooled results (nine RCTs, $n = 2307$; standard mean difference 0.02, 95% CI −0.09 to 0.14) suggested that there may be no effect on condom use. The CoE was 'moderate', however, meaning that further research is likely to have an important impact on the confidence in the estimate of effect and may change the estimate.[36] Apart from the pilot safetxt RCT,[32] none of the included trial reports indicated that unintended consequences had been assessed systematically, so the effect of text messaging interventions on adverse events is uncertain. The effects of text messaging interventions on other behavioural and biological outcomes, including treatment adherence,[32] partner notification[32,50] and STI occurrence,[32] are uncertain due to low or very low CoE.

Development of the safetxt intervention

A description of the intervention and its theoretical rationale has been published (*Figure 1*).[32]

The intervention was informed by the capability, opportunity and motivation model of behaviour (COM-B).[51] According to this model, behaviours are influenced by an individual's capability, opportunity and motivation to carry out the behaviours. Capability, opportunity and motivation for safer sex are influenced by the context: the individual's knowledge, self-efficacy, intentions, attitudes and skills; the relationship's quality and intimacy and the degree of trust in the relationship; and social factors, such as gender norms and roles. The opportunity to carry out safer sex behaviours is also influenced by broader socioeconomic and structural factors, which were not targeted in this intervention and so do not appear in the theoretical model.

The intervention employs educational, enabling and incentivising behavioural change functions to increase capability and motivation to carry out safer sex behaviours and, hence, increase correct STI treatment, partner notification, condom use and self-testing and partner testing for STIs before sex without a condom, leading to reduced STIs. The specific aspects of capability that the intervention was hypothesised to alter were knowledge about how to prevent STIs and correct treatment of STIs, condom use knowledge and self-efficacy, condom negotiation self-efficacy and partner notification self-efficacy. Increased knowledge regarding the health consequences of STIs and altered attitudes to partner notification were hypothesised to increase motivation for safer sex practices. The messages were developed based on behaviour change theory; evidence-based behaviour change techniques; the content of effective face-to-face safer sex interventions; the factors known to influence safer sex behaviours; the views of 82 young people collected in focus groups; and a questionnaire completed by 100 people aged 16–24 years. We ensured that the young people included in the focus groups and completing the questionnaire were from diverse socioeconomic and ethnic groups and included those living in cities, towns and rural areas of the UK (London, Manchester, Cambridgeshire and Norfolk).

Messages were written and adapted based on young people's preferences as expressed in focus groups. Participants preferred messages with a non-judgemental and credible tone, short messages written in a positive style and those providing practical information regarding what needed to be done, why and how. They wanted no more than four messages per day and wanted the message frequency to reduce within the first 2 weeks. Positive approaches to sexuality and reproduction should recognise the part played by trust and communication, as well as pleasurable sexual relationships, in promoting well-being and enabling people to fulfil their sexual and reproductive health and rights.[52] The scope of the safetxt intervention was limited as some content was considered inappropriate for delivery by text message.

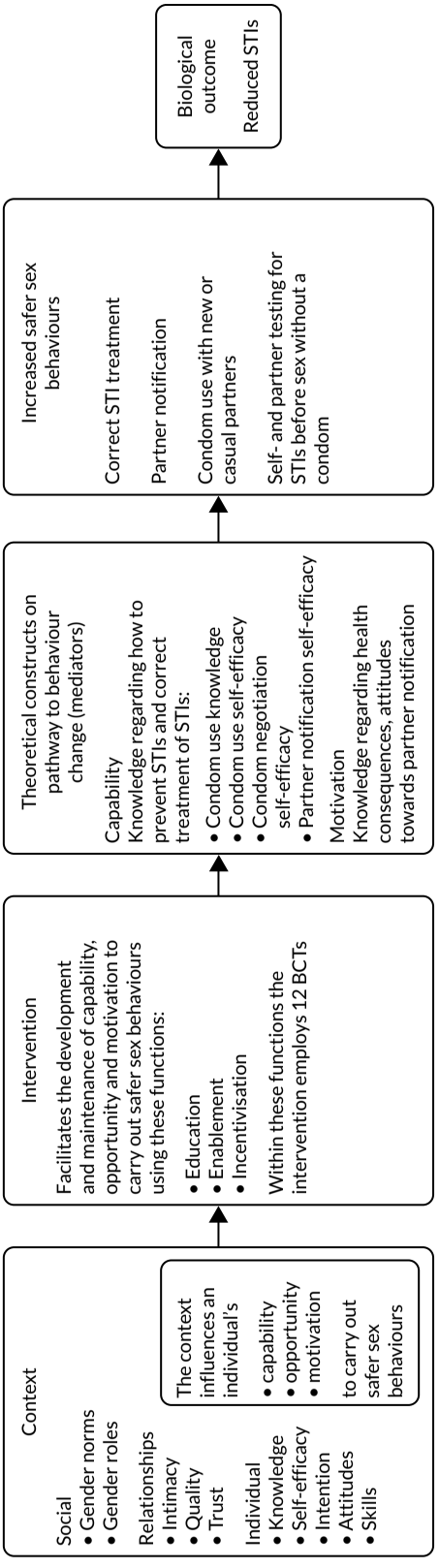

FIGURE 1 Safetxt theoretical model. BCT, behaviour change technique.

Effective face-to-face interventions include content regarding gender roles, sexual pleasure and relationships, but this content, when adapted for delivery by text message, was considered too personal, intrusive and unacceptable, and so messages containing this content were removed from the intervention. Many effective face-to-face interventions include reviewing behavioural goals as behaviour change techniques, but these were considered too intrusive for delivery by text message. For some behaviours, instead of action plans, only suggestions of when, where and how risk reduction behaviours could be carried out were considered acceptable.

In a qualitative study with young people, coding and analysing the interviews led to the development of a theoretical framework for the mechanism of action, including how the intervention is hypothesised to work in increasing safer sex behaviours.[53] Prerequisites for an acceptable intervention from young people's perspectives included that the content be simple and engaging and resonate with personal experiences. The tone was perceived to be trustworthy, friendly, professional, enabling, non-judgemental and non-pressured. The findings from the interviews suggest that the intervention could work by providing information, skills, reminders and reinforcement to young people via a channel that is convenient and accessible to them. For example, the texts appeared to help by providing new knowledge on how to put a condom on or having a reminder text facilitating condom use, and breaking down assumptions about how chlamydia infection is transmitted. The messages could also work by allowing recipients to reflect on their behaviour. The information participants received in text messages that chlamydia is common, that one may not know that they have it and that it is easily curable was said to have allayed fears and reduced stigma, which in turn increased participants' confidence in telling a partner about an infection and/or helped them talk to their partner about the importance of protecting themselves against STIs, by, for example, being given words that they could use when having these discussions or sharing the actual texts. Messages were also shared with friends and siblings, initiating conversations about sexual health. The fact that this was done in a way that reduced stigma and was not pressured or judgemental assisted the communication with others. Social support for safer sex behaviours was increased through enhanced conversations with partners as well as sharing information and skills with others such as friends and siblings. There was less suggestion from the interviews that, aside from reduced stigma, other attitudes had shifted. Stigma associated with STIs can result in young people not accessing appropriate care and services,[54] and therefore its inclusion in our health promotion intervention addressing sexual health was considered key.

Based on recipients' feedback, the intervention was refined further for the main trial. We ensured that messages were relevant to men who have sex with men and women who have sex with women by seeking their views on the intervention in further interviews or a focus group. For example, we ensured that the pronouns used were gender-neutral. Additional content was included to provide examples of how others have negotiated condom use in ongoing sexual relationships and post-exposure prophylaxis (PEP) for HIV transmission and infection prevention. Participants reviewed new messages and reported that they were relevant, easy to understand and acceptable. We demonstrated that interactive support via text message is particularly acceptable in the area of sexual health intervention.[32,53,55]

The safetxt intervention delivered in the randomised controlled trial

The intervention delivered in the RCT aimed to increase safer sex in three ways: (1) encouraging participants to correctly follow STI treatment instructions, including informing partner(s) about infection; (2) promoting condom use with new or casual partners; and (3) encouraging participants to obtain testing for STIs prior to unprotected sex. Participants in the intervention group received regular messages delivered by text message in community settings in accordance with a predetermined schedule.

Over the first 10 days, participants are sent messages targeting engagement with the intervention, taking treatment, avoiding sex for 7 days after treatment and telling partner(s) about an infection. These messages provide non-judgemental, non-stigmatising information about STIs. They provide

suggestions about when, where and how to tell partner(s) about an infection and examples of how others have told partners, covering a range of different types of relationship (e.g. casual, long term).

Messages then target condom use and testing for STIs before having sex without a condom with a new partner. The topics covered are risk assessment, instructions on how to use condoms, positive aspects of condom use, tips on preventing condom problems and examples of how others have resolved condom use problems. Participants are prompted to think about their own success in achieving safer sex strategies, risks they have taken and what they could do differently in the future. Messages include advice regarding testing for STIs before having unprotected sex with a new partner. Participants are sent links to support for those concerned about partner violence, and web-based information regarding contraception, alcohol and sexual risk, how to use a condom and general communication about sex. The messages provide social support for safer sex behaviours and acknowledge participants' experiences.

The intervention employs educational, enabling and incentivising behaviour change functions and 12 behaviour change techniques. Here we provide a list of each behaviour change technique used and example text messages from the message set for women who have sex with men and were diagnosed with chlamydia:

- information about health consequences of behaviour [e.g. 'You can make sure you don't get another infection (1) by getting the person you are having sex with treated, (2) by using condoms every time you have sex and (3) by you and your partner getting tested before sex without a condom and by having another test in 3 months'; or 'If Chlamydia is left untreated or you keep getting it again, this can affect your ability to get pregnant. One way to avoid this is by getting a check-up before sex with new partners.']
- instruction on how to carry out the behaviour [e.g. 'To treat the infection, take the tablets and then don't have sex (oral, vaginal and anal) for 7 days while the infection clears'; or 'One reason a condom may split is because there is air trapped inside. To prevent this, hold the tip of the condom between your forefinger and thumb and roll it down, making sure there are no air bubbles']
- demonstrations of risk reduction behaviour (e.g. 'There are lots of other ways of telling the person you are having sex with that they need treatment. Here are some examples of how some people started the conversation: "I said that if I didn't respect you I wouldn't be telling you this. It's awkward to tell people but it's not right not to, is it? They may not know. You can't just let them walk round with an infection".')
- social support (e.g. 'If you can't face telling them, you can ask the clinic to contact them for you and they won't mention your name'); emotional support (e.g. 'Here are how others felt when they found out that their test was positive: "I never thought I'd get chlamydia. I'll use a condom in the future or get a check-up with them first".')
- social rewards (e.g. 'You made the right decision to get a test.')
- non-specific incentives (e.g. 'Regular check-ups & check-ups with new partners means infections can be treated before they cause problems.')
- encouragement to add objects to the environment (e.g. 'Having condoms with you makes it more likely you'll use one. Find a time to put a few in your purse. You could also keep a supply in places where you have sex.')
- anticipated regret (e.g. 'You can't tell if someone has an infection just by looking at them. Ask yourself if having sex without a condom is worth taking the risk.')
- reframing (e.g. 'I said using a condom was about respecting each other.')
- problem-solving [e.g. 'If he says condoms aren't comfortable you could try a different brand. Some guys find they can feel more with thinner condoms (which are still safe).']
- action-planning techniques (e.g. 'Think about when, where and how you will talk to them about condoms and how you could start the conversation.').[56]

The information on safer sexual practices is in accordance with existing guidelines.[57]

The messages are tailored according to gender and sexual orientation. Women who have sex with men only (WSM), MSM, men who have sex with men and women (MSMW) and women who have sex with men and women (WSMW) are sent messages about how others had negotiated condom use. WSM, WSMW and men who have sex with women (MSW) are sent messages about emergency contraception. MSM and MSMW are sent messages about PEP. Women who have sex with women only (WSW) are not sent messages about condom use. The information provided is specific to the STI diagnosed. This tailoring results in different numbers of messages being sent to those of different gender and sexual orientation.

The core message sets include 74 messages for WSM and WSMW; 42 messages for WSW; 69 messages for MSW and 79 messages for MSMW; and 76 messages for MSM. Recipients can request additional messages on specific topics. Participants are sent four messages per day for days 1–3, and then one or two messages per day for days 4–28, two or three messages per week for month 2 and two to five messages per month for months 3–12 (see *Appendix 1*).

Patient and public involvement

Patients and the public were involved in all phases of this study. Prior to developing the intervention, we discussed possible safer sex interventions with young people based at Southwark Further Education College. Those aged 16–24 years were invited to take part in a discussion group by one of the research team at the end of a class or by a researcher approaching students in the college canteen. Five discussion groups were convened in a private room, each comprising 2–10 participants (total of 25 participants). The participants were enthusiastic about receiving information and support via mobile phone. Patient views informed the intervention development through their participation as research participants in designing the content of the intervention. The views of the target audience were collected in nine focus groups, which informed the tone, style, frequency, duration and content of the intervention. Some research participants wrote some sections of the messages. King's College Hospital has an active user group of young people wishing to contribute to SRH research. We met with a group of 14 patient representatives to seek their views on the trial design. Their views influenced our follow-up procedures. They asked that materials be posted by normal (not recorded) delivery in a coloured envelope and wanted to receive a text message saying that the materials had been posted so that they could look out for the package. We modified the patient information, questionnaires and consent procedures based on feedback from this group. A patient representative was included in the Trial Steering Committee (TSC); it provided comments on all trial materials and provided advice during the trial. A limitation of our patient involvement work was that we did not have a patient advisory group providing advice throughout the trial. At the time of writing this report we have an active group of five patient representatives making plans about how they can be actively involved in disseminating the trial results widely once they are published.

Aim

The primary objective of this trial was to quantify the effects of the safetxt intervention on chlamydia or gonorrhoea infection at 1 year compared with a control group receiving usual care and messages about trial participation.

The secondary objectives were to determine the effects of safetxt on partner notification and condom use at 4 weeks and on condom use and STI testing at 1 year. To explore which intervention components are effective, data were collected on the theoretical constructs on the pathway to behaviour change influenced by the intervention components. We planned to establish the cost-effectiveness of the intervention.

The intervention development work was funded by the UK National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as project number 10/93/04. This trial was funded by the NIHR Public Health Research programme as project number 14/182/07.

Chapter 2 Trial methods

The methods were prespecified in our trial protocol, with updated versions published on our trial website and in a peer-reviewed journal.[58] (A list of protocol amendments along with dates of ethics approvals can be found in *Appendix 2*.)

Study design

Safetxt was a parallel-group, individual-level, randomised superiority trial in which care providers and outcome assessors were blinded to allocation. The trial used a 1 : 1 allocation ratio and was designed to establish the effects of a safer sex intervention delivered by text message on the incidence of chlamydia and gonorrhoea infection over 12 months.

Study setting

Participants were recruited from 92 sexual health clinics across the UK. Full details of the clinics are provided in *Acknowledgements*. The clinics were in cities, towns and rural areas of England, from Cornwall in the south-west to Kent in the east and Northumberland and Cumbria in the north, and in East Lothian in Scotland.

Participants

Inclusion criteria

- Either:
  - a positive chlamydia or gonorrhoea test result or diagnosis of NSU in the last 2 weeks
  - treatment started for chlamydia, gonorrhoea or NSU in the last 2 weeks.
- Own a personal mobile phone.
- Age 16–24 years (according to clinic data).
- Able to provide informed consent (patients who lacked the mental capacity to do this and those unable to understand English were not recruited).

Exclusion criterion

Known to be a sexual partner of someone already recruited to the trial.

Recruitment

Identification of participants

Recruiting clinics identified potential participants using a number of different strategies depending on their existing care pathways.

Recruitment staff in clinics identified potentially eligible patients from clinic records. Recruitment staff checked with potential participants whether or not they met the eligibility criteria and provided those eligible with a patient information sheet and verbal information about the trial. If the patient wanted more time to consider their participation, recruitment staff provided a link to the trial's enrolment

website through which patients could enrol themselves online within 2 weeks. On days when recruiting staff were not present in clinics, eligible patients could still be identified by recruiting staff reviewing clinic attendance records afterwards. Recruitment staff telephoned patients who had agreed to be contacted about research. When clinic staff contacted a patient with test results by text or telephone, they checked whether or not the patient met the inclusion criteria and asked the patient if they would be interested in the trial. Recruitment staff provided information about the trial verbally over the telephone and gave the patient the link to the enrolment website so that they could enrol themselves within 2 weeks. When patients visited the enrolment website, they could read the full patient information sheet. Some clinics provided links to the trial website by text message or e-mail along with their contact details in case the participant had further questions.

Fully informed consent

Participants provided written informed consent either in person with recruitment staff or online via the trial randomisation website (see *Report Supplementary Material 1* and *2*). For face-to-face recruitment, the original signed and dated consent forms were held securely at the site as part of the trial site file. Once the consent form and baseline questionnaire had been completed, recruitment staff entered both of these on the randomisation website and randomised the participant. If a participant was recruited and enrolled online, they provided informed consent and completed the baseline questionnaire on the randomisation website (see *Report Supplementary Material 3*). All electronic consent forms were stored electronically on the trial database.

Randomisation

Randomisation was computer-based, independent, automated and remote from the recruiting clinic, and carried out in a 1 : 1 allocation ratio.

Protecting against bias

The remote independent randomisation by computer ensured random allocation and allocation concealment. Owing to the nature of the intervention, participants were made aware of their treatment allocation. The intervention was delivered by computer, ensuring that investigators were unaware of the allocation sequence (thereby ensuring allocation concealment). As the intervention was automated, neither investigators nor clinic staff had any role in intervention delivery. The automated delivery was monitored by an information technologist who had no role in the research aspects of the trial. Both the laboratory staff assessing STIs and the statisticians were blinded to treatment allocation until the code was broken for the main analysis.

Treatment groups

Safetxt intervention group

The intervention is fully described in *Chapter 1*. The intervention aimed to increase safer sex in three ways: (1) encouraging participants to correctly follow STI treatment instructions including informing partner(s) about infection; (2) promoting condom use with new or casual partners; and (3) encouraging participants to obtain testing for STIs prior to unprotected sex. Participants in the intervention group received regular messages delivered by text message in community settings in accordance with a predetermined schedule. The intervention was informed by COM-B.[51] It aimed to influence the knowledge, beliefs, self-efficacy, skills, and social and interpersonal factors that have important effects on motivation, capability and opportunity to reduce sexual risk behaviour. The intervention content was tailored according to gender, sexuality and type of infection.

Control group

Participants in the control group received a monthly untailored text message asking for information about changes in postal or e-mail addresses. An example control group message is 'Thank you for taking part in the texting study. Remember to let us know if your contact details have changed by replying to this text or emailing safetxt@lshtm.ac.uk'. All participants received usual care and were free to seek any other existing services or support. The control group was not attention matched as during the pilot work young people reported that it was irritating to receive the same number of messages as the intervention group about another health topic when they had just been diagnosed with a STI.

All messages were sent automatically from a large database to an aggregator, which conveyed messages to each participant in the community via its network. The success of message delivery at each step was monitored by the aggregator and computer system that generated the messages. A member of the trial team was automatically notified if there was any failure in the delivery of messages. All participants were able to set embargoed times when they did not want to receive messages. Participants were able to stop text messages, but continue with the trial follow-up, by responding to text messages with 'stop'.

Outcomes

Primary outcome

The primary outcome was the incidence of chlamydia and gonorrhoea infection at 12 months.

Secondary outcomes

Secondary outcomes at 4 weeks

- Clinic attendance by partner for treatment.
- Whether or not participants took the (prescribed antibiotic) treatment and avoided sex for 7 days after treatment.
- Whether or not they told the last person they had sex with before the test to get treatment.
- Whether or not their partner took the treatment and they avoided sex with this person for 7 days after taking the treatment.
- Condom use at last sex.

Intermediate outcomes at 4 weeks

Data regarding the theoretical constructs underlying the components of the intervention (behaviour change mediators) were measured using the items below or existing scales:[59]

- knowledge relevant to the consequences of behaviour and how to avoid infection
- attitudes towards partner notification
- correct condom use self-efficacy[60]
- self-efficacy in negotiating condom use[61]
- self-efficacy in telling a partner about an infection.[62]

Secondary outcomes at 1 year

- Diagnosed with any STI after joining the trial according to self-report and confirmed by postal test results and clinic records.
- Condom use at last sex.
- Sex with someone new since joining the trial.
- Condom use at last sex with someone new.
- STI testing for self prior to sex with someone new, confirmed by clinic record.
- Participant's report as to whether or not their last new partner had been tested for STI prior to having sex with them.

- Number of sexual partners since joining the trial.
- Number of text messages read.
- Whether or not anyone else read the messages.
- Contamination between intervention and control group.
- Experience of partner violence.
- Car accident where the participant was the driver in the past year.

We also provided a free-text comment box where we asked 'Did anything good or bad happen as a result of being involved in the study or receiving the text messages? Please describe'.

Assessment of outcomes

Objective data

Testing positive for chlamydia or gonorrhoea

At 12 months, all participants were sent a self-test nucleic acid amplification test (NAAT) kit (urine for men, with additional pharyngeal and anal swabs for MSM, and self-taken vulvo-vaginal swab for women), which was returned by post and analysed in an accredited laboratory used by Preventx Limited (Sheffield, UK). The sensitivity and specificity, respectively, of self-taken tests for chlamydia is 94.1% and 99.7% with a vaginal swab, 98.1% and 99.5% with a urine sample and 91.4% and 98.2% with a rectal swab. The sensitivity and specificity, respectively, of self-taken tests for gonorrhoea is 100% and 99.8% with a vaginal swab, 100% and 99.5% with a urine sample, 92.3% and 87.9% with a rectal swab, and 100% and 87.8% with a pharyngeal swab. Additionally, for all participants, data on STI testing and results from the time of recruitment for the entire 12-month trial follow-up periods were collected from all recruiting clinics. Participants who self-reported a positive diagnosis of chlamydia or gonorrhoea at the 12-month follow-up were also asked where they had been tested. If a participant reported using a different service (e.g. a general practitioner or a sexual health clinic other than that at which they had been initially recruited), the service was contacted to verify the diagnosis.

Testing positive for any other sexually transmitted infection

The data on STI testing and results collected from all recruiting clinics included information on diagnoses of STIs other than chlamydia and gonorrhoea during the entire 12-month trial period since recruitment.

Sexually transmitted infection testing for self, prior to first sex with most recent new partner

The data on STI testing and results collected from all recruiting clinics included information on any STI tests conducted during the study period. Only *testing* was verified by clinic data; we were not able to verify whether testing occurred *prior* to first sex with most recent new partner.

Clinic attendance by partner for treatment

Recruiting clinics provided data on whether trial participants' sexual partners had attended the clinic for STI treatment after participants' initial STI diagnosis. Not all clinics collected sexual contact testing information.

