NIHR HTA Programme

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The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), based at the University of Southampton, manages evaluation research programmes and activities for the NIHR

Health Technology Assessment Programme
National Institute for Health Research
Evaluation, Trials and Studies Coordinating Centre
University of Southampton, Alpha House
Enterprise Road, Southampton, SO16 7NS

tel: +44(0)23 8059 5586
fax: +44(0)23 8059 5639

email: hta@hta.ac.uk
web: www.hta.ac.uk

Project Title: Can text messages increase safer sexual health behaviours in young people? Intervention development and pilot trial.

Planned investigation

Research Objectives

Part A: To carry out formative evaluation aimed at developing an acceptable and appropriate mobile phone based intervention to promote safe sexual health behaviour.

- To develop safer sex text messages based on up to date empirical evidence, behaviour change theory, and the views of sexual health counsellors and young people;
- To development-test the messages among panels of young people to ensure that acceptability, appropriateness and comprehensibility are built into the design;
- To assess the acceptability, appropriateness and comprehensibility of the resultant text messages among, a sample of 100 participants

Part B: The work will lead on to a pilot randomised controlled trial of the mobile technology based sexual health intervention developed, for which we will seek separate ethical approval.

Existing research

New results from our txt2stop smoking cessation trial show that text-messaging interventions can sustain health behaviour change in the long term. The text based intervention doubled biochemically verified smoking cessation at six months: 10.7% txt2stop versus 4.9% control, RR 2.20 (95% CI 1.80-2.68)(2). Other recent trials show that text messaging interventions have been effective in increasing adherence to antiretroviral medication and health workers adherence to malaria treatment guidelines(3-4). Thus mobile phone text messaging has the potential to be a powerful way of influencing behavioural change(5).

In our systematic review of randomised controlled trials of mobile technology based interventions designed to improve health or health care services(6), there were 3 trials employing short message service (SMS)/ text messages designed to improve sexual health(7-9). All three trials had a high or unclear risk of bias and/ or were underpowered to detect effects. Lim et al reported that mobile phone based sexual health interventions can increase discussion of sexual health with a health care professional (OR 2.92, 95% CI 1.66-5.15) and increase STI testing (OR 2.51, 95% CI 1.11-5.69)(7). Delemere et als small trial reported no statistically significant effects on unprotected sex and the number of new partners(9). Menon-Johansson et al demonstrated that conveying chlamydia results by text message can reduce the time from test result to diagnosis and treatment, but had no effect on the time from first contact to treatment (8). Whilst some trial results look promising, to date, the effects of text messaging on key safer sex behaviours, including: telling your partner about your infection, correctly following treatment advice, obtaining STI testing for yourself and your partner prior to unprotected sex and condom use, has not been reliably established.

Support via text message is likely to be acceptable to young people and might increase safer sexual health behaviours. Mobile phones are able to provide confidential and non-

judgemental support, which is essential for a sexual health intervention(10). Interactive support can be delivered at any time, in any location, thus ensuring privacy, which is especially important for young people. Behaviour change techniques used in effective face-to-face interventions can be modified for delivery via text message(11-12). The content can be personalised for different gender and ethnic groups. Recipients referred to the text messaging support we developed in txt2stop as: '*being 'a 'friend' it felt like someone was holding your hand throughout.' (*Female*)* and *'you've got someone there giving you a bit of support, which is what you need isn't it?' (*Male*)(2).*

We have identified and described the behaviour change techniques found in effective face-to-face interventions that reduce STI infection. We adapted Abraham and Michie's typology of behaviour change techniques for use for sexual health behaviour changes interventions. We used our typology to describe the behavioural change techniques used in interventions included in our systematic review of RCTs of interventions promoting condom use (6, 12-18). We will use similar behaviour change techniques adapted for delivery by SMS message in our intervention.

In preparation for submitting a bid similar to that now called for, we developed preliminary content, and then conducted interviews and focus groups discussions with young people. The discussions suggested that the preliminary content was welcomed, effectively communicated sensitive issues and was effective in portraying gender and ethnic appropriate content.

