

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

Submission date 29/06/2009	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 03/07/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/09/2015	Condition category Mental and Behavioural Disorders	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Pilot study and definitive fully randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

University of York
York
United Kingdom
YO10 5DD

Sponsor information

Organisation

University of York (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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