Self-reported data

Self-reported outcome data were collected at 4 weeks (see *Report Supplementary Material 4*) and at 12 months (see *Report Supplementary Material 5*). Hard-copy questionnaires collecting outcome data were sent by post to participants. A URL link to a web-based data entry form was also sent to participants via text message and e-mail. Participants chose their preferred methods of submitting outcome data. Paper-based self-reported outcome data were entered into the web-based data entry form directly by a trial assistant blinded to treatment allocation.

Non-responders received further contact by telephone call, e-mail and text message. Trial assistants collected outcome data by telephone and recorded these on a hard-copy data form. All hard-copy data forms were entered into the online trial database. Where possible, discrepant data were verified with participants and corrected.

Follow-up procedures

The study team based at London School of Hygiene & Tropical Medicine Clinical Trials Unit collected follow-up data between 20 May 2016 and 28 February 2020. We collected follow-up data at two time points: 4 weeks and 1 year post randomisation. Questionnaires were sent to participants at 4 weeks and 1 year, and a STI test kit was sent at 1 year. The current contact details of non-responders were checked with the person nominated by participants at randomisation for contact in the event of non-response.

An unconditional £5 cash incentive was sent with questionnaires at 4 weeks and 1 year, and a conditional £20 cash incentive was sent after the STI test kit had been returned. We notified participants by text message 1 week before each time point (i.e. 3 and 51 weeks) and asked them to respond if they had changed their address.

We contacted non-responders at 4 weeks by post, text message, e-mail and telephone at several time points until they returned their questionnaire. At weeks 5 and 8 they were contacted by e-mail and at weeks 6, 10, 12 and 14 they were contacted by telephone, text message or post. At week 14, they were contacted by post for a response to the key questions only (i.e. 'Did you tell the last person you had sex with before you tested positive to get treatment?' and 'Was a condom used the last time you had sex?').

The primary outcome was assessed using chlamydia and gonorrhoea tests collected by post at 1 year and clinic records of completed tests during the 12-month trial follow-up period. STI test kits were posted (in P650 standard packaging) to respondents. Directions in the pack were for participants to provide a vaginal swab (women), a urine sample (men), an oral swab (men who have sex with men) or anal samples (men who have sex with men) and then place this in the packaging before posting it to the laboratory using the prepaid and addressed envelope. The test kits were identified by laboratory number only, rendering the laboratory staff blind to the participant's allocation. The results of the STI testing were reported on the secure trial laboratory site by laboratory code. Laboratory codes and participant identification numbers were linked at the trial co-ordinating centre. Self-reported data were collected by post or any method to which the participant had agreed at enrolment (i.e. mobile phone or e-mail).

Non-responders were contacted at 1 year by post, text message, e-mail and telephone at several time points until they returned their questionnaire and/or STI test kit. At week 55 they were contacted by telephone and e-mail. At weeks 57, 59 and 61 they were contacted by telephone, text message and post. At week 62 they were contacted by telephone, text message and post for a response to the key questions only [i.e. 'Have you been diagnosed with chlamydia, gonorrhoea or non-specific urethritis (NSU) after joining the study?', 'Where did you get tested?' and 'Where did you get treated?'].

We included data from participants for whom there was evidence of a STI test conducted elsewhere (i.e. a test result not obtained through the safetxt STI postal test kit). Clinic records were checked by clinic staff to confirm self-reported data regarding STI tests, STI diagnoses after joining the trial and partner attendance for treatment. We also included data from tests conducted at the clinic at which participants had been recruited. If participants were tested elsewhere, they sent evidence of their STI test results to the study team for confirmation that the test had been carried out at another service. Alternatively, we asked participants for permission to contact their service provider to confirm that they had been tested there.

Data management

Data were held on a secure system and password protected. Any data on paper were locked in a cabinet in a room that was locked unless staff were working in the room. Access to the building is only by London School of Hygiene & Tropical Medicine identification cards. All trial procedures were in accordance with the principles of Good Clinical Practice. The essential documents of the sponsor/trial organisers and investigators will be retained for at least 10 years after the completion of the trial. In accordance with the London School of Hygiene & Tropical Medicine's retention requirements, primary research data will be retained for 10 years following the completion of the trial. In accordance with the Data Protection Act 2018,[63] personally identifiable data about participants were not kept longer than necessary and were deleted within 3 months of the end of the trial. If a patient withdrew from the trial, attempts were made to contact them to determine if they were still happy for any further data collected from clinics to be used. If no contact could be made with the patient, we assumed that they had withdrawn from the whole trial and did not want their data to be used.

Data monitoring, quality assurance and preparation

All data systems were set up with checks to alert the trial assistants if the data being entered were illogical, inconsistent or incomplete. A random sample of 10% of questionnaire data entered at 1 and 12 months was double checked in March 2017. As no errors were found, a further random sample of 100 participants' 1- and 12-month data were checked in March 2020. Again no errors were found. STI tests were conducted in accredited laboratories and the results data were entered manually into the database directly. All positive test results were double checked. Melissa J Palmer prepared and coded the data for analysis (see the statistical analysis plan[64] for full details).

Sample size

Original sample size justification

Two main factors determine the number of participants needed in a trial: the estimated event rate and the size of the treatment effect.

Estimated event rate

The estimated event rate for the incidence of STI at 1 year was 20%, based on the event rate in cohort studies and the pilot trial.[4,32]

Size of treatment effect

Because the intervention can be administered to large populations at low cost, even a modest reduction in treatable STIs would be worthwhile. Therefore, the trial has been designed to detect a reduction in chlamydia or gonorrhoea infection of 20% compared with 16% (relative risk 0.8), which is similar to the effects of face-to-face safer sex interventions.[5]

Numbers needed

In the pilot trial, there was 2% contamination between the intervention and the control group. If the real difference in STI infection at 1-year follow-up was 20% compared with 16%, then with contamination of 2% the trial would detect a difference of 19.9% compared with 16% [this is calculated based on 2% of the control group having an infection rate the same as the intervention group = $(98\% \times 20\%) + (2\% \times 16\%) = 19.9\%$]. To detect this difference, there is a 90% chance that a trial with 5000 participants will achieve a p-value of < 0.05, even allowing for 20% losses to follow-up.

The NIHR Public Health Research programme board requested an assessment of heterogeneity in effects of the intervention according to key subgroups. While recognising that subgroup analyses will

still be underpowered, a trial with 90% power for the primary outcome will have greater power for assessing differences in effect of the intervention in subgroups than a trial powered to 80% for the primary outcome.

Revised sample size justification

The TSC reviewed the blinded event rate after 546 patients had completed 12 months' follow-up and recommended an increase in the sample size to 6250 because of a lower than expected event rate of 15.6%.

We reviewed the blinded primary outcome event rate (chlamydia or gonorrhoea at 12 months) across intervention and control participants randomised into the safetxt trial between 1 April 2016 and 1 December 2016. We selected this time period to allow sufficient time for the completion of our follow-up procedures. Of 546 participants randomised during this period, 26 had a positive postal sample test result at the 12-month follow-up. All clinics taking part searched their records to identify participants who had attended with a chlamydia or gonorrhoea infection between randomisation and the 12-month follow-up. An additional 59 participants were diagnosed with chlamydia or gonorrhoea in clinics between randomisation and follow-up who did not have a positive postal test result. Thus, the primary outcome event rate based on validated events at this time point was $(26 + 59)/546 = 15.6\%$.

Revised sample size

Assuming a control group event rate of 17%, a trial of 5900 participants would give us 90% power (with a two-sided alpha of 5%) to detect a relative risk of 0.8 in the primary event rate (17% vs. 13.6%), allowing for 20% losses to follow-up. To allow for 2% of the control group reading the intervention messages, the required sample size needed to be increased to 6250, reflecting an event rate of 16.9% $[(17\% \times 0.98) + (13.6\% \times 0.02)]$ compared with 13.6%. The effect size (relative risk 0.8) and 90% power are identical to those of the original sample size calculation.

Analysis

Definition of populations for analysis

All analyses were conducted according to randomised group regardless of whether or not the participants received the allocated intervention (i.e. analyses estimated the intention-to-treat effects).

Major protocol deviations

Major protocol deviations are reported in *Chapter 4*, *Recruitment, randomisation and exclusions*. If participants were randomised again in error less than 4 weeks after they had been randomised the first time, they were removed from the trial if allocated to both groups or retained as one participant if allocated to the same group twice.

If participants were randomised again in error more than 4 weeks after the first randomisation, then the first randomisation was retained and any subsequent randomisations were deleted. The rationale for this was that participants were recruited by clinic staff when they were diagnosed with chlamydia, gonorrhoea or NSU. If a participant was recruited and randomised more than 4 weeks after a first randomisation, this was likely to be because they had been identified subsequently as having chlamydia, gonorrhoea or NSU; that is, in these circumstances being randomised more than once was contingent on the participant having a diagnosis of chlamydia/gonorrhoea/NSU (the primary outcome) after the first randomisation.

General statistical considerations

All statistical tests and CIs were two-sided. Significance was considered at the 0.05 level and CIs were at the 95% level. Statistical analysis was performed using Stata 16 software (StataCorp LP, College Station, TX, USA).

Assumptions about missing data

Assumptions about missing data are important here because (1) losses are expected to be high (20%), (2) the reasons for losses will also be important and are likely to be related to outcomes, and (3) by imputation you could potentially increase power. Data are assumed 'missing at random' (MAR). A MAR assumption assumes that missing data for participants who did not complete follow-up are similar to data from participants who completed follow-up, based on similar baseline covariates (i.e. that missingness is independent of the missing data).[65] We conducted the primary analysis under a MAR assumption (conditionally on the adjustment variables in the model) and then performed sensitivity analyses under different assumptions for the missing data, as explained below. In addition, we conducted a complete-case analysis as a supplementary analysis.

Missing baseline covariates

The database requires all items on the baseline questionnaire to be submitted to randomise. Therefore, there were no missing baseline covariates.

Missing primary outcome data

Missing primary outcome data occurred if:

- participants did not return their completed STI self-test kit

and

- no testing information was identified from clinic records (because participants either did not test at the clinic they were recruited from or tested at a different health service from the one they were recruited from/provided information about and this service did not provide data)

or

- testing information from clinic records showed that the participant received a negative test result for chlamydia and gonorrhoea less than 12 months post randomisation (i.e. so it is possible that after the clinic test they contracted chlamydia or gonorrhoea during the follow-up period).

Primary analysis

Analysis of the primary outcome

A detailed statistical analysis plan[64] was published prior to data analysis and unblinding of the trial. The primary analysis was independently coded and performed by two statisticians. The primary outcome was binary, and we compared the incidence of chlamydia or gonorrhoea infection at 1 year in each group. Our substantive primary analysis model was a logistic regression, adjusted for the prespecified baseline covariates (age, type of STI at baseline, sexuality and ethnicity) to improve the efficiency of the analysis and avoid chance imbalances.[66] The covariates to adjust for were carefully selected, using knowledge of previous studies and the literature, to achieve these aims while avoiding collinearity issues.

For the primary analysis, we used multiple imputation by chained equations (MICE)[67] to obtain inference for the intervention effect, assuming that missing outcome values were MAR. That is, we created 100 imputed data sets and fitted the primary analysis logistic regression model to each of these, using (as is standard practice with multiple imputation) Rubin's rules[68] to combine the results for final inference.

To maximise the plausibility of the MAR assumption, and to estimate the intervention effect as precisely as possible, we added a number of auxiliary variables to the imputation model. As described in the statistical analysis plan,[64] these were chosen from a prespecified list of baseline and week 4

follow-up data. The most useful auxiliary variables for multiple imputation are those that are the strongest independent predictors of the missing outcome values. Therefore, as described in the statistical analysis plan, we used forward stepwise regression of outcome on baseline (omitting randomised allocation) with *p*.enter (0.09), *p*.exit (0.1) to identify any auxiliary variables (in addition to those in the substantive model) to be included in the imputation model.

The auxiliary variables identified by this process and included in the imputation model (in addition to those in the primary analysis model) were as follows:

- number of sexual partners at 4 weeks
- attitude, being the sum of four variables: (a) 'Most people with STI will tell their partner (1, strongly disagree, to 5, strongly agree); (b) 'It is my responsibility to tell my partner if I have an STI' (1, strongly disagree, to 5, strongly agree); (c) 'My partner would be glad if I let them know' (1, strongly disagree, to 5, strongly agree); and (d) 'My partner would think badly of me if I tell them I have an STI (1, strongly disagree, to 5, strongly agree) [note that the score for (d) is reversed before being added to the other scores]
- type of infection (baseline)
- tested before sex with a new partner (baseline).

We used the 'augment' option in Stata's 'mi impute chained' command to guard against possible collinearity issues in the imputation. We imputed separately in each treatment allocation group.

We report the adjusted ORs along with the 95% CIs and *p*-values both from the analysis using multiple imputation and from fitting the primary analysis model to the subset of patients with complete records on all of the variables in the primary analysis model.

Analysis of the secondary outcomes

The analysis of the secondary outcomes followed the same procedure as the analysis of the primary outcome, again as detailed in the statistical analysis plan. We used MICE and estimated the difference between the groups using logistic regression for binary outcomes and report ORs with 95% CIs and *p*-values. Regressions were adjusted for the covariates.

Analysis of the intermediate outcomes

The intermediate outcome measure comprised multiple ordinal scales. Using data from the first 1025 randomised participants, we assessed the construct validity of the intermediate outcomes and refined them using confirmatory factor analysis. The originally specified confirmatory factor analysis model was based on the a priori factor structure of the model (which items loaded on which factors), as shown in *Table 1*. For this original model, the goodness-of-fit indices indicated borderline fit (root-mean-square error of approximation 0.083; comparative fit index 0.936; Tucker–Lewis index 0.923). After the modification indices were examined to identify sources of poor fit, the model was revised. The variable 'most people who have an STI will tell their partner' was dropped from the model as it had a low factor loading of 0.287 on attitudes to partner notification. The variable relating to how easy or difficult it would be to 'put a condom on' was dropped owing to cross-loadings (indicating a lack of discriminant validity) between the 'correct condom use self-efficacy' factor and the 'self-efficacy in negotiating condom use' factor. Finally, we allowed the error terms of the variables 'How easy or difficult would it be to tell the last person you had sex with that you had an STI' and 'How easy or difficult would it be to tell the last person you had sex with to get treatment' to correlate, and did the same for the equivalent variables that referred to a 'new partner'. We considered this appropriate given that the correlations of error terms between these pairs of variables is likely to be a case of an 'item priming effect'.[69] It seems reasonable that the answer to the first question in each of these pairs will directly affect how the respondent answers the 'treatment' item, as informing a partner of one's infection is a prerequisite to informing them that they will need treatment. Once these changes had been applied, the revised model showed good fit to the data (root-mean-square error of approximation 0.052,

TABLE 1 Intermediate outcomes and corresponding questionnaire items

Theoretical construct	Question item	Answer options
Knowledge related to STIs	To what extent do you agree or disagree with the following:	
	If someone had a STI, they would know	1. Strongly disagree 2. Disagree 3. Unsure 4. Agree 5. Strongly agree
	STIs are rare	As above
	I can tell if someone has an STI	As above
Attitudes towards partner notification	To what extent do you agree or disagree with the following:	
	Most people who have an STI will tell their partner[a]	As above
	It's my responsibility to tell a partner if I get diagnosed with an STI	As above
	If I tell my partner I have an STI, my partner would be glad I let them know	As above
	If I tell my partner I have an STI, my partner would think badly of me	As above
Self-efficacy in telling a partner about an infection	How easy or difficult would it be to:	
	Tell the *last* person you had sex with that you had an STI	1. Very easy 2. Easy 3. Unsure 4. Difficult 5. Very difficult
	Tell the *last* person you had sex with to get treatment	As above
	Tell a new partner you had an STI	As above
	Tell a new partner to get treated	As above
Correct condom use self-efficacy	How easy or difficult would it be to:	
	Put a condom on[a]	As above
	Keep a condom from drying out during sex	As above
	Keep a condom from breaking or coming off during sex	As above
	Keep a condom on while withdrawing the penis	As above
	Keep a condom on from start to finish	As above
Self-efficacy in negotiating condom use	Imagine that you and your partner have sex but do not use condoms. You want to start using condoms. How easy or difficult would it be for you to tell your partner that you want to use condoms?	As above
	Imagine that you are having sex with someone new. You want to use condoms. How easy or difficult would it be for you to tell them that you want to use condoms?	As above
	Imagine that you are having sex with someone new. You want to use condoms. How easy or difficult would it be for you to tell them that you will not have sex unless you use condoms?	As above

a Variable dropped from the model, as explained in *Analysis of the intermediate outcomes*.

comparative fit index 0.980, Tucker–Lewis index: 0.975). Furthermore, multigroup analyses across genders, sexual orientation and mode of questionnaire (telephone vs. written) indicated measurement equivalence across these groups.

The impact of the intervention on these refined intermediate outcome measures was examined. To aid interpretability, we present the results of two analyses. One is based on summing the responses to each item contributing to that intermediate measure and using a linear regression to test for a difference in mean scores between the groups. The second analysis extends the confirmatory factor analysis measurement model described above into a structural equation model, using the allocation as the main predictor variable, thereby estimating the impact of the intervention on the intermediate outcomes in the absence of measurement error. These regressions were adjusted for the same covariates as the primary analyses.

Secondary analyses

Complete-case supplementary analysis

As a comparison with the primary imputation analysis, we analysed the effect of the intervention on the primary outcome by including only complete primary outcome data in the analysis. We used logistic regression adjusted for the covariates. We report the adjusted ORs along with the 95% CIs and *p*-values.

Subgroup analyses

Recognising that the trial was not powered to detect effect differences in subgroups, we conducted exploratory subgroup analyses for the primary outcome to determine if the intervention effect varied by baseline characteristics. The subgroup analysis was conducted on the multiple imputation data set. The subgroups had been prespecified[64] and included age (16–19, 20–24 years), gender (female, male), sexual orientation (MSM or MSMW, MSW, WSM or WSMW), ethnic group (white British/other white background, black/black British, all other groups), and, as a measure of socioeconomic status, adjusted Indices of Multiple Deprivation for use across the UK[70] [quintiles 1 and 2 (least deprived), quintile 3, quintiles 4 and 5 (most deprived)]. Across the subgroups, we assessed heterogeneity of treatment effect with a test for interaction using logistic regression.[71–75] Interaction test *p*-values are presented but should be interpreted with caution due to the exploratory nature, the multiple tests performed and the low power of the interaction test. We estimated ORs along with 95% CIs for each subgroup. Intervention effect estimates by subgroups are presented in a forest-type plot. As this was an exploratory analysis of potentially influential characteristics, we did not hypothesise effect directions. Age and gender are considered the two key subgroups and the analyses of these subgroups were conducted first.

Analysis of additional data collected

The additional data collected are described by group in the following sections, but we did not conduct a formal comparison between the groups.

Contamination

We assessed the potential for contamination between the intervention and the control group and calculated the proportion of intervention respondents who shared messages with other trial participants and the proportion of control respondents who read other participants' messages.

Intervention dose

To estimate the intervention dose received, we present the proportions of participants in the intervention group who report reading 'all', 'most', 'few' and 'none' of the intervention messages. We also report the proportion of messages successfully sent from the SMS gateway.

Participants' feelings regarding others reading their messages

Among participants in the intervention group who reported that someone else had read the messages, we present the proportions who felt 'happy', 'unhappy' and 'unsure' about it.

Adverse events

At 12 months, we collected data on experience of partner violence in the last year and involvement in car accidents where the participant was the driver in the last year. Partner violence can be a consequence of partner notification and in some contexts where mobile phone privacy is not assured, receiving messages by mobile phone on sensitive topics has been shown to increase risk of partner violence among those at risk.[76,77] Car accidents are a demonstrated harm of text messaging.[78]
We present the proportion of participants who reported each adverse outcome by intervention group and the *p*-value (calculated by a chi-squared test or Fisher's exact if fewer than five events).

Chapter 3 Strategies to increase recruitment and follow-up in the safetxt trial

Background

Achieving full recruitment and high follow-up in RCTs remains a significant challenge. In 2017, a review found that just 56% of RCTs published in the *Health Technology Assessment* journal recruited to their final target.[79] This leaves the remaining trials underpowered, reporting less precise results than planned, which could lead to potentially beneficial interventions not being implemented due to lack of clear evidence of their effects.[80] Achieving high follow-up is even more challenging for studies that collect data on sensitive topics, such as sexual health.[81,82] Failure to achieve high follow-up can reduce trial power and is a threat to trial validity, as those lost to follow-up may differ from those followed up.[83] Failure to fully recruit or achieve high follow-up may also waste valuable time and resources, or additional resources may be needed to fully recruit.[80]

There is little research on increasing recruitment success in clinical trials that focuses on interventions targeted at recruiters.[80] The few studies that are available found that sites who had site initiation visits recruited more participants[80] and that having all staff present at site initiation visits is deemed beneficial for trial progress.[84] Effective planning for the trial is consistently noted as an important factor of successful recruitment.[85,86] Communication is frequently raised as important for recruitment success; sites that receive additional communication strategies recruit more participants on average and in less time.[80] Regular communication through a variety of methods, tailored to individual sites and used to convey a variety of messages, is highlighted as important for trials to recruit successfully.[84,85,87] Monitoring is also frequently highlighted as important for recruiting effectively. Constant monitoring enables bottlenecks in recruitment to be identified[88] and flexible and rapid solutions to recruitment issues to be provided.[86]

A wide range of approaches to increasing trial follow-up and follow-up for postal, e-mail and telephone questionnaires have been evaluated in RCTs. Achieving high follow-up on sensitive topics such as sexual health, especially among young people, is challenging; for example, in the UK, response rates to the Natsal-3 sexual health survey were 57.7%,[89] and the response rate to a previous survey and trial involving STI postal tests among young people was 31.5%[90] and 45.5%, respectively.[91] We previously reported our approach to developing trial follow-up procedures that were used in our pilot trial to achieve over 80% follow-up with 200 young people.[92]

In this chapter, we detail our approach to recruitment and document how we adapted our follow-up procedures during the safetxt trial. We provide practical examples of our strategies to share our learning about trial recruitment and follow-up.

Methods

Recruitment

To optimise recruitment processes, we adopted a dynamic collaborative approach with our recruiting sites. We considered good communication to be central to our collaborative approach and successful recruitment. This began with the site initiation, where an initial recruitment strategy was developed and the relationship was established. We asked sites to ensure that key recruiters were present, and we attended the training in person whenever possible to enhance the relationship with the main contacts. Throughout the trial, we met new site staff whenever possible, at least via teleconference,

to promote a positive relationship with the sites, enabling good communication. The aim of maintaining regular contact with sites with regular updates was to keep the trial in the forefront of their minds, and enable us to be aware of any possible issues as, or even before, they arose. This allowed us to respond to queries quickly, monitor recruitment, quickly identify any problems with recruitment and address them through discussion with the site teams, and work with sites to adapt recruitment strategies in response to new issues such as changes in clinics. Working with sites allowed us to take into account different competing deadlines and workloads. We were able to have a productive collaborative approach to recruitment as the trial progressed, based on the relationships that we had established with our recruiting teams.

We used a range of methods for communicating different types of information. We conducted visits and used telephone, e-mail, letters, newsletters, social media and our website to convey information to our sites.

Newsletters

Newsletters were our primary form of regular communication with all sites. We issued a newsletter at the start of every month while the trial was recruiting, which was sent to all clinic staff for whom we had an e-mail address (see *Report Supplementary Material 6*). The newsletters covered a range of topics and presented information in a variety of ways to make sure that this was interesting and relevant.

Recruitment updates were shared in every newsletter. Overall recruitment numbers were always presented, with additional monthly figures highlighting a variety of other recruitment numbers. This could include each site's monthly total; sites whose monthly figure had improved; top recruiting leaderboards, based on overall and monthly numbers; recruitment countdowns as the end of recruitment approached; average recruitment figures per site; and sites that had reached recruitment milestones, such as having recruited 100 participants.

We also included staff profiles of the Trial Management Group in the initial newsletters and also when new staff joined the team. These profiles briefly described the staff member's role in the trial and gave a 'fun fact' about them and their contact details. This was designed to help to build relationships with the sites and keep the sites up to date with who was working with them in the trial.

The newsletters included site updates such as new sites opening and interviews with recruiting sites in order to share recruitment processes and tips with the other sites. Other updates the newsletters highlighted were the introduction of certificates for staff who recruited participants, competitions for hampers of treats and staff who had been nominated by their site as a top recruiter. Wherever possible, we included pictures of clinic staff in order to help build a sense of community among all of our recruiting sites.

The newsletters also included reminders of recruitment tips and relevant information. Examples of these included the inclusion/exclusion criteria, how to use the enrolment website and how to use the recruitment materials we sent to the sites. We also highlighted participant concerns from the screening logs and provided solutions for addressing these concerns when recruiting.

Finally, the newsletters were a useful space for communicating any general trial updates. These included key changes arising from amendments, any upcoming conferences or meetings at which safetxt was going to be presented and any upcoming conferences we were hosting. We also used the newsletters to highlight feedback from the meetings we held for the clinic staff in a visually appealing way, rather than just a listing these in a Microsoft Word (Microsoft Corporation, Redmond, WA, USA) document. Moreover, we used the newsletters to provide updates on other aspects of the trial that were ongoing, such as beginning follow-up and how follow-up was progressing, and including positive quotations from participant feedback.

Recruitment techniques

Throughout the recruitment period we implemented four techniques to facilitate and improve recruitment as the trial progressed. We were able to respond to recruitment challenges with helpful activities and solutions because of our established relationship with the sites and continuous communication. Technique 1 enabled us to evaluate our recruitment progress, and techniques 2–4 provided interventions for increasing recruitment numbers.

Technique 1: monitoring and reviewing recruitment progress

We continually evaluated each site's recruitment progress throughout the recruitment period. We identified barriers to recruitment by monitoring daily recruitment numbers, allowing us to quickly identify dips in recruitment that we could discuss with a member of the recruiting team. For example, recruiting staff may have changed work patterns to cover walk-in clinics rather than appointments. As a result, the recruitment strategy would need to be adjusted; ideas for recruitment strategies could come from another site's recruitment experience. Continuous monitoring of, and a swift response to, changes in recruitment numbers allowed us to quickly address any possible recruitment problems in collaboration with the site.

Screening log data regarding the proportion of those approached joining the trial were collected from sites and reviewed monthly, allowing us to address systemic recruitment challenges. The screening logs was to highlight any sites experiencing a high rate of declinations, suggesting that we revisit its recruitment strategy. The log also included any reasons for patients declining to participate (see *Report Supplementary Material 7*). Common responses were discussed by the Trial Management Group and possible solutions were fed back to sites. For example, some participants were concerned about receiving post. We gave recruiting sites an example of our envelopes to show participants that these were opaque and had no identifying logos or stamps on the outside. The screening logs also gave us an opportunity to think about recruitment barriers from the patient perspective. Patients frequently declined to enrol at the clinic because they did not have time to do so after their appointment, so research staff were encouraged to incorporate discussing the trial with patients while they waited for their appointment. Thus, screening logs proved a valuable resource for addressing recruitment challenges highlighted by rates of, and reasons for, participant declinations.

Technique 2: facilitating shared learning

We facilitated sharing learning regarding recruitment skills and strategies for increasing recruitment, primarily by encouraging collaboration between sites. We held four teleconferences throughout the trial, the main focus being to discuss recruitment. These discussions enabled sites to identify common challenges and share ideas of how to overcome them. Site staff also shared ideas for motivating recruiting staff and tips for how they had increased recruitment at their site. Groups for the teleconferences were split between 2 days, and we ensured that both high- and low-recruiting sites were in each so as to best facilitate mutual learning. We disseminated the discussion with all sites after the meetings. Although the discussions were organised by us (i.e. the LSHTM trial team) and centred on recruitment, we encouraged the sites to lead the discussions themselves, which enabled the investigators to take ownership of their ideas and successes. We also held two meetings in London for all sites to attend. Nurses gave presentations on their experiences recruiting and we held talks from speakers on topics related to recruiting in clinical trials and sexual health, as well as a workshop on effective communication. Providing opportunities for sites to collaborate and learn from each other's experiences proved extremely valuable in generating practical and implementable ways to improve recruitment.

Another approach we took to increase learning and recruitment skills was revisiting our recruiting sites. By physically visiting the sites, we gained an insight into the clinic environment and what could help to improve recruitment. Visiting both the sites that recruited well and those that were not recruiting as well also helped to highlight which elements of the clinic pathways and techniques were enabling recruitment. Visiting sites after there had been staff changes, and asking all clinic staff to be available, also helped to motivate clinic staff and refresh their engagement with the trial.

The engagement of all clinic staff, rather than just one recruiting staff member, enabled the identification of eligible patients at all potential points in the clinic pathway. For example, reception staff attending the site visit offered to help to notify recruiting staff when a patient arrived for their appointment. Site visits while recruitment was ongoing helped staff to continue to optimise their clinic environment for recruitment, and increase staff's confidence in their recruiting skills.

Technique 3: tailored recruitment materials

We created and improved recruitment supporting materials throughout the recruitment period. We developed recruitment and promotional packs containing posters aimed at potential participants, posters aimed at clinic staff, stickers for computer monitors and checklists for keeping track of eligible patients (see *Report Supplementary Material 8*). These packs were sent to all sites and feedback was encouraged. We also encouraged site staff to share any locally produced materials for promoting recruitment with other recruiting sites. For example, reminder stickers and computer pop-ups were shared and adapted for other sites to use locally. Sharing materials between sites was beneficial for staff who worked in similar clinic environments, as the Trial Management Group might not always have had the best insight into how to optimise recruitment as part of their day-to-day processes. This also motivated the sites that produced the materials, who we would thank in trial-wide distributed newsletters. Materials designed to improve recruitment can be continually re-evaluated and updated as recruitment progresses to address new challenges, refresh information and incorporate feedback from the individuals who use these materials to make them more useful.

Technique 4: sustaining motivation

We used a number of approaches designed to help increase and sustain motivation.

Achievable goals

One approach was to provide individually tailored targets and feedback for each site. We set achievable and realistic targets, for example to recruit one more participant than their average number of recruits, or to recruit one more participant than the previous month. This helped to motivate sites that may have lacked experience and resources or those clinics seeing fewer patients, which may not have been able to achieve the high recruitment numbers that some other sites can easily achieve. The rationale for this was when sites are able to meet their target this increases their confidence and motivation to recruit again.

Feedback and rewards

We also aimed to motivate sites by offering a number of conditional and unconditional rewards. Sites that met or exceeded targets were highlighted in our monthly newsletters and e-bulletins that were distributed to everyone involved in the trial, and sites also received acknowledgement from the Trial Management Group. Sites were contacted mainly by telephone or e-mail praising their recruitment efforts and highlighting how important their achievement was to the overall success of the trial. Individual feedback is important for demonstrating to each and every site its importance in the trial, and to increase its self-efficacy in recruiting.

We held frequent competitions that were not always contingent on recruiting the largest numbers to win. For example, sites that recruited one more participant than the previous month were entered into a prize draw for hampers of snacks and promotional materials such as mugs (see *Report Supplementary Material 9*). These competitions aimed to motivate smaller sites that were unable to reach the larger recruitment numbers achieved at other sites, encouraging them to improve their recruitment numbers and meet achievable goals. We also sent unconditional incentives to sites during quiet recruitment periods, for example holiday periods. This included motivational recruitment packs that contained recruitment materials along with sweets or biscuits. We sent letters to the sites' chief executives, thanking the research team for their efforts in the trial (see *Report Supplementary Material 10*). Finally, we provided certificates to sites for reaching milestones. These were awarded either to the site or to specific staff for recruiting a

certain number of participants (see *Report Supplementary Material 11*). The certificates were helpful as they could be included in nursing appraisals. Rewards to sites, both conditional and unconditional, are crucial to let all sites know their contribution is valued, in turn motivating them to continue putting efforts into recruiting.

Follow-up

From the outset we employed the evidence-based follow-up procedures developed from our pilot work and described in *Chapter 2*.[81] From May 2018, the Trial Management Group increased its efforts to improve follow-up rates by addressing barriers to follow-up identified from participant feedback and by readdressing findings from evidence-based research.[93,94]

Utilising participant feedback

Participants gave feedback about their experiences in the study during the follow-up telephone calls and in the 1-year questionnaires. We used this information to improve trial follow-up procedures and materials. Some non-responders reported that they had not returned their STI test kits because they had to 'buy a stamp' or 'go to the post office', indicating that they were not aware that all of the follow-up materials could be returned using the freepost envelope and boxes. As a result of this information, we produced additional instructions demonstrating visually how to return the materials by freepost and without a stamp. We enclosed postage slips with the visual instructions with 1-year follow-up letters from May 2018 (see *Report Supplementary Material 12*). Instructions for posting follow-up materials were also restated during the follow-up telephone calls with participants.

Our follow-up contact with non-responders revealed that many participants changed their address during the study as they were at university or travelling. We were aware that at least 40% (2516/6248) of participants changed address at least once during their time in the study. If participants changed address but did not notify our team, acquiring their new address was often challenging and time-consuming. In response to this insight, we developed our materials to encourage newly consented participants to contact us with their new address if this changed over the period of the study and to increase their awareness of the 1-year follow-up date. In August 2018, we updated the postal thank-you slips that participants received after returning 4-week questionnaires so that these included a reminder that the participant would be contacted again in 1 year (see *Report Supplementary Material 13*).

It was common for participants to inform recruiting staff that they would be changing address soon. We kept a record on our database of the participants who provided this information so that we could confirm their address before they were sent follow-up letters. We also created pocket cards for recruiting staff to give to participants when they joined the study (see *Report Supplementary Material 14*). These were used from August 2018 for participants to keep a record of the 1-year follow-up date and was a convenient way for participants to record the contact details of the study team. Participants were encouraged to keep the card for the duration of the study so that they could notify the study team if they changed address during the 1-year follow-up period.

We used both landline and mobile phones to contact non-responders because some participants communicated a preference to receive calls from one or the other type of phone. Owing to the sensitive nature of the study, staff used a friendly but professional tone when speaking to participants over the phone to encourage participants to feel at ease. We followed a telephone script during calls, which was regularly reviewed and developed at Trial Management Group meetings. Edwards *et al.*[93] have shown that the odds of response reduce when 'survey' is mentioned in e-mails. Therefore, we did not use this term when corresponding with participants. We also took this into account when considering the terminology used during phone calls to participants. Rather than asking participants if they had time to complete a 'survey' or 'questionnaire', we asked them if they had time to answer 'some questions'.

If participants answered the phone at a time inconvenient for them, we asked them to suggest another day and time when we could call them back. We reminded them that we would also send the link to

the online questionnaire later that day, and if it was more convenient to complete the questionnaire online instead then we would not need to follow up again by telephone. The date and time when we planned to carry out the return telephone calls were logged in a spreadsheet. The study team worked a range of shifts so that participants could be contacted at different times of the day and evenings.

If participants were on holiday when we called, we arranged a date and time of day to call them back when they returned. Information that participants shared during follow-up calls was logged in a spreadsheet so that if, for example, they were 'in Dubai for 3 weeks' we would keep a record of when we were going to call them back. We felt that recalling information that they shared also helped to build a rapport with participants.

If participants were living abroad when we called them, we asked their permission to send the follow-up letters to their overseas address. We included the funds in their local currency for participants to return the STI test kit back by post. We also sent their £20 conditional incentive in their local currency if that was what they preferred.

When participants joined the study, we asked them to provide the e-mail address and telephone number of an alternative contact. We asked their alternative contact for updated details if the contact information that the participant had initially provided was no longer valid.

Regular contact with the recruiting teams was essential for improving both recruitment and follow-up rates. We planned to have regular contact with the teams through a series of one-to-one telephone meetings, teleconference sessions and face-to-face meetings, where possible. As the recruiting teams made the initial contact with participants, they were able to provide useful insights into some of the participants' concerns about follow-up enabling us to address these. User research conducted for the safetxt pilot study showed a preference for blue envelopes so that these would be recognisable to the participant only. We also encouraged recruiting teams to tell participants that they would be notified by text message 1 week before letters were sent. If they were concerned about receiving post at their home address, they could monitor the letters to ensure that these could be identified easily and opened discreetly.

Some participants mentioned that they had not returned their STI test kit because they had completed a test elsewhere. In response to this, we updated the follow-up letter to clarify that we would like participants to return the study test kits even if another test had been carried out elsewhere. If participants declined to complete another test kit, we gained their permission to obtain the relevant test results from their recent place of testing.

Readdressing findings from evidence-based methods and pilot study

We reflected on how evidence-based methods[93] could be introduced in the main study. Evidence showed that handwritten and hand-stamped envelopes led to more follow-up responses than printed and franked envelopes. Therefore, we amended the return methods we used for non-responders at 1 year. If they had not returned their STI test kit after three postal attempts, they were asked to return their follow-up questionnaire in a handwritten and hand-stamped envelope.

Evidence-based methods show that the odds of response may increase with prize draws.[93,94] Therefore, we held a monetary prize draw in February 2019 for participants who had not returned their postal STI test kit. There was an opportunity for two participants to win £50 for returning their samples. A second prize draw was held in February 2020 for an opportunity for participants not included in the first prize draw to win a prize draw for returning their samples. Evidence-based methods show that the odds of response were increased when a deadline was given.[93] We asked participants to return the kit within 1 month to be entered into the draw. Edwards *et al.*[93] showed that the odds of response increase by half when including a statement that others had responded. The text message to notify participants about the prize draw stated that 'others had responded' to the prize draw.

Evidence-based methods also show that the odds of response is triple when a picture is included in an e-mail.[93] We included a picture in the e-mails to non-responders at 1 year from October 2019 (see *Report Supplementary Material 15*).

From May 2018, we modified our follow-up procedures (*Table 2*). The follow-up letters and instructions for returning samples were made shorter and simpler. We sent non-responders a STI test kit at three time points (weeks 57, 59 and 61) and reviewed the response rates after each occasion. As the response rate increased at each time point, we added another time point from August 2018 so that non-responders after this date were also sent a STI test kit at week 62, as well as being contacted by telephone, text message and post. In July 2019, another time point was added so that non-responders were contacted by telephone, text message and post with a questionnaire and/or STI test kit at week 64.

Results

Our highest-recruiting month saw 360 participants recruited, exceeding our peak monthly target of 350 participants. Based on recruitment strategies discussed at the site initiations, 88% of clinics screened pre-booked appointments and 60% of clinics identified patients from walk-in appointments. The strategy used depended on the type of appointments the clinic ran, with many clinics having both types available. Sixty-nine per cent of clinics planned to recruit patients when they contacted them with test results. The clinics that did not use this approach did not for a number of reasons, including because their results text messages could not be adapted, or that staff contacting patients with test results were not trained in Good Clinical Practice. Many sexual health clinic services were reconfigured or altered during the recruitment period, meaning that the recruitment strategies used at some clinics changed during the course of the trial.

Although we saw increases in recruitment figures following our interventions (*Figure 2*), the time it took from implementing an intervention to it having an effect on sites varied depending on the type of intervention. For example, in May 2017 we sent refreshed recruitment packs to all sites and increased contact with sites that were finding it hard to recruit. It was time-consuming to put together the recruitment packs and post these to 53 sites. Contact with lower recruiters was carried out in accordance with a schedule of increasing regular contact over several weeks. As a result, the impact from such interventions was not seen immediately but was delayed until a couple of months later.

TABLE 2 Follow-up procedures introduced from May 2018

Procedure	Date(s) introduced
Created postage slip with freepost instructions	May 2018
Updated thank-you slips with the 1-year follow-up date	August 2018
Created pocket cards with details of the study team and 1-year follow-up date	July 2018
Developed telephone script used to contact participants	May 2018
Updated participant letters to a shorter, simpler version	May 2018
Prize draw for returning 1-year test kit	March 2019, March 2020
Updated patient-facing materials stating that ‘others had responded’	March 2020
Included a picture in follow-up e-mails	October 2019
Sent follow-up materials at additional time point	July 2019

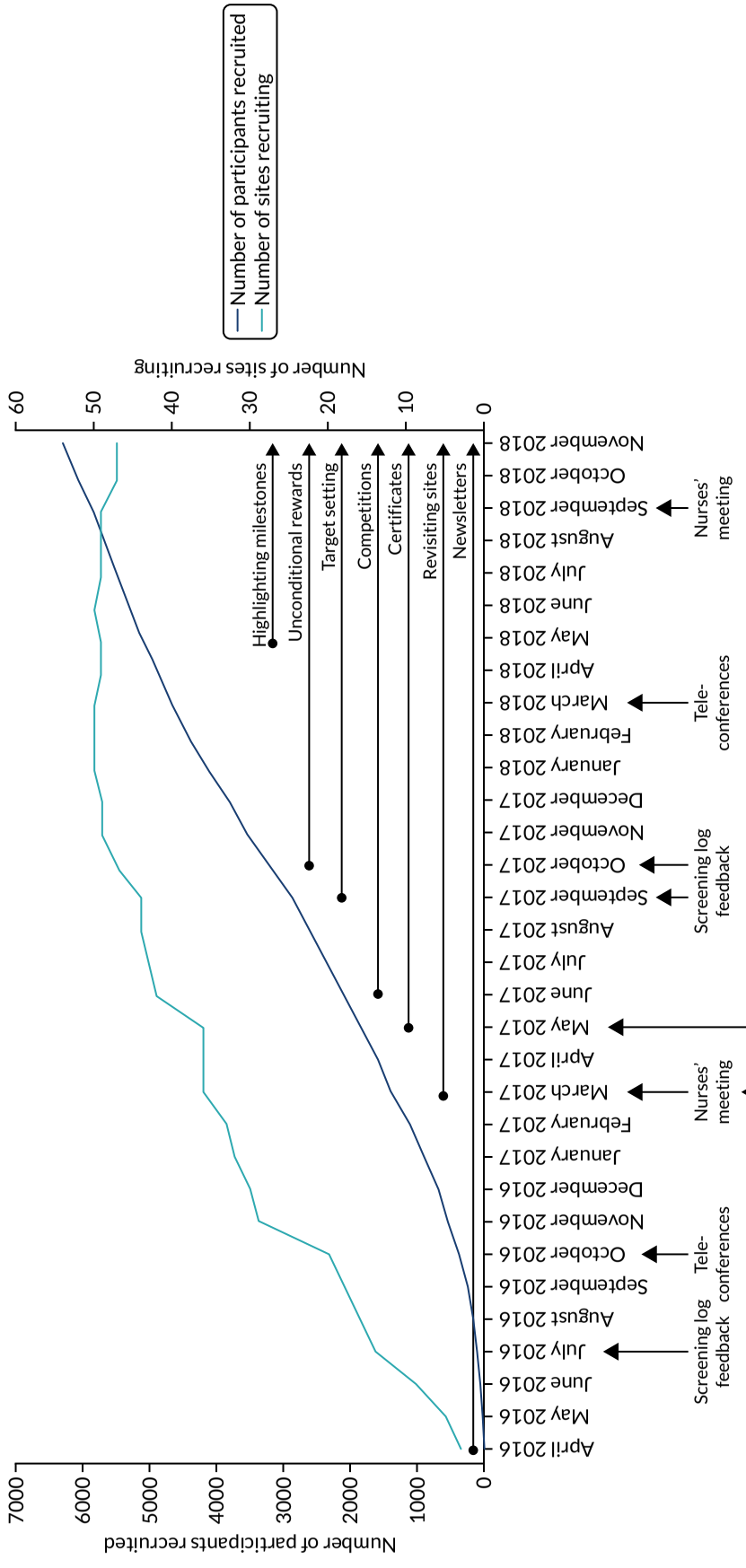

FIGURE 2 Recruitment progress and when recruitment interventions were implemented.

Interventions were ongoing and cumulative to strategies already employed. For example, after certificates had been introduced in May 2017 these were available to and requested by sites throughout the remainder of the recruitment period.

A total of 5457 participants (88%) completed the 4-week questionnaire (intervention, 2710/3123, 87%; control, 2747/3125, 88%). A total of 4675 participants (75%) provided data for the primary outcome (intervention, 2329/3123, 75%; control, 2346/3125, 75%), with 4871 out of 6248 (78%) providing data for the 12-month questionnaire.

Discussion

Our dynamic collaborative approach to recruitment (*Figure 3*) combined activities deemed important for recruitment success in clinical trials into one cyclical approach, involving good communication and joint working with recruiters and recruiting sites, constant evaluation and new approaches to overcome recruitment challenges, from the outset of opening recruitment sites and throughout the trial recruitment period. Recruitment progress was constantly evaluated, interventions designed to address recruitment challenges arising from these evaluations were implemented, and recruitment progress was continuously evaluated. The initial site set-up was crucial to planning successful recruitment, anticipating recruitment barriers and building a strong relationship foundation with recruiting sites. At the core of the approach was regular, engaging, responsive communication, which we see as key to successful recruitment.

Follow-up in the safetxt trial was the responsibility of the trial co-ordinating centre. Important elements of our approach were learning from participants about barriers to follow-up, monitoring follow-up, developing new approaches to increase follow-up based on monitoring and participants' experience, and employing evidence-based follow-up methods. At least 40% of our trial population changed address at least once and, therefore, keeping track of these changes was an essential element of achieving postal STI test follow-up among young people in this trial. It is important to note that any one of the recruitment or follow-up interventions mentioned is likely to have a small effect on its own; rather, it was the cumulative effect of continued efforts that led to success.

