ISRCTN12326962 https://doi.org/10.1186/ISRCTN12326962

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

Registration date
03/02/2020

Overall study status
Completed

Last Edited
02/05/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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 enroling 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
270432

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

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
United Kingdom

England

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

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

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?
Results article		09/06/2023	16/10/2023	Yes	No
Results article		01/04/2024	02/05/2024	Yes	No
Protocol article		26/04/2021	28/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		19/08/2021	16/10/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes