

# Integrating smoking cessation treatment into online psychological care

<b>Submission date</b> 19/01/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/02/2023	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/12/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Smoking is the world's leading cause of preventable illness and death. People with depression/anxiety are twice as likely to smoke compared to people without depression/anxiety. Quitting smoking can significantly improve your mental health as well as your physical health. Research shows that people with depression/anxiety are more likely to quit smoking if they get psychological support. This study aims to offer service users information about smoking and mental health, and help to quit smoking, alongside their psychological therapy in SilverCloud. The researchers want to see if service users are interested in this support to quit smoking and if this support and the tasks involved in the study are acceptable to patients and to mental health professionals.

### Who can participate?

Adults who are regular tobacco smokers and about to start online therapy using SilverCloud

### What does the study involve?

SilverCloud users, who would like to take part, will be randomly allocated to receive one of two treatments (i.e., have a 50/50 chance of receiving either treatment). Participants will either receive information about stopping smoking alongside their usual psychological therapy on SilverCloud (intervention group) or receive information about stopping smoking at the end of their participation in the study (control group).

During the study, the researchers will collect information about participants' well-being and smoking habit. This information will be collected via an online survey, from SilverCloud, or from their mental health service. Follow-up data about participants' smoking status, mental health symptoms, and experience with the treatment will be collected three and six months after starting the study via email or telephone. If participants have quit smoking, they will be asked to provide a saliva sample via post to check nicotine levels. Participants will receive a £5 shopping voucher for completing each follow-up.

Participants in the intervention group will be invited to take part in a one-to-one interview at the end of the study to discuss their experiences.

What are the possible benefits and risks of participating?

Quitting smoking is the best thing people can do for their physical health and overall well-being. Participants who take part in the study might increase their chances of quitting smoking. There are unlikely to be risks to participants' personal safety or health by taking part in this study, as all the treatments offered are part of usual care.

Where is the study run from?

Department of Psychology at the University of Bath (UK)

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

October 2021 to December 2024

Who is funding the study?

Cancer Research UK (CRUK)

Who is the main contact?

smokingstudy@bath.ac.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

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### Type(s)

Public, Scientific

### Contact name

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

304857

### **Central Portfolio Management System (CPMS)**

51952

## **Study information**

### **Scientific Title**

IntEgrating Smoking Cessation treAtment into usual online Psychological care for people with common mEntal illness: an online randomised feasibility and pilot study

### **Acronym**

ESCAPE

### **Study objectives**

This feasibility and pilot study aims to investigate the feasibility and acceptability to patients and psychological well-being practitioners of a tailored and integrated smoking cessation intervention delivered as part of usual online treatment via SilverCloud, and the feasibility and acceptability of trial procedures.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 23/03/2022, Wales Research Ethics Committee 6 Swansea (Wales National Pool, Sketty Lane, Swansea SA2 8QG; +44(0)1686 252101, (0)2920 230457, (0)7920 565664; Wales. REC6@wales.nhs.uk), ref: 22/WA/0051

### **Study design**

Two-armed pragmatic online randomized controlled feasibility and pilot study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

## Health condition(s) or problem(s) studied

Smoking cessation treatment for patients with common mental illness

## Interventions

A two-armed, pragmatic, online, randomised, and controlled feasibility and pilot trial will be used to test the acceptability and feasibility of an online smoking cessation intervention, and the trial procedures, offered alongside usual online psychological treatment (via SilverCloud). We will recruit adult smokers who are eligible for online treatment via the SilverCloud mental health treatment platform (e.g., people with anxiety and/or depression). Participants will be randomised via an algorithm in the Qualtrics online platform (<https://www.qualtrics.com/uk/>) to the treatment arm (i.e., smoking cessation psychoeducational information, behavioural support and medication signposting provided alongside usual online mental health treatment) or control arm (i.e., usual online mental health treatment with signposting to NHS smoking cessation services at the end of the trial). SilverCloud usual care includes a self-guided, online mental health programme, depending on the service, patients are offered supported SilverCloud treatment for approximately 6-12 weeks with up to six online or telephone reviews with a mental health practitioner.

## Intervention Type

Behavioural

## Primary outcome(s)

Self-reported quit attempt (at least 24 hours quit) measured using an online questionnaire at 2, 4, 6, 8 and 10 weeks, and 3-month follow up

