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

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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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Scientific summary

The safetxt RCT

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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.

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