



● A randomised controlled trial
● of a safer sex intervention
● delivered through mobile
phone messaging

Summary Trial Protocol Version 2

1. Introduction

Younger people 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. The risk of adverse health effects increases with repeated infections. Those with an STI are more likely to acquire further STIs and HIV, if exposed. The highest prevalence of STI is in socio-economically deprived areas and among people with larger numbers of sexual partners. Re-infection rates following treatment are high: up to 30% for Chlamydia and 12% for gonorrhoea at one year.

safetxt builds on successful intervention development work and a pilot trial. The trial was commissioned by the NIHR to develop a safer sex intervention delivered by text message and to evaluate its acceptability to young people and the feasibility of a trial to establish its effects. The theory and evidence-based intervention employs 12 behaviour change techniques and is designed to reduce STIs in young people by supporting them in telling a partner about an infection, using condoms and obtaining testing before unprotected sex with a new partner.

Messages were written and adapted based on young people's preferences expressed in focus groups. Participants expressed a preference for messages with a non-judgmental and credible tone, short messages written in a positive style and those providing practical information regarding what needed to be done, why and how.

Without new effective interventions the Department of Health is unlikely to achieve its aims in increasing safer sex behaviours and reducing STI. Safer sex behaviours include condom use, notifying partner(s) about an existing STI and STI testing reduce the risk of STI, but young people may lack the knowledge, confidence and skills needed to adopt these behaviours.

The intervention delivered by text message provides acceptable, broad reach and low cost support which could enable more young people to adopt safer sex behaviours and so reduce STI.

If it proves to be effective, the low cost intervention could have an important impact on the sexual health of young people in the UK. A number of service providers have already expressed an interest in implementing the intervention, if proven effective. There is likely to be international interest in the impact of the intervention as short written messages delivered via mobile phones are increasingly used for behavioural support worldwide and sexually transmitted infections remain an important cause of morbidity and mortality. Identifying which intervention components are effective has the potential to generate general principles to inform similar interventions in the future.

2. Research objectives

- To establish the effectiveness of a safer sex intervention delivered by mobile phone messaging on STI infection at one year.
- To establish the effect of the intervention on partner notification and condom use at 4 weeks.
- To establish the effect of the intervention on partner notification, condom use and STI testing at one year.
- To explore which components of the intervention are effective by collecting data on the theoretical constructs influenced by the intervention components and on the pathway to behaviour change.
- To establish the costs and cost-effectiveness of the intervention.

3. Outcome measures

Primary outcome

Cumulative incidence of Chlamydia and gonorrhoea infection at one year assessed by NAAT tests: urine for men with pharyngeal and anal swabs for MSM and self-taken vulvo-vaginal swab for women.

4. Research design

Trial design

safetxt is single blind randomised controlled trial to establish the effects of a safer sex intervention delivered by text message on the cumulative incidence of Chlamydia and gonorrhoea infection.

Potential participants testing positive for Chlamydia, gonorrhoea or diagnosed with non-specific urethritis (NSU) will be identified from STI testing services by research staff based at the service.

They will provide potential participants with information about the trial at one of three time points:

- 1) When potential participants attend the service and are diagnosed with Chlamydia, gonorrhoea or NSU
- 2) When potential participants receive positive test results for Chlamydia or gonorrhoea by phone
- 3) When potential participants collect treatment for Chlamydia, gonorrhoea or NSU from services

Allocation

Participants will be randomly allocated, using a remote computer based randomisation system, to a safer sex intervention delivered by text messaging, or to a control group.

5. Trial population

Inclusion criteria

Participants will:

- Either;
 - have received a positive Chlamydia or gonorrhoea test result or have been diagnosed with NSU in the last two weeks
 - Or have started treatment for Chlamydia, gonorrhoea or NSU in the last two weeks
- own a personal mobile phone
- be aged 16 to 24
- be able to provide informed consent

Exclusion criteria

- known to be a sexual partner of someone already recruited to the trial

6. Planned interventions

Planned intervention

Intervention: regular messages delivered by text message to influence safer sex behaviours.

The intervention aims to increase safer sex in three ways:

1. Encouraging participants to correctly follow STI treatment instructions and inform partner(s) about infection
2. Promoting condom use with new or casual partners
3. Encouraging participants to obtain testing for STI prior to unprotected sex.

The intervention text message content has been developed in collaboration with young people, and has been shown to be acceptable, comprehensible and relevant.

Frequency of messages

Time period	Frequency of messages
Days 1-3	Four messages per day
Days 4-28	1-2 messages per day
Month 2	2-3 messages per week
Months 3-12	2-5 messages per month

Control treatment

Control: a monthly text message asking participants to provide information about changes in postal or email addresses.

7. Data collection and follow up

	Baseline	4 weeks	One year
Baseline questionnaire at randomisation	X		
Postal questionnaire		X	X
Posted STI kit			X

Participants will be sent a £5 unconditional incentive with each postal request i.e. when sending the 4 weeks questionnaire and 1 year test and questionnaire. Participants who return the test sample will be sent £20.