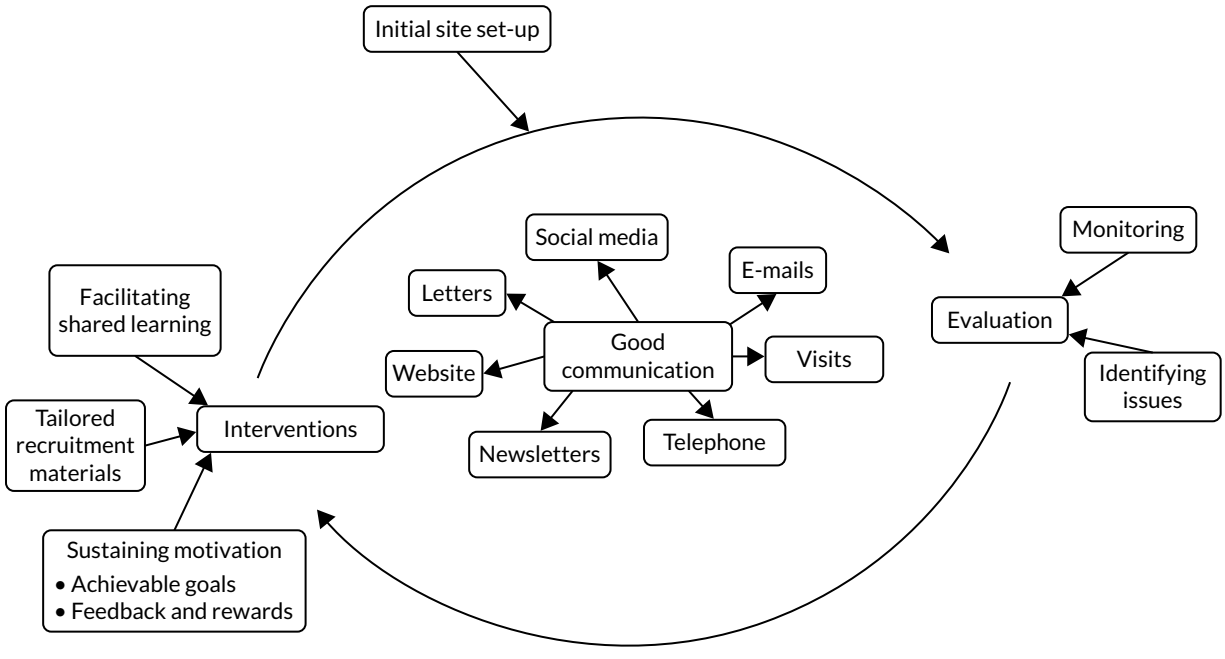

FIGURE 3 A dynamic and collaborative approach to trial recruitment.

Evidence from specific trials can be difficult to apply to other trial settings and participant populations.[79,80] For example, it is especially challenging to achieve full recruitment and high follow-up in research with young people and about sexual health, such as the safetxt trial population. Therefore, the techniques explained in our approach may need to be tailored specifically to other trial settings and patient groups, if implemented. Although some of the interventions or elements of our approach have been previously described, recruitment and follow-up in other trials could benefit from adopting our dynamic, collaborative approach to recruitment and co-ordinated approach to follow up.

Our approach is limited in that we did not test our recruitment or follow-up techniques in such a way that cause and effect could be reliably established. However, we believe, based on our improvement in recruitment rate and recruiting to target, that our approach was successful in aiding recruitment. Walters *et al.*'s[79] review showed that just 56% of trials met their recruitment target, and multicentre trials achieved an average recruitment rate of 0.86 patients per centre per month. We met our recruitment target and exceeded this recruitment rate, demonstrating our approach's success in supporting recruitment.

Chapter 4 Trial results

Recruitment, randomisation and exclusions

Between 1 April 2016 and 23 November 2018, 20,476 young people were assessed for eligibility in 92 sexual health services across the UK (*Figure 4*). Of these, 14,217 were excluded before randomisation (7316 were eligible but declined and 6901 were eligible and approached by text message or e-mail but did not respond). Informed consent was provided by and baseline data were submitted through the trial database system for 6259 participants. Eleven participants were excluded after randomisation because of duplicate randomisations. This resulted in 6248 participants included in the trial, with 3123 randomised to the intervention group and 3125 randomised to the control group. A total of 281 out of 6248 (4.5%) participants withdrew from the trial after allocation: 134 out of 3123 (4.3%) in the intervention group and 147 out of 3125 (4.7%) in the control group.

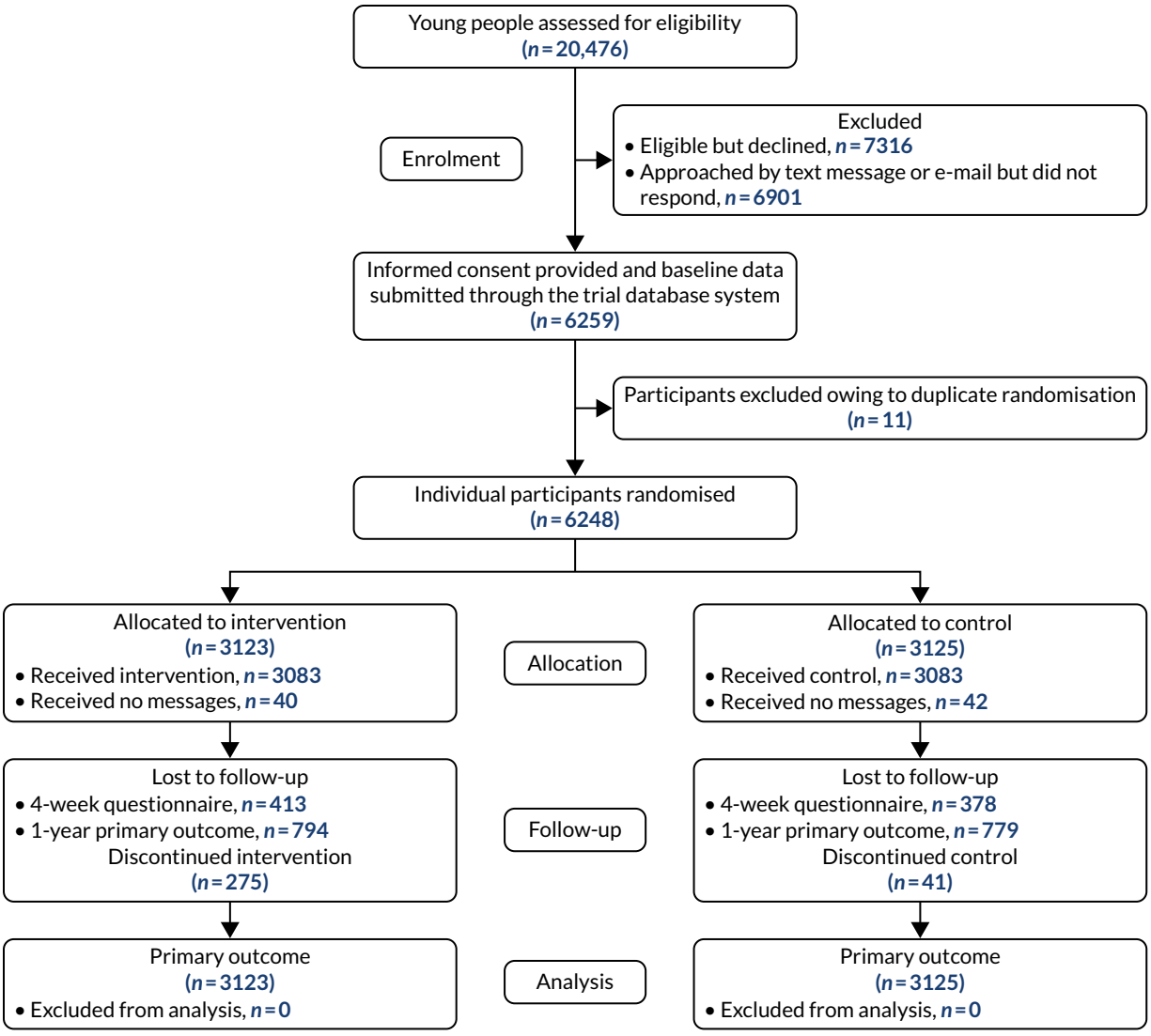

FIGURE 4 The CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

Baseline characteristics

Table 3 reports the baseline characteristics of the trial participants. The mean age of participants was 20 years, and 63% (3942/6248) were aged 20–24 years. Sixty-five per cent (4067/6248) of participants were female and 78% (4864/6248) were white British/other white background. Half (3091/6195) of participants were from the two most deprived Index of Multiple Deprivation (IMD) quintiles.[95] Baseline sociodemographic characteristics were similar between the treatment groups.

TABLE 3 Baseline characteristics

Characteristic	Group, *n* (%)		
	Intervention (*N* = 3123)	Control (*N* = 3125)	All participants (*N* = 6248), *n* (%)
Age group (years)			
16–19	1189 (38.1)	1117 (35.7)	2306 (36.9)
20–24	1934 (61.9)	2008 (64.3)	3942 (63.1)
Age (years)			
Mean (SD) age (based on integer)	20.3 (2.1)	20.4 (2.1)	20.3 (2.1)
Gender			
Female	2047 (65.5)	2020 (64.6)	4067 (65.1)
Male	1065 (34.1)	1097 (35.1)	2162 (34.6)
Non-binary	11 (0.4)	8 (0.3)	19 (0.3)
Ethnicity grouped			
White British/other white background	2428 (77.7)	2436 (78.0)	4864 (77.8)
Black/black British – Caribbean/African/other	380 (12.2)	347 (11.1)	727 (11.6)
Asian/Asian British – Bangladeshi/Chinese/ Indian/Pakistani/other	89 (2.8)	91 (2.9)	180 (2.9)
Mixed background	174 (5.6)	205 (6.6)	379 (6.1)
Other background	52 (1.7)	46 (1.5)	98 (1.6)
IMD quintile[a]			
1 and 2 – least deprived	955/3099 (30.8)	951/3096 (30.7)	1906/6195 (30.8)
3	608/3099 (19.6)	590/3096 (19.1)	1198/6195 (19.3)
4 and 5 – most deprived	1536/3099 (49.6)	1555/3096 (50.2)	3091/6195 (49.9)
Age (years) at which left education[b]			
≤ 16	436/2996 (14.6)	450/2990 (15.1)	886/5986 (14.8)
≥ 17	1352/2996 (45.1)	1348/2990 (45.1)	2700/5986 (45.1)
I am still in full-time education	1208/2996 (40.3)	1192/2990 (39.9)	2400/5986 (40.1)
Gender and orientation			
WSM	1901 (60.9)	1855 (59.4)	3756 (60.1)
MSW	790 (25.3)	778 (24.9)	1568 (25.1)
WSW	20 (0.6)	17 (0.5)	37 (0.6)
MSM	226 (7.2)	258 (8.3)	484 (7.7)
WSMW	125 (4.0)	147 (4.7)	272 (4.4)

TABLE 3 Baseline characteristics (*continued*)

Characteristic	Group, *n* (%)		All participants (*N* = 6248), *n* (%)
	Intervention (*N* = 3123)	Control (*N* = 3125)	
MSMW	49 (1.6)	60 (1.9)	109 (1.7)
NBSM	7 (0.2)	3 (0.1)	10 (0.2)
NBSW	1 (0.0)	2 (0.1)	3 (0.0)
NBSMW	3 (0.1)	3 (0.1)	6 (0.1)
Not stated	1 (0.0)	2 (0.1)	3 (0.0)
Baseline diagnosis			
Chlamydia	2449 (78.4)	2433 (77.9)	4882 (78.1)
Gonorrhoea	283 (9.1)	303 (9.7)	586 (9.4)
Gonorrhoea and chlamydia	159 (5.1)	155 (5.0)	314 (5.0)
Gonorrhoea or NSU	27 (0.9)	32 (1.0)	59 (0.9)
NSU	125 (4.0)	123 (3.9)	248 (4.0)
Unknown	80 (2.6)	79 (2.5)	159 (2.5)
Condom used at last sex			
Yes	747 (23.9)	806 (25.8)	1553 (24.9)
No	2314 (74.1)	2273 (72.7)	4587 (73.4)
Unsure	62 (2.0)	46 (1.5)	108 (1.7)
Condom used at first sex with last new partner			
Yes	981 (31.4)	1035 (33.1)	2016 (32.3)
No	2065 (66.1)	2010 (64.3)	4075 (65.2)
Unsure	77 (2.5)	80 (2.6)	157 (2.5)
Tested before sex with last new partner			
Yes	1242 (39.8)	1243 (39.8)	2485 (39.8)
No	1798 (57.6)	1787 (57.2)	3585 (57.4)
Unsure	83 (2.7)	95 (3.0)	178 (2.8)
Partner tested before sex with last new partner			
Yes	437/3120 (14.0)	457/3125 (14.6)	894/6245 (14.3)
No	1189/3120 (38.1)	1181/3125 (37.8)	2370/6245 (38.0)
Unsure	1494/3120 (47.9)	1487/3125 (47.6)	2981/6245 (47.7)
Number of partners in last 12 months			
0	5/3120 (0.2)	2/3122 (0.1)	7/6242 (0.1)
1	496/3120 (15.9)	538/3122 (17.2)	1034/6242 (16.6)
≥ 2	2619/3120 (83.9)	2582/3122 (82.7)	5201/6242 (83.3)

NBSM, non-binary people who have sex with men only; NBSMW, non-binary people who have sex with men and women; NBSW, non-binary people who have sex with women only.

a Reduced denominator, as IMD quintile missing for some participants who provided an invalid postcode.

b Reduced denominator, as education information missing for some participants due to non-response.

Note

Data are *n* (%), mean (SD) or *n*/*N* (%).

Loss to follow-up

Follow-up was completed between 1 May 2016 and 28 February 2020. A total of 5457 participants (88%) completed the 4-week questionnaire (intervention, 2710/3123, 87%; control, 2747/3125, 88%). A total of 4675 participants (75%) provided data for the primary outcome (intervention, 2329/3123, 75%; control, 2346/3125, 75%).

Primary analysis results

Primary and secondary outcomes

Primary and secondary outcomes are reported in *Table 4*. The incidence of chlamydia/gonorrhoea infection was 22.2% (693/3123) in the intervention group and 20.3% (633/3125) in the control group (OR 1.13, 95% CI 0.98 to 1.31; $p = 0.085$). At 4 weeks, partner notification was 85.6% in the intervention group and 84.0% in the control group (OR 1.14, 95% CI 0.99 to 1.33; $p = 0.078$) and partner attendance for treatment, according to data from clinics that routinely collect these, was 11.7% in the intervention group and 13.0% in the control group (OR 0.88, 95% CI 0.75 to 1.02; $p = 0.095$). At 4 weeks, condom use at last sex was 42.0% in the intervention group and 39.6% in the control group (OR 1.12, 95% CI 1.00 to 1.25; $p = 0.045$). This difference was sustained at 12 months, with 33.8% in the

TABLE 4 Primary and secondary outcomes

Outcome	Group, *n* (%)		OR (95% CI)	*p*-value
	Intervention (*N* = 3123)	Control (*N* = 3125)		
Primary outcome (12 months)				
Incidence of chlamydia or gonorrhoea infection	693 (22.2)	633 (20.3)	1.13 (0.98 to 1.31)	0.085
Secondary outcomes (4 weeks)				
Correctly treated for their STI (took the prescribed antibiotic treatment and avoided sex for 7 days after treatment)	2798 (89.6)	2769 (88.6)	1.11 (0.94 to 1.32)	0.224
Told the last person they had sex with before they tested positive that they needed to get treatment	2673 (85.6)	2625 (84.0)	1.14 (0.99 to 1.33)	0.078
Partner attended clinic for treatment (identified from clinic records)	365 (11.7)	406 (13.0)	0.88 (0.75 to 1.02)	0.095
Condom use at last sex	1312 (42.0)	1238 (39.6)	1.12 (1.00 to 1.25)	0.045
Secondary outcomes (12 months)				
Condom use at last sex	1056 (33.8)	975 (31.2)	1.14 (1.01 to 1.28)	0.038
≥ 2 sexual partners since joining the trial	1777 (56.9)	1713 (54.8)	1.11 (0.99 to 1.24)	0.063
Sex with someone new since joining the trial	2177 (69.7)	2106 (67.4)	1.13 (1.00 to 1.28)	0.059
Condom use at first sex with most recent new partner	1699 (54.4)	1522 (48.7)	1.27 (1.11 to 1.45)	0.001
STI testing for self, prior to first sex with most recent new partner (testing confirmed by clinic record)	1234 (39.5)	1278 (40.9)	0.95 (0.82 to 1.11)	0.518
Most recent new partner was tested for STI prior to sex with them	977 (31.3)	881 (28.2)	1.16 (0.94 to 1.43)	0.158
Car accident in the past year where the participant was the driver	106 (3.4)	100 (3.2)	1.05 (0.76 to 1.47)	0.758
Experience of partner violence in the past year	103 (3.3)	103 (3.3)	1.00 (0.71 to 1.41)	0.986
Diagnosed with 'any' STI after joining the trial according to postal test results and clinic records	693 (22.2)	647 (20.7)	1.11 (0.96 to 1.27)	0.148

Data are *n* (%) estimated from imputed data; analyses based on intention-to-treat principle; logistic regression analysis (using MICE) adjusted for prespecified baseline covariates (age, type of STI at baseline, sexuality and ethnicity).

intervention group and 31.2% in the control group reporting using condoms at last sex (OR 1.14, 95% CI 1.01 to 1.28; $p = 0.038$). At 12 months, 54.4% of participants in the intervention group reported condom use at first sex with most recent new partner compared with 48.7% in the control group (OR 1.27, 95% CI 1.11 to 1.45; $p = 0.001$). There was no difference in participants testing before sex with a new partner (according to self-report and clinic data), with 39.5% in the intervention group and 40.9% in the control group doing this (OR 0.95, 95% CI 0.82 to 1.11; $p = 0.518$), and the self-reported effect on partners being tested prior to sex with the participant was 31.3% in the intervention group compared with 28.2% in the control group (OR 1.16, 95% CI 0.94 to 1.43; $p = 0.158$). There was weak evidence of an increase in having two or more partners since joining the trial (56.9% intervention, 54.8% control; OR 1.11, 95% CI 0.99 to 1.24; $p = 0.063$) and sex with someone new since joining the trial (69.7% intervention, 67.4% control; OR 1.13, 95% CI 1.00 to 1.28; $p = 0.059$). The effect on any STI was 22.2% in the intervention group compared with 20.7% in the control group (OR 1.11, 95% CI 0.96 to 1.27; $p = 0.148$). There was no evidence that self-reported partner violence or road traffic accidents were greater in the intervention group than in the control group.

Intermediate outcomes

The effects of the intervention on the intermediate outcomes (measured by summing items) are reported in *Table 5*. The intervention was associated with small increases in knowledge related to STIs (coefficient 0.10; $p = 0.035$) and in correct condom use self-efficacy (coefficient 0.32; $p < 0.01$). *Table 6* presents the results of

TABLE 5 Intermediate outcomes comparing the intervention group with the control group (summed items)

Intermediate outcome	Group, mean (SD)		Coefficient (beta)[a] (95% CI)	*p*-value
	Intervention ($n = 2656$)	Control ($n = 2705$)		
Knowledge related to STIs	12.38 (1.84)	12.29 (1.84)	0.10 (0.01 to 0.20)	0.035
Attitudes towards partner notification	11.59 (1.74)	11.63 (1.74)	−0.04 (−0.14 to 0.05)	0.366
Self-efficacy in telling a partner about an infection	11.55 (3.80)	11.53 (3.90)	0.04 (−0.17 to 0.24)	0.718
Correct condom use self-efficacy	14.57 (2.90)	14.27 (2.97)	0.32 (0.16 to 0.47)	< 0.001
Self-efficacy in negotiating condom use	11.35 (2.50)	11.32 (2.60)	0.03 (−0.10 to 0.17)	0.642

SD, standard deviation.

a Complete-case analysis linear regression of summed items, adjusted for same baseline characteristics as primary analysis: age, ethnicity, type of infection at baseline and sexuality group.

Note

Ranges of possible scores: knowledge, 3–15; attitudes towards partner notification, 3–15; self-efficacy in telling a partner about an infection, 4–20; correct condom use self-efficacy, 4–20; self-efficacy in negotiating condom use, 3–15.

TABLE 6 Intermediate outcomes comparing the intervention group with the control group (structural equation model)

Intermediate outcome	Coefficient (beta)[a]	*p*-value
Knowledge related to STIs	0.081	0.021
Attitudes towards partner notification	0.031	0.388
Self-efficacy in telling a partner about an infection	0.020	0.549
Correct condom use self-efficacy	0.118	< 0.001
Self-efficacy in negotiating condom use	0.000	0.996

a Complete-case analysis results from structural equation model (using latent variable intermediate outcomes). Coefficients are standardised so that the interpretation is follows: compared with the control group, the intervention group has 0.081 standard deviations greater knowledge related to STIs. Adjusted for same baseline characteristics as primary analysis: age, ethnicity, type of infection at baseline and sexuality group.

the structural equation modelling, estimating the impact of the intervention on the intermediate outcomes in the absence of measurement error. The results are consistent with those presented in *Table 5*, with the intervention resulting in a small increase in knowledge related to STIs and in correct condom use self-efficacy.

Secondary analyses

Complete-case analysis

When only those participants with completed primary outcome data were included in the primary analysis model ($n = 4675$), the OR was similar, at 1.14 (95% CI 0.98 to 1.31; $p = 0.08$).

Subgroup analysis

There was no evidence that the effect of the intervention was different among participants in any of the prespecified subgroups (*Figure 5*).

Additional trial data

A small proportion of participants reported that they knew someone else in the study (intervention, 137/2414, 5.7%; control, 141/2453, 5.8%). Overall, the proportion of intervention group participants who reported that their messages were read by another participant was 1.5% (37/2414) and the proportion of control group participants who reported that they read another participant's messages was 1.3% (32/2453; *Table 7*).

Additional non-prespecified analyses

Sensitivity analyses

We performed sensitivity analyses under different assumptions from the primary analysis MAR assumption.

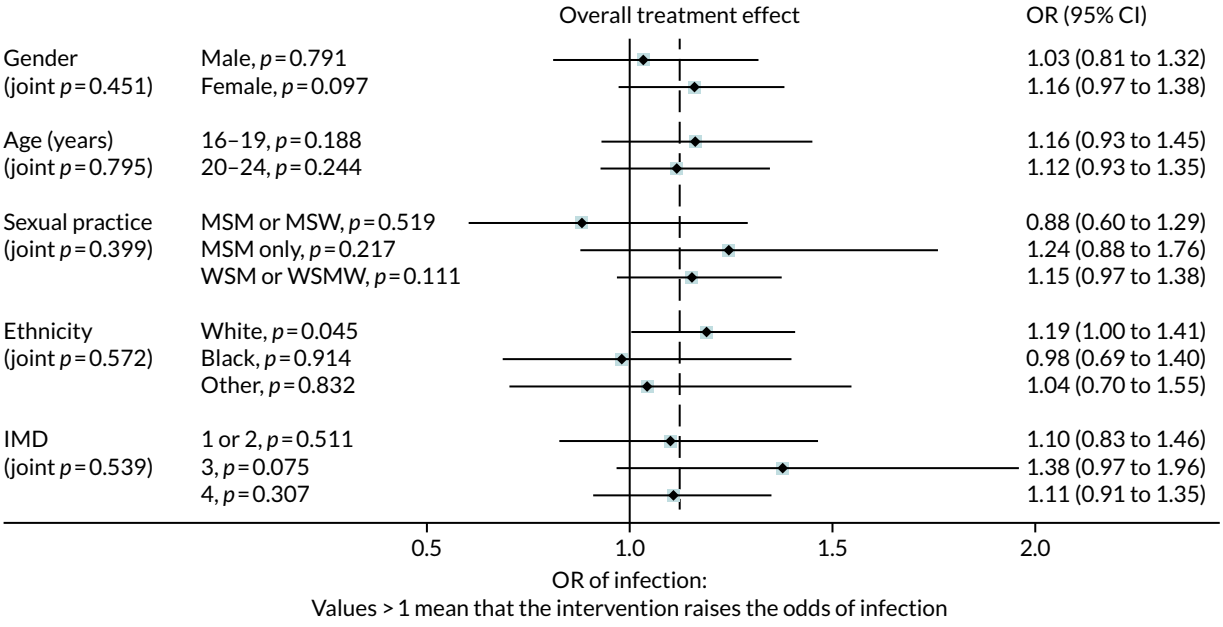

FIGURE 5 Primary outcome by prespecified subgroup.

