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A feasibility study of a smoking cessation app in early intervention services

Submission date
20/12/2021

Recruitment status
No longer recruiting

Registration date
07/01/2022

Overall study status
Completed

Last Edited
07/01/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There is an increasing amount of investment, research, and innovation around using digital technologies in novel ways to improve people's physical health. However, the extent to which these new digital or "mHealth" solutions are accessible, usable, and beneficial for people with mental illness is under-researched. This is despite people with mental illness already experiencing drastic disparities in physical health, having a 2-3 fold risk of cardiovascular diseases, and an approximately 15-year reduced life expectancy compared to the general population.

A key contributing factor towards this is the disproportionately high rates of tobacco smoking in people with mental illness. Therefore, to begin addressing this gap, this study will examine the acceptability and feasibility of using the 'Smoke Free' app to support smoking cessation in young people in the early stages of treatment for a severe mental illness such as a psychotic disorder, termed 'first-episode psychosis' (FEP).

This study will aim to determine the feasibility and acceptability of using a smartphone app to engage young adults with SMI in smoking cessation in EIS.

Who can participate?
Regular smokers aged 18 to 35 years old with 'first-episode psychosis' (FEP).

What does the study involve?
30 participants with FEP will be recruited from Early Intervention Services (EIS) in the NHS. Each participant will be introduced to the Smoke Free smartphone app and asked to use this for a period of 6 weeks. Participants' usage of the app, their attitudes, and behaviours around smoking cessation will be measured before and after the intervention, alongside survey-style questions on their physical and mental well-being.

What are the possible benefits and risks of participating?
We hope the smoke free app will benefit peoples' health and help them with their desire to quit smoking. The information we gain from this research may also help us improve the physical health in young adults with mental health conditions.

Some individuals could find the questions in the assessments about physical/mental health distressing or upsetting to answer. However, participants are welcome to skip any questions they prefer not to answer, and can withdraw from the study at any point. As the app provided is smoking cessation app, we do not anticipate any risks from using this for participants. However, if participants do experience any issues, problems, upsetting events or adverse effects from using the app, they will be encouraged to contact the study team about this.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
January 2021 to January 2024

Who is funding the study?
The National Institute for Health Research (UK) and Medical Research Council (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
303451

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 51218, IRAS 303451

Study information

Scientific Title
Using smartphone apps for smoking cessation in first-episode psychosis: a feasibility study

Study objectives
A publicly-available app, 'Smoke Free', will be feasible for use to support smoking cessation among young people treated for psychosis in NHS Early Intervention Services.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/12/2021, West London Research Ethics Committee (The Old Chapel, Royal Standard Place, London, NG1 6FS; +44 (0)207 1048098; westlondon.rec@hra.nhs.uk), ref: 21/LO/0865

Study design
Non-randomized interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Tobacco smoking in young people with 'first-episode psychosis' (FEP)

Interventions
The study aims to determine the acceptability and feasibility of using the 'Smoke Free' app in Early Intervention Services (EIS), for supporting smoking cessation in young adults with first-episode psychosis (FEP). Acceptability and feasibility will be established through data gathered

on eligibility, referral, and recruitment rates for the study, quantitative levels of user engagement with the smoking cessation app, and qualitative feedback on satisfaction with using an app in this way and for this problem (smoking).

Potential participants will be identified by members of their clinical care team, and subsequently alerted to the study by their care teams (e.g. care coordinators and physical health support workers), to be asked if they would be interested in participating. The clinical staff who approach the potential participants to inform them of the trial will also have flyers and participant information sheets on hand, to provide to the service users either in person or via email or text message.

Those service users who are interested in participating and agree to have their details passed over to the research team will then be contacted by the research team. Following this, the research team will arrange to conduct an initial telephone screening over the phone (to determine eligibility), and provide further information about the study.

Alternatively, potential participants may opt to complete an online form to receive further information, express their interest, request to be contacted about participation. Service users will be able to find the online form via the link/QR code on the recruitment/advertisement materials (i.e. the study flyer/posters distributed in the clinical services or online webpages /social media). The flyers/advertisements containing the link to the online form will also be shared through any contact lists/databases of service users interested in hearing about research opportunities. The online form itself will tell people of their eligibility for the study, provide the Participant information sheet, and then request basic contact information for those who are interested/eligible for joining. Following the completion of that form, a member of the research team will contact the service user directly via phone/email to undertake their screening, and arrange an enrolment/informed consent meeting.

Screening will be completed on Zoom/telephone depending on participant preference, using a Telephone Screening Proforma to ask several questions on individuals' eligibility, by determining their current status as an Early Intervention Service user, age, smoking status and smartphone ownership. A screening number will be assigned to each potential participant, and an electronic screening log will link this number to either a study number, for those who are eligible, or an anonymous log of the reason for ineligibility, for all failed screenings. Any contact information or personal data for ineligible participants (or those who do not consent to the study) will be permanently deleted, while the necessary data from eligible and subsequently enrolled participants will be kept in line with the study's procedures for secure storage of PID.

Enrolment and Data Collection:
Enrolment to the study will take place either online (via Teams or Zoom) or face to face (at the University or mental health service locations), depending on participant preference. In this, participants will be provided with further information about the study and address any questions participants might have, and then provide written or audiorecorded consent (as described elsewhere).

Upon enrolment to the study, participants will be asked to download the smoke free app. The research team will go through the features of the app and then ask participants to complete the baseline questionnaire, collecting data on participants smoking attitudes and behaviours along with their physical and psychological well-being. Participants will then be asked to complete the follow-up questionnaire 6 weeks later, collecting the same data. In both cases, these questionnaires will be administered over the phone, online or in-person depending on participant preference, with the research workers. Participants will be reimbursed and thanked

for their time with 2 £20 shopping vouchers at the beginning and end of the study, for completing the baseline and follow-up assessments respectively. The questionnaires will consist of ~30 items and will take around 15 min to complete.

A subgroup of participants will also be invited to participate in a qualitative substudy after the 6-week intervention period. This will consist of semi-structured interviews, conducted in-person (at the University, mental health clinic, or another public place of participants' choosing) or online (via Zoom or MS Teams) by trained researchers experienced in qualitative methods. Only the audio of the interviews will be recorded, using University laptops which are password protected. Furthermore, recordings will be deleted immediately following transcription. They will last no more than 60 min, and all participants will be compensated with a further £20 voucher for their time.

Data handling and record-keeping:
All study outcome data will be pseudoanonymised from point of collection. All outcome data from the pre-post measures will be stored on secure University servers, and only accessible to the research team. App usage data will necessarily be collected by the Smoke Free app itself, but stored to unique participant ID numbers. Study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities, or from the NHS Trust, for monitoring and auditing purposes and this may include access to personal information.

Personally identifiable information will be stored separately and securely from data relating to research participants. The pseudonymisation key will be encrypted and stored in a separate share on Research Data Storage. All digitallycollected data will be stored on the University of Manchester's Research Data Storage Service(RDS). IT Services at the University provides the RDS as centrally-hosted and administered data storage for use by research staff. Of course, these secure, password-protected servers meet all necessary standards of data security for the purposes of such research at the University of Manchester. Paper-collected data (such as paper Consent forms) will be stored in a locked filing cabinet in the locked office of the research team.

Along with our individual-level study data, we will also obtain some population-level usage data descriptives from the Smoke Free app collaborators, providing mean values of app usage from a geographically-matched sample of Smoke Free app users with comparable levels of smoking behaviours in the general population. This data is automatically collected by the app, and information will be provided to us in aggregated formats (i.e. means and standard deviations for the sample group) by the Smoke Free team. As only aggregated sample means will be needed for these analyses, no individual-level data collection from our team will be necessary with regards to the comparison sample of general population usage.

Intervention Type
Behavioural

Primary outcome measure
Feasibility measured using the following indicators:
1. Referral rates measured as the number of service users who are interested in using an app for quitting smoking, and thus referred to the study over the study period, at baseline
2. Recruitment rates measured as the proportion of referred individuals who successfully enroll in the study (having been willing and able to download the app and join the intervention) and those who did not meet eligibility criteria (and reasons for this), at baseline
3. Retention rates and therefore the feasibility of studying the impact of ‘Smoke-Free’ in the context of EIS, to gain sufficient outcome data, measured as the proportion of enrolled

individuals who successfully complete the end-point assessments of the study at 6 weeks
4. Engagement levels measured from the automatically-recorded app usage metrics, including frequency of usage per week, sustenance of usage, and levels of engagement with the various app features collected continuously over the 6 week study period

Secondary outcome measures
1. Smoking Behaviour measured using the following:
1.1. Self-reported smoking measured using the Heaviness of Smoking Index (HSI) at baseline and 6 weeks
1.2. Abstinence from smoking measured using self-report assessments at baseline and 6 weeks, and also throughout the study via the app, which will also send participants a push notification one month after their set quit date. The app will ask the following question: 'Have you smoked at all in the last month?' Response options will be: 'No, not a puff'; '1–5 cigarettes'; or 'More than 5 cigarettes'. Those who respond 'No, not a puff' will be considered abstinent.
1.1. Attitudes towards smoking measured using standardised questions for 'Readiness to quit smoking' and 'Confidence to quit smoking at baseline and 6 weeks'. Readiness will be assessed with the question "How ready are you to quit smoking within the next month (0=Not at all; 10= 100% ready)?", while Confidence is assessed by, "How confident are you that you will quit smoking within the next month (0=Not at all; 10=100% confident)?".
2. Perceived health status measured using the following:
2.1. Quality of life measured using the Smoking Cessation Quality of Life (SCQoL) acute questionnaire at baseline and 6 weeks
2.2. Psychological wellbeing measured using the short form of the Depression, Anxiety, and Stress Scale (DASS 21) at baseline and 6 weeks
2.3. Adverse events reported by participants their care teams at any point over the course of the trial. Information on any adverse events experienced will be requested from participants at 6 weeks.
3. Subjective experience of 'Smoke Free' measured using one-to-one semi-structured interviews with participants perspectives on app-based smoking cessation generally at baseline and 6 weeks
4. Service user's opinions on desirability and utility of smoking cessation apps in FEP, and the optimal content and delivery of such interventions measured using one-to-one semi-structured interviews with participants at baseline and 6 weeks

Overall study start date
13/01/2021

Completion date
09/01/2024

Eligibility

Key inclusion criteria
1. Aged between 18–35 years (inclusive)
2. A current service user of Early Intervention Services (defined as having a designated care coordinator within the service)
3. A self-reported regular smoker (defined as smoking ≥5 cigarettes per day)
4. Interested in reducing/quitting tobacco consumption using a smartphone app

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Currently prescribed clozapine
2. No access to a compatible iPhone or Android smartphone device
3. Inability to give informed consent (as assessed during recruitment)
4. Insufficient command of English language to engage with assessments/intervention

Date of first enrolment
01/03/2022

Date of final enrolment
28/11/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Pennine Care NHS Trust
225 Old Street
Ashton-under-lyne

United Kingdom
OL6 7SR

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

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Sponsor type
University/education

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http://www.manchester.ac.uk/

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research (NIHR) (UK)

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
Planned publication in a international, peer-reviewed medical journal.

Intention to publish date
01/07/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from PI Firth based at 3.005 Jean Mcfarlane Building, University of Manchester, Oxford Road, Manchester, U.K., M13 9PL Telephone: 0161 306 7811 Email: Joseph.firth@manchester.ac.uk. Only anonymised data will be available. This data will be made available in this way to other research teams based at academic institutions from 2 years after fellowship completion; allowing time for exclusive use of data by the research team for publication and innovation, prior to making the data available for broader usage. Consent for data to be shared in this way will be gained from participants during enrolment to the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No