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Integrating smoking cessation treatment into online psychological care

Submission date
19/01/2023

Recruitment status
No longer recruiting

Registration date
02/02/2023

Overall study status
Completed

Last Edited
20/03/2025

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
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

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Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
304857

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 304857, 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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

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

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 measure
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

Secondary outcome measures
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

Overall study start date
01/10/2021

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

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
England

United Kingdom

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre
Cornwall Partnership NHS Foundation Trust
Carew House
Beacon Technology Park
Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

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

Study participating centre
Leicestershire Partnership NHS Trust Mental Health Services
George Hine House
Gipsy Lane
Humberstone
Leicester
United Kingdom
LE5 0TD

Study participating centre
Lincolnshire Partnership NHS Foundation Trust
St George's
Long Leys Road
Lincoln
United Kingdom
LN1 1FS

Study participating centre
TalkPlus NE Hants & Farnham
The Meads Business Centre
19 Kingsmead
Farnborough
United Kingdom
GU14 7SR

Study participating centre
Southern Health NHS Foundation Trust
Tatchbury Mount Hospital
Calmore
Southampton
United Kingdom
SO40 2RZ

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

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

Sponsor information

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University of Bath

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Sponsor type
University/education

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

ROR
https://ror.org/002h8g185

Funder(s)

Funder type

Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 13/03/2025:
The manuscript with the results of the feasibility study is to be submitted to Lancet Digital Health a high-impact peer-reviewed journal in the next 2-3 weeks.

Previous publication and dissemination plan:
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/04/2025

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 if 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?
HRA research summary			28/06/2023	No	No
Protocol article		19/04/2024	22/04/2024	Yes	No
Statistical Analysis Plan	version 1.0	06/03/2024	12/11/2024	No	No
Plain English results		13/03/2025	13/03/2025	No	Yes
Basic results		20/03/2025	20/03/2025	No	No