

Promoting smoking cessation in Bangladeshi and Pakistani male adults: pilot randomised controlled trial

Submission date
08/06/2006

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
11/09/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
22/11/2011

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

Contact name

Prof Aziz Sheikh

Contact details

Professor of Primary Care Research & Development
Division of Community Health Sciences: GP Section
University of Edinburgh
20 West Richmond Street
Edinburgh
United Kingdom
EH8 9DX
Aziz.sheikh@ed.ac.uk

Additional identifiers

Protocol serial number

G0501288

Study information

Scientific Title

Study objectives

As of 02/07/2007:

The aims of this work are to:

1. Refine two ('clinic' and 'clinic + outreach') models of using trained community smoking cessation workers to deliver smoking cessation services (Phase 1)
2. Conduct a pilot randomised controlled trial comparing the likely uptake and effectiveness of these models of care (Phase II of the complex interventions framework)

Previous hypotheses:

The aims of this work are to:

1. Refine two ('clinic' and 'clinic + outreach') models of using