

A Smoking Cessation Intervention for Severe Mental Ill Health Trial (SCIMITAR)

Submission date 29/06/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/09/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/41/05

Study information

Scientific Title

A Smoking Cessation Intervention for Severe Mental Ill Health Trial: a pilot study and definitive randomised evaluation of a bespoke smoking cessation service

Acronym

SCIMITAR

Study objectives

1. Bespoke smoking cessation service for people with severe mental ill health is more acceptable than usual GP care
2. Bespoke smoking cessation service for people with mental ill health is more clinically effective than usual GP care in facilitating smoking cessation
3. Bespoke smoking cessation service for people with mental ill health is more cost effective than usual GP care in facilitating smoking cessation

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Pilot study and definitive fully 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Tobacco addiction in severe mental illness

Interventions

Active intervention: mental health nurse trained in smoking cessation counselling 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 with mental ill health. This service will be in

line with current National Institute for Clinical Excellence (NICE) guidelines for smoking cessation services and will include group support sessions for patients with mental ill health, pharmacotherapies to aid smoking cessation in addition to regular follow up by the smoking cessation officer.

Control intervention: GP or mental health specialist following current NICE guidelines for smoking cessation services. This may include pharmacotherapies to aid smoking cessation, access to self-help materials and referral to local NHS stop smoking clinics.

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

Smoking cessation measured at 12 months post-recruitment (validated using carbon monoxide measurements).

Secondary outcome measures

1. Self reported smoking cessation at 4, 6 and 12 months
2. Health related quality of life (36-item short form health survey [SF-36])
3. Health-state utility (EQ5D) at 4, 6 and 12 months

Overall study start date

01/06/2010

Completion date

31/12/2012

Eligibility

Key inclusion criteria

Adults of all ages (either sex) with severe and enduring mental illness who currently smoke.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Patients with alcohol dependence
2. Patients with co-morbid drug addiction

Date of first enrolment

01/06/2010

Date of final enrolment

31/12/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of York

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

University of York (UK)

Sponsor details

Heslington

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Sponsor type

University/education

Website

<http://www.york.ac.uk>

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

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2015		Yes	No
Results article	results	01/05/2015		Yes	No