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The ESCAPE study: offering smoking cessation treatment as part of routine psychological care

Submission date
09/05/2018

Recruitment status
No longer recruiting

Registration date
15/05/2018

Overall study status
Completed

Last Edited
13/03/2025

Condition category
Mental and Behavioural Disorders

[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. In the UK, smoking rates have decreased from 46% during the 1970s to about 19% in recent years. However, smoking rates in people with mental illness have remained around 37%. People with depression/anxiety are twice as likely to smoke compared to people without depression/anxiety. Importantly, research suggests that if you give up smoking, this could result in improvements in mental health. People with mental illness are more likely to quit smoking if they receive psychological support, as well as receiving smoking cessation medication. For these reasons, this study will offer mental health service users help to quit smoking alongside their routine psychological therapy, to see if quit smoking treatments are accepted by service users and psychologists, and are feasible and successfully implemented in this setting. A smoking cessation intervention has been designed with service users, psychologists, and smoking cessation specialists. This study is testing the feasibility of incorporating this smoking cessation treatment into routine psychological care for people with depression and anxiety, to see whether it is accepted by service users and psychologists and whether it can be successfully implemented in NHS psychological therapy settings.

Who can participate?
Patients aged 18 or older with depression who are about to start psychological therapy, and who smoke and want to quit

What does the study involve?
Participants are randomly allocated to one of two treatments. Both treatments are very similar and involve behavioural, psychological support and medicine to help participants to quit. The difference between the treatments is that one is delivered alongside psychology therapy, and the other treatment involves being referred to the local stop smoking service at the end of the IAPT therapy. Participants allocated to receive the smoking treatment alongside their psychology therapy talk to their Psychological Wellbeing Practitioner about their smoking for up to 15 minutes during each therapy appointment. They are guided through behavioural techniques to support them through the quit attempt. The Psychological Wellbeing Practitioner also talks about the psychology of quitting, and how quitting might improve mental health. In addition, participants receive a smoking cessation medication of their choice to help with

withdrawal symptoms. Participants allocated to receive smoking treatment after their psychology therapy is finished receive a referral to their local stop smoking service, who offer a very similar treatment as described above based at their service. Treatment lasts a maximum of 12 weeks over 7 appointments.

What are the possible benefits and risks of participating?
Quitting smoking is the best thing one can do for your physical health and your overall wellbeing. By taking part one might increase your chances of quitting smoking. Also, the results from this study will help to inform a large study examining the effectiveness of offering smoking cessation treatment in psychological therapy settings. There are unlikely to be risks to participants' personal safety or health by taking part in this study, as all of the treatments offered are clinically proven to be safe. Due to the nature of mental health, participants may find taking part overwhelming, and they are welcome to leave the session and withdraw their information at any time and can contact Dr Gemma Taylor to discuss this afterwards. Alternatively, participants can contact Sane Mental Health Helpline on 0300 304 7000, or their health care provider.

Where is the study run from?
Bath and North East Somerset Primary Care Talking Therapies Service (UK), Black Country Healthcare NHS Foundation Trust (UK), and North East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to December 2022

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr Gemma Taylor, gmjm20@bath.ac.uk

Study website
https://www.escapestudy.com/

Contact information

Type(s)
Public

Contact name
Dr Gemma Taylor

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Additional identifiers

EudraCT/CTIS number

IRAS number
239339

ClinicalTrials.gov number

Secondary identifying numbers
Funder ID: C56067/A21330, IRAS 239339

Study information

Scientific Title
intEgrating Smoking Cessation treatment As part of usual Psychological care for dEpression and anxiety (ESCAPE): a randomised and controlled, multicentre, acceptability, feasibility and implementation trial

Acronym
ESCAPE

Study objectives
The aim of this study is to examine if it is possible to treat tobacco addiction alongside usual IAPT care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Health Service Research Ethics Committee, 19/03/2018, IRAS ID: 239339

Study design
Randomized controlled multicentre trial with nested qualitative methods

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

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 addiction (smoking)

Interventions
The randomisation sequence will be generated using computer software, RedCap (i.e., an online central randomisation service provided by Bristol Medical School). Randomisation will be stratified by site and blocked, and participants will be randomised using a 1:1 algorithm to ensure an equal number of participants in the treatment and control arms. Allocation concealment will be ensured as the randomisation code will not be released until the IAPT client has been recruited into the trial, which takes place after participant eligibility has been assessed, participant identifier has been recorded and consent gained to take part in the trial and to being randomly allocated to treatment condition. Randomisation will be requested via RedCap by the researcher who recruited and consented the participant into the trial. RedCap will send a response to the researcher informing them which treatment the participant will be receiving. Randomisation can only be requested once and after participant identifier, eligibility and consent has been recorded, and therefore implementation cannot be influenced by the PWP, participant, the research or clinical team.

