ISRCTN14068059 https://doi.org/10.1186/ISRCTN14068059

E-cigarettes for smoking cessation and reduction in people with a mental illness

Submission date
20/06/2023

Recruitment status
No longer recruiting

Registration date
05/01/2024

Overall study status
Completed

Last Edited
09/04/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Tobacco smoking is the single largest contributor to health inequalities for people with mental illness (PWMI). Developing and implementing ways to address this widening health gap has been identified as a priority in the NHS Long Term Plan and the 2019 Tobacco Control Plan for England. E-cigarettes have been suggested as a potentially particularly helpful way to support people with mental illness quit smoking or substantially reduce consumption. However, there have been no fully powered trials to assess this potential. The researchers completed a feasibility study in January 2023 and are now ready to proceed to a full randomised controlled trial (RCT). The aim of this study is to assess the effectiveness and cost-effectiveness of providing an e-cigarette starter kit to PWMI treated in the community to aid smoking cessation and harm reduction.

Who can participate?
Adults (aged over 18 years) receiving treatment for a mental illness in primary or secondary care, who smoke regularly

What will the study involve?
Participants are randomly allocated to one of two groups. Group 1 will receive an e-cigarette and e-liquid to use for 4 weeks in addition to the usual care they are receiving. In Group 2, initially participants will continue to receive their care as usual but will receive an e-cigarette and some e-liquid at the end of the study at the 6-month follow-up.
Participants who are assigned to the group that receives the e-cigarette will be given an e-cigarette starter kit (an e-cigarette containing e-liquid and an information leaflet). They will also receive a brief face-to-face consultation with a clinician, who will explain how to use the e-cigarette and provide information to enable participants to make positive changes to their smoking behaviour. Participants will be provided with an e-liquid supply for 4 weeks. Participants who are assigned to the group that does not receive an e-cigarette will continue to receive their usual care package and will be provided with an e-cigarette and some e-liquid after the 6-month follow-up. Both groups will be encouraged to consider quitting and to set a target quit date soon. However, if they choose not to set a quit date that is also okay.
A member of the research team will ask several questions at the beginning of the study and again after 1 and 6 months. Participants will be given the opportunity to do this at home on an

electronic device (by completing the questionnaires online) or in person at a place to suit them; this process may take up to 1 hour. The questions will ask about current smoking status, smoking habits and mental and physical health. Participants may also be asked to breathe into a carbon monoxide monitor which can be done at a place that is convenient for them.

What are the possible benefits and risks of participating?
Participants may make positive changes to their smoking behaviour and provide data which could help thousands of smokers to quit smoking for good. They will receive a shopping voucher each time they complete the follow-up questionnaires and receive an e-cigarette which they can keep.

Where is the study run from?
Mental Health Trusts and GP practices mainly in Yorkshire (UK)

When is the study starting and how long is it expected to run for?
March 2023 to July 2025

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Dr Anna-Marie Marshall, a.marshall@york.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Elena Ratschen

Contact details
Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904 320000
elena.ratschen@york.ac.uk

Type(s)
Principal Investigator

Contact name
Prof Lion Shahab

Contact details
University College London
1-19 Torrington Place
London
United Kingdom
WC1E 6BT

+44 (0)20 7679 1805
lion.shahab@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Yan Ding

ORCID ID
http://orcid.org/0000-0002-8439-9682

Contact details
Department of Health Sciences
Faculty of Sciences
Area 4, Alcuin Research Resource Centre
University of York
Heslington
United Kingdom
YO10 5DD
+44 (0)1904 32 5600
yan.ding@york.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
328528

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58155, IRAS 328528

Study information

Scientific Title
E-cigarettes for Smoking Cessation And reduction in People with mEntal illness (ESCAPE)

Acronym
ESCAPE

Study objectives
The main aim is to assess the effectiveness and cost-effectiveness of providing an e-cigarette starter kit to people with mental Illness (PWMI) treated in the community to aid smoking cessation and harm reduction, as an adjunct to ‘usual care’.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/10/2023, Yorkshire & The Humber - South Yorkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8021; southyorks.rec@hra.nhs.uk), ref: 23/YH/0199

The ethical approval covers a process evaluation and the process evaluation started on 17/02 /2025 and will be ended on 31/08/2025.
We submitted a substantial amendment to IRAS to enable the main trial's ethical approval to cover the process evaluation. We received a favorable opinion from the REC regarding this amendment on 10 February 2025 and a HRA and HCRW approval on 14 February 2025.

Study design
Multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice, Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Smoking cessation using an e-cigarette in patients living in the community who have a mental illness

Interventions
The intervention allocation will be determined by block computer randomisation to ensure that each trial site has an equal proportion of intervention and control group participants. Randomisation will occur after consent to take part in the study has been obtained via sealed envelope.

The intervention group will be offered an e-cigarette starter kit, compliant with EU regulation, and an information leaflet about e-cigarettes, in addition to usual care. A 20 mg/ml strength DOTPRO e-cigarette starter kit (https://www.liberty-flights.co.uk/DOT-PRO/DOT-PRO-Vape-Kit /) will be offered in a choice of flavours. The starter kit containing a pod-based e-cigarette, a 4-week supply of refill pods and an information leaflet will be provided to participants by their clinician at their scheduled appointment. At the scheduled appointment with a clinician, a brief consultation will also be conducted with participants to provide necessary instructions for the use of the kit lasting between 5-10 minutes. All participants will be encouraged to consider

quitting and to set a target quit date within a week, told that smoking cessation is beneficial for their mental and physical health and that e-cigarettes are a safe and effective way to achieve smoking cessation.

The control group will receive care as usual, as outlined above and they will be told that smoking cessation is beneficial for their mental and physical health.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ICON e-cigarette

Primary outcome measure
1. Self-reported 7-day point prevalence abstinence measured using a questionnaire (question written in-house) at 6 months
2. Co-verified quit (main outcome) measured using a CO monitor (smokylizer) at 6 months

Secondary outcome measures
1. General smoking-related characteristics, abstinence, quit attempts and methods (including e-cigarettes), measured using a questionnaire (questions written in-house) at baseline, 1 month and 6 months
2. Nicotine dependence measured using the Fagerstrom Test for Nicotine Dependence at baseline, 1 month and 6 months
3. Strength of urges to smoke measured using the SUTS questionnaire at baseline, 1 month and 6 months
4. Motivation to quit measured using the Motivation To Stop Scale (MTSS) at baseline, 1 month and 6 months
5. Mental wellbeing measured using PHQ-9 and GAD-7 at baseline and 6 months
6. Alcohol use measured using AUDIT-C at baseline and 6 months
7. Health-related quality of life measured using EQ-5D-5L at baseline and 6 months
8. Attrition measured using a questionnaire (questions written in-house) at 1 month and 6 months
9. Adherence rate measured using a questionnaire (questions written in-house) at 1-month follow-up
10. Cost-effectiveness measured using a questionnaire (questions written in-house) at baseline, 1 month and 6 months
11. Adverse events measured using a questionnaire (questions written in-house) at 1 month and 6 months

Overall study start date
01/03/2023

Completion date
05/07/2025

Eligibility

Key inclusion criteria
1. Adults (aged >18 years)
2. Receiving treatment for a mental illness in primary or secondary care
3. Smokes regularly and have smoked combustible cigarettes in the past 7 days)
4. Must be willing to address their smoking behaviour, either by attempting to quit or by reducing their consumption
5. Must have the capacity to provide consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
616

Total final enrolment
95

Key exclusion criteria
1. Patients must not have had an inpatient admission in the last 3 months
2. Smokers who are currently using e-cigarettes regularly (at least weekly)
3. Patients who are participating in other smoking cessation trials
4. Patients who are receiving treatment for drug or alcohol use
5. Patients who have a diagnosis of Alzheimer’s disease or dementia
6. Patients who are pregnant or breastfeeding

Date of first enrolment
27/03/2024

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Bradford District Care NHS Foundation Trust
New Mill
Victoria Road
Saltaire
Shipley
United Kingdom
BD18 3LD

Study participating centre
Sheffield Clinical Commissioning Group Hq
722 Prince of Wales Road
Darnall
Sheffield
United Kingdom
S9 4EU

Study participating centre
Oxford NHS Foundation Trust
Littlemore Mental Health Centre
Sandford Road
Littlemore
Oxford
United Kingdom
OX4 4XN

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Fieldhead
Ouchthorpe Lane

Wakefield
United Kingdom
WF1 3SP

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
Duncan Macmillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Lancashire and South Cumbria NHS Foundation Trust
Sceptre Point
Sceptre Way
Walton Summit
Preston
United Kingdom
PR5 6AW

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
County Hall
Trust Headquarters
Martineau Lane
Norwich
United Kingdom
NR1 2DH

Study participating centre
CRN North East and North Cumbria
LCRN Level2
Regent Point
Regent Farm Road
Gosforth
Newcastle Upon Tyne
United Kingdom
NE3 3HD

Study participating centre

Woodstock Bower Surgery
Kimberworth Road
Rotherham
United Kingdom
S61 1AH

Study participating centre
Clifton Medical Centre
239 Doncaster Gate
Rotherham
United Kingdom
S65 1DA

Study participating centre
My Health
Strensall Health Care Centre
Southfields Road
Strensall
York
United Kingdom
YO32 5UA

Study participating centre
Mosborough Health Centre
Doctors Surgery
34 Queen Street
Mosborough
Sheffield
United Kingdom
S20 5BQ

Study participating centre
Bartholomew Medical Group
Goole Health Centre
Woodland Avenue
Goole
United Kingdom
DN14 6RU

Study participating centre

Bridge View Medical Group
Southwick Health Centre, The Green, Southwick
Sunderland
United Kingdom
SR5 2LT

Study participating centre
Springwell Medical Group
Jack Cohen Health Centre, Springwell Road
Sunderland
United Kingdom
SR3 4HG

Study participating centre
Snaith and Rawcliffe Medical Group
The Marshes
Butt Lane
Snaith
Goole
United Kingdom
DN14 9DY

Sponsor information

Organisation
University of York

Sponsor details
Heslington
York
England
United Kingdom
YO10 5DD
+44 (0)1904 320000
michael.barber@york.ac.uk

Sponsor type
University/education

Website
http://www.york.ac.uk/

ROR

https://ror.org/04m01e293

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results from the feasibility and full RCT will be shared with study participants via email or text message, which will include a link to blog posts regarding study results. PH and SH, together with lay representatives of the steering committee will assist in ensuring that blog posts and other relevant approaches to dissemination are understandable to a lay audience and will also assist with dissemination (e.g. via social media). If they wish to, participants can also assist with dissemination, and we will work together to prepare social media/blog posts that they can share. The researchers will also work with local press (e.g. Yorkshire Post, Sheffield Star, Doncaster Free Press newspapers) to communicate study results to the local population. In addition, we will approach media offices of Universities and Trusts involved in the study and the Yorkshire and Humber CRN to disseminate study results internally. At the national level, the researchers aim to publicise study results through their partners (ASH, NSCST and Equally Well) as well as their contacts within Public Health England and NICE. At the international level, findings from both the feasibility and full RCT will be presented at relevant conferences (Society for Research of Nicotine and Tobacco; Society of Behavioral Medicine, Royal College of Psychiatrists etc) and the publication of study protocol, and results from both trials in high impact, relevant journal (e. g. JAMA Psychiatry, Lancet Psychiatry). Further, the researchers will plan a media briefing with the Science and Media Centre with whom we have a good working relationship.

Intention to publish date
30/04/2026

Individual participant data (IPD) sharing plan

Data will be available upon request from Dr Anna-Marie Marshall (a.marshall@york.ac.uk). Consent from participants was required and obtained. Participants will be allocated a participant number, the names of participants will not appear on the paper-based or online data stored at the University. The NHS code of confidentiality will be adhered to for all patient data and for data.

IPD sharing plan summary

Available on request