Our intervention will be developed building on our previous work and experience in: developing an effective text messaging intervention, conducting systematic reviews and content analysis of mobile phone text messaging and condom promotion interventions and developing preliminary content for a mobile phone intervention promoting sexual health.

Research methods:

Part A: Intervention development.

Our theoretical model is based on both theory of behaviour and theory of behaviour change (see figure 1).

Theory of behaviour: Behaviour is influenced by motivation, capability and opportunity(19). In the case of sexual behaviour, knowledge, beliefs, self-efficacy and skills as well as social and interpersonal influences have important effects on motivation, capability and opportunity (20-21). Our intervention aims to alter these factors to reduce sexual risk behaviour in three ways. First, by encouraging those in the target audience to use condoms with new or casual partners. Second, by encouraging participants to obtain testing for STI for themselves and their sexual partner(s) prior to unprotected sex. Third, by urging participants to correctly follow instructions for STI treatment and informing partner(s) about infection.

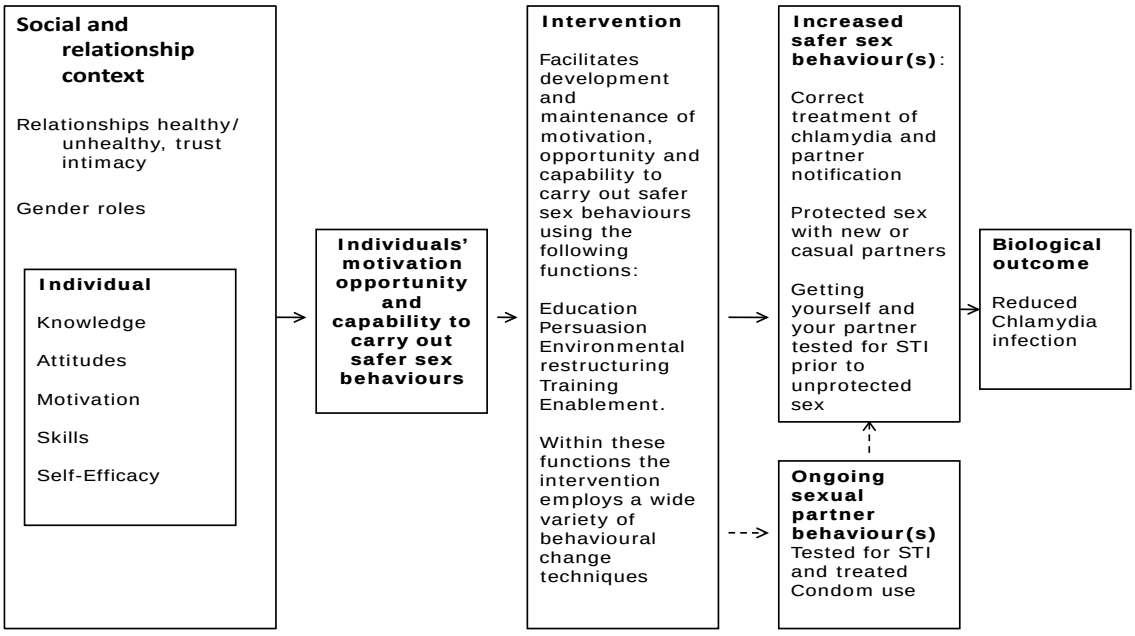
Theory of behaviour change: Interventions designed to change behaviour can be characterised according to the intervention functions(19). Functions that can be employed in text messaging interventions include: education, persuasion, environmental restructuring (encouraging people to change their environment to support the behaviour), training and enablement. We will employ these functions in our text messaging intervention. Within these functions a wide variety of behaviour change techniques can be employed. Our

intervention will include the behaviour change techniques we identified in face-to-face interventions that reduced STI infections(14-18). The behaviour change techniques described in effective face to face interventions include:

- personal risk assessment,
- addressing the misconception that you can assess another person's risk simply by their appearance (refs),
- reporting others' approval of safer sex,
- providing normative information about others' behaviour,
- goal setting and action planning (planning when, where and how to engage in a behaviour),
- identifying barriers to safer sex behaviours and strategies to overcome them,
- reviewing behavioural and outcome goals,
- providing feedback,
- providing information and instruction on when, where and how to carry out behaviour, eroticising condom use, demonstrating behaviour (e.g. condom use, communication regarding condom use and/or infection),
- social support,
- relationships (covering young people's views about good and bad relationships and participants own assessments regarding the type of relationship they wanted/ had)
- gender roles (covering gender expectations around sexual activity e.g. the role of 'romance' in sexual activity for women).