Both treatments are very similar and involve behavioural, psychological support and medicine to help participants to quit. The difference between the treatments is that one will be delivered alongside psychology therapy, and the other treatment will involve being referred to the local stop smoking service at the end of the IAPT therapy.

Participants assigned to receive the smoking treatment alongside their psychology therapy will talk to their Psychological Wellbeing Practitioner about their smoking for up to 15 minutes during each therapy appointment. They will be guided through behavioural techniques to support them through the quit attempt. The Psychological Wellbeing Practitioner will also talk about the psychology of quitting, and how quitting might improve mental health. In addition, participants receive a smoking cessation medication of their choice to help with withdrawal symptoms.

Participants assigned to receive smoking treatment after their psychology therapy is finished will receive a referral to their local stop smoking service, who will offer a very similar treatment as described above based at their service.

Treatment will last a maximum of 12 weeks over 7 appointments.

Intervention Type
Mixed

Primary outcome measure
Retention in the smoking cessation treatment, measured at treatment appointments 1 to 6

Secondary outcome measures
Current secondary outcome measures as of 08/02/2021:
Smoking-related:
1. Biochemically-verified 7-day point prevalence smoking cessation at 3 and 6 months after baseline
2. Number of cigarettes smoked per day, measured at enrolment, treatment appointments 1 to 6, and 3 and 6 months after baseline

3. Heaviness of Smoking Index, measured at enrolment, treatment appointments 1 to 6, and 3 and 6 months after baseline

Mental health-related:
1. Symptoms of depression, measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, treatment appointments 1 to 6, and 3 and 6 months after baseline
2. Symptoms of anxiety, measured with General Anxiety Disorder-7 (GAD-7) questionnaire at baseline, treatment appointments 1 to 6, and 3 and 6 months after baseline

Service-related:
1. Number of “Did Not Attends”, number of planned and completed IAPT sessions, measured at treatment appointments 1 to 6

Acceptability and feasibility
1. Participant and clinician acceptability and satisfaction of intervention as assessed by questionnaires and qualitative interviews at 3 months after baseline. Interviews also explore the acceptability and feasibility of data collection procedures and the impact of smoking cessation treatment on usual care and psychological recovery.

Implementation-related
1. Intervention delivery checklist and qualitative analysis of intervention delivery measured at treatment appointments 1 to 6

Secondary outcome measures as of 03/10/2019:
Smoking-related:
1. Biochemically-verified 7-day point prevalence smoking cessation at 3 and 6 months after baseline
2. Number of cigarettes smoked per day, measured at enrolment, treatment appointments 1 to 6, and 3 and 6 months after baseline
3. Heaviness of Smoking Index, measured at enrolment, treatment appointments 1 to 6, and 3 and 6 months after baseline

Mental health-related:
Symptoms of depression, measured using PHQ-9

Service-related:
Number of “Did Not Attends”, number of planned and completed IAPT sessions, measured at treatment appointments 1 to 6

Acceptability and feasibility
Participant and clinician acceptability and satisfaction of intervention as assessed by questionnaires and qualitative interviews, interviews also explore acceptability and feasibility of data collection procedures, and impact of smoking cessation treatment on usual care and psychological recovery. Assessed at 3 months after baseline

Implementation-related
intervention delivery checklist, qualitative analysis of intervention delivery, measured at treatment appointments 1 to 6

Secondary outcome measures as of 30/11/2018:
Smoking-related:
1. Biochemically-verified 7-day point prevalence smoking cessation at 3 months after baseline

2. Number of cigarettes smoked per day, measured at enrolment, treatment appointments 1 to 6 and 3 months after baseline
3. Heaviness of Smoking Index, measured at enrolment, treatment appointments 1 to 6 and 3 months after baseline

Mental health-related:
Symptoms of depression, measured using PHQ-9

Service-related:
Number of “Did Not Attends”, number of planned and completed IAPT sessions, measured at treatment appointments 1 to 6

Acceptability and feasibility
Participant and clinician acceptability and satisfaction of intervention as assessed by questionnaires and qualitative interviews, interviews also explore acceptability and feasibility of data collection procedures, and impact of smoking cessation treatment on usual care and psychological recovery. Assessed at 3 months after baseline

Implementation-related
intervention delivery checklist, qualitative analysis of intervention delivery, measured at treatment appointments 1 to 6

Previous secondary outcome measures:
Smoking-related:
1. Biochemically-verified 7-day point prevalence smoking cessation at 3 months after baseline
2. Number of cigarettes smoked per day, measured at enrolment, treatment appointments 1 to 6 and 3 months after baseline
3. Heaviness of Smoking Index, measured at enrolment, treatment appointments 1 to 6 and 3 months after baseline

Mental health-related:
1. Symptoms of depression, measured using PHQ-9
2. Symptoms of anxiety, measured using GAD-7

Service-related:
Number of “Did Not Attends”, number of planned and completed IAPT sessions, measured at treatment appointments 1 to 6

Acceptability and feasibility
Participant and clinician acceptability and satisfaction of intervention as assessed by questionnaires and qualitative interviews, interviews also explore acceptability and feasibility of data collection procedures, and impact of smoking cessation treatment on usual care and psychological recovery. Assessed at 3 months after baseline

Implementation-related
intervention delivery checklist, qualitative analysis of intervention delivery, measured at treatment appointments 1 to 6

Overall study start date
01/01/2018

Completion date

31/12/2022

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Has current diagnosis of depression (clinician administered PHQ-9 score of ≥ 10) and/or anxiety (clinician administered GAD-7 score of ≥8) (note: other mental health comorbidities are allowable)
3. Self-reported, daily tobacco smoker of at least 1 year
4. Interested in receiving help to quit smoking tobacco
5. Eligible for IAPT treatment on a one-to-one basis over the telephone or face-to-face
6. About to start psychological therapy for depression/anxiety in IAPT

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
157

Total final enrolment
135

Key exclusion criteria
1. Already started IAPT treatment
2. Considered too unwell by research or clinical team (i.e. the IAPT provider)
3. Pregnant or breastfeeding

Date of first enrolment
01/06/2018

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bath and North East Somerset Primary Care Talking Therapies Service
Hillview Lodge
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Black Country Healthcare NHS Foundation Trust
The Beeches
Penn Hospital
Penn Road
Wolverhampton
United Kingdom
WV4 5HN

Study participating centre
North East London NHS Foundation Trust
Research and Development
1st floor Maggie Lilley Suite
Goodmayes Hospital
lford
United Kingdom
IG3 8XJ

Sponsor information

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University of Bath

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Sponsor type

University/education

ROR
https://ror.org/0524sp257

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
The trialists will be submitting the protocol to a peer reviewed journal and will submit the results in a peer-reviewed medical journal at the end of 2019.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
This project will have a restricted-access sharing policy because of the sensitive nature of the data being collected from participants (https://data.bris.ac.uk/sensitive-research-data/). Data will be 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 Bristol's Data Repository (https://data.bris.ac.uk) by the Research Data Services (https://data.blogs.ilrt.org/). Data will be stored for 25 years. Administration, transcript and audio data will be destroyed after the study period and will not be shared. All data listed on the University's online Research Data Repository (https://data.bris.ac.uk) will be noted formally in academic citations with a Digital Object Identifier (DOI). During dissemination to academic, NHS, and IAPT client collaborators – access to the Research Data Repository will be noted. The study will have a webpage, which will also

include a link to the online Research Data Repository and details about applying for access. Please contact Dr Gemma Taylor for access.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/01/2019	05/11/2019	Yes	No
Statistical Analysis Plan	version 1	19/10/2021	19/10/2021	No	No
Statistical Analysis Plan	version 1.1	04/11/2021	04/11/2021	No	No
Other publications	Service-user experiences	08/12/2022	12/12/2022	Yes	No
Other publications	Embedded qualitative study	12/10/2022	10/07/2024	Yes	No
Results article		11/03/2025	13/03/2025	Yes	No