TABLE 7 Additional trial data

Process variable	Group, *n/N* (%)	
	Intervention	Control
Participant knew someone else taking part in the study	137/2414 (5.7)	141/2453 (5.8)
. . . they read participant's messages	37/2414 (1.5)	32/2453 (1.3)
. . . participant read their messages	38/2414 (1.6)	34/2453 (1.4)
Did anyone read the messages sent to you?		
Yes	342/2416 (14.2)	Not applicable
No	1971/2416 (81.6)	
Unsure	103/2416 (4.3)	
How did you feel about them reading the messages?		
Happy	224/342 (65.5)	Not applicable
Unhappy	35/342 (10.2)	
Unsure	83/342 (24.3)	
How many of the messages did you read?		
All	1506/2412 (62.4)	Not applicable
Most	661/2412 (27.4)	
Few	229/2412 (9.5)	
None	16/2412 (0.7)	

Complete-case analysis.

Sensitivity analysis 1

We completed the multiple imputation model including the clinic testing variable as an additional covariate. On this imputed data set, we conducted one sensitivity analysis with the new imputations from this model where all negative clinic tests that had missing outcome data were considered positive. The result from this analysis had an OR of 1.13 (95% CI 0.997 to 1.28; $p = 0.05$).

Sensitivity analysis 2

Using the same imputed data set (with the clinic testing variable as an additional covariate), we conducted a second sensitivity analysis in which all negative clinic tests that had missing outcome data were considered negative. The result of this analysis had an OR of 1.12 (95% CI 0.97 to 1.29; $p = 0.13$).

Sensitivity analysis 3

We followed the primary analysis that assumed data were MAR but in imputing missing values, controlled the odds of STI diagnosis to be one-quarter, half, one, two and then four times as large as that predicted by the imputation model; these sensitivity parameters were varied factorially for the two randomised groups (giving 24 sensitivity scenarios besides the primary analysis). The results were identical to the primary outcome result (OR 1.13, 95% CI 0.98 to 1.31; $p = 0.085$). This was due to (1) perfect prediction in the imputation model and (2) using the same random number seed to start each sensitivity analysis.

Per-protocol analysis

We conducted a per-protocol analysis in which participants who had 12-month primary outcome data were classified as having received the treatment they had been allocated to, according to the following criteria: (1) they did not stop the messages, (2) they were not among the few participants who did not receive any messages and (3) they reported that they had read all or most of the messages. The baseline

characteristics of these participants were similar between the groups (see *Appendix 3*). The OR of the incidence of chlamydia/gonorrhoea in this analysis was 1.17 (95% CI 0.99 to 1.38; $p = 0.06$).

Primary analysis adjusting for baseline number of partners

We conducted a post hoc analysis replicating the analysis but adding the baseline number of partners (< 2 or ≥ 2 partners) to the imputation model as an additional covariate for both the primary outcome and the outcome number of partners. The OR of incidence of chlamydia/gonorrhoea in this analysis was 1.13 (95% CI 0.98 to 1.31; $p = 0.087$), and the OR of number of partners was 1.10 (95% CI 0.98 to 1.23; $p = 0.11$).

Path analysis

Had the intervention been effective in reducing STIs, we intended to carry out a path analysis to identify which (if any) of the intermediate outcomes mediated this effect. However, in the absence of a positive intervention effect on the primary outcome, we examined whether or not there was evidence for a mediatory role of the intermediate outcomes in the intervention effect on the secondary outcome of condom use at first sex with a new partner (the secondary outcome on which the intervention had the greatest positive effect).

Two intermediate outcomes, 'knowledge' and 'correct condom use self-efficacy', were positively associated with the intervention. However, only 'correct condom use self-efficacy' was associated with condom use at first sex with a new partner, and so this was the only potential mediator of the intervention effect on condom use.

We used a path analysis to estimate the effect of the intervention on condom use at first sex with a new partner through a direct path, and specified an indirect path via the intermediate outcome 'correct condom use self-efficacy'. The results indicated that the indirect path accounted for a small proportion of the overall effect of the intervention on condom use (total effect coefficient 0.109, $p = 0.016$; total indirect path coefficient 0.015, $p = 0.015$). Therefore, there is evidence that correct condom use self-efficacy was a partial mediator of the effect of the intervention on condom use at first sex with a new partner.

Pooled analysis with the safetxt pilot trial data

The pooled analysis of the safetxt main trial and pilot trial on the incidence of chlamydia/gonorrhoea showed substantial heterogeneity ($I^2 = 55\%$).

To explore heterogeneity, we conducted one additional subgroup analysis.

We conducted a pooled analysis with all of the main trial and pilot trial data from participants diagnosed with a STI at baseline (where the intervention group had been allocated to receive content targeting partner notification, condom use and STI testing). The pooled OR was 1.12 (95% CI 1.02 to 1.24; $n = 6915$; $I^2 = 0\%$) (*Figure 6*).

Fixed-effects model

The remaining subgroup of pilot trial participants was participants aged 16–24 years who reported having two or more partners and unprotected sex in the last year but no STI at baseline. These participants were sent the safetxt content targeting STI testing and condom use only. The effect of the safetxt content targeting STI testing and condom use only on the incidence of chlamydia/gonorrhoea was 2/58 (3.8%) in the intervention group and 8/53 (15.1%) in the control group (OR 0.20, 95% CI 0.04 to 0.99).[32]

FIGURE 6 Pooled analysis of main trial and pilot trial: incidence of gonorrhoea or chlamydia infection (objectively assessed at 12 months) among participants diagnosed with a STI at baseline. a, Incidence of chlamydia/gonorrhea at 12 months, subsample of participants diagnosed with an STI at baseline; b, incidence of chlamydia/gonorrhea at 12 months. df, degrees of freedom. M–H, Mantel–Haenszel.

Chapter 5 Analysis of the open free-text comments

Aim

The aim of this analysis is to describe young people's views of the safetxt text intervention and control messages as expressed in open feedback comments.

Methods

On the final sheet of the 12-month questionnaire was an open-ended question, 'Did anything good or bad happen as a result of being involved in the study or receiving the text messages? Please describe', followed by a blank space in which participants could write a response.

Two researchers (AG and SB) not involved in the development of the safetxt intervention or previously involved in the safetxt trial independently coded the free-text comments and categorised data by theme. Anasztazia Gubijev used Microsoft Excel® 2019 (Microsoft Corporation, Redmond, WA, USA) and Sima Berendes used NVivo version 12 (QSR International, Warrington, UK). Both researchers initially took a purposive sample of 12% ($n = 390$) questionnaires and checked these for consistency of analysis. Once this was complete, Anasztazia Gubijev and Sima Berendes independently analysed all of the remaining free-text comments in all questionnaires. The findings were compared with the previously published findings from qualitative interviews with participants in the pilot trial.[53]

We compared the themes identified in analysis of the open feedback comments with the themes identified in the qualitative research. We described where the themes were similar and where new themes or new aspects of the themes emerged.

Results

Fifty-six per cent ($n = 3526$) of participants provided comments in the open feedback section of the 12-month questionnaire, 72% of those who completed a 12-month questionnaire. In total, 51% of intervention group participants and 53% of control group participants left open feedback comments. The comments varied in length. Most were only a few sentences long, with some participants providing longer feedback. Many participants in both the intervention and control group simply stated 'no', 'nothing' or 'not applicable'.

Participants across all sociodemographic backgrounds provided open feedback comments, and the characteristics of respondents were similar to the characteristics of safetxt trial participants (*Table 8*).

Taking part in the study

Most participants, in both the intervention and the control group, who commented about being part of the study were very positive about taking part:

> *Thank you so much for allowing me to take part in this study it's been amazing. Shame it has to end. What you do/did is amazing. I would love to join the team myself.*
>
> *24 years, WSM, intervention*

TABLE 8 Open feedback respondent characteristics

Characteristic	Group		Total (*N* = 3526)
	Intervention (*N* = 1745)	Control (*N* = 1781)	
Age group (years), *n* (%)			
16–19	649 (37.2)	635 (35.7)	1284 (36.4)
20–24	1096 (62.8)	1146 (64.4)	2242 (63.6)
Gender, *n* (%)			
Female	1177 (67.5)	1176 (66.0)	2353 (66.7)
Male	561 (32.2)	600 (33.7)	1161 (32.9)
Non-binary	7 (0.4)	5 (0.3)	12 (0.3)
Ethnicity, grouped, *n* (%)			
White British/other white background	1385 (79.4)	1398 (78.5)	2783 (78.9)
Black/black British – Caribbean/African/other	189 (10.8)	190 (10.7)	379 (10.8)
Asian/Asian British – Bangladeshi/Chinese/ Indian/Pakistani/other	53 (3.0)	56 (3.1)	109 (3.1)
Mixed background	93 (5.3)	116 (6.5)	209 (5.9)
Other background	25 (1.4)	21 (1.2)	46 (1.3)
IMD quintile,[a] *n*/*N* (%)			
1 and 2 – least deprived	577/1733 (33.3)	572/1772 (32.3)	1149/3505 (32.8)
3	333/1733 (19.2)	356/1772 (20.1)	689/3505 (19.7)
4 and 5 – most deprived	823/1733 (47.5)	844/1772 (47.6)	1667/3505 (47.6)
Education level,[b] *n*/*N* (%)			
Left education at the age of ≤ 16 years	230/1726 (13.3)	216/1755 (12.3)	446/3481 (12.8)
Left education at the age of ≥ 17 years	741/1726 (42.9)	803/1755 (45.8)	1544/3481 (44.4)
I am still in full-time education	755/1726 (43.7)	736/1755 (41.9)	1491/3481 (42.8)
Gender and orientation, *n* (%)			
WSM	1089 (62.4)	1072 (60.2)	2161 (61.3)
MSW	396 (22.7)	403 (22.6)	799 (22.7)
WSW	13 (0.7)	11 (0.6)	24 (0.7)
MSM	137 (7.9)	156 (8.8)	293 (8.3)
WSMW	74 (4.2)	92 (5.2)	166 (4.7)
MSMW	28 (1.6)	41 (2.3)	69 (2.0)
NBSM	5 (0.3)	1 (0.1)	6 (0.2)
NBSW	0 (0)	2 (0.1)	2 (0.1)
NBSMW	2 (0.1)	2 (0.1)	4 (0.1)
Not stated	1 (0.1)	1 (0.1)	2 (0.1)
Baseline diagnosis, *n* (%)			
Chlamydia	1393 (79.8)	1394 (78.3)	2787 (79.0)
Gonorrhoea	160 (9.2)	185 (10.4)	345 (9.8)

TABLE 8 Open feedback respondent characteristics (*continued*)

Characteristic	Group		Total (*N* = 3526)
	Intervention (*N* = 1745)	Control (*N* = 1781)	
Gonorrhoea and chlamydia	74 (4.2)	84 (4.7)	158 (4.5)
Gonorrhoea or NSU	14 (0.8)	20 (1.1)	34 (1.0)
NSU	63 (3.6)	61 (3.4)	124 (3.5)
Unknown	41 (2.4)	37 (2.1)	78 (2.2)

NBSM, non-binary people who have sex with men only; NBSMW, non-binary people who have sex with men and women; NBSW, non-binary people who who have sex with women only.
a Reduced denominator, as IMD quintile was missing for some participants who provided an invalid postcode.
b Reduced denominator, as education information was missing for some participants due to non-response.

> *. . . After joining, it quickly became evident that I was a subject in the test that wouldn't receive texts. As somebody who is quite highly sexually active . . . it makes sense to take part if it could help somebody else who was like me. For that reason I'm very happy to have participated and hope that you get some conclusive results.*
>
> *24 years, MSM, control*

A small number of participants reported mixed feelings about taking part, as it reminded them about their STI.

Engagement with the intervention text messages

Most recipients were positive about receiving the intervention:

> *Sexual health is something we need to be talking to each other about as I don't think allot of people understand how dangerous unprotected sex can be, I think this study needs to be a regular thing and be sent to everyone thank you so much for all your help :)*
>
> *23 years, WSM, intervention*

Tone and convenience

In agreement with previous qualitative interview findings, participants who commented on the tone of the text messages found them to be friendly, reassuring and helpful, and written in a non-judgemental manner.[53] Free-text feedback also confirmed previous findings that mobile phone delivery was both an appropriate and a convenient way to access intervention content.

Frequency and timing of texts

Participants reported that they liked receiving regular safer sex text messages:

> *. . . Texts were useful reminders always had them sort of in my brain due to frequency etc. random times of the day helped as I could be anywhere out with friends, at home or at work. I would be happy to continue receiving texts.*
>
> *16 years, WSMW, intervention*

Some participants found the messages too frequent, especially at the start. Several participants described texts as 'annoying' or 'overwhelming'. A few reported that some of the messages were too similar and needed to be more varied. Others wanted more messages especially later in the study. Suggestions from participants for changes in the timing and frequency of messages often focused on having some form of control over message frequency.

Sharing messages and facilitating communication

Many participants reported sharing text messages, most commonly with friends, housemates and family members such as siblings:

> *. . . I read most of the messages to my 3 housemates.*
>
> *22 years, WSM, intervention*

> *. . . I did let friends read some of the messages received in the survey.*
>
> *20 years, WSM, intervention*

Sharing text messages often facilitated open and honest dialogues about sexual health and helped many participants feel less embarrassed about broaching this topic:

> *Discussed the study with family and friends and felt more open and aware. Myself and my partner discuss diseases and previous partners. The study helped me to approach this topic.*
>
> *22 years, WSMW, intervention*

> *I had to explain some painful portions of my past to my new partner. Overall not a bad thing, just difficult.*
>
> *21 years, WSM, intervention*

A few control participants mentioned that being involved in the study had made them more open to talking with friends about sexual health.

> *. . . as a result [of being in the study] I am open to talking to and warning my friends about them [STIs] (much more that I was before)*
>
> *18 years, WSM, control*

Some participants brought up confidentiality concerns regarding their messages being seen by others and said that they felt uncomfortable leaving their phone unattended in case the messages appeared on their phone:

> *. . . on some occasions when a text would come through and someone else was looking at my phone, it made me feel self-conscious as I didn't want people to know my intimate health details.*
>
> *19 years, WSM, intervention*

> *The only problem I had with the texts was that I found them embarrassing and would worry about others seeing them - particularly family members and co-workers.*
>
> *21 years, WSM, intervention*

Impact on knowledge

Several participants commented on the impact that the study had on increasing their knowledge. Participants reported that the messages were 'clear', 'concise' and 'informative'. Participants reported the impact on their general knowledge of practising safer sex, including new ways to protect themselves, how STIs are contracted, the risks and consequences of unprotected sex and the need to go for regular testing. Feedback mirrored previous findings:

> *. . . it educated me on other things I wasn't aware of and it was very nice to know I had support on my phone.*
>
> *24 years, WSM, intervention*

> *I feel a lot more knowledgeable about chlamydia and other [sexually transmitted diseases].*
>
> *20 years, WSM, intervention*

However, not all participants felt that the text messages had had an impact on their knowledge:

> *The texts didn't really affect me + only really told me things I already knew so they just got a bit annoying/patronising.*
>
> *20 years, MSM, intervention*

> *The majority of the information was already known to me so I did not pay much attention to some of the texts.*
>
> *21 years, MSW, intervention*

Although comments regarding impact on knowledge were more common from intervention group participants, a few control group participants felt that taking part in the study alone had had an impact on their sexual health knowledge:

> *I was able to learn about new ways to protect myself. More information about sexually transmitted diseases . . . This helped me relax and think more rationally when sex came about.*
>
> *17, MSM, control*

Impact on attitudes and behaviour

There were several areas where participants reported an impact on their attitudes and behaviour which reflected previous findings on partner notification, reassurance and reduction of stigma, condom use and STI testing. However, new areas emerged, including reports of a general sense of awareness and caution about sexual health with impacts on sexual relationships, increased confidence and reduced embarrassment, resulting in more discussions about sexual health and a reduced sense of isolation from being diagnosed with a STI.

Awareness of the importance of sexual health and caution

Several participants reported an increase in their awareness and caution about their sexual health due to being reminded of the potential risks:

> *I've thought more seriously about how seriously unprotected sex could change/[a]ffect your life.*
>
> *21 years, MSW, intervention*

> *Getting texts every now and then definitely made me more cautious about my sexual health.*
>
> *22 years, MSW, intervention*

Impact on sexual relationships

This greater awareness reportedly influenced some participants in wanting to know and trust a partner before being sexually active with them.

Although one participant was aware that knowing someone did not mean that that person could be trusted, comments about 'trusting' people whom they knew were more common, as was the assumption that these people would be less likely to have a STI:

> *Made me more aware and careful when having sex, I didn't just trust someone because I knew them.*
>
> *18 years, WSM, intervention*

> *The constant reminder made me not have casual sex with people I had met on a night out, and instead have sex with people I knew, trusted and would tell me the truth regarding whether they had been checked or not. The study definitely was a positive thing to be a part of.*
>
> *18 years, WSM, intervention*

However, some control group participants also reported greater caution about starting new sexual relationships. Both intervention and control participants reported feeling that knowing a sexual partner meant that that person was less likely to have a STI:

> *I now understand how easy STIs are to catch, and the importance of really knowing the individual before being sexually active. Also the importance of being regularly tested.*
>
> *21 years, WSM, control*

> *. . . I was in the group that didn't receive texts about safe sex, however just being involved in the study and completing the questionnaires gave me a greater awareness of the benefits of practicing safe sex even after the shock from my initial diagnosis wore off . . .*
>
> *18 years, WSM, control*

Confidence and greater agency

Several participants reported an increased confidence and greater ability to assert their needs, without specifying to which behaviours this related:

> *It was helpful, made me rethink how important safe sex is. How much risk we put ourselves in, as well as difficult situations. I put my health first rather than pleasing others or being irresponsible. You enjoy it more when you control the controllable and prevent any problems for the future. Thank you, very helpful!*
>
> *23 years, WSM, intervention*

One participant reported that the study had increased their confidence in starting a sexual relationship after they had been diagnosed with a STI:

> *The study gave me the confidence to engage in a new sexual relationship with a new partner without worrying about unwanted consequences.*
>
> *17 years, WSM, intervention*

Interestingly, an increase in sexual confidence was also reported by a control group participant:

> *I gain my confidence to say no when I want to.*
>
> *22 years, MSMW, control*

Reduced embarrassment and increased communication about sex and sexual health

The text messages reduced embarrassment about sexual health, as some participants said that they found it hard to talk face to face about these issues. For some participants, the messages helped normalise the idea of talking more openly about sexual health:

> *I think sexual health is something that needs to be less of a taboo and more openly spoken – this is something I now feel happy talking about with my partner . . .*
>
> *23 years, WSM, control*

> *Since the study I've been more aware of being safe especially with new partners and being fully open with them about the topic instead of being shy/embarrassed. It's normalized the idea of being open with talking about safe sex.*
>
> *20 years, WSM, intervention*

However, one participant felt that the text messages made them feel like they should be more ashamed:

> *I don't find it difficult or embarrassing to talk to my partner about condoms and chlamydia, but a lot of the messages assumed so and that kinda made me feel like I should be ashamed.*
>
> *23 years, WSM, intervention*

Despite not receiving the intervention text messages, a few control group participants reported that being in the study had helped them have more open conversations about sexual health:

> *It has made me and my partner to talk about subjects, that can sometimes be difficult to discuss and made us more open with each other.*
>
> *22 years, WSM, control*

> *Enabled me to have open, comfortable & honest dialog[ue] with my younger siblings about sexual health & safe sex . . .*
>
> *23 years, MSM, control*

Reduced sense of isolation and stigma in having a sexually transmitted infection

Many participants said that taking part in the study had reassured them about feeling less like they were 'the only one' after being diagnosed with a STI. This was seen in both intervention and control group participants:

> *. . . very helpful to feel less like you were the only one.*
>
> *21 years, MSW, intervention*

> *It made me feel like I was not alone with getting an STI.*
>
> *19 years, WSMW, control*

Participants also frequently commented on the reduction of stigma and shame and that they felt 'less embarrassed' about STIs as a result of the text messages:

> *Good for reminding you . . . and removes the stigma.*
>
> *24 years, WSM, intervention*

> *Thanks to studies like these, there is less shame . . . so I received the help I needed to get right away.*
>
> *23 years, WSM, intervention*

However, reduction in embarrassment was also reported by a control group participant:

> *. . . I also feel happier . . . not having to feel embarrassed if I did have an STI.*
>
> *18 years, MSW, control*

Partner notification

Most participants who chose to comment on partner notification said that they notified their partners. Participants in the intervention group commonly reported that the text messages aided them in being able to speak to their partners about their infection more confidently and encourage them to go for testing and treatment:

> *The text study was really helpful and insightful it helped me to be able to tell my sexual partner that I had been given a positive result for chlamydia and it helped me understand how to speak to him and tell him, after speaking to him he now gets regular checks and so do I . . .*
>
> *23 years, WSM, intervention*

> *Made me feel more comfortable and confident to talk about sexual health with my partner. I was scared about telling him but the advice helped me realise the importance of talking about it and important to practi[s]e safe sex.*
>
> *18 years, MSMW, intervention*

Not all participants had a positive experience of telling their partners about their infection. We noted that this was raised more by the control group participants:

> *Bad – calling those possibly infected (transmitted by myself).*
>
> *21 years, MSW, control*

Condom use

Several participants reported practising safer sex by using condoms more often. This was perceived to have resulted from an increase in their confidence about knowing the precautions to take to be protected from STIs:

> *I feel by taking part I have been educated on what I should do to help me to have safer sex.*
>
> *21 years, MSM, intervention*

> *. . . made me more aware of precautions to take.*
>
> *18 years, MSM, intervention*

Participants commented that they considered more carefully whether or not it was worth having unsafe sex rather than just 'going for it':

> *On numerous occasions I did think twice before having unprotected sex, which I doubt I [would] have if I didn't read the texts.*
>
> *19 years, MSM, intervention*