We will modify the behaviour change techniques for delivery by text message.

Figure 1. A summary of our theoretical model



Planned interventions:

The intervention: The intervention aims to increase safer sex in three ways. First, by encouraging those in the target audience to use condoms with new or casual partners. Second, by encouraging participants to obtain testing for STI for themselves and their sexual partner(s) prior to unprotected sex. Third, by urging participants to correctly follow instructions for STI treatment and informing partner(s) about infection. We will develop messages targeting each of these behaviours.

We will provide information on safer sexual practices in accordance with existing guidelines (BASH)(22). For those diagnosed with Chlamydia we will provide information regarding correct treatment. Messages will target motivation for condom use, testing prior to unprotected sex and correct treatment of an STI. Messages will take account of the fact that that an important motivation for using condoms in younger people is pregnancy prevention rather than prevention of STI(28). Communication skills in relation to telling a partner about an infection, condom use and sex will be addressed by providing examples of how other young people have chosen to communicate with a partner (14-18). Participants will be encouraged to identify the challenges to safer sex and plan how they can overcome these challenges(14-18). Participants will be able to request information and examples of how other young people have addressed the challenges they face in relation to key areas covering: making sure a condom is available, negotiating condom use, alcohol and not using condoms and telling my partner or getting someone else to tell them I have Chlamydia. We will address beliefs about assessing a partner's sexual risk specifically covering the misconception that you can assess a partner's sexual risk according to how they look. We will send messages regarding others' approval of safer sex, and normative information about others' behaviour. Previous text messages that we have developed have included empathetic statements and have been supportive and encouraging in their style. The messages in this intervention will be written in a similar style. For each specific behaviour we will encourage participants to set goals and plan actions. For example, where participants have opted to tell their partner themselves that they have an STI, messages will encourage participants to plan when, where and how they will tell their partner. Messages will provide reminders regarding stated goals such as telling a partner about an infection and feedback. We will raise issues such as sexual pleasure and safer sex and asking young people to consider what they think is a good relationship and covering issues such as trust, intimacy and gender roles(14, 16). The messages will be tailored for participants of different gender and level of sexual risk behaviour to give personally relevant information and feedback(14, 16, 29).

Text message development methods.

This will involve three steps: 1) development of messages, 2) panel assessment, and 3) evaluation of messages by a sample of 100 young people (see flow chart part A).

1)Developing preliminary messages:

We will develop messages based on our understanding of behaviour and behaviour change and with the input of sexual health counsellors, trained motivational interviewers and young people. We will ensure that the content of the text messages is consistent with the British Association for Sexual Health and HIV current safer sex advice(22) which recommends

focusing on increasing motivation, skill acquisition including communication skills and provision of information about safer sexual practices.

To ensure that the content, tone and style of the messages is appropriate we will use a similar approach to the one used to develop our previous effective text messaging intervention(23-24). A sexual health motivational interviewing trainer (Melanie Otterwill) will generate messages. Sexual health counsellors with motivational interviewing training based at the Sexual Health Department, Guys and St Thomas' Hospital will review the messages generated and produce additional messages.

2) Testing the messages in a panel:

