

Mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand

Submission date 11/11/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/11/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Tobacco smoking is recognised as one of the leading health threats globally. In Thailand, support to quit smoking through the Thailand National Quitline (TNQ) is available free of charge to the public. The services offer behavioural counselling and a number of follow-up counselling calls. The latter service are only provided for smokers who set a quit date within a month however. Smokers who do not receive any additional support are unlikely to succeed in quitting smoking on their own compared to those who received the follow-up calls. Text messaging program to support behaviour change have been shown to help people quit smoking. Additional text messages to the TNQ services may help smokers change their mind and set a quit date with the TNQ. The aim of this study is to test whether motivational text messages improves uptake of TNQ smoking cessation service and increases the amount of people who manage to quit smoking. Eight different messages will be compared in order to find out which one is the most effective.

Who can participate?

Thai smokers who call the Thailand National Quitline and have not set a quit date within one month.

What does the study involve?

Participants are asked to complete an online questionnaire after they have agreed to take part. They are then randomly assigned to receive one of eight sets of text messages twice a day for 30 days. Participants may receive one of the following sets of messages:

1. Messages thanking participants for being part of project (contain no behaviour change)
2. Messages aimed at increasing smokers' capability to quit
3. Messages aimed at increasing opportunity to support smoking cessation
4. Messages aimed at increasing motivation to quit
5. Messages aimed at increasing smokers' capability to quit and opportunity to support smoking cessation

6. Messages aimed at increasing smokers' capability to quit and motivation to quit
7. Messages aimed at increasing opportunity to support smoking cessation and motivation to quit
8. Messages aimed at all behavioural components

At the end of the first and sixth months, participants are asked to complete an online questionnaire, which will be similar to the questions asked at the start of the study. There are other channels to complete the questionnaires available for participants (by email or by post) who do not have access to internet. Some of participants are asked to come to a smoking cessation clinic to receive a free carbon monoxide test to confirm their smoking status.

What are the possible benefits and risks of participating?

There is no direct benefit from participating in this trial. The research team hope that participants will gain more knowledge about the harm of smoking and the benefits of quitting smoking. Information from this study may help improve the Thailand National Quitline in the future. There are no risks of physical injury or harm to participants. Participants may feel uncomfortable answering the questionnaires or may not wish to take a carbon monoxide breath test. Participants are free to opt out from the study at any time without any negative consequences.

Where will the study take place?

The study is run by Thailand National Quitline (Thailand)

When is the study starting and how long is it expected to run for?

December 2015 to December 2017

Who is funding this study?

1. Health Intervention and Technology Assessment Program (Thailand)
2. Thai Health Promotion Foundation (Thailand)

Who is the main contact?

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1-3-106-2559

Study information

Scientific Title

Testing the combination of mobile health interventions for smoking cessation services uptake and smoking cessation: a factorial randomised trial in Thailand

Study objectives

The aim of this study is to test whether text messages aimed at different behavioural components (i.e. increase smokers' capability to quit, increase opportunity to support smoking cessation, and increase smokers' motivation to quit) improve smoking cessation rates.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. School of Medicine Research Ethics Committee (SoMREC) University of Leeds, 31/10/2016, ref: MREC16-001
2. Institute for the Development of Human Research Protections (IHRP) Thailand, 27/09/2016

Study design

Single-centre factorial randomised controlled trial

Primary study design

Interventional

Secondary study design

Full factorial randomised trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

Participants will be randomly assigned to receive one of the eight interventions in a 1:1:1:1:1:1:1:1 ratio. In order to avoid potential chance of imbalance across eight intervention groups, two stratification factors, age groups (3 strata including 18-30, 31-40 and above 40) and intention-to-quit smoking (2 strata including 1-5 and 6-10) will be used in this trial. Stratified permuted blocks within six strata will be produced prior to randomisation begins using computer-generated random schedule.

1. Messages thanking participants for being part of project (contain no behaviour change)
2. Messages aimed at increasing smokers' capability to quit
3. Messages aimed at increasing opportunity to support smoking cessation
4. Messages aimed at increasing motivation to quit
5. Messages aimed at increasing smokers' capability to quit and opportunity to support smoking cessation
6. Messages aimed at increasing smokers' capability to quit and motivation to quit
7. Messages aimed at increasing opportunity to support smoking cessation and motivation to quit
8. Messages aimed at all behavioural components

Participants will receive text messages through their mobile phone twice a day for 30 days. All participants will be asked to complete online questionnaires at baseline, 1-month follow up and 6-month follow-up. A simple random sample of 20% of participants living in the Bangkok Metropolitan Area will be asked to visit smoking cessation clinic for the carbon monoxide breath test at 6-months follow-up.

Intervention Type

Primary outcome measure

Abstinence is measured using a self-reporting questionnaire at baseline and 1 month.

Secondary outcome measures

1. Abstinence is measured using self-reporting questionnaire across follow-up (baseline, 1-month and 6-months)
2. Abstinence is measured using self-reporting questionnaire with verification using expired air carbon monoxide (CO) test at 6 months
3. Setting of quit date is measured through self-reporting questionnaire across follow-up period (baseline, 1-month and 6-months)
4. Quality of life is measured using EQ-5D-5L across follow-up period (baseline, 1-month and 6-months)
5. Behaviour to support smoking cessation is measured using self-reporting questionnaire across follow-up period (baseline, 1-month and 6-month)
6. Intervention fidelity is measured by recording the number of text received and number of text read at 1-month follow up
7. Technology engagement e.g. shared text, statements about the programme, and request for subscription, is measured by self-reporting questionnaire at 1-month follow up

Overall study start date

02/12/2015

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Smokers aged above 18
2. Received a single brief counselling session for smoking cessation from the TNQ and did not set a quit date within one month
3. Own a mobile phone with at least the ability to send and receive SMS text messages
4. Be able to read and write Thai
5. Provision of informed online consent

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 1670, at least 208 in each arm (8 arms)

Key exclusion criteria

Not meeting the inclusion criteria

Date of first enrolment

03/12/2016

Date of final enrolment

01/06/2017

Locations

Countries of recruitment

Thailand

Study participating centre

Thailand National Quitline

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Sponsor information

Organisation

Leeds Institute of Health Sciences

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Sponsor type

University/education

Website

<http://medhealth.leeds.ac.uk/lihs>

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Research organisation

Funder Name

Health Promotion Economic Evaluation Collaborative Center, Thailand

Funder Name

Thai Health Promotion Foundation, Thailand

Results and Publications

Publication and dissemination plan

Manuscripts will be prepared for publication in peer-reviewed journals, aim to publish around one year after the trial end date. Conference presentations will be prepared and delivered at relevant conferences.

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Miss Pritaporn Kingkaew (umpk@leeds.ac.uk or pritaporn.k@hitap.net)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4	12/10/2016	23/11/2016	No	Yes
Participant information sheet	version V2	22/09/2016	23/11/2016	No	Yes