> *Made me become more aware and careful when having sex, I didn't just trust someone because I knew them. So condoms were always used.*
>
> *18 years, WSM, intervention*

An increase in the use of condoms was more commonly reported in casual relationships than with regular partners; however, some participants saw the value in using condoms with all partners:

> *Definitely have been more careful by trying to remember to be protected. I have been in a relationship for the most recent part which is why I chose not to wear a condom.*
>
> *20 years, WSM, intervention*

> *. . . always use condoms even with a regular partner.*
>
> *16 years, WSM, intervention*

However, although some made an effort to use condoms more frequently, this was not always done on every occasion:

> *I made more effort to use a condom. However sometimes we'd only use one the first time then the rest without one. Which is basically pointless using one in the first place. It's just so hard when you're in the moment. Will try harder in future.*
>
> *20 years, WSM, intervention*

> *I haven't used a condom every time since partaking in this study however I have used more frequently.*
>
> *21 years, WSM, intervention*

Negotiation of and confidence in being able to bring up the topic of condom use was also mentioned:

> *I felt more confident to ask my sexual partners to use a condom.*
>
> *21 years, WSM, intervention*

> *My partner asked if we can ditch the condom, but I didn't know how to say to him I don't want to. So I just nonchalantly showed him the message, pretending I just got a message and the message happened to be about condom. Later that evening, he asked if I actually don't want to ditch using condom and I said yes.*
>
> *22 years, WSM, intervention*

Some participants perceived the risk of pregnancy to be greater than the risk of catching an STI and were therefore less concerned about using condoms:

> *I read all the text messages, and they did help remind me to use a condom with new partners, and not take risks. However, because I have a Mirena coil, I feel I am less concerned about getting pregnant (which I ultimately consider to be worse than catching a sexually transmitted disease), I feel I am still too trusting in new partners about the status of their sexual health.*
>
> *21, WSM, intervention*

Some attributed changes in condom use to being diagnosed with a STI rather than to the messages:

> *I have been better at using a condom – but this may be just because of getting chlamydia last year, not because of the texts.*
>
> *18 years, WSM, intervention*

However, although comments on practising safer sex were more common in intervention group participants, they were not unique to them:

> *I have been smarter with thinking about the consequences of my actions before going through with them. I understand how important it is now to practice safe sex.*
>
> *18 years, WSM, control*

> *Yeah I have been more careful.*
>
> *18 years, WSM, control*

> *I was considerably more cautious about having unprotected sex - made much more effort to use protection.*
>
> *21 years, MSMW, control*

> *Since receiving the texts I have always used a condom even though I have been with same person for over 12 months.*
>
> *21 years, WSM, control*

Sexually transmitted infection testing

Many participants reported that they had been tested as a result of being in the study, as the text messages had served as a reminder to get tested or to get tested more frequency. However, participants did not always specify whether they got tested prior to first sex with a new partner or only after unprotected sex:

> *I thought it was a really good reminder to keep updated whenever you have a new sexual partner. Most people including me brush off going to the clinic but having the texts made me remember its just not worth it.*
>
> *21 years, WSM, intervention*

> *The monthly texts acted as an indirect reminder to get tested.*
>
> *18 years, NBSM [non-binary people who have sex with men only], control*

The messages also normalised the idea of going for testing:

> *Getting tested is not scary at all.*
>
> *23 years, MSW, intervention*

> *Reminds me that it's okay to be checked regularly.*
>
> *20 years, WSM, intervention*

However, normalising the idea of testing was not always directly due to the text messages:

> *Getting checked for an STI became less of a big deal to me, this was more down to visiting the sexual health clinic however.*
>
> *21 years, MSW, intervention*

There were also a number of comments from control group participants that receiving messages simply reminding them that they were in a safer sex study made them get tested more frequently and access the resources and service provisions available to them:

> *The monthly texts remind me to think about getting tested. They make me aware that I should get regularly tested, which I do. Since joining the study I have taken a greater interest in my sexual health. I've even had an HIV test . . . Testing for chlamydia is something I now do regularly.*
>
> *17 years, WSM, control*

> *If I hadn't been part of the study I would not think to get tested as often . . . or think to ask about whether my partner has been tested recently.*
>
> *22 years, WSM, control*

Relationship status and intervention usefulness

Some participants in a 'relationship' reported that the intervention content was not relevant to them but would be useful if they were single or for those with more casual partners. This was true for various aspects that the intervention targets, including condom use and STI testing:

> *Due to being in a relationship I only have the 1 partner, however I feel the information via texts would be useful for someone single.*
>
> *22 years, WSM, intervention*

> *I was more frequently reminded of protection options regarding sexual intercourse and the risk of STDs/STIs. However, these were of limited use to me as I am in a monogamous relationship.*
>
> *19 years, WSM, intervention*

However, it is important to note that a change in relationship status could mean that the intervention could still be useful in the future:

> *I continued to still not use condoms . . . my boyfriend doesn't like them as he feels like they don't feel as good. However, if I was single I would definitely 100% use condoms with anyone I have sex with.*
>
> *17 years, WSM, intervention*

A suggestion for change was to include more varied text messages:

> *The text messages were a good reminder to get checked, however I have been with the same person since the survey started. I think the texts should be more varied, as after a while I'd skip over them. Maybe more of the texts that had interesting facts.*
>
> *23 years, MSW, intervention*

Although participants reported that the study was less relevant to those in a relationship, receiving the text messages enabled important information to be passed on to peers:

> *Although I, myself did not use protection due to only being with my long term partner. This study has helped me pass on vital info to my friends to make sure they stay safe when sleeping with multiple people*
>
> *18 years, WSM, intervention*

There were similar comments from control participants in a 'relationship':

> *The study reminds you and makes you think about safe sex, If I were to be single it would definitely be more effective and make you more careful with new partners.*
>
> *23 years, MSW, control*

Discussion

The open feedback comments were consistent with the findings from qualitative research previously published, in that recipients liked the tone and convenience of messages, which were described as reassuring and helpful.[53] The messages reportedly increased knowledge, reduced stigma, enabled participants to tell their partner about their infection more confidently and increased condom use and STI testing. In contrast to the previous qualitative research findings, whereas some participants reported that the messages frequency was about right or too few, others reported that there were too many messages or there were too many messages to start with and then too few in the longer term. There were also a few reports of concerns regarding the confidentiality of messages.

Participants' reports also encompassed new themes or new aspects of the themes previously described. Some reported greater awareness and concern about their sexual health, with an impact on decisions regarding having sex only with people they 'knew' or could trust. Some reported greater agency and confidence in asserting their needs or wishes in relation to choosing whether or not and with whom to have sex. One reported that the study had given them the confidence to start a new relationship after their STI. Reduced embarrassment contributed to greater agency, resulting in participants being able to talk with partners and others about sex and safer sex practices, including condom use. Some reported a reduced sense of 'being the only one' diagnosed with a STI and, hence, less stigma regarding having a STI.

A number of control group participants reported that an impact of participating in the study was that their embarrassment had reduced because they had realised that they were not the only person to have a STI and changed their behaviour even though they had not received the intervention. Participants attributed this to the impact of taking part in the study; the impact of the monthly control group message about trial participation, reminding them of their STI and the importance of safer sex; or the impact of having a STI.

Strengths and limitations

A strength of the findings is that free-text comments were provided by over 3000 participants and analysed by two researchers not previously involved in the intervention development or trial. Other than asking about whether or not anything 'good or bad' had resulted from taking part in the study,

the topics for feedback were not predefined. A strength of our analysis was the triangulation of results with the previous qualitative research findings about recipients' experiences of the intervention. It is reassuring that the findings were highly consistent with the previous qualitative findings. The response rate was 52%, so there may be non-response bias. The experience of those not leaving a free-text comment may be different from that of those who completed this section. However, participants across all sociodemographic groups provided comments, and the characteristics of respondents were similar to the characteristics of trial participants. It is not possible to blind participants receiving a behavioural intervention, and this could introduce bias in the ascertainment of feedback. All free-text feedback was brief, optional and completed at the end of involvement in the trial, so it is was not possible to explore participants' views in depth or to follow up on feedback.

Discussion in relation to the existing literature

The overwhelmingly positive feedback from the free-text comments to this text messaging intervention is in line with findings from the pilot study.[53] Positive approaches to sexuality and reproduction should recognise that trust and communication, as well as pleasurable sexual relationships, should play a part in promoting well-being and enabling people to fulfil their sexual and reproductive health and rights.[52] The open feedback comments suggested that recipients perceived the intervention to have benefits in broader aspects of sexual health such as confidence and agency in communicating about sexual health and condom use with partners and others.

Consistent with other trials of behaviour change interventions, feedback from control group participants suggests that there is likely to be a strong Hawthorne effect, whereby the control group messages unrelated to safer sex and participation in the trial influenced attitudes and behaviour. In line with other research, the experience of having a STI also altered behaviour.[96–98] A full discussion of the open feedback comment findings in relation to the trial findings is provided in *Chapter 7*.

Conclusion

Overall, according to recipients' views expressed in open feedback comments, the safetxt intervention had a positive impact on many aspects of broader definitions of positive sexual health.

Chapter 6 Preliminary economic modelling

Introduction

As the trial results failed to show a beneficial effect of the intervention on STIs, we did not complete a full cost-effectiveness analysis. This chapter presents the methodology for the proposed cost-effectiveness analysis, alongside the parameters gathered and the model schematic. The model was programmed in Microsoft Excel 2019 and is available on the trial website (https://safetxt.lshtm.ac.uk/publications/).

Methods

Model structure

This model considers the impacts of an England-wide roll-out of this intervention for 1 year, with the parameters detailed in *Table 9*. We developed a gender-stratified flow chart model simulating the number of eligible individuals we expect either to be reinfected with chlamydia or gonorrhoea or in whom their original chlamydia or gonorrhoea infection has persisted. We then estimate the proportion of individuals who will, as a result of their persistent/reinfection, suffer from sequelae associated with chlamydia and gonorrhoea (*Figure 6*). This model aims to explore the impact of the safetxt intervention on reducing the proportions of individuals with reinfections or persisting infections over the period of 1 year.

TABLE 9 Model parameters

Parameter description	Assumed value and distribution	Data source(s)	Notes and assumptions
Proportion with reinfection or persistent gonorrhoea infection at 1 year (intervention group)	~U(12.9, 21.0)	safetxt	From safetxt trial data, examining gonorrhoea infection at follow-up compared with gonorrhoea at baseline in the intervention group (range is based on 95% CI of the data)
Proportion with reinfection or persistent gonorrhoea infection at 1 year (control group)	~U(11.5, 18.9)	safetxt	From safetxt trial data, examining gonorrhoea infection at follow-up compared with gonorrhoea at baseline in the control group (range is based on 95% CI of the data)
Proportion with reinfection or persistent chlamydia infection at 1 year (intervention group)	~U(18.4, 22.0)	safetxt	From safetxt trial data, examining chlamydia infection at follow-up compared with chlamydia at baseline in the intervention group (range is based on 95% CI of the data)

continued

TABLE 9 Model parameters (*continued*)

Parameter description	Assumed value and distribution	Data source(s)	Notes and assumptions
Proportion with reinfection or persistent chlamydia infection at 1 year (control group)	~U(16.1, 19.5)	safetxt	From safetxt trial data, examining chlamydia infection at follow-up compared with chlamydia at baseline in the control group (range is based on 95% CI of the data)
New diagnoses of gonorrhoea in those aged 16–24 years over 1-year period	Females: ~U(9472–14,208) Males: ~U(11,047–16,571)	Mitchell *et al.*[99]	New infections in those aged 15–24 years in England 2019 (assumed uniformly distributed with a ±20% uncertainty range)
New diagnoses of chlamydia in those aged 16–24 years over 1-year period	Females: ~U(69,787–104,681) Males: ~U(37,475–56,209)	Mitchell *et al.*[99]	New infections in those aged 15–24 years in England 2019 (assumed uniformly distributed with a ±20% uncertainty range)
Proportion of those aged 16–24 years who own a personal mobile phone	U(0.98–1.00)	Free *et al.*[58]	Almost complete coverage of mobile phone access in this age group
Number of partners traced (intervention)		safetxt	
Number of partners traced (control)		safetxt	
Number of contacts needed to be traced to prevent one secondary infection	Females: ~U(1.12–1.68) Males: ~U(1.62–2.42)	Althaus *et al.*[100]	Reference value is for chlamydia among individuals aged < 25 years considering all partnership types. However, assumed to be equal for both chlamydia and gonorrhoea (no range given in reference, so assumed a ±20% uncertainty range uniformly distributed)
Proportion of gonorrhoea infections that lead to symptoms associated with uncomplicated infection ('symptomatic infection')	Females: ~U(0.25, 0.50) Males: ~U(0.50, 0.85)	Farley *et al.*,[101] Institute of Medicine,[102] Satterwhite *et al.*[103]	Range of values across three studies. Values from Farley *et al.*[101] (lower end values of ranges) appear to be assumed values or drawn from Wiesner and Thompson.[104] Values from the Institute of Medicine[102] (middle values of ranges, not directly used) obtained from testing, symptom questionnaire and medical record follow-up in a study of individuals in the USA aged 18–29 years. Values from Satterwhite *et al.*[103] (upper end values of ranges) estimated by a committee of experts in the USA
Proportion of chlamydia infections that lead to symptoms associated with uncomplicated infection ('symptomatic infection')	Females: ~U(0.20, 0.30) Males: ~U(0.11, 0.75)	Farley *et al.*,[101] Institute of Medicine,[102] Satterwhite *et al.*[103]	Range of values across three studies. Values from Farley *et al.*[101] (lower end values of ranges) appear to be assumed values or drawn from Wiesner and Thompson.[104] Values from the Institute of Medicine[102] (middle values of ranges, not directly used) obtained from testing, symptom questionnaire

TABLE 9 Model parameters (*continued*)

Parameter description	Assumed value and distribution	Data source(s)	Notes and assumptions
			and medical record follow-up in a study of individuals in the USA aged 18–29 years. Values from Satterwhite *et al.*[103] (upper end values of ranges) estimated by a committee of experts in the USA
Proportion of those with gonorrhoea and chlamydia infection who develop PID	Females: ~U(0.13, 0.19)	Price *et al.*[105]	Estimate obtained from an evidence synthesis of observational studies and randomised controlled trials. Values are for chlamydia but assumed to be similar for gonorrhoea
Proportion of those with PID who develop chronic pelvic pain	Females: ~U(0.14, 0.22)	Yeh *et al.*[106]	Estimate based on value and range used in an economic modelling study
Proportion of those with PID who develop ectopic pregnancy	Females: ~U(0.022, 0.032)	Low *et al.*[107]	Estimate obtained by meta-analysis of values from two studies of women who have ever had a positive chlamydia test. The first study[107] was done in Swedish women up to age 35 years
Proportion of those with PID who develop tubal factor infertility	Females: ~U(0.054, 0.080)	Low *et al.*[107]	Estimate obtained by meta-analysis of values from two studies of women who have ever had a positive chlamydia test. The first study[107] was done in Swedish women up to age 35 years
Proportion of those with gonorrhoea or chlamydia infection who develop epididymitis	Males: ~U(0.00, 0.02)	Institute of Medicine,[102] Adams *et al.*[108]	Estimate based on value estimated by a committee of experts in the USA[103] and value used in previous modelling study[108]
Health state utility value for asymptomatic gonorrhoea infection	1	Institute of Medicine[102]	It is assumed that there is no direct health loss associated with asymptomatic gonorrhoea infection
Health state utility value for symptomatic gonorrhoea infection	Females: ~U(0.77, 0.93) Males: ~U(0.76, 0.92)	Institute of Medicine[102]	Values were estimated by a committee of experts in the USA based on 'mild' symptoms in women and urethritis in men, both with outpatient treatment (assumed uniformly distributed with a ±10% uncertainty range)
Health state utility value for symptomatic chlamydia infection	Females: ~U(0.81, 0.99) Males: ~U(0.76, 0.0.92)	Institute of Medicine[102]	Values were estimated by a committee of experts in the USA based on 'mild' symptoms in women and urethritis in men, both with outpatient treatment (assumed uniformly distributed with a ±10% uncertainty range)

continued

TABLE 9 Model parameters (*continued*)

Parameter description	Assumed value and distribution	Data source(s)	Notes and assumptions
Health state utility value for PID	Females: ~N(0.87, SD 0.26)	Jackson *et al.*,[109] Smith *et al.*[110]	Mean time trade-off estimate for inpatient women without previous PID. Considered to be best available estimate among those found in a previous systematic review
Health state utility value for chronic pelvic pain	Females: ~N(0.79, SD 0.29)	Jackson *et al.*,[109] Smith *et al.*[110]	Mean time trade-off estimate for women without previous PID. Considered to be best available estimate among those found in a previous systematic review
Health state utility value for ectopic pregnancy	Females: ~N(0.87, SD 0.26)	Jackson *et al.*,[109] Smith *et al.*[110]	Mean time trade-off estimate for women without previous PID. Considered to be best available estimate among those found in a previous systematic review
Health state utility value for tubal factor infertility	Females: ~N(0.84, SD 0.29)	Jackson *et al.*,[109] Smith *et al.*[110]	Mean time trade-off estimate for women without previous PID. Considered to be best available estimate among those found in a previous systematic review
Health state utility value for epididymitis	Males: ~U(0.46, 0.78)	Zwart *et al.*[111]	Taken from an economic modelling study
Duration of health loss associated with symptomatic gonorrhoea infection (years)	Females: ~U(0.019, 0.080) Males: ~U(0.019, 0.080)	Institute of Medicine,[102] Satterwhite *et al.*[103]	Range of values across two studies. Values from Satterwhite *et al.*[103] (lower end values of ranges) estimated by a committee of experts in the USA. Values from Farley *et al.*[101] (upper end values of ranges) appear to be assumed values or drawn from Wiesner and Thompson[104]
Duration of health loss associated with symptomatic chlamydia infection (years)	Females: ~U(0.062, 0.092) Males: ~U(0.015, 0.023)	Institute of Medicine[102]	Values estimated by a committee of experts in the USA (assumed uniformly distributed with a ±20% uncertainty range)
Duration of health loss associated with PID (years)	Females: ~U(0.024, 0.036)	Jackson *et al.*[109]	Modal value used by previous economic modelling studies as reviewed by Jackson *et al.*[109] (assumed uniformly distributed with a ±20% uncertainty range)
Duration of health loss associated with chronic pelvic pain (years)	Females: ~5 years with a lag of 5 years until development	Jackson *et al.*;[109] lag estimate from Institute of Medicine[102] and Yeh *et al.*[106]	Modal value used by previous economic modelling studies as reviewed by Jackson *et al.*[109] (assumed uniformly distributed with a ±20% uncertainty range)
Duration of health loss associated with ectopic pregnancy (years)	Females: ~U(0.062, 0.092) with a lag of 5 years until development	Jackson *et al.*;[109] lag estimate from Institute of Medicine[102] and Yeh *et al.*[106]	Modal value used by previous economic modelling studies as reviewed by Jackson *et al.*[109] (assumed uniformly distributed with a ±20% uncertainty range)

TABLE 9 Model parameters (*continued*)

Parameter description	Assumed value and distribution	Data source(s)	Notes and assumptions
Duration of health loss associated with tubal factor infertility (years)	Females: ~10 years with a lag of 5 years until development	Jackson *et al.*;[109] lag estimate from Institute of Medicine[102] and Yeh *et al.*[106]	Conservative value taken from those used by previous economic modelling studies as reviewed by Jackson *et al.*[109] (assumed uniformly distributed with a ±20% uncertainty range)
Duration of health loss associated with epididymitis (years)	Males: ~N(0.014, 0.022)	Institute of Medicine[102]	Values were estimated by a committee of experts in the USA (assumed uniformly distributed with a ±20% uncertainty range)
Treatment cost of chlamydia, £	~U(28.49–39.77)	Adams *et al.*[108]	Includes receiving results, treatment and partner notification; costs scaled from 2012 data (assumed uniformly distributed with a ±20% uncertainty range)
Treatment cost of gonorrhoea, £	~U(108.04–134.45)	Adams *et al.*[108]	Includes receiving results, treatment partner notification and follow-up appointment; costs scaled from 2012 data (assumed uniformly distributed with a ±20% uncertainty range)
Treatment cost per case of PID, £	Females: ~U(164.30–246.46)	Aghaizu *et al.*[112]	Includes clinician time, consumables and treatment. Based on scaled cost from £163.00 mean cost in 2008 (assumed uniformly distributed with a ±20% uncertainty range)
Treatment cost per case of chronic pelvic pain per year, £	Females: ~U(2206.39–3695.36)	Armour *et al.*[113]	Based on study in Australia, which has comparable costs to the UK. Average per-person, per-year costs for health care were estimated to be international US$2528–4234 for total health costs in 2017. We translate to UK currency and scale to 2020 costs. We assume on average that chronic pelvic pain will start exactly mid-way throughout the year in which it is contracted
Treatment cost per case of ectopic pregnancy, £	Females: ~U(1119.94–1679.90)	Thomas and Cameron[114]	Based on scaled cost from £1228 mean cost in 2008 (assumed uniformly distributed with a ±20% uncertainty range)
Treatment cost per case of tubular infertility, £	Females: ~U(699.55–6295.97)	NICE[115]	Costed on average as one round of IVF, scaled from £3123 in 2013. However, as the proportion of women with tubular infertility who will undergo IVF is unknown and the average number of IVF

continued

TABLE 9 Model parameters (*continued*)

Parameter description	Assumed value and distribution	Data source(s)	Notes and assumptions
			treatments given to couples in the UK is 1.8, we assume a uniform distribution and include a wide ±80% to encapsulate a large degree of uncertainty
Treatment cost per case of epididymitis, £	Males: ~U(164.30–246.46)	Adams *et al.*[116]	Based on scaled cost from £142 mean cost in 2004 (assumed uniformly distributed with a ±20% uncertainty range)
Cost of texts (per person), £	Option 1: 2.52 Option 2: free	safetxt	Option 1 is based on the safetxt trial SMS provider costs, which at the cheapest are 3.5 pence per text with, on average, 72 SMS messages sent to each participant (£2.52 in total). Option 2 utilises existing infrastructure within the NHS, which provides free SMS text messaging to patients such as MJOG or Accurx
Cost of maintenance (yearly), £	Option 1: 300.00 Option 2: free	safetxt	Option 1 is based on the cost of the virtual mobile number given by the safetxt trial provider at £25 per month (£300 in total). Option 2 utilises existing infrastructure within the NHS, which provides free SMS text messaging to patients

IVF, in vitro fertilisation; PID, pelvic inflammatory disease; SD, standard deviation.

The input population consists of the expected number of individuals in England who will meet the eligibility criteria over the next year. This is estimated from looking at the number of chlamydia and gonorrhoea infections diagnosed in 2019 among those aged 15–24 years using data from Public Health England.[99] The model then uses trial data to estimate the proportions of this population who will be reinfected with chlamydia or gonorrhoea and whether this will be a symptomatic or an asymptomatic infection. The model then examines the existing literature to estimate the number of individuals who will develop common sequelae. In females, this consists of pelvic inflammatory disease, which can in turn progress to chronic pelvic pain, ectopic pregnancy and tubal factor infertility. In males, the only sequelae considered is epididymitis (*Figure 7*).

