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Smoking cessation for severe mental ill health trial

Submission date
15/01/2015

Recruitment status
No longer recruiting

Registration date
16/01/2015

Overall study status
Completed

Last Edited
15/02/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Smoking is an important health issue, not just in the general public but also among people with severe mental ill health, and a large proportion of people who have experienced severe mental illnesses, such as schizophrenia or bipolar disorder, smoke. Not only are these people more likely to smoke, they smoke more heavily, are more addicted to nicotine and are less likely to receive help in quitting, compared to the general population. Smoking is a preventable health hazard, with proven associations with diseases such as cancer and heart disease. Smoking behaviour contributes to the poor physical health of people with severe mental ill health, increasing their risk of an early death. The introduction of public smoking bans and other government anti-smoking strategies have highlighted the smoking issue, prompting people to consider giving up smoking. Nicotine is the addictive component of smoking, causing smokers to have extreme difficulty in quitting. Various drugs and services are available to people wanting help to quit. However, these are targeted at the general public and it is not known if and how well these would work in people with severe mental ill health. People with mental health problems do express a desire to stop smoking, but they may require different strategies and greater support to help them quit smoking. To address this problem, we aim to evaluate a 'bespoke smoking cessation' (BSC) service specifically tailored to individual patients with severe mental ill health.

Who can participate?
People with a diagnosis of severe mental ill health who smoke and would like to stop or cut down on smoking.

What does the study involve?
Participants will be randomly allocated into one of two groups: a bespoke smoking cessation intervention or usual GP care. Those allocated to the bespoke smoking cessation intervention will be assigned a mental health nurse or allied health professional trained to deliver smoking cessation interventions. They will work with the patient and the patient's GP or mental health specialist to advise on anti-smoking medication and provide behavioural support in the form of information, support and motivation sessions on cutting down to quit, setting quit dates and maintaining smoking abstinence. They will also regularly check the health and smoking status of

the patient. This service is similar to that used in regular smoking cessation services, but with the specific adaptations of support, medication and tailoring support to the individual needs of patients with severe mental ill health.

What are the possible benefits and risks of participating?
Stopping smoking is the single most helpful thing people can do to improve their health. Stopping smoking also has the added benefit of saving a lot of money that would have spent on cigarettes. Stopping smoking can lead to withdrawal symptoms. These are normal symptoms which may be particularly strong when someone first quits, but should lessen over time.

Where is the study run from?
The main centre of the trial is York. We also expect to recruit participants from Manchester, Durham, Leeds, Sheffield, Leeds, London and Southampton.

When is the study starting and how long is it expected to run for?
The study will start recruiting in July 2015 and will recruit for 18 months. Participants will then be followed up for 12 months. An additional follow up will be carried out 3 years post randomisation. This follow up was not in the original protocol and the decision to include the additional follow up was made in 2018.

Who is funding the study?
The trial is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
N/A

IRAS number

ClinicalTrials.gov number
N/A

Secondary identifying numbers
HTA 11/136/52

Study information

Scientific Title
Smoking Cessation for Severe Mental Ill Health Trial (SCIMITAR+): a definitive randomised evaluation of a bespoke smoking cessation service

Acronym
SCIMITAR+

Study objectives
1. A bespoke smoking cessation service for people with severe mental ill health is more clinically effective than usual GP care in helping people to stop smoking
2. A bespoke smoking cessation service for people with severe mental ill health is more cost effective than usual GP care in helping people to stop smoking

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 01/04/2019:
REC approval for the 3 year follow up was given by NRES Committee Yorkshire & The Humber - Leeds East REC, 25/01/2019, ref: 18/YH/0499

Previous ethics approval:
NRES Committee Yorkshire & The Humber - Leeds East REC, 19/03/2015, ref: 15/YH/0051

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Tobacco addiction in severe mental ill health

Interventions
Active intervention: bespoke smoking cessation tailored to the needs of people with severe mental ill health delivered by mental health nurse or other health professional trained in smoking cessation counselling. The nurse or other health professional will work in conjunction with the patient and patients' GP or mental health specialist to provide a smoking cessation service individually tailored to each patient. This service will be in line with current National Institute for Clinical Excellence (NICE) guidelines for smoking cessation services.

Control intervention: usual care.

The total duration for the treatment and follow-up combined will be 12 months post-recruitment. This applies for both active and control intervention arms of the trial.

Intervention Type
Behavioural

Primary outcome measure
Self-reported smoking cessation at 12 months post-recruitment verified by carbon monoxide breath measurement

Secondary outcome measures
All secondary outcomes will be measured at the 6 and 12 month timepoints:
1. Reduction in the number of cigarettes smoked per day (self-report)
2. Dependence on smoking as assessed by the Fagerstrom Nicotine Dependence Questionnaire
3. Level of motivation as assessed by the Motivation to quit questionnaire
4. Patient Health Questionnaire 9 (PHQ-9)
5. Health Related Quality of Life (SF-12)
6. EuroQol EQ-5D

Added 24/10/2016:
7. BMI
8. Health service use, collected via a bespoke questionnaire

Added 28/08/2018:
9. Anxiety measured using GAD-7 at baseline, 6 and 12 months

Overall study start date
01/01/2015

Completion date

01/07/2018

Eligibility

Key inclusion criteria
As of 14/10/2016:
Adults of all ages (either sex) with a documented diagnosis of severe and enduring mental illness (schizophrenia or delusional/psychotic illness or bipolar disorder) who currently smoke at least 5 tobacco cigarettes per day and are interested in cutting down or quitting smoking

Initial:
Adults of all ages (either sex) with severe and enduring mental illness who currently smoke and are interested in cutting down or quitting smoking

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Total final enrolment
526

Key exclusion criteria
1. Patients with alcohol dependence
2. Patients with co-morbid drug addiction
3. Non-English speaking

Added 14/10/2016:
1. Lack of capacity to consent
2. Pregnant or breastfeeding
3. Currently receiving advice from a stop smoking adviser

Date of first enrolment
01/07/2015

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Health Sciences
University of York
Heslington
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/01/2017	30/01/2017	Yes	No
Results article	results	19/01/2018	29/03/2019	Yes	No
Results article	results	01/05/2019	15/04/2019	Yes	No
Results article	results	01/09/2019	27/09/2019	Yes	No
Results article	results	15/10/2020	22/10/2020	Yes	No
Results article	cross-sectional study results	01/09/2020	17/05/2021	Yes	No
Other publications	SWAT results	20/11/2019	15/02/2023	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No