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

Submission date
17/03/2016

Recruitment status
No longer recruiting

Registration date
17/03/2016

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sexually transmitted infections (STIs) are common in young people. Easy-to-treat conditions such as chlamydia or gonorrhea are particularly common, and can lead to major health problems if left untreated. Practicing safe sex by using condoms and getting tested for STIs before they stop using condoms with a new partner, lowers the risk of getting an infection. Likewise, people with an infection are less likely to get another infection if they tell their partner. These practices can be very difficult for young people however. The use of text messages offering support has been shown to be very effective in other areas, such as quitting smoking, as so it is possible that it could also help encourage safe sex, getting tested for STIs and helping people to tell their partner if they are infected. The aim of this study is to find out whether delivering support using text messages over the course of one year is an effective way of reducing STIs by promoting safe sex and regular STI testing.

Who can participate?
Young adults aged between 16 and 24 who have had a positive chlamydia or gonorrhoea test in the last two weeks and own a mobile phone.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group receive regular text messages for one year (one-two per day for one month, two-three per week for the second month and then two-five per month for the rest of the study). These messages are tailored to individual participants based on gender, sexual orientation and which STI they have been diagnosed with. The messages contain information about treatment for their STI as well as promoting condom use to encourage safe sex. The messages also offer support on how to tell their partner so that they can be tested and treated. Participants in the second group receive a monthly text message for a year, asking them to provide information about any changes in the contact details. These participants receive usual care and are free to seek treatment and support as needed. After one year, participants are re-tested in order to find out how many have an STI. The number of participant's partners who also came for treatment is also recorded.

What are the possible benefits and risks of participating?
Participants may benefit from the trial as they may find the messages helpful and may learn about safer sex behaviours. There are very few risks in taking part. Completing the questionnaires and providing a sample will take up some time. It is possible that the messages could be read by someone other than the participant. Participants are advised to password-lock their phones and delete messages after they read them. Data will be collected regarding whether other people viewed messages and whether the participant was happy/unhappy about this. Data will be collected about involvement in road traffic accidents as they are the only demonstrated harm resulting from text messaging.

Where is the study run from?
London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
April 2016 to May 2020

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Caroline Free
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CPMS 20710

Study information

Scientific Title
Safetxt: A randomised controlled trial of an intervention delivered by mobile phone messaging to reduce sexually transmitted infections (STI) by increasing sexual health precaution behaviours in young people

Study objectives
The aim of this study is to establish the effectiveness of a safer sex intervention delivered by mobile phone messaging on STI infection at 1 year; partner notification and condom use at 4 weeks; and partner notification, condom use and STI testing at 1 year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Riverside Research Ethics Committee, 16/10/2015, ref: 15/LO/1665

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Infectious Diseases; Subtopic: Infectious Diseases; Disease: Infectious Diseases and Microbiology

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

Control group: Participants receive a monthly text message asking the participant to provide information about changes in postal or email addresses

Intervention group: Participants receive regular messages delivered by text message to influence safer sex behaviours. The intervention employs education, enabling and incentivising behaviour change functions and twelve behaviour change techniques identified in effective face to face safer sex interventions. The information on safer sexual practices is in accordance with existing guidelines. The intervention text message content has been developed in collaboration with young people and has been shown to be acceptable, comprehensible and relevant. Participants will be sent messages at the following frequencies:
1. 4 messages per day for days 1-3
2. 1-2 messages per day for days 4-28
3. 2-3 messages per week for month 2
4. 2-5 messages per month for months 3-12

Intervention Type
Other

Primary outcome(s)

Cumulative incidence of Chlamydia and gonorrhoea infection at one year assessed by NAAT (nucleic acid amplification test) tests: urine for men with pharyngeal and anal swabs for MSM (men who have sex with men) and self-taken vulvo-vaginal swab for women.

Key secondary outcome(s))

Current secondary outcome measures as of 30/10/2019:
Measured at 4 weeks:
Behaviours:
1. Whether participants took the (prescribed antibiotic) treatment and avoided sex for 7 days after treatment, self-reported on 4-week questionnaire
2. Whether they told the last person they had sex with before testing positive, that they needed to get treatment, self-reported on 4-week questionnaire
3. Clinic attendance by partner for treatment, identified from clinic records
4. Condom use at last sex, self-reported on 4-week questionnaire

Process outcomes – scores of the theoretical constructs underlying the components of the intervention (behaviour change mediators):
1. Attitudes towards partner notification, self-reported on 4-week questionnaire
2. Self–efficacy in telling a partner about an infection, self-reported on 4-week questionnaire
3. Self–efficacy in negotiating condom use, self-reported on 4-week questionnaire
4. Correct condom use self-efficacy, self-reported on 4-week questionnaire
5. Knowledge related to STIs, self-reported on 4-week questionnaire

Measured at 1 year:
STIs:
1. Diagnosed with any STI after joining the trial according to self-report confirmed by postal test results and clinic records, self-reported on 1-year questionnaire

Behaviours:
1. Condom use at last sex, self-reported on one year questionnaire
2. Number of sexual partners since joining the trial, self-reported on one year questionnaire
3. Sex with someone new since joining the trial, self-reported on one year questionnaire
4. Condom use at first sex with most recent new partner, self-reported on one year questionnaire
5. Self-reported sexually transmitted infection testing for self - prior to first sex with most recent new partner, self-reported on 1-year questionnaire
6. Sexually transmitted infection testing for self - prior to first sex with most recent new partner, confirmed according to clinic record that testing occurred
7. Participant's report as to whether their most recent new partner was tested for sexually transmitted infection prior to sex with them, self-reported on 1-year questionnaire
8. Number of sexual partners since joining the trial, self-reported on 1-year questionnaire
9. Reading and sharing of intervention content, self-reported on 1-year questionnaire
10. Number of text messages read, self-reported on one year questionnaire
11. Whether anyone else read the messages, if yes how did the participant feel about them reading the messages? Self-reported on 1-year questionnaire
12. Reading someone else's messages in the trial (to be reported for control group participants), self-reported on 1-year questionnaire
13. Someone else in the trial reading participants' messages (to be reported for intervention group participants), self-reported on 1-year questionnaire

Potential harms:
1. Car accident where the participant was the driver in the past year, self-reported on one year questionnaire
2. Experience of partner violence in the past year, self-reported on one year questionnaire

Previous secondary outcome measures:
1. Clinic attendance by partner for treatment is determined at 4 weeks
2. Whether participants took the treatment and avoided sex for 7 days after treatment is determined at 4 weeks

Completion date
06/05/2020

Eligibility

Key inclusion criteria
1. Aged 16 to 24 inclusive
2. Received a positive chlamydia or gonorrhoea test result or have been diagnosed with NSU in the last 2 weeks
3. Own a personal mobile phone
4. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Upper age limit
24 years

Sex
All

Total final enrolment
6248

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

Date of first enrolment
01/04/2016

Date of final enrolment

27/11/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
London School of Hygiene and Tropical Medicine
Keppel Street
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Sponsor information

Organisation
London School of Hygiene and Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/09/2022	29/09/2022	Yes	No
Results article	Qualitative results	24/10/2023	26/10/2023	Yes	No
Protocol article	protocol	08/03/2020	11/03/2020	Yes	No
HRA research summary			20/09/2023	No	No
Other publications	Secondary data analysis	07/11/2024	20/11/2024	Yes	No
Statistical Analysis Plan	version v6	10/06/2020	19/06/2020	No	No