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

Submission date
29/06/2009

Registration date
03/07/2009

Last Edited
14/09/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
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

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	Date created	Date added	Peer reviewed?	Patient-facing?

| [Results article](#) | results | 01/03/2015 | Yes | No |
| [Results article](#) | results | 01/05/2015 | Yes | No |