To each disease state we attached a cost relating to treatment and considered the duration of the induced states and their associated health utilities measured in quality-adjusted life-years (QALYs). We then estimated the costs averted and health benefits gained from implementing the intervention. Although the model considers the intervention running for only 1 year, we estimated the effects of the intervention on an individual over longer periods of time due to the long delay involved in the development of some sequelae and their long-term impacts.

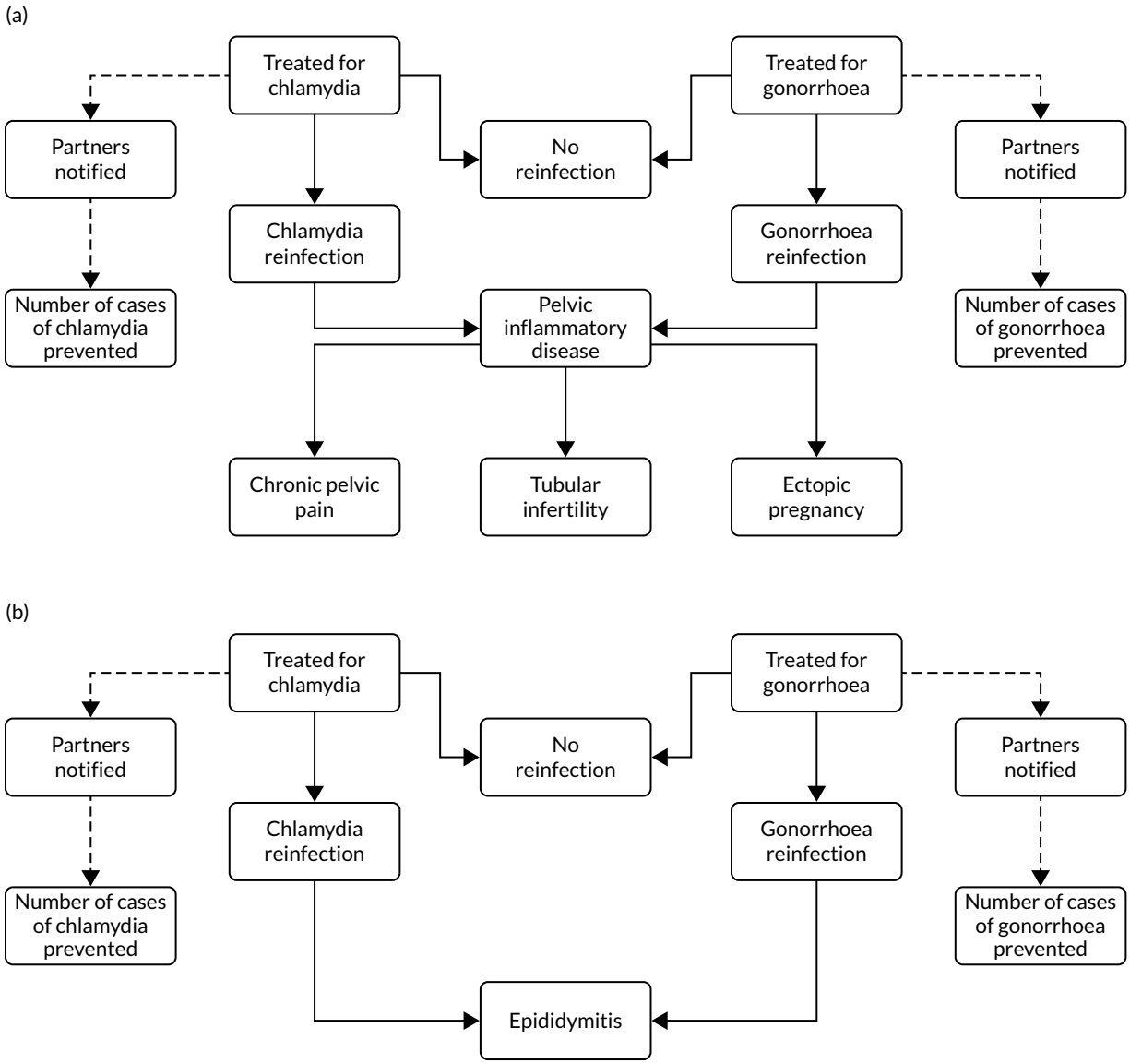

FIGURE 7 Flow chart model showing disease progression in (a) females and (b) males. Solid arrows represent possible health state transitions. Dashed arrows represent the additional impacts of partner notification and number of secondary cases prevented.

As a separate measure, we also included the functionality to estimate the expected number of secondary infections (infections occurring in the subsequent partners of those who were contact traced from an index case) likely to be prevented by the increased partner notification driven by the intervention. We used an estimate of the expected number of secondary infections prevented using findings from a previous study, which estimated these values based on the number of partners traced for those 16–24 years of age and further stratified by gender.[100] Finally, we considered the costs of the intervention, including the cost of the intervention per individual in terms of the cost of text messages and maintenance of the virtual mobile number. We performed 1000 individual model projections, sampling parameters from within their range of uncertainty to ascertain a 95% credibility interval for our results. The primary outputs were total costs, QALYs and incremental cost-effectiveness ratios (ICERs).

Key model assumptions and limitations

The number of individuals aged 16–24 years assumed to have had a previous chlamydia or gonorrhoea infection over a 1-year period was attained from 2019 data from Public Health England.[99] These data were for those aged 15–24 years and so largely overlapped with those for our desired age group;

however, we did not adjust to remove the data from those aged 15 years as the proportion of infections contributed by this age group is not obvious. This may potentially mean that we have overestimated the number of incident infections. Conversely, however, we assumed that each infection from our data set was within a unique individual and that, largely, chlamydia and gonorrhoea incidence would be similar in 2018/19 and 2020/21, despite the trend of rising numbers of diagnoses,[99] which could lead to an underestimate of the number of incident infections.

We also assume that in the 1-year period of the intervention individuals would be limited to one further infection matching their baseline diagnosis (or persistence of their current chlamydia or gonorrhoea infection). We did not consider co-infection at this stage. We also assume cautiously that for the chronic conditions of tubular infertility and chronic pelvic pain the loss of QALYs and costs of health care would continue for 5 and 10 years, respectively. However, these conditions may continue to affect individuals beyond this duration. For these two conditions, we discounted the QALYs lost and costs incurred at a rate of 3.5% per year, also including a delay until the onset of these sequelae alongside ectopic pregnancy of 5 years. Symptomatic infections, pelvic inflammatory disease and epididymitis are assumed to be present within the first year of infection and so the associated QALYs and costs were not subject to the discount rate. We also assumed that all infections would be eventually treated over the course of the individual's lifetime and so incurred a cost for treatment for every incident infection. However, we are aware than, in reality, a proportion of infections and associated sequelae go untreated. Many of these assumptions can be scrutinised under one-way sensitivity analysis.

Costs and utilities

We took the perspective of the NHS deciding whether or not to implement this intervention, measuring the costs and benefits from its perspective and ignoring the monetary societal costs of infection and health complications. We used a threshold of £20,000 per QALY gained to indicate if the intervention was cost-effective. We considered these NHS-based costs to include treatment costs of chlamydia and gonorrhoea, plus the expected costs involved in treating resultant sequelae. QALYs were assigned to each individual sequelae alongside the sequelae's expected duration. The full details of all costs and health utilities gathered in the course of this work are in *Table 9*.

Main analysis

The primary outcomes included the QALYs gained, the difference in cost and the total cost per QALY gained, expressed as the mean ICER between standard care and standard care with the additional text-based intervention. The secondary outcomes were the number of infections prevented (including secondary transmissions), and associated sequelae prevented from occurring in intervention participants. We aimed to display results comparing the ICER between the status quo scenario without the safetxt intervention and with the safetxt intervention and employ the 95% credible interval to highlight uncertainty.

Scenario and sensitivity analyses

Throughout this work, we aimed to give our mean value for each result alongside the 95% credible interval, representing the range of the most central 95% of all model runs. We also conducted preliminary one-way sensitivity analyses to evaluate the robustness of the model findings in which we varied different key parameter values. We considered two primary scenarios: (1) no additional cost is incurred by the intervention owing to existing NHS infrastructure and, therefore, additional expenses are negligible, and; (2) 50% of gonorrhoea and chlamydia infections go untreated, leading to reduced treatment costs.

Next steps

The model has been developed to the point of a functional draft. If the cost analysis had gone forward, this would have been fine-tuned for costs of treatment and explored with a clinical team. Some of the costs, such as for treating tubal factor infertility, are complex and difficult to fully determine. Alternative parameter distributions could also be applied to parameter estimates that throughout we

found to be highly uncertain. For many parameters we made use of uniform distributions as we could only obtain a point value from the literature or were faced with a significant range between different sources in the literature. The model could also easily be adapted to be UK focused by scaling up the population included proportionately or using further data from the devolved nations. Furthermore, the model could readily be extended to 10,000 or 100,000 parameter samples if required. Finally, further sensitivity analyses could also be undertaken, examining alternative costings, probabilities of disease transmission or differences in reinfection/persistence rates for chlamydia and gonorrhoea.

Chapter 7 Discussion

Our trial provides clear evidence that the safetxt safer sex support intervention, delivered by mobile phone text messaging, does not reduce the incidence of chlamydia and gonorrhoea at 12 months, with slightly more infections in the intervention group. The intervention effect is similar in all of the prespecified subgroups. There is a suggestion that slightly more participants in the intervention group than in the control group reported informing their partner of their infection. According to limited clinic data, this did not translate into more partners attending for treatment. The intervention increased condom use at last sex at 4 weeks and 12 months and increased condom use at first sex with the most recent new partner at 12 months. The intervention did not alter STI testing before sex with new partners. The intervention increased the intermediate outcomes of knowledge regarding STIs and increased self-efficacy in how to use condoms but did not increase self-efficacy in condom communication or self-efficacy in partner notification regarding STI. Although the intervention did not aim to alter the number of sexual partners that participants had, there was a suggestion that the proportion of people with a new partner and with two or more partners was slightly higher in the intervention group than in the control group. For other secondary outcomes, the intervention was in the direction of benefit, except the outcome 'diagnosed with any STI', but the CIs encompassed no effect. Contrary to our theoretical model (see *Figure 1*), the increases in condom use and suggestion of change in other behaviours did not translate into reductions in chlamydia and gonorrhoea. Instead, there was the suggestion that chlamydia and gonorrhoea infections may have been slightly higher in the intervention group.

Strengths and limitations

Our trial had many strengths. The design, conduct and reporting of the trial followed CONSORT (Consolidated Standards of Reporting Trials) recommendations.[117] We ensured allocation concealment by using computer-based randomisation remote from the recruiting clinic site. Baseline prognostic factors were well balanced between the groups. Data collection and laboratory and statistical analyses were carried out blinded to treatment allocation. The primary outcome was known for 75% of participants in both the intervention and the control group. It is challenging to achieve high follow-up for objective or self-reported outcomes in trials of sexual health interventions with young people. Although we used evidence-based methods and developed our own trial specific procedures to achieve higher follow-up for laboratory-assessed chlamydia and gonorrhoea than other trials with similar populations,[91,118] some potential for bias remains. Our primary analysis used multiple imputation methods because MICE is recognised as a way of reducing bias in and increasing the precision of trial results.[28,67] Losses to follow-up are not likely to have resulted in significant bias, as the complete-case, additional and sensitivity analyses making different assumptions regarding missing data all showed similar results. The higher than anticipated event rate in the control group improved the precision of the trial results. Highly sensitive and specific NAAT PCR (polymerase chain reaction) tests were used to assess chlamydia and gonorrhoea infection. Our recruitment across the UK and across sociodemographic groups, combined with no evidence of heterogeneity of effects in subgroups, suggests that the results are generalisable across the UK. The primary analyses were on an intention-to-treat basis.

Our trial also had some limitations. It is possible that involvement in behaviour change trials confers a Hawthorne effect, whereby the behaviour of the control group alters as a result of participating in the trial. Trial follow-up procedures could be experienced as a form of behavioural monitoring that can alter behaviour. However, the follow-up procedures at the end of the trial would have been unlikely to have influenced the acquisition of STIs during the trial, and the follow-up procedures were the same for both groups, so this would not result in differential bias. Many control group participants reported in the open feedback section of the 12-month questionnaire that the monthly messages reminding participants to let the LSHTM trial team know about changes in address or contact details indirectly

acted as reminders regarding safer sex, which may have reduced the intervention effect estimates measured in the trial. However, text message reminders alone are known to have only small effects on sexual behaviour.[33,34] As > 40% of participants in our trial changed their contact details or address at least once, it would not have been feasible to have achieved high follow-up without monthly reminder messages. Our conclusion, that the safetxt intervention content confers a small benefit on some safer sex behaviours but may increase numbers of partners and STIs, remains valid. Changes in self-reported behaviour in both groups between baseline and follow-up are notable; for example, the proportion of participants reporting two or more partners in the preceding year was 83.9% in the intervention group and 82.7% in the control group at baseline and 56.5% in the intervention group and 54.7% in the control group at the 12-month follow-up. These self-reported changes are also consistent with changes in behaviour reported following STI diagnosis in the wider literature.[96–98] Participants were not blinded to their allocation, which could have affected the self-reported outcomes; however, this would not have influenced the STI test results, as analyses were completed at an independent laboratory and the data were entered by a blinded researcher. Clinic data regarding partner attendance for treatment were incomplete as not all clinics collect these data or do so consistently. We randomised 11 people twice and excluded them from the analysis, but this would not have influenced our results. If other participants obtained a new mobile phone number and used a false name and date of birth, then they could have been randomised twice. It is not very plausible that participants would have gone to this effort to join our trial. If this occurred, it could reduce the power of the trial to detect an impact of the safetxt intervention. Our sample size calculation allowed for 2% of control participants viewing intervention messages, which was based on the safetxt pilot trial. If we assume that all control participants who reported that they read another participant's messages read intervention messages, this would mean that there was 1% contamination (32/3125), so our trial has greater power to detect a difference in infection between the groups than planned.

Interpretation of the results

The safetxt intervention was hypothesised to reduce the incidence of chlamydia and gonorrhoea by increasing condom use with new partners, increasing testing before sex with new partners and increasing partner notification. According to the theory of change, the safetxt intervention would achieve this by increasing knowledge regarding STI, increasing self-efficacy in how to use condoms and self-efficacy in communication about condoms with partner(s), and increasing self-efficacy in telling partner(s) about their infection. The intervention did not aim to influence the number of partners or number of new partners. The intervention worked partly in the way hypothesised. The intervention increased self-efficacy in how to use condoms and knowledge but there was no difference in other intermediate outcomes. Overall, the modest increases in condom use and no change or suggestion of slight changes in other behaviours targeted did not result in a reduction in chlamydia and gonorrhoea infection.

There is a suggestion of slight increases in the incidence of chlamydia and gonorrhoea at 12 months in the intervention group compared with the control group, and there are a number of possible explanations for this. First, we considered whether or not these results could have occurred as a result of small chance imbalances in sexual behaviour between the intervention and control groups at baseline. Post hoc analyses adjusting for the number of partners in the previous 12 months at baseline did not alter the effects of the intervention on the primary outcome, namely the incidence of chlamydia and gonorrhoea, or the effects of the intervention on the proportion of people with two or more partners. It is not likely in a large trial such as ours that the effect would be due to other unmeasured differences in sexual risk behaviours between the groups at baseline. Second, we explored whether or not the effect could be due to follow-up data not being MAR as our primary analysis assumes. Additional, non-prespecified analyses, making a range of different assumptions about STI rates in those lost to follow-up in the intervention and control groups, yielded similar results to our primary analysis. Third, we explored whether or not the results could be because those in the control

group were more likely than those in the intervention group to have been tested at a site other than their recruiting clinic between randomisation and follow up and, therefore, were less likely to have had a positive test result confirmed in our data set. There is no evidence to support this. We asked all participants reporting a positive STI test where they had been tested, and we sought data from all testing sites, not just the clinics involved in trial recruitment. Furthermore, the proportion of positive tests confirmed by testing sites (clinics, general practitioner surgery, online service or other) was the same in the intervention and control groups. Finally, we conducted a post hoc per-protocol analysis to explore the intervention effect among those who received the whole intervention. In this per-protocol analysis, there were slightly higher odds of chlamydia and gonorrhoea infection at 12 months than in the primary intention-to-treat analysis. The participants in the intervention group in the per-protocol analysis were slightly younger than those in the control group, but the per-protocol analysis adjusted for the same variables as the primary analysis, including age. The participant characteristics were otherwise similar. The consistency of the results in the primary, complete-case, additional and sensitivity analyses, combined with the slightly increased effect size in the per-protocol analysis, adds to the weight of evidence suggesting that the intervention may have slightly increased the incidence of chlamydia and gonorrhoea at 12 months.

The slightly higher proportions of the intervention group having a new partner and having two or more partners at 12 months is likely to have contributed to the increased incidence of chlamydia and gonorrhoea. However, our understanding of the mechanism of action for the unanticipated effect on sexual partnerships and increased STIs is limited as the trial was not designed to explore this. Our prior qualitative research and the analysis of open feedback comments provide little direct evidence from participant reports regarding why this may have occurred. There was one comment that the intervention 'gave me the confidence to engage in a new sexual relationship with a new partner without worrying about unwanted consequences' as well as many comments about how the intervention had increased caution about sexual relationships.

It is not likely that the approaches to promoting condom use in safetxt resulted in increased STIs as these approaches were adapted from and similar to the content of face-to-face interventions that increase condom use and reduce STIs.[12–14,16,17] Our analysis exploring heterogeneity in the pooled effect of the pilot trial and main trial data (see *Chapter 4*, *Pooled analysis with the safetxt pilot trial data*) is consistent with this view. This analysis suggests that the effects of safetxt content about condom use and STI testing on the incidence of chlamydia/gonorrhoea remain uncertain, but may differ from the effects of content that targets condom use, STI testing and partner notification among those diagnosed with a STI.

To promote partner notification, the intervention was designed to provide non-stigmatising, non-blaming STI information and examples of how others notified partners. We reviewed our qualitative research findings published in 2016 to consider plausible mechanisms for the unanticipated effects found.[53] The first possible mechanism relates to recipients' reports in our qualitative research that the intervention reduced stigma about having a STI. In both groups, the proportion of participants with two or more partners is lower at the 12-month follow-up than at recruitment. However, if there was less stigma regarding STIs in the intervention group, then this may have resulted in a slightly higher proportion of participants in the intervention group with two or more partners at 12-month follow-up, in turn influencing STI infections. This is consistent with other research demonstrating that lower levels of stigma measured in individuals are associated with a larger number of partners, although in this research lower stigma was also associated with reduced rates of adolescent pregnancy.[119] Lower levels of societal stigma towards MSM measured at a country level have been associated with higher levels of both precautionary behaviours and country-level HIV prevalence,[120] with the highest unmet need for HIV treatment in countries that have high levels of societal stigma towards MSM. Previous research has also demonstrated that lower levels of stigma regarding sex, STIs and sexuality are associated with higher levels of precautionary behaviours, such as testing for or obtaining treatment for HIV/STIs and using PEP and emergency contraception, and lower rates of unplanned pregnancy, whereas experiences

of stigma have negative impacts on emotional and mental well-being.[121–126] In keeping with this wider research evidence, we note that levels of STI testing in clinic were slightly higher in the intervention group (1549/3123, 49.6%) than in the control group (1477/3125, 47.4%). Levels of STI in the postal samples collected at 12 months as part of the trial procedures were similar in both groups (170/3123, 5.44%, in the intervention group and 165/3125, 5.28%, in the control group), and almost all of the excess STIs in the intervention group were diagnosed and treated in clinics during the 12 months' follow-up.

Some other trials have reported on interventions that inadvertently increased STI rates through increasing the number of partnerships.[127] In the safetxt intervention group, the balance of risk and precautionary behaviours may have resulted in slightly increased STI rates compared with the control group.

Positive approaches to sexuality and reproduction should recognise the part played by trust and communication, as well as pleasurable sexual relationships, in promoting well-being and enabling people to fulfil their sexual and reproductive health and rights.[52] Our qualitative research and open feedback from participants suggest that, from young people's perspectives, many aspects of positive sexual and reproductive well-being were met by the safetxt intervention, such as impacts on confidence, agency, communication and precautionary behaviours. However, ethically, this should be achieved without increasing STIs and risks to physical health.

The long-term effects of the safetxt messages on condom use at 12 months were larger than those reported at 12 months in RCTs of single sessions of face-to-face counselling, telephone counselling, videos or other interactive digital interventions such as websites.[15,19,128–130] Some intensive face-to-face behaviour change interventions involving multiple weekly group meetings achieve reductions in STI and larger increases in condom use at 12 months than the safetxt intervention, but these have not proven practical for widespread implementation.[12–14,16,17] Our previous systematic review showed that messaging interventions probably increase STI testing (at any point in time, not specifically prior to sex with new partners) in general populations of young people,[37] but our trial shows that testing before sex with new partners was not increased. STI testing prior to sex with new partners requires planning in relation to the timing of first sex, which may not reflect how many sexual relationships start.
The intervention may have had little or no effect on partner notification or correct treatment of STI, as levels of partner notification and correct treatment in the control group in our trial were already high and high in comparison with partner notification levels reported in the UK.[26,27] In the UK, most clinics have partner notification pathways that both the intervention and the control group would have received, so it is possible that the effect of messages would be different in a setting where partner notification pathways are less developed.

Implications for health-care services

The safetxt intervention did not reduce STIs and may have slightly increased STIs, so we cannot recommend the implementation of the safetxt intervention as delivered to participants and evaluated in this trial in the NHS.

The components of the safetxt intervention promoting condom use were effective, and providers could consider implementing these. The safetxt condom promotion content was developed based on the content of face-to-face interventions that increased condom use and reduced STIs. The safetxt condom promotion content had larger effects at 12 months on condom use than web, video or telephone counselling or single sessions of counselling evaluated in RCTs.[15,18,128,131–134] Based on a cost of 5 pence per message, the condom promotion content costs £1.80 per person. Text messaging services are embedded in many primary care and NHS services. It would be relatively straightforward and low cost for health-care providers to send messages targeting condom use and condom use skills to at-risk 16- to 24-year-olds who opt to receive such messages.

Implications for further research

Our unexpected findings highlight the importance of evaluating novel health communication interventions in well-powered RCTs to reliably establish their effects, especially in the complex area of sexual behaviour. We have limited insight into the unanticipated impacts of the safetxt intervention identified in our RCT. These occurred despite earlier uncontrolled evaluations suggesting high acceptability and positive behavioural impacts of the intervention. The elements of the safetxt intervention targeting partner notification may have inadvertently increased sexual partnerships and the incidence of chlamydia and gonorrhoea, the mechanism of which could be explored in future work. We conducted some further qualitative interviews at the end of participants' involvement in the trial that may provide further insights into the mechanism of action of the intervention. These are being analysed and will be reported in a separate publication.