We will convene six panels of young people (aged 16-24) to advise us regarding their preferences for the intervention, the acceptability, comprehensibility and appropriateness of the text messages developed and suggestions for improvement. We will recruit members for the panels from three geographical areas: an inner city in the south of England (SE London), a city in the north of England (Greater Manchester) and a rural area (Cambridgeshire). Participants in the chlamydia-screening program in these three areas will be invited by recruiting nurses to join the panel. The nurse will provide service users with verbal and written information regarding the aim of the panel and their role. We will convene panels of men only, women only and panels mixed by gender. We will ensure that panels include teenagers and those in their twenties and that membership represents a range of ethnic groups. Prior to the panel the research assistant (RA) will obtain informed written consent from panel members. The RA will elicit panel members' preferences for the intervention and seek comments from them on each of the preliminary messages developed, specifically asking about the acceptability, comprehensibility and appropriateness of the text messages developed and suggestions for improvement. A second facilitator will make notes during the meeting and with the participants agreement the RA will record the meeting, documenting their comments using a unique identifying number. All feedback obtained will remain confidential and data used in publications or reports will be anonymised. According to the feedback received, we will retain, discard or modify messages and retest them. We will seek further feedback regarding the modified messages by email or telephone according to participants' preferences.

3) Testing the message with 100 participants: Methods.

We will then ask 100 young people (aged 16-24) to score text messages regarding their acceptability, comprehensibility and appropriateness. These participants will be recruited from sexual health services, GP surgeries and pharmacies located in the three geographical areas (SE London, Manchester, Cambridgeshire). Recruiting staff will include nurses, doctors and pharmacists (depending on how services are organised locally). All recruiting staff will receive training in recruitment procedures. The eligibility criteria for the questionnaire study are (aged 16-24 with a mobile phone and tested positive for Chlamydia or reporting unsafe sex in the last year (more than one partner and at least one occasion of unprotected sex). Recruiting staff will ask all eligible young people to complete the questionnaire. Recruiting staff will record the number of people approached and the number agreeing to participate. They will provide written and verbal information about the study and will seek informed

written consent. Participant will be asked to complete the questionnaire in a private room. The questionnaire will include the text messages for the intervention. Participants will be asked to score each of the messages using a 5 point scale regarding whether they agree or disagree with the statements regarding the comprehensibility of messages and whether they find the messages acceptable, relevant or helpful. There will be space for participants to give their open comments regarding any of the messages and provide suggestions regarding how messages could be improved. We will conduct a descriptive analysis reporting the median and IQR score for each message regarding their comprehensibility, acceptability, relevance and helpfulness. The participant responses will inform final modifications to the messages.

Part B: Based on the work conducted we will then seek separate ethical approval for a pilot randomised controlled trial of the mobile technology based sexual health intervention developed:

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Ethical arrangements

Risks and anticipated benefits for trial participants and society, including how benefits justify risks

Fully informed consent: Participants will be provided with study information and given the opportunity to ask questions.

Participants' rights:

Participants will be able to contact the trial co-ordinating centre by text message to the short code number or by telephone call. Participants will be able to withdraw from the study at any point.

Participants' safety. The messages provide support and are 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 aware that they are in abusive sexual relationships. The research is taking place within community sexual health service settings, any participant raising a personal sexual issue will be linked into the local appropriate services. All participants will be provided with a general list of help lines they can contact, including help lines offering support for people experiencing violence.
Informing potential participants of possible benefits and known risks: The study information will include clear information about how to access appropriate counselling services for people in abusive relationships.

Proposed time period for retention of relevant trial documentation

10 years

Proposed action to comply with 'The Medicines for Human Use Regulations Act 2004'

Not applicable, as this is a trial of a behavioural change intervention

Research governance:

The nominated sponsor of our research study is the London School of Hygiene and Tropical Medicine. We plan to establish the following research committees:

- Trial Steering Committee (TSC)- this will comprise an independent chair, two Service Users, one other independent member, Prof Ian Roberts, Dr Caroline Free, Dr Rebecca French. It will meet every 6 months after the pilot trial has commenced.
- Management Group (MG)- Permanent members of the group will be Caroline Free, Rebecca French and the research fellow. Co-applicants will be invited to join the group during the phases of the research where their expertise is required for example Susan Michie, Kaye Wellings and Graham Hart will be invited to the group during the intervention development phase. During the trial the data manager will join the group.

Essential documents of the Sponsor/trial organisers and investigators, from trials that are not to be used in regulatory submissions will be retained for at least ten years after completion of the trial.

