

A research study to assess the feasibility of evaluating a smoking cessation app that delivers 'context aware' advice in real time

Submission date 29/11/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/02/2020	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/05/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A lapse (any smoking) early in a quit attempt is strongly associated with reduced success of quitting smoking. Smokers are more likely to succeed if they use lapse prevention strategies. However, few smokers are skilled in using such strategies, and few interventions are specifically aimed at helping people to manage cue-induced cravings, which account for about half of all lapses. Researchers have developed a theory-guided Just-In-Time Adaptive Intervention (JITAI) smartphone app (Quit Sense), which provides smokers with in-the-moment support to help manage cue-induced cravings. The app uses a learning tool and location-sensing to tailor the timing and content of support messages when smokers spend time in self-identified high-risk locations. This study aims to estimate key parameters to inform a definitive randomised controlled trial (RCT), including outcome and health economic data completion rates, cost of recruitment using online advertising, app installation and engagement rates, the app's effect on the anticipated primary outcome and hypothesised mechanisms of action, and participant views of the app.

Who can participate?

Current smokers (at least 7 cigarettes per week), age 16 and above, willing to make a quit attempt in the next 14 days (after enrolling in the study)

What does the study involve?

Participants are presented with the study information via the study website and those interested in participating are taken through eligibility screening questions. Eligible participants are taken through the consent procedure (online with an e-signature). Participants then complete a short online questionnaire and afterwards are randomly allocated to one of two groups. These are the 'usual care' group which receive an SMS referral to the NHS'S SmokeFree website and the Quit Sense app group which receive an SMS referral to the NHS SmokeFree website plus the Quit Sense app. At the 6-week follow-up, participants are sent first a link by SMS to an online questionnaire and then a follow-up reminder by SMS. Participants who still do not complete the survey are then given a follow-up telephone call. Additionally, at the 6-week follow-up, around 1 in 8 participants will be invited to give a telephone interview about their

experiences of the trial as part of the qualitative process evaluation. At 6.5 months after enrolment (referred to as 6-month follow up), participants are sent a link by SMS to the final follow-up online questionnaire, with similar follow-up procedures as with the 6-week follow-up. Participants who have reported not having smoked in the past 7 days are sent a saliva sample kit by post in order to verify smoking status using salivary cotinine.

What are the possible benefits and risks of participating?

While the researchers cannot promise that participating in the trial will help participants to stop smoking, the important information gained from their involvement will help improve the support given to people in the future who want to quit smoking. Participants may find that being part of this trial helps to motivate them in their quit attempt. Participants will be sent a link to the NHS SmokeFree website and may also receive the Quit Sense app. The digital quit smoking support may include advice and support notifications, which some people may find unhelpful or even irritating. However, participants can stop receiving these at any point.

Where is the study run from?

The study is run from the School of Health Sciences and Norwich Clinical Trials Unit at the University of East Anglia (UEA) in the UK. The study setting is online with the intervention delivered on the participants' smartphone.

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

June 2019 to September 2021

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Dr Felix Naughton

f.naughton@uea.ac.uk

Study website

<https://www.quitsense.phpc.cam.ac.uk/>

Contact information

Type(s)

Scientific

Contact name

Dr Felix Naughton

ORCID ID

<http://orcid.org/0000-0001-9790-2796>

Contact details

School of Health Sciences

University of East Anglia

Edith Cavell Building

Norwich

United Kingdom

NR4 7UL

+44 (0)1603 593459
f.naughton@uea.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

270432

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

R205959, IRAS 270432, CPMS 44526

Study information

Scientific Title

Feasibility randomised controlled trial among online smokers of a smoking cessation smartphone app (Quit Sense) that delivers 'context aware' behavioural support in real time

Acronym

Quit Sense Feasability Trial

Study objectives

Principal Question: Can a randomised controlled trial of a smoking cessation smartphone app (Quit Sense) be feasibly delivered online among smokers?

Rationale for study: To conduct a feasibility randomised controlled trial of Quit Sense to inform a definitive effectiveness trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/12/2019, HRA Wales REC 7 committee (Building 1, St David's Park, Carmarthen, SA31 3HB, UK; Tel: +44 (0)1267 611164, +44 (0)1874 615949; Email: Wales.REC7@wales.nhs.uk), REC ref: 19/WA/0361

Study design

Two-arm feasibility randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

https://norwichcrtu.uea.ac.uk/ctudocs_public/quit_sense/QuitSense_Participant_Information_Sheet.pdf

Health condition(s) or problem(s) studied

Preventing smoking relapse, managing cue-induced cravings

Interventions

The researchers have developed a theory-guided Just-In-Time Adaptive Intervention (JITAI) smartphone app (Quit Sense), which provides smokers with in-the-moment support to help manage cue-induced cravings.

The user sets a quit date and trains the app to learn about their smoking behaviour via the app's smoking logging tool. This requires the user to log in the app each smoking episode and the situational context when they 'light up' in real time while the app records geolocation using location sensors.

After their quit date has passed, the app monitors the user's location and if they enter a location where they previously reported smoking, lapse prevention support is triggered, individually tailored using the context information collected while training the app. Support continues for up to 3 months.

Additional features include: tailored feedback after smoking behaviour is logged, an End of Day (EoD) survey with feedback, a 'my profile' section to display the smoking-related data collected by the app, a library of quitting advice, once daily support messages (up to 28 days post-quit attempt) and an option to reset their quit date in case of relapse.

Smokers (N=160) are recruited via online adverts and are randomized to either a 'usual care' arm (link to NHS SmokeFree website) or a 'usual care' plus Quit Sense arm with outcomes collected at 6 weeks and 6 months follow-up via the study website or telephone, and during app usage.

Intervention Type

Other

Primary outcome measure

As this is a feasibility trial there is no primary outcome. Outcomes will be collected to enable an estimation of key parameters to inform a future trial, in line with MRC guidance, and to provide preliminary information about the impact of the intervention:

1. Completeness of the anticipated primary outcome for a future definitive trial (self-reported abstinence with biochemical validation at 6.5 months post enrolment)
2. Cost per recruit, based on recruitment advertising costs gathered by the online recruitment company (Nativve) during the trial recruitment phase (February-March 2020)
3. Rates of app installation, use and support delivery fidelity measured using initialisation data recorded by the Quit Sense app during the period of participant engagement with the app (for

approximately 3 months post enrolment in study)

4. Completion of smoking cessation-related resource use and quality of life (EQ-5D-5L) data at enrolment and in the 6.5-month online follow-up survey

Secondary outcome measures

1. Abstinence rate of usual care arm, using the anticipated primary outcome for a future definitive trial: self-reported abstinence in the previous 6 months allowing for no more than five cigarettes and not smoking in the previous week measured at the 6.5 month follow up, biochemically validated among those reporting abstinence by a saliva cotinine or anabasine collected by post

2. Hypothesised mechanisms of action of Quit Sense:

2.1. Lapse incidence (any smoking, even a puff), which is highly predictive of relapse

2.2. Lapse prevention strategy use, which is associated with lapse prevention

2.3. Self-efficacy, which prospectively predicts lapse and relapse to smoking

2.4. The Strength of Urges to Smoke (SUTS) measure, which prospectively predicts abstinence and is superior to other urge measures in doing so

2.5. Automaticity and associative processes subscales from the Wisconsin Inventory of Smoking Dependence Motives (WISDM-37), which is a validated measure with good psychometric properties

This data will be collected 6 weeks after participants enrolment in the trial

Overall study start date

01/06/2019

Completion date

15/09/2021

Eligibility

Key inclusion criteria

1. Current smokers (at least 7 cigarettes per week)

2. Willing to make a quit attempt in the next 14 days

3. Has primary use of an Android smartphone (version 5.0 and above)

4. Age 16 years and above

5. Resident in England

6. Able and willing to provide informed consent using the web-based form

Participant type(s)

Other

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

200

Total final enrolment

209

Key exclusion criteria

1. Not previously participated in this trial
2. At present the app and related study materials are in English and so potential participants would require an understanding of basic written English in order to give informed consent and engage with the study

Date of first enrolment

27/11/2020

Date of final enrolment

18/01/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of East Anglia

School of Health Sciences

Edith Cavell Building

Norwich

United Kingdom

NR4 7UL

Sponsor information

Organisation

University of East Anglia

Sponsor details

Norwich Research Park

Norwich

England

United Kingdom

NR4 7TJ

+44 (0)1603 456161

rin.fmh@uea.ac.uk

Sponsor type

University/education

Website

<https://www.uea.ac.uk/>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 16/10/2023:

The protocol was published <https://pubmed.ncbi.nlm.nih.gov/33903144/> (open access) and the researchers published the Statistical Analysis Plan (SAP) on the Open Science Framework (<https://osf.io/mt6s5>). The results of the trial have been published in Nicotine and Tobacco Research (open access) <https://pubmed.ncbi.nlm.nih.gov/37055073/>

Previous publication and dissemination plan:

The protocol will be published and made open access and the researchers plan to publish the Statistical Analysis Plan (SAP) on the Open Science Framework. The results of the trial will be disseminated regardless of the findings.

Intention to publish date

01/09/2022

Individual participant data (IPD) sharing plan

Research data provided by trial participants will be entered under the participants PID number onto the central database stored on the servers based at Norwich Clinical Trials Unit, University of East Anglia, UK. After completion of the trial research data will be retained on the servers of NCTU for ongoing analysis of secondary outcomes for a period of 20 years. Any personally identifiable research data such as location data from the Quit Sense app will only be accessible to members of the Quit Sense trial team and to external regulators if requested. This data will be stored for 20 years. Requests for access to trial data will be considered, and approved in writing where appropriate, after formal application to the TMG or TSC. Considerations for approving access are documented in the TMG and TSC Terms of Reference. Personal contact information (names, numbers, addresses) will be stored for 12 months after the study to allow for the dissemination of findings, after which this data will be destroyed. Location data collected by the app will not be made available as an open dataset outside of Quit Sense collaborations because the information could potentially identify participants.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/04/2021	28/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		09/06/2023	16/10/2023	Yes	No
Statistical Analysis Plan		19/08/2021	16/10/2023	No	No
Results article		01/04/2024	02/05/2024	Yes	No