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**Title: TXT2STOP: a pilot randomised controlled trial of mobile phone based smoking cessation support**

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## **Abstract**

**Aim** To conduct a pilot randomised controlled trial of mobile phone based smoking cessation support intervention for the UK population.

**Design** Randomised controlled trial (TXT2Stop).

**Setting:** Community

**Participants** 200 participants responding to radio, poster and leaflet based promotions regarding the trial.

**Main outcome measures:** The response rate for the outcome measures planned for the main trial. Participants' qualitative responses to open-ended questions about the intervention content. Secondary outcomes were the outcomes planned for the main trial including the point prevalence of self reported smoking at 4 weeks and pooled effect estimate for the short term results for the STOMP and txt2stop trials.

**Results:** The response rate at 4 weeks was 96% and at 6 months was 92%. The results at 4 weeks show a doubling of self reported quitting RR (95% CI) 2.08(1.11-3.89) 26% vs. 12%. The pooled effect estimate combining txt2stop and a previous NZ trial in the short term is RR (95% CI) 2.18 (1.79-2.65).

**Conclusions** Mobile phone based smoking cessation is a novel and innovative means of delivering smoking cessation support which doubles the self reported quit rate in the short term. It could represent an important, but as yet largely unused medium to deliver age appropriate public health measures. The long term effect of this mobile phone based smoking cessation support will be established by a large RCT currently in recruitment.

## **BACKGROUND**

Most of those killed by tobacco started smoking as teenagers and smoking contributes to the death of one in two of those who continue to smoke past 35 years of age<sup>1,2</sup>.

Mobile phones provide a new channel for individualised programmes to be delivered inexpensively wherever the person is located. For many people mobile phones are always carried with them, therefore the intervention can take place at anytime. The text message programme can also be personalised. Furthermore, mobile phone based interventions can provide the anonymity that many people like<sup>3,4</sup>.

The STOMP (STOp smoking with Mobile Phones) trial of a text message-based smoking cessation intervention showed a two-fold increase in self-reported quit rates at 6 weeks (239 (28%) vs 109 (13%), relative risk 2.2, 95% CI 1.79, 2.70)<sup>5</sup>. Some limitations in the study, however, affected the validity of the results at six months. First, there was differential loss to follow-up at 6 months. Second, only a small sample of self-reporting quitters were selected for biochemical validation through salivary cotinine testing.

We conducted a pilot study for a randomised controlled trial that will assess reliably whether mobile phone-based support can improve smoking cessation rates at 6 months in the UK. We set out to adapt the STOMP intervention for a UK population, test the study methods and evaluate the effect of the intervention on the point prevalence of smoking at 4 weeks.

## **METHODS**

Ethical approval was obtained from the London School of Hygiene and Tropical Medicine Ethics Committee.

### **Modifying the intervention for the UK**

The STOMP intervention contains over 1000 text messages<sup>5</sup>. To modify the intervention, youth smoking cessation counsellors, cognitive behavioural therapists, motivational interviewing trained smoking cessation counsellors and potential participants reviewed all text messages in a series of focus groups. Each text message was reviewed in at least two focus groups of participants. The STOMP intervention included a month of free texting. It was not possible to provide this aspect of STOMP in the UK where numerous mobile phone companies are in operation.

## **The pilot randomised controlled trial**

Txt2stop is a single-blind randomised controlled trial. The intervention is delivered by computer and the allocation is unknown to all investigators collecting or analysing outcome data.

### *The interventions*

Control group. Participants in the control group received fortnightly, simple, short, generic text messages.

Intervention group. The txt2stop intervention is a composite intervention that includes key elements of existing effective interventions as identified in systematic reviews<sup>6-9</sup>. These elements include: making a public declaration; setting a quit date; self monitoring; intra-treatment support from a quit buddy; extra-treatment support by encouraging testing family and friends for support, problem solving; distraction techniques. Participants are asked to identify their interests and issues related to quitting, such as fitness or weight gain, so that individually tailored text messages can be sent. A text 'Crave' function allows participants to request an immediate message of support whenever they experience cravings for a cigarette. Daily text messages commence at randomisation with a count down to quit day and then five messages per day for 4 weeks post quit day. The intervention continues with a maintenance package of three text messages per week for 26 weeks.

### *Procedures*

We advertised the txt2stop pilot trial using the radio, leaflets and posters. Participants registered their interest via text message. Research Assistants (RA) contacted those who registered an interest. Eligible participants were: aged 16 years or more, currently smoking cigarettes daily and interested in quitting, a current owner of a mobile phone, living within an hour of London, familiar with text messaging capabilities and able to provide informed consent to participate in the study. There were no restrictions on the use of other smoking cessation treatments or methods. Eligible participants were sent the participant and consent information. Participants sent their consent via a text message. The RA directly entered baseline data into the web-based trial entry form linked to the database. An electronic link to the computer-based randomisation resulted in the generation of a unique identifying number and allocation to the intervention or control group. The system then automatically generated intervention or control group texts according to the allocation. To ensure a reasonable balance on key factors which may influence the success of the smoking cessation intervention, the allocation used a minimisation algorithm, balancing for: sex (male/female), age (16-18 years, 19-34 years, > 34 years), educational level (to age 16 years or less, > age 16 years), socio-economic status (employment manual, non manual, not applicable), and the Fagerstrom Test for Nicotine Dependence (FTND - 5 or less, >5).

Follow up was at 4 weeks and 6 months. All self reported outcome data was collected by mobile phone or email. Salivary cotinine testing was used to verify any self-reported smoking cessation at 6 months<sup>10</sup>. Test kits were mailed to participants containing a stamped addressed envelope. Participants were also contacted to arrange collection of a salivary cotinine sample in person. Samples were stored in a freezer and delivered in batches to the ABS laboratory where they were analysed.

### *Outcomes*

Outcomes for the pilot study were the point prevalence of smoking at 4 weeks, the response rate for the primary outcome measure for the main trial; baseline smoking cessation rate in the control group; the proportion of participants whose assessed smoking status differed between salivary cotinine samples collected by post and in person; and participants' qualitative responses to open-ended questions about the intervention content.

We collected outcome data pertaining to the primary and secondary outcomes planned for the main trial. The primary outcome for the main trial is self-reported abstinence (point prevalence, i.e. no smoking in the past 7 days) at 6 months post-randomisation, with reports of abstinence verified by salivary cotinine testing using a cut-off of 7 ng/ml of cotinine<sup>11,12</sup>. Secondary outcomes at 6 months are: 28 day continuous abstinence, self reported continuous abstinence since a quit day, involvement in any vehicle crashes, and pain in the thumb.

#### *Sample size*

The pilot phase aimed to recruit 200 participants, and was not powered for outcomes at 6 months.

#### *Statistical analysis*

All analyses were based on the intention-to-treat principle and were conducted in STATA version 9.0. We estimated the relative risk and 95% confidence intervals of smoking cessation at 4 weeks and 6 months. We report the findings treating losses to follow up as smokers and excluding losses to follow up. As the txt2stop programme is based on the New Zealand STOMP programme we used random effects meta-analysis to give pooled estimates for the short term results of the txt2stop and STOMP trials<sup>13</sup>.

## **RESULTS**

#### *Modifying the intervention for the pilot trial*

Based on feedback from 62 participants we made four types of modification to txt2stop: we changed specific words e.g. different terms used in the UK; we changed culturally specific references e.g. sports personalities; we changed the framing of text messages e.g. to involve more 'suggestion' and 'less telling'; and we altered or removed some texts e.g. texts which participants found 'too American', 'irritating' or 'patronising'.

#### *The pilot randomised controlled trial*

We recruited the target of 200 participants within 18 days from the trial launch and closed the trial to further recruitment. The average age of participants was 36 (sd 9) and 126 (62%) were men. Sixty six (33%) were in manual occupations. Participants smoked a median of 20 cigarettes per day (inter quartile range IQR 12-22).

Using evidence-based methods<sup>14</sup> we achieved 98% short term follow up, and 92% long term follow up in both intervention and control groups. Two participants withdrew from the study as they didn't like the text messages or found the text messages too frequent. There were no instances where the postal salivary cotinine sample showed the participant had quit smoking and the sample collected in person showed the participant was smoking.

The txt2stop messages were described as ‘very good’, and ‘very motivating.’ Some reported that specific aspects of the program were helpful: ‘I found myself talking myself out of having another cigarette when my buddy was the one craving one.’ or ‘Every time I was craving a cigarette I’d get a text and it would stop me. They’d always arrive at the right time’. Quit buddies were described as ‘great’ by some but others were disappointed with their quit mate. Some participants wanted to be able to re set a quit date or set their own start time for the messages. A number of participants found the text abbreviations hard to understand and wanted messages in standard English. Some found the programme ‘too intense’ and ‘intrusive’ whilst others wanted the intensive phase to continue longer.

The short term results at 4 weeks, assuming losses to follow up as smokers, showed a doubling of self reported quitting from 12% (12/98) in the control group to 26% (26/102) in the intervention group (RR (95% CI) 2.08(1.11-3.89). The pooled effect estimates for short-term abstinence in the txt2stop and STOMP trials was RR (95% CI) 2.18 (1.79-2.65). There were no other statistically significant outcomes (table 1).

**Table 1: Outcomes**

<b>Outcome</b>	<b>Intervention group N (%)</b>	<b>Control group N (%)</b>	<b>RR (95%CI)</b>	<b>Chi-squared p-value</b>
<b>4 weeks</b>				
Self-reported quitting*	26 (25.7%)	12 (12.8%)	2.02 (1.08-3.76)	0.02
Self reported quitting**	26 (25.5%)	12(12.2%)	2.08 (1.11-3.89)	0.02
<b>6 months</b>				
<b>Primary outcome for the main trial:</b>				
Self reported no smoking in last seven days and salivary cotinine <7ng/ml*	8 (8.5%)	6 (6.7%)	1.28 (0.46-3.53)	0.6
Self reported no smoking in last seven days and salivary cotinine <7ng/ml**	8 (7.8%)	6 (6.1%)	1.28 (0.46-3.56)	0.6
<b>Secondary outcomes – smoking:</b>				
Self reported no smoking in last 7 days*	15 (15.5%)	19 (20.4%)	0.76 (0.41-1.40)	0.3
Self reported 28 days continuous abstinence*	14 (14.4%)	17 (18.1%)	0.80 (0.42-1.53)	0.4
<b>Secondary outcomes – adverse:</b>				
Self reported involvement in vehicle crashes*	1 (1.0%)	4 (4.3%)	0.24 (0.03-2.11)	0.2
Pain in thumb while texting*	0 (0.0%)	1 (1.1%)	-	0.3

\*missing data excluded

\*\* missing data treated as smokers

## DISCUSSION

The txt2stop intervention effect and the pooled effect estimate for the txt2stop and STOMP trials show a doubling in self reported quitting in the short term.

Using evidence-based methods we addressed the limitations of the earlier STOMP trial. Participants' comments enabled us to modify the intervention for the UK and helped illustrate how specific components of the intervention may help participants quit.

Mobile phones are a novel, promising and innovative new means of delivering smoking cessation support. They could represent an important, but as yet largely unused, medium to deliver age appropriate public health measures. The long term effects of such interventions need to be established.

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### **What is already known**

- a New Zealand trial demonstrated that mobile phone based smoking cessation support can be effective in the short term
- long term effects and the consistency in different populations remains uncertain

### **What this paper adds**

- tailoring and updating content to suit the UK public is feasible, and the programme is technically transferable
- the txt2stop pilot shows that the txt message program doubles the quit rate in the short term
- evidence-based retention techniques can ensure long-term follow up in this target group and a trial main trial powered to assess long-term cessation rates is feasible



**Table 2: Examples of text messages**

<b>Type or timing of message</b>	<b>Message</b>
In lead up to quit date	TXT2STOP: To make things easier for yourself, try having some distractions ready for cravings, and think up some personal strategies to help in stressful situations.
In lead up to quit date	TXT2STOP: Why are you quitting? To be fitter, costs too much or what?
In lead up to quit date	TXT2STOP: Remembr pros & cons of smoking? Display your reasons for quitting where you can see them.
On quit date	TXT2STOP: This is it! - QUIT DAY, throw away all your fags, TODAY is the start of being QUIT forever, you can do it!
After quit day	TXT2STOP: "Quick result! Carbon monoxide has now left your body! Check out your health at <a href="http://www.txt2stop.org">www.txt2stop.org</a>
After quit day	TXT2STOP: How long does it take for the cigarette chemicals to leave your body? 2 hours, 2 days or 2 weeks - we will send you the answer later today.
After quit day	Nicotine withdrawal may make you restless, irritable, frustrated, sleepless, or accident prone - but these things will pass and you will start to feel the benefits after 3 or 4 days.
After quit day	TXT2STOP: Cat, 21 frm London says "I've been quit for 2 months, at 1st it was tricky but I got through it and now I'm really proud to be smoke free.
After quit day	TXT2STOP: Well done, you've got past the 1st week, over the next few weeks your circulation will improve making walking & running a lot easier.
In response to txt CRAVE request	Cravings last less than 5 minutes on average. To help distract yourself, try sipping a drink slowly until the craving is over.

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