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Can text messages increase safer sexual health behaviours in young people?

Submission date
19/03/2013

Recruitment status
No longer recruiting

Registration date
27/03/2013

Overall study status
Completed

Last Edited
20/10/2017

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Mobile phones offer a low cost way of helping people change their behaviour. New results from a smoking cessation trial show that text message support can help people sustain behaviour change in the long term, doubling smokers chances of stopping at six months. Mobile phones may be a particularly good way of providing safer sex support for young people. Text message support is likely to be acceptable to young people and may be able to change safer sex behaviours. Support via mobile phones is confidential and the content can be personalised according to the issues young people face. Young people can text for advice and support at any time of day or night. In this initial study, we will develop a text message intervention for young people and evaluate how well this works in promoting safer sexual health behaviour in this population. The intervention aims to encourage: condom use; testing of sexually transmitted infections (STIs) prior to unprotected sex; correct follow up for STI treatment and partner notification about infection.

Who can participate?
Participants will be male & female aged 16-24 who have been diagnosed with Chlamydia and/or who have had unsafe sex in the last year (more than one partner and at least one occasion of unprotected sex) and who own a mobile phone.

What does the study involve?
With the input of young people, sexual health counsellors, experts in sexual health and behaviour change, we will develop text messages to reduce sexual risk behaviours. After obtaining written informed consent, we will ask panels of young people about the acceptability, comprehensibility and appropriateness of the text messages. We will also ask 100 participants to score text messages and interview up to 15 participants about the messages after they have had a chance to implement the advice in them. According to their feedback, we will retain, discard or modify the messages.
We will then conduct a initial study (called a pilot randomized controlled trial) with 200 young people in the Chlamydia screening programme/ Participants will be randomly allocated to either receive the intervention or to be in a control group (who do not receive the intervention) in order to test all trial methods and procedures. A web-based link to an independent randomisation service will allocate participants to intervention or control groups. The system

will automatically generate text messages according to allocation. The control group will receive a monthly message about the importance of being in a study.
The pilot study will test the computerised systems that will send the text messages to participants. It will also test recruitment, follow up procedures, acceptability of the intervention, message frequency and timing.
We will also undertake qualitative interviews with 25 participants to find out about their experiences of the study. According to their preferences these will be conducted either face-to-face or over the phone.

What are the possible benefits and risks of participating?
The intervention provides support and is unlikely to cause any harmful effects. Even small changes in sexual health behaviour will outweigh any plausible risks from using mobile phones. The support might make some participants more aware that they are in abusive sexual relationships. To address this, we will provide clear information about how to access appropriate counselling services for people in abusive relationships.

Where is the study run from?
The study is run from the Department of Population Health at the London School of Hygiene and Tropical Medicine (UK).

When is the study starting and how long is it expected to run for?
The study started in March 2013 and is anticipated to end in March 2015.

Who is funding the study?
The National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/93/04

Study information

Scientific Title
Can text messages increase safer sexual health behaviours in young people?: qualitative research & pilot randomized controlled trial

Study objectives
Can text messages increase safer sexual health behaviours in young people?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Bentham, Development ethical approval granted 06/11/2012, REC ref 12/LO/1329; Pilot ethical approval anticipated April 2013

Study design
Mixed methods: Qualitative research & Pilot Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Sexual health

Interventions
Mobile phone texting intervention (supportive safer sex text messages using behaviour change techniques) vs. control (fortnightly messages about the importance of being in the trial)

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
The main factors relating to the design of the main trial we will be collecting include: recruitment rates (number of people randomised per month) and completeness of follow up. We will assess the number of young people recruited at the time of 1) testing, 2) provision of test results or 3) treatment collection. We will assess the number of people enrolled face to face from services or opting to enrol on line.

Secondary outcome measures
Condom use at last sex; condom use with new partners; Chlamydia infection; number of sexual partners in last 12 months; STI testing prior to unprotected sex with new partners; participants' report of partner testing for STIs prior to unprotected sex with them.

At 1 month we will assess:
Condom use at last sex for Chlamydia tests and self reported data
For those diagnosed with Chlamydia at the time of recruitment we will assess treatment compliance (did they take the medication), abstinence or protected sex for one week and until the partner is treated and partner notification of sexually transmitted infection.

At 12 months, we will assess:
Chlamydia infection for men through a urine test and for women using a self taken vaginal swab
condom use at last sex
condom use with new partners
the number of sexual partners in last 12 months
sexually transmitted infection testing for self prior to unprotected sex with new partner(s).
participants report that the partner was tested for sexually transmitted infection prior to unprotected sex with them.

Overall study start date
01/03/2013

Completion date
01/03/2015

Eligibility

Key inclusion criteria
Chlamydia screening programme participants diagnosed with Chlamydia and/or who have had unsafe sex in the last year (more than one or more partner and at least one occasion of unprotected sex); owner of a mobile phone.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Key exclusion criteria
Eligible participants who are non-English language speakers will be excluded from the study as the text messages will be delivered in English. Those that are unable to provide informed consent (e.g. people with severe learning difficulties) will be excluded from this study.

Date of first enrolment
01/03/2013

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
England

United Kingdom

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

Organisation
London School of Hygiene and Tropical Medicine (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	development of follow-up procedures	15/01/2016		Yes	No
Results article	results	23/12/2016		Yes	No