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

Submission date	**Recruitment status**	[X] Prospectively registered
28/09/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/03/2025	Other	

Plain English summary of protocol

Background and aims
Even though the number of smokers in the UK has decreased in the general population, the number of people with mental illness who smoke remains high. People with mental illness are more than twice as likely to be smokers as the general population, have higher levels of nicotine dependence, and tend to smoke more, leading to an increased risk of smoking-related illness and premature death. People with mental illness are just as motivated to quit as those who do not have a mental illness, but they find it more difficult to do so and often require specialist help. More and more evidence is accumulating to show that e-cigarettes are an effective smoking cessation aid. However, no adequately powered randomized controlled trial has tested this. We aim to conduct a randomised controlled feasibility trial of an e-cigarette starter kit (4-week supply and leaflet) as an adjunct to usual care for smokers with mental illness treated in the community.

Who can participate?
Adult (over 18 years) smokers with an interest in quitting or cutting down their smoking who have a mental illness can participate.

What does the study involve?
Participants will be assigned either to a group that receives the e-cigarette, (participants will be given an e-cigarette starter kit including an e-cigarette, 4 weeks supply of e-liquid, and an information leaflet) or usual care. Participants in the e-cigarette group will also receive a brief consultation with a clinician either over the phone, online, or face-to-face, who will explain how to use the e-cigarette and provide information to enable participants to make positive changes to their smoking behaviour. For those assigned to the group that does not receive an e-cigarette, they will continue to receive their usual care package with no change. Both groups will be encouraged to consider quitting and to set a target quit date soon. Data will be collected at baseline (demographic information, information about smoking status, mental and physical health.) and again at 1-month follow-up (this may also include a CO reading and an optional interview about the study).

What are the benefits and risks of participating?
By participating in this research, we hope it will lead to participants making positive changes to

their smoking behaviour. Participants will also have an influence on the future refinement and changes that we might need to make for the full randomised controlled trial, which may become standard practice for treatment and help thousands of smokers to quit smoking for good. For those who wish to be interviewed, we will provide a voucher for their time.
Side effects are sometimes experienced after quitting smoking (these can include irritability, depression, restlessness, poor concentration, increased appetite, light-headedness, disturbed sleep, nicotine craving). Side effects are also associated with e-cigarette use (these can include coughing, dry mouth, and throat, shortness of breath, mouth and throat irritation, and headaches).

We will ask questions about the participant and their mental health. Some people may feel uncomfortable answering these. Participants can opt-out, stop, take a break, or withdraw from the study you will be able to do so at any time and will be supported in this by the research team.

Where is the study run from?
Three Trusts will be involved in this pilot: Tees, Esk, and Wear Valleys NHS Foundation Trust (TEWV –the largest mental health Trust in England) will be the host Trust. TEWV has numerous sites across Yorkshire. Bradford District Care Trust (BDCT) will also include a minimum of two sites. TEWV and Bradford will recruit from secondary care. SHSC/Sheffield CCG will facilitate recruitment in primary care sites only. SHSC/Sheffield CCG will approach 2-3 primary care networks to participate.

When is the study starting and how long will it run for?
September 2021 to November 2022

Who is funding the study
Yorkshire Cancer Research (UK)

Who is the main contact
Professor Lion Shahab, lion.shahab@ucl.ac.uk
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
303022

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 303022

Study information

Scientific Title
E-cigarettes for Smoking Cessation And reduction in People with mEntal illness - a randomised pilot feasibility trial

Acronym
ESCAPE pilot Trial

Study objectives
The primary research objective is to assess the feasibility and acceptability of an e-cigarette-based intervention and associated research processes in people with a mental illness, establishing central parameters for the design of a definitive Randomized Controlled Trial (RCT), including recruitment and retention rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/12/2021, Health and Care Research Wales (Castlebridge 4, 15 - 19 Cowbridge Rd E, Cardiff, CF11 9AB; +44 (0)29 2023 0457; HCRW.approvals@wales.nhs.uk), ref: 21/NE/0202

Study design
Randomized controlled feasibility trial with an embedded process evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
The use of e-cigarettes for smoking cessation for people with mental illness.

