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

Submission date	Recruitment status
29/06/2009	No longer recruiting
Registration date	**Overall study status**
03/07/2009	Completed
Last Edited	**Condition category**
14/09/2015	Mental and Behavioural Disorders

✓ Prospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Simon Gilbody

Contact details
Area 4, Seebohm Rowntree Building
Department of Health Sciences
University of York
Heslington
York
United Kingdom
YO10 5DD
+44 (0)1904 321370
sg519@york.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

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 hypothesis
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

Condition
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

Overall study end date
31/12/2012

Eligibility

Participant 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

Participant exclusion criteria

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

Recruitment start date
01/06/2010

Recruitment end date
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
York
England
United Kingdom
YO10 5DD
+44 (0)1904 430000
mm714@york.ac.uk

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