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

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
29/06/2009		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
03/07/2009		[X] Results		
Last Edited	Condition category	Individual participant data		
14/09/2015	Mental and Behavioural Disorders			

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

**Prof Simon Gilbody** 

#### Contact details

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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

#### Study design

Pilot study and definitive fully randomised controlled trial

#### Primary study design

Interventional

#### 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** 

Results article	results	01/03/2015		Yes	No
Results article	results	01/05/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes