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Is a mobile phone app delivering cognitive behavioural therapy effective at helping people quit smoking?

Submission date
13/12/2018

Recruitment status
No longer recruiting

Registration date
18/12/2018

Overall study status
Completed

Last Edited
18/01/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Smoking continues to be the largest cause of preventable death and disease across the world. Therefore, providing effective treatment to help smokers quit is a major public health goal. The most effective way to help people quit smoking is using medications (i.e. nicotine replacement therapy; NRT) together with high intensity behavioural support. However, behavioural therapy offered on the NHS is low intensity, and is only being accessed by 5.9% of smokers looking to quit.

In this study we will test a mobile app that delivers high intensity behavioural support to smokers looking to quit. The form of therapy delivered is cognitive behavioural therapy (CBT), which works by changing the way one thinks, and therefore, how one behaves, in challenging situations. More than 500,000 users have already downloaded the app over the past year, and we have published three pilot studies using results from this programme (PMID: 29907557, 29669708, 27777216).

The aim of this study is to investigate the effectiveness of this novel digital CBT mobile app in helping individuals to quit smoking, compared to participants receiving “very brief advice” (https://www.nice.org.uk/guidance/ng92/chapter/recommendations#very-brief-advice).

Who can participate?
Adults, (male and female), aged 18 years and over who have been smoking at least 5 cigarettes a day for the past one year and would would like to quit smoking in the next 30 days.

What does the study involve?
Eligible participants will attend an initial meeting for consent and baseline questionnaires. They then receive the intervention and are monitored for smoking status and secondary outcomes at 4 weeks, 26 weeks, and 52 weeks after their quit date. Each participant will also be offered free NRT.

What are the possible benefits and risks of participating?
There are no general risks to participants associated with digital CBT, the type of therapy involved in this research study. Participants may feel emotionally uncomfortable at times as they can explore feelings and experiences. However, therapy is delivered on a positive note; participants are taught useful coping skills to manage uncomfortable feelings, and have access to a chatbot and human support with a doctor or psychologist via the app. People that quit smoking experience a withdrawal period that may include cravings, anxiety, irritability, depression, and weight gain. Participants in the treatment group are taught techniques to deal with these symptoms through cognitive behavioural therapy, and those in the control group are given advice on how to deal with such symptoms and to seek support if they feel it is needed. All participants are made aware that they can contact the research team at any point, and to contact their GP if they are at all concerned about their health as a result of their smoking cessation attempt.
Lastly, there may be some burden as a result of participants having to travel to the research centre for the initial session. However, we will primarily recruit from the area close to the research centre, and appointments will be scheduled at a convenient time for participants.

Where is the study run from?
N/A - participants will attend for their baseline visit at a number of community settings across London

When is the study starting and how long is it expected to run for?
February 2018 to January 2021 (updated 03/07/2019, previously: July 2020)

Who is funding the study?
Digital Therapeutics Inc.

Who is the main contact?
Sarrah Peerbux, sarrah@digithera.ai

Study website
http://www.thesmokingsurvey.com/

Contact information

Type(s)
Public

Contact name
Miss Sarrah Peerbux

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.1

Study information

Scientific Title
Randomised controlled trial assessing efficacy of a novel cognitive behavioural therapy app for smoking cessation for healthy adults

Study objectives
A mobile phone app-enabled cognitive behavioural therapy intervention for smoking cessation is superior to the current treatment standard (“very brief advice”) as measured by the 4-week success rate in quitting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
HSC REC A, Northern Ireland. REC, 23/10/2018, ref. 18/NI/0171.

Study design
Single-blind, randomized, controlled, concealed allocation, clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Tobacco use

Interventions
Randomisation: Participants are randomly assigned into the treatment and control arm at a 50: 50 ratio.

Group 1 (Intervention): Participants in the intervention arm receive access to a behavioral intervention (cognitive behavioral therapy; CBT) delivered through a mobile application. This consists of several sessions per week completed by the participant on their phone at their convenience, and without involvement of a healthcare professional.

Group 2 (control): Those in the control arm receive a session of “very brief advice” delivered by a trained professional immediately after randomisation. More information is available at http://www.ncsct.co.uk/publication_very-brief-advice.php.

Duration of treatment: 4-weeks
Duration of follow-up: 1 year

We confirm that there is no wash-out period between the two trial conditions as this is not a crossover trial.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 24/07/2019:
Self-reported 7-day point prevalence abstinence at 4-weeks post quit date

Previous primary outcome measure:
Abstinence at 4 weeks post agreed quit date confirmed as self-reported “no puff of smoke” (using a questionnaire) in the past 2 weeks.

Secondary outcome measures
Current secondary outcome measures as of 24/07/2019:
1. 7-day point prevalence abstinence at week 26 and 52
2. Number of quit attempts at week 4, 26, and 52
3. Client Satisfaction with the intervention at week 4 (treatment only)
4. Participant changes in confidence levels, knowledge, attitudes and perceptions related to smoking cessation at week 4
5. Participant changes in self-efficacy at week 4, 26, and 52
6. Participant changes in self-reported health and wellbeing at week 4, 26, and 52
7. Self-reported abstinence at 4-weeks post quit date confirmed by ‘no puff of smoke’ in the past two weeks
8. Sustained abstinence at 24 and 52 weeks, defined as a self-report of smoking no more than five cigarettes from 2 weeks after the target quit date

Previous secondary outcome measures:
All outcomes are assessed using questionnaires completed by the participant.
1. Successful quit attempt as defined in the primary outcome at 26 and 52 weeks
2. 7-day point prevalence abstinence at week 4, 26, and 52
3. Number of quit attempts at week 4, 26, and 52
4. Client Satisfaction with the intervention at week 4 (treatment only)
5. Participant changes in confidence levels, knowledge, attitudes and perceptions related to

smoking cessation at week 4
6. Participant changes in self-efficacy at week 4, 26, and 52
7. Participant changes in self-reported health and wellbeing at week 4, 26, and 52

Overall study start date
01/02/2018

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Aged 18 or older
2. Has been smoking at least five cigarettes a day for at least one year
3. Desires to quit in the next 30 days
4. Can attend appointments at one of several locations around London
5. Using Apple iPhone (5th generation or higher) or Android phone (version 18 or higher)
6. Working proficiency in English language

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Total final enrolment
531

Key exclusion criteria
1. Currently using any other form of support for smoking cessation (including Bupropion, Varenicline, behavioural support) or any other stop smoking applications
2. Has a serious health condition (as decided by the study team)
3. Currently pregnant
4. Has a diagnosed mental health condition for which medication is currently being prescribed

Date of first enrolment
17/01/2019

Date of final enrolment
20/11/2019

Locations

Countries of recruitment
United Kingdom

Study participating centre
N/A
United Kingdom
N/A

Sponsor information

Organisation
Digital Therapeutics Inc.

Sponsor details
Unit 118 The Record Hall
16 Baldwins Gardens
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EC1N 7RJ

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Digital Therapeutics Inc.

Results and Publications

Publication and dissemination plan
We will disseminate the study results through peer-reviewed scientific journals, conference presentations, and through publications on our website. We intend to publish a first paper reporting on the 4-week outcomes, followed by a second paper describing the long-term follow-up data.

Intention to publish date
30/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be made available on request. Data can be requested from Sarrah Peerbux (sarrah@digithera.ai).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/10/2020	08/10/2020	Yes	No
Results article	Secondary outcomes	26/10/2022	18/01/2023	Yes	No
HRA research summary			28/06/2023	No	No