Project timetable and milestones

Expertise

Our team is ideally placed to conduct this research developing and conducting a pilot trial of a mobile phone based intervention to reduce sexual risk behaviours. We have an established record in sexual health research (KW, GH, RF, CF, KD, JB) and in the development and evaluation by randomised controlled trial of a mobile phone based behaviour change intervention which more than doubled biochemically validated outcomes (CF, IR, PE). We delivered our effective intervention to almost 6,000 participants and achieved 95% follow up for a biochemically validated behavioural outcome (CF, PE, IR).

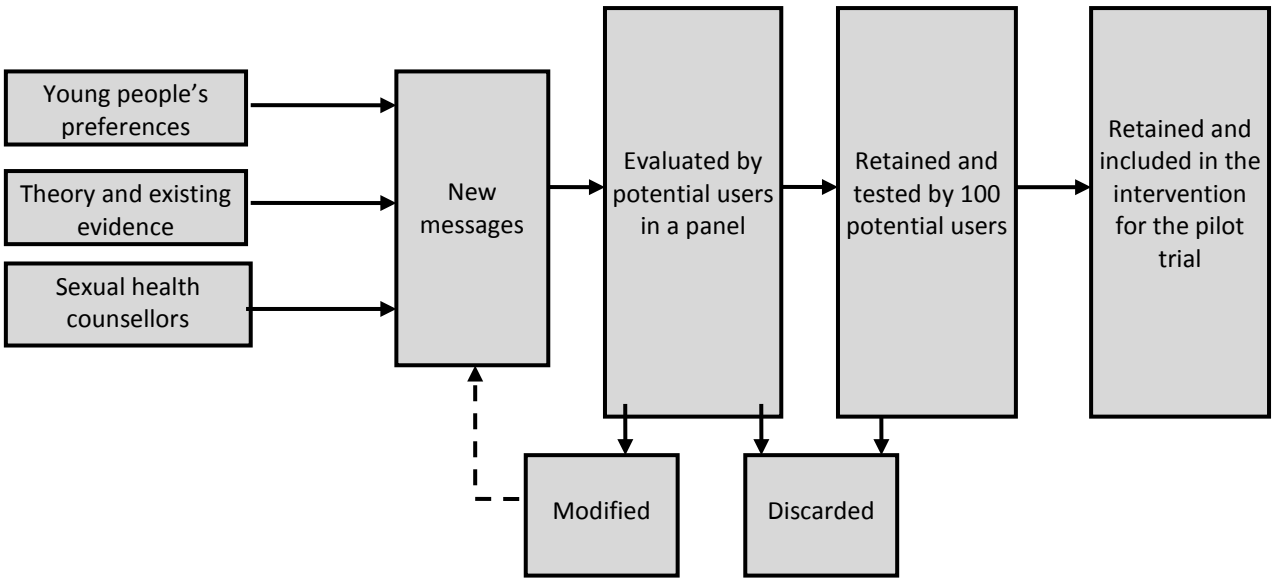
Our sexual heath research experience includes: expertise in qualitative research with young people (CF, KD, JB, PB, RF, KW ,GH,), sexual behaviour data collection (KW, GH, JB), sexual health interventions for the UK (MRC-funded Sexual Health Communication Tool, My Contraceptive Tool, MRC-funded internet based sexual health intervention and face-to-face sexual health interventions) (JB, GH, CF, RF. KW) and the epidemiology of sexual behaviour and STI (KW, GH, KD, CF, RF, PB). Our team includes a leading health psychologist (SM) with wide-ranging expertise in designing and evaluating behaviour change interventions, including those using mobile phone technology. The trial will be co-ordinated from the accredited Clinical Trials Unit at LSHTM. We also have expertise in analysis and achieving high follow up in trials (PE, IR, CF, TC, KF), systematic reviews (IR, PE, CF, RF, IM) and epidemiology (IR, KF, CF, PE, TC, IM). The team has a good track record of successful collaboration.

Service users

We will involve young people (users) at every stage of intervention development and testing. During the intervention development, we will convene panels of potential users who we will ask for their views and feedback regarding the intervention. One hundred potential users will evaluate the resultant text messages. The Trials Steering Committee will include two young people. We will provide young people involved in the research with the study results.

Flow diagram

Part A: Developing the intervention messages



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