Interventions

The intervention consists of an e-cigarette starter kit containing a third generation e-cigarette (Aspire PockeX), a four-week supply of e-liquid (a choice of flavors and concentrations will be offered) and an information leaflet. Intervention delivery will take place at a previously scheduled appointment with a clinician. The control condition is usual care.

Allocation will be determined by block computer-randomisation. Participants will be informed or of their allocation either online via a link or in-person via a sealed envelope.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
The Aspire PockeX electronic cigarette.

Primary outcome(s)
1. Feasibility and acceptability outcomes: The primary feasibility outcome measures in the feasibility trial will be consenting rate and recruitment frequency.
1.1. Consenting rate will be calculated from the number of eligible participants approached who consent to take part in the study.
1.2. Recruitment frequency will be calculated as the number of eligible patients at each site who agree to participate in the trial per month.
1.3. The attrition rate will be measured as the number of participants who fail to complete follow-up at 1 month.

2. Clinical (smoking-related) outcomes:
2.1. Continuous abstinence assessed at 1-month will be defined as not having smoked in the two weeks prior to follow-up, verified by a CO reading below 10 ppm, in keeping with the standard measure used in Stop Smoking Services.

Key secondary outcome(s))
1. Feasibility and acceptability outcomes:
1.1. Fidelity will be assessed by randomly sampling two intervention sessions per site with trained staff, audio-recording them and coding the use of behaviour change techniques during intervention deliver period
1.2. Characteristics of ‘usual care’ in different locations will be also noted, recording two interactions of patients with CMHTs or GPs at each site at baseline and using short pro-forma with control group participants at 1-month follow-up
1.3. Participant burden of data collection will be assessed via qualitative interviews conducted online or via telephone with participants to assess acceptability.

2. Clinical (smoking-related) outcomes:
2.1. Self-reported abstinence 2-4 weeks from enrollment or target quit date (whichever is later) will be recorded at 1-month follow-up. The change in cigarette consumption (and reduction in exhaled breath CO reading) from baseline to 1-month follow-up will be calculated in both intervention and control group participants.

3. Clinical (mental health-related) outcomes: General and mental health functioning will be assessed using most recent diagnosis (if available), antipsychotic medication use, and acute

events (e.g. hospitalisation) in the last year. Mental health symptoms will be assessed with the PHQ-9 [Gilbody et al., 2007], GAD-7 [Spitzer et al., 2006] and SF-12 questionnaires [Ware et al., 1996] at 1 month follow-up.
4. Cost effectiveness: We will pilot service use questionnaires for health economic analysis and assess the health care utilisation data returned. We will calculate the costs of delivering the intervention and the control condition as the basis for the full RCT, for which a cost-effectiveness analysis is planned. Data will be collected at baseline and 1-month.
5. Serious Adverse Events (SAE): Adverse events (AE) will be recorded at 1-month follow-up as part of the follow-up questionnaires participants complete.

Completion date
30/11/2022

Eligibility

Key inclusion criteria
1. Adults (> 18 years)
2. Receiving treatment for a mental illness under the care of secondary care psychiatric community teams or community mental health teams (CMHTs)
3. Smoker (who smoke regularly and have smoked combustible cigarettes in the past 7 days)
4. Be willing to address their smoking behaviour, either by attempting to quit or by reducing their consumption and have the capacity to provide consent.
5. Have the capacity to consent (assessed by patient's care coordinator)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Patients must not have had an inpatient admission in the last 3 months according to their health care record.
2. Smokers who are currently using e-cigarettes regularly (at least weekly)
3. Those who are participating in other smoking cessation trials
4. Those being treated for co-morbid drug or alcohol problems
5. Those who have a diagnosis of Alzheimer’s disease or dementia
6. Those who are are pregnant or breastfeeding

Date of first enrolment
07/03/2022

Date of final enrolment
18/07/2022

Locations

Countries of recruitment
United Kingdom

England

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

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

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

Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request from Dr Anna-Marie Marshall (a.marshall@york.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/01/2025	07/01/2025	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3	21/09/2021	30/09/2021	No	No