## Key secondary outcome(s)

1. Engagement with, and completion of, the online smoking cessation and mental health programmes measured using SilverCloud data over 12 weeks.
2. Self-reported smoking cessation medicine and e-cigarette use measured using an online questionnaire at baseline, 2, 4, 6, 8 and 10 weeks, and 3 and 6 months follow up.
3. Depression and anhedonia (Patient Health Questionnaire; PHQ-9) measured using SilverCloud data at baseline and at 2, 4, 6, 8 and 10 weeks, and 3 and 6 months follow up by online questionnaire
4. Anxiety (General Anxiety Disorder Questionnaire; GAD-7) measured using SilverCloud data at baseline and at 2, 4, 6, 8 and 10 weeks, and 3 and 6 months follow up by online questionnaire
5. Quality of health measured using an online questionnaire at 3 and 6 months follow up
6. Self-reported smoking cessation measured using an online questionnaire at the 3-month follow-up (4-weeks abstinent) and 6-month follow-up (prolonged 12-week abstinence)
7. Saliva cotinine (i.e., 15 nanograms per millilitre), or salivary anabasine (<1ng/ml) if using nicotine, measured to confirm smoking abstinence, using saliva sample testing kits that will be posted to participants with a pre-paid envelope to send to ACM Bioanalytical Services (<https://www.acmgloballab.com/bioanalytical-services>) laboratory for testing at the 3 and 6-month follow-ups (for those reporting cessations)
8. Patient acceptability and satisfaction with the intervention measured using an online questionnaire and qualitative interview conducted remotely online or by telephone (intervention arm only) at the 6-month follow-up
9. Patient acceptability with the trial procedures measured using an online questionnaire at the 6-month follow-up
9. Clinician acceptability of the intervention measured using an online questionnaire and qualitative interview conducted remotely online or by telephone at the end of the trial
10. Engagement with the mental health treatment service (e.g., number of attended/missed

appointments, discharge/completion status) measured using NHS service data collected over 12 weeks

**Completion date**

31/12/2024

## Eligibility

**Key inclusion criteria**

1. Adult (aged 18+ years),
2. Self-reported regular (daily or non-daily) smokers
3. Eligible for SilverCloud treatment, according to therapists/psychological wellbeing practitioners
4. Comorbidities are allowed

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

310

**Key exclusion criteria**

1. Aged under 18
2. Non-smoker
3. Not eligible for SilverCloud treatment

**Date of first enrolment**

07/02/2023

**Date of final enrolment**

31/12/2023

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**North East London NHS Foundation Trust**

West Wing

C E M E Centre

Marsh Way

Rainham

England

RM13 8GQ

**Study participating centre**

**Cornwall Partnership NHS Foundation Trust**

Carew House

Beacon Technology Park

Dunmere Road

Bodmin

England

PL31 2QN

**Study participating centre**

**Devon Partnership NHS Trust**

Wonford House Hospital

Dryden Road

Exeter

England

EX2 5AF

**Study participating centre**

**Greater Manchester Mental Health NHS Foundation Trust**

Prestwich Hospital

Bury New Road

Prestwich

Manchester

England

M25 3BL

**Study participating centre**

**Leicestershire Partnership NHS Trust Mental Health Services**

George Hine House  
Gipsy Lane  
Humberstone  
Leicester  
England  
LE5 0TD

**Study participating centre**

**Lincolnshire Partnership NHS Foundation Trust**

St George's  
Long Leys Road  
Lincoln  
England  
LN1 1FS

**Study participating centre**

**TalkPlus NE Hants & Farnham**

The Meads Business Centre  
19 Kingsmead  
Farnborough  
England  
GU14 7SR

**Study participating centre**

**Southern Health NHS Foundation Trust**

Tatchbury Mount Hospital  
Calmore  
Southampton  
England  
SO40 2RZ

**Study participating centre**

**South West Yorkshire Partnership NHS Foundation Trust**

Trust Headquarters  
Fieldhead Hospital  
Ouchthorpe Lane  
Wakefield  
England  
WF1 3SP

**Study participating centre**  
**Surrey and Borders Partnership NHS Foundation Trust**  
18 Mole Business Park  
Randalls Road  
Leatherhead  
England  
KT22 7AD

## Sponsor information

**Organisation**  
University of Bath

**ROR**  
<https://ror.org/002h8g185>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Cancer Research UK

**Alternative Name(s)**  
CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Other non-profit organizations

**Location**  
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: <https://researchdata.bath.ac.uk/>

At the end of the study, we will archive anonymised research data. Data will be uploaded to the University of Bath's Research Data Archive (<https://researchdata.bath.ac.uk/>). All data and data access will be restricted (<https://researchdata.bath.ac.uk/policies/>). Data is made available to approved bona-fide researchers, after they have signed a data access agreement, the person will be granted access to the University of Bath's Research Data Archive (<https://researchdata.bath.ac.uk/>) by the Research Data Services (<https://data.blogs.ilrt.org/>). Participants will consent to this process at the start of the study. Data stored in the Archive will have a Data Object identifier (DOI).

## IPD sharing plan summary

Stored in non-publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		05/12/2025	18/12/2025	Yes	No
<a href="#">Protocol article</a>		19/04/2024	22/04/2024	Yes	No
<a href="#">Basic results</a>		20/03/2025	20/03/2025	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>		13/03/2025	13/03/2025	No	Yes
<a href="#">Statistical Analysis Plan</a>	version 1.0	06/03/2024	12/11/2024	No	No