New approaches to increase partner notification and safer sex are needed. Future interventions aiming to reduce the harmful effects of stigma in the area of sexual health should consider the potential impacts of interventions on sexual partnerships in their development phase. Further research to identify ways of achieving the benefits of stigma reduction without increasing STI risk is needed. The importance of RCTs in reliably evaluating the effects of interventions cannot be overemphasised.

Future research should evaluate the effects of blended interventions, as their effects on behaviour and STI outcomes could be larger than those of text messages or other digital media alone. Safetxt and other interventions delivered by automated text message have small impacts on behaviour.[28,34]

We were not able to include all of the elements we would have liked in the safetxt intervention, as some content was not considered acceptable for delivery by text message (e.g. content on relationships).[32] A blended intervention with content delivered through a range of media, including some interactions with a real person, would have allowed us to include all of these elements. Such a blended intervention may also be feasible to implement in the NHS and other health-care services.

The use of artificial intelligence (AI)-facilitated interventions could be explored. AI could address some of the limitations that our intervention delivered by text messages had for some participants. For example, an intervention using AI-assisted learning could generate a more tailored intervention, allowing the most relevant content likely to result in the largest behaviour change to be shown to participants, taking into account their relationships and other contextual factors. Such an intervention could also be more responsive to changes in individuals' circumstances over time, enhancing its effectiveness.

Conclusions

The safetxt intervention did not reduce the incidence of chlamydia and gonorrhoea; instead, there were slightly more STIs in the intervention group. The intervention increased knowledge, self-efficacy regarding how to use condoms and condom use at 12 months. Providers could consider implementing the content of the safetxt intervention targeting condom use. Even when uncontrolled evaluations suggest benefits, randomised controlled trials are essential for evaluating health communication interventions, which can have unanticipated effects.

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Trial Steering Committee

Professor Pippa Oakeshott (chairperson), Professor Caroline Free (chief investigator), Dr Andrew Copas, Dr Michael Brady, Professor Michael Ussher and Colum McGrady (patient representative); the observers were Rosemary Knight and Kimberley Potter. As the risk of harm from the intervention was considered low, the analysis was conducted once, at the end of the trial. There was no separate Data Monitoring and Ethics Committee. The TSC took on the ethical responsibility for the trial and monitored adverse events.

Trial Management Group

Professor Caroline Free, Ona McCarthy, Melissa Palmer, Irrfan Ahmed, Kimberley Potter, Lauren Jerome, Rosemary Knight, Megan Knight, Zahra Jamal, Faran Dhaliwal, Rebecca Matthews (December 2015–August 2016) and Rebecca Swinson (August 2016–August 2017)

Trial Statisticians

James Carpenter, Tim Morris and Phil Edwards. George Ploubidis provided oversight of the analysis of intermediate measures conducted by Melissa Palmer.

Collaborators

Caroline Free, Graham Hart, Julia Bailey, Ian Roberts, Rebecca French, Phil Edwards, Susan Michie, Katy Turner, Paula Baraitser, John Cairns, Karen Devries, Ford Hickson, Kaye Wellings, Ona McCarthy and Melissa Palmer.

Contributing trusts and health boards

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Contributions of authors

Caroline Free (https://orcid.org/0000-0003-1711-0006) (Professor of Primary Care and Epidemiology, General Practitioner, Honorary Consultant in Sexual and Reproductive Health, trials, mixed methods research, digital and behavioural interventions) led and takes responsibility for the development of the intervention, the trial design, conduct and analysis and the writing up of the research.

Melissa J Palmer (https://orcid.org/0000-0003-3937-8070) (Assistant Professor, SRH, Quantitative Research) prepared data for the TSC, wrote the statistical analysis plan, analysed the quantitative intermediate measures, prepared tables, contributed to trial recruitment, was a member of the Trial Management Group throughout, developed trial recruitment and follow-up materials, wrote up the intermediate measures analysis and contributed to the report.

Kimberley Potter (https://orcid.org/0000-0002-4273-207X) (Trial Manager) was responsible for the day-to-day management of the tria and the setting-up, co-ordination and communication with trial sites. She was joint lead of the Trial Management Group, wrote the first draft of *Chapter 3*, *Follow-up* and commented on the final report.

Ona L McCarthy (https://orcid.org/0000-0002-9902-6248) (Assistant Professor, SRH, Mixed-Methods Research) co-developed the intervention, intermediate measures, and trial recruitment and follow-up procedures and materials. She contributed to the trial design and writing the statistical analysis plan, was a member of the Trial Management Group and contributed to writing the report.

Lauren Jerome (https://orcid.org/0000-0002-6959-1529) (Assistant Trial Manager) contributed to trial recruitment and follow-up, developed recruitment and follow-up procedures and materials, liaised with trial sites, was a member of the Trial Management Group throughout, wrote drafts of *Chapter 3* and commented on the report.

Sima Berendes (https://orcid.org/0000-0001-7000-868X) (Research Fellow, SRH) analysed open feedback data, conducted the updated systematic review of existing evidence and wrote the first draft of that section in *Chapter 1*, and contributed to the writing of the report (*Chapter 1*, *Chapter 5* and revision and editing of various other sections).

Anasztazia Gubijev (https://orcid.org/0000-0003-4317-5866) (Research Fellow, Qualitative Research, SRH) analysed the open feedback comments, wrote the first draft of *Chapter 5* and contributed to the updated systematic review of existing evidence.

Megan Knight (https://orcid.org/0000-0003-2902-4818) (Trials Assistant) conducted trial recruitment and follow-up, developed trial follow-up procedures and liaised with trial sites, and was a member of the Trial Management Group throughout.

Zahra Jamal (https://orcid.org/0000-0002-3817-6795) (Trials Assistant) conducted trial follow-up, developed trial follow-up procedures, worked with the patient and public involvement group on trial results dissemination and was a member of the Trial Management Group.

Farandeep Dhaliwal (https://orcid.org/0000-0002-1106-5884) (Trials Assistant) conducted trial follow-up, developed trial follow-up procedures and was a member of the Trial Management Group.

James R Carpenter (https://orcid.org/0000-0003-3890-6206) (Professor of Statistics) wrote the statistical analysis plan and analysed the data.

Tim P Morris (https://orcid.org/0000-0001-5850-3610) (Senior Research Associate in Statistics) commented on the statistical analysis plan and analysed the data.

Phil Edwards (https://orcid.org/0000-0003-4431-8822) (Associate Professor in Statistics) wrote the statistical analysis plan in the grant application, commented on the statistical analysis plan and final report and contributed to whole-team meetings.

Rebecca French (https://orcid.org/0000-0002-1962-5022) (Associate Professor) contributed to the intervention development, supervised the analysis of open feedback comments and contributed to whole-team meetings.

Louis Macgregor (https://orcid.org/0000-0003-3611-2453) conducted and wrote up the health economics analysis.

Katy ME Turner (https://orcid.org/0000-0002-8152-6017) designed, supervised and co-wrote *Chapter 6* and contributed to whole-team meetings.

Paula Baraitser (https://orcid.org/0000-0002-3354-6494) (Consultant in SRH, Mixed Methods Research) co-developed the initial concept of safetxt, contributed to intervention development, contributed to whole-team meetings and commented on the final report.

Ford CI Hickson (https://orcid.org/0000-0003-0395-374X) (SRH, Mixed Methods Research) led the adaptation of the safetxt intervention for men who have sex with men, contributed to whole-team meetings, and contributed to interpreting the mechanism of unanticipated effects of the intervention.

Kaye Wellings (https://orcid.org/0000-0003-1053-8640) (SRH, Mixed Methods Research) contributed to intervention development and whole-team meetings, and commented on the research application, protocol and final report.

Ian Roberts (https://orcid.org/0000-0003-1596-6054) (Clinical Trials) commented on the trial design and protocol, contributed to whole-team meetings and commented on the final report.

Julia V Bailey (https://orcid.org/0000-0002-5001-0122) (Senior Lecturer, SRH Clinician and Researcher, Mixed Methods, Digital Interventions) contributed to intervention development, commented on the application and final report, and contributed to whole-team meetings.

Graham Hart (https://orcid.org/0000-0001-9676-6577) (SRH) commented on the concept, application and final report, and contributed to whole-team meetings.

Susan Michie (https://orcid.org/0000-0003-0063-6378) (Health Psychology, Behaviour Change) contributed to the intervention design and whole-team meetings and commented on the final report.

Tim Clayton (https://orcid.org/0000-0002-1266-3288) (Clinical Trials) commented on the application and protocol, provided clinical trials advice and commented on the final report.

Karen Devries (https://orcid.org/0000-0001-8935-2181) (Professor of Social Epidemiology, Trials, Intervention Design, Epidemiology) contributed to intervention development, and commented on the application, protocol and final report.

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Ethics statement

Ethics approval was provided by the NHS Health Research Authority – London – Riverside Research Ethics Committee (REC reference 15/LO/1665) and the London School of Hygiene & Tropical Medicine (reference 10464).

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review. We will make data available to the scientific community with as few restrictions as feasible.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data are vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

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Appendix 1 Example text messages

Examples of text messages for safetxt intervention group participants listed by topic and by day after enrolment (selected messages are some of those sent to male heterosexual participants with chlamydia infection at baseline).

Treatment and 7 days' abstinence after treatment

Day 1

You made the right decision to get a test. Getting treated quickly means you are less likely to have any problems.

Chlamydia is a common bacterial infection that's easy to treat with antibiotics. To treat the infection, take the tablets and then don't have sex (oral, vaginal and anal) for 7 days while the infection clears.

Day 2

It's common to get re-infected with chlamydia. To avoid getting it again, the next steps are: Day 1) get treated Day 2) tell the person you're having sex with to get treated 3) don't have sex for 7 days (oral, vaginal or anal) after you and your partner(s) have been treated.

Telling partner (after initial diagnosis)

Day 1

Most people who have an infection don't know. Your partner(s) could be infected so it's important to tell them that they need treatment too.

Day 2

There's no exact way to let them know they need treatment but it helps to think about what you're going to say. You could stick to facts, like: it's easy to treat and you can have it without knowing, so no-one can really tell who had it first.

Here are a few examples of how others told their partner: 'I said "I don't really want to tell you this but I have to- I found out I have chlamydia." It's awkward to tell people but it's not right not to, is it? They may not know. You can't just let them walk round with an infection'; "I just couldn't tell some partners so the clinic offered to do it for me. They gave me the option of keeping my name out of it." **Text Day 1 to hear more**.

[If texted Day 1:

"For people I didn't see any more I just texted them."

"I said 'chlamydia is common and most people don't know they have it, so there is no way of knowing who had it first.'" **Text 2 to hear more**.]

[If texted 2:

"I just said how it was – that I'd been to a clinic and found out I had chlamydia and got treated."

"I told them getting tested and treated is free, you won't need an examination."]

Day 3

You might be thinking about how they'll react when you tell them. You could try practising what you're going to say.

The best way to prevent chlamydia spreading is to tell anyone you have had sex with in last 6 months that they need treatment. If it's not doable, you can ask the clinic to contact them for you and they won't mention your name.

How others felt after a positive sexually transmitted infection test

Day 4

Here are how others felt when they found out that their test was positive: 'I never thought I'd get chlamydia. I'll use a condom in the future or get a check-up with them first.' **Text 3 to hear more**

[If texted 3:

'I didn't know who to talk to at first so I just looked it up on the Internet. It was like the clinic told me – really common and easy to treat.'

'I was angry with my partner because they had had other partners and I hadn't. But it was better to know and get treated.'

Preventing reinfection, and information on specific sexually transmitted infections (depending on type of sexually transmitted infection participants had at baseline)

Day 5

You can make sure you don't get another infection by: 1) getting the person you are having sex with treated 2) using condoms every time you have sex and 3) by you and your partner getting tested before sex without a condom and 4) by having another test in 3 months.

Chlamydia is common so it's worth thinking about how you can make sure you don't get it in the future.

Day 6

Most people who have an infection don't know. You can't tell if someone has an infection just by looking at them or by how well you know them.

Condom use

Day 6

Ask yourself if having sex without a condom is worth taking the risk.

Day 7

It saves a lot of trouble in the end if you and your partner(s) get tested before you have sex.

Day 8

Think back to a time (or times) when you had sex with a condom. Think about the situation and why you used a condom.

Think back to a time (or times) when you had sex without a condom. Think about why you didn't use one. Ask yourself how you could you do things differently next time.

Day 10

You might like it if the person you are having sex with puts on the condom for you.

Day 11

A lot of the time, sex isn't planned. So it's best to always have a condom on you. Find a time to put a few in your wallet. You could also keep a supply in places where you have sex (bedroom, partner's house, car).

Day 14

If condoms aren't comfortable, you could try a different brand or kind. Some men find they can feel more with thinner condoms (which are still safe).

Day 17

One reason a condom may split is because there is air trapped inside. To prevent this, hold the tip of the condom between your forefinger and thumb and roll it down, making sure there are no air bubbles.

Day 18

To avoid the condom falling off after sex, while the penis is still hard, hold the condom in place while withdrawing the penis. **Text 4 for more tips on how to avoid condom problems.**

If texted 4:

Another reason a condom could split is because it ripped when you opened the packet. To prevent this, before you open the packet, feel for the rim of the condom and push it aside, making sure you don't tear the condom when you open the packet.

It could also split if the condom is out of date. Make sure to check this before you use it and before you put it in your wallet.

Day 20

You can also use water or silicone-based lubricants with condoms. There are a few brands to choose from, like K-Y Jelly & Durex Play, which you can find at chemists.

But don't use anything oil-based (like Vaseline) because they can make the condom break.

Day 22

As you know, sometimes people take risks when they are drunk or taking drugs that they wouldn't normally do. This website has some info on these kinds of situations: LINK. **Text 5 to hear from others.**

www.nhs.uk/Livewell/Sexandyoungpeople/Pages/Sexandalcohol.aspx

If texted 5:

"The best thing I did for my sex life was drink less – it's bad enough trying to get an erection when you're pissed, never mind trying to put a condom on."

Day 24

Make sure the condom has a BSI Kitemark or CE mark on the wrapper. That means they've been tested to make sure it's quality.

Day 40

When you just start seeing someone, it can be awkward to bring up condoms. Most people are happy to talk about condoms though.

More than likely they're thinking the same thing and will be relieved that you brought it up first. It can help to think about what you'll say beforehand.

Day 54

If you're new to condoms, using them can be tricky at first but it gets a lot easier with practise.

Sexually transmitted infection testing

Day 26

Here's what one person said about getting tested: 'For me getting a check up is about respecting myself. If I can't respect myself then others won't either'.

Day 36

Getting a check up before sex with someone new means you don't have to worry afterwards.

Day 47

If you make it a habit for you and your partner(s) to get tested before you have sex, you can avoid a lot of hassle and regret later.

Day 201

Regular check-ups & check-ups with new partners mean infections can be treated before they cause problems.

Contraception

Day 15

Emergency contraception (the 'morning after pill') can be taken up to three or five days (depending on the kind) after sex without a condom but it's best to take it as soon as possible. You can get it at most chemists and at sexual health services.

Day 28

If you're worried about your partner(s) not taking contraception, mention that it's free on the NHS and it's easy to drop in to your nearest sexual health clinic.

Talking about sex

Day 34

When talking about sex with you partner(s) being light-hearted but sensitive can make your partner feel more encouraged rather than criticised.

More information after reinfection/new sexually transmitted infection

Day 217

If you've received a positive test result for a sexually transmitted infection since joining the study and want more text messages on how to not get it again, email the study coordinator, Ona, at safetxt@lshtm.ac.uk

Appendix 2 List of protocol amendments

Amendment number	Submission Date	Approval date	Summary of changes
1 – substantial	16 November 2015	24 November 2015	• Randomisation changed to simple randomisation 1 : 1 allocation ratio • Reformatted the protocol • Clarified patient withdrawal • Finalised questionnaires
2 – non-substantial	8 February 2016	17 March 2016	• Protocol and patient information sheet updated • Addition of new sites
3 – substantial	1 June 2016	23 August 2016	• Patient information sheet simplified and clarified • Consent form simplified and clarified, addition of results provided by clinic/general practitioner and collected long-term outcomes • 4-week follow-up letters included • Addition of new sites
4 – non-substantial	11 July 2016	19 September 2016	• Addition of sites
5 – substantial	21 October 2016	4 January 2017	• Inclusion criteria updated • Research staff to contact eligible patients by phone/text • Baseline and 4-week questionnaires clarified • Patient information sheet version number updated • Consent form updated to include data sharing • Posters for clinics
6 – non-substantial	19 January 2017	24 January 2017	• Baseline questionnaire clarified • Addition of sites
7 – non-substantial	6 February 2017	16 February 2017	• Baseline questionnaire clarified
8 – substantial	3 May 2017	22 May 2017	• Informing participants of 1-year test results • Collection and disclosure of partner violence • 1-year follow-up letters
9 – non-substantial	26 July 2017	8 August 2017	• Thank-you slip • Addition of sites
10 – substantial	5 March 2018	29 March 2018	• Extension of recruitment end date • Changes of principal investigator • Addition of sites • 4-week questionnaire clarified • 1 year letters clarified
11 – substantial	24 April 2018	09 May 2018	• Recruitment sample size increased • Exclusion criteria clarified • Patient information sheet clarified on length of data storage • Postage instructions
12 – non-substantial	22 May 2018	22 May 2018	• Consent form version number updated to reflect patient information sheet
13 – non-substantial	26 June 2018	27 June 2018	• Recruitment end date extended
14 – substantial	20 July 2018	2 August 2018	• Recruitment end date extension • Prize draw • Test kit to send with fifth mail-out • Pocket card for research nurses • Thank-you slip updated

Amendment number	Submission Date	Approval date	Summary of changes
15 – non-substantial	4 October 2018	8 October 2018	• Addition of sites
16 – substantial	8 May 2019	5 July 2019	• Opt-out of further remote data collection • Key questions updated • Include a sixth test kit mail-out
17 – non-substantial	1 August 2019	21 August 2019	• MSM 1-year letters clarified • Letters footer updated to University of London • Wording altered on some letters to be more encouraging • Changes of principal investigator • Pictures to send with follow-up e-mails
18 – substantial	17 October 2019	11 November 2019	• Additional qualitative interviews to conduct with up to 30 participants, and all associated documents • Change of principal investigator at Sheffield
19 – substantial	17 December 2019	6 February 2020	• Minor updates to sections of the protocol • Updated participant documents for qualitative interviews and follow-up e-mails • Change of principal investigator at Kent
20 – non-substantial	14 February 2020	14 February 2020	• Change of principal investigator at Calderdale and Huddersfield NHS Foundation Trust

Appendix 3 Description of participants in the per-protocol population

TABLE 10 Description of participants in the per-protocol population

Characteristic	Intervention (*N* = 2019), *n* (%)	Control (*N* = 2229), *n* (%)	Total (*N* = 4248), *n* (%)
Age group (years)			
16–19	778 (38.5)	799 (35.8)	1577 (37.1)
20–24	1241 (61.5)	1430 (64.2)	2671 (62.9)
Gender			
Female	1398 (69.2)	1506 (67.6)	2904 (68.4)
Male	614 (30.4)	717 (32.2)	1331 (31.3)
Non-binary	7 (0.3)	6 (0.3)	13 (0.3)
Ethnicity grouped			
White British/other white background	1618 (80.1)	1780 (79.9)	3398 (80.0)
Black/black British – Caribbean/African/other	219 (10.8)	223 (10.0)	442 (10.4)
Asian/Asian British – Bangladeshi/Chinese/Indian/ Pakistani/other	46 (2.3)	59 (2.6)	105 (2.5)
Mixed background	104 (5.2)	140 (6.3)	244 (5.7)
Other background	32 (1.6)	27 (1.2)	59 (1.4)
Age (years) at which left education			
≤ 16	283/2000 (14.2)	298/2199 (13.6)	581/4199 (13.8)
≥ 17	861/2000 (43.1)	997/2199 (45.3)	1858/4199 (44.2)
I am still in full-time education	856/2000 (42.8)	904/2199 (41.1)	1760/4199 (41.9)
Gender and orientation			
WSM	1296 (64.2)	1375 (61.7)	2671 (62.9)
MSW	429 (21.2)	485 (21.8)	914 (21.5)
WSW	16 (0.8)	12 (0.5)	28 (0.7)
MSM	152 (7.5)	186 (8.3)	338 (8.0)
WSMW	85 (4.2)	118 (5.3)	203 (4.8)
MSMW	33 (1.6)	46 (2.1)	79 (1.9)
NBSM	5 (0.2)	1 (0)	6 (0.1)
NBSW	0	2 (0.1)	2 (0)
NBSMW	2 (0.1)	3 (0.1)	5 (0.1)
Not stated	1 (0)	1 (0)	2 (0)

continued

TABLE 10 Description of participants in the per-protocol population (*continued*)

Characteristic	Intervention (*N* = 2019), *n* (%)	Control (*N* = 2229), *n* (%)	Total (*N* = 4248), *n* (%)
Baseline diagnosis			
Chlamydia	1606 (79.5)	1758 (78.9)	3364 (79.2)
Gonorrhoea	182 (9.0)	217 (9.7)	399 (9.4)
Gonorrhoea and chlamydia	97 (4.8)	110 (4.9)	207 (4.9)
Gonorrhoea or NSU	17 (0.8)	18 (0.8)	35 (0.8)
NSU	71 (3.5)	77 (3.5)	148 (3.5)
Unknown	46 (2.3)	49 (2.2)	95 (2.2)
Baseline condom used last sex			
Yes	500 (24.8)	569 (25.5)	1069 (25.2)
No	1486 (73.6)	1624 (72.9)	3110 (73.2)
Unsure	33 (1.6)	36 (1.6)	69 (1.6)
Baseline condom used new partner			
Yes	653 (32.3)	730 (32.8)	1383 (32.6)
No	1325 (65.6)	1448 (65.0)	2773 (65.3)
Unsure	41 (2.0)	51 (2.3)	92 (2.2)
Baseline tested before sex new partner			
Yes	787 (39.0)	900 (40.4)	1687 (39.7)
No	1174 (58.1)	1263 (56.7)	2437 (57.4)
Unsure	58 (2.9)	66 (3.0)	124 (2.9%
Baseline partner tested before sex new partner			
Yes	282/2018 (14.0)	321 (14.4)	603/4247 (14.2)
No	773/2018 (38.3)	836 (37.5)	1609/4247 (37.9)
Unsure	963/2018 (47.7)	1072 (48.1)	2035/4247 (47.9)
Baseline number of partners			
0	4/2018 (0.2)	2/2227 (0.1)	6/4245 (0.1)
1	310/2018 (15.4)	372/2227 (16.7)	682/4245 (16.1)
≥ 2	1704/2018 (84.4)	1853/2227 (83.2)	3557/4245 (83.8)

NBSMW, non-binary people who have sex with men and women; NBSW, non-binary people who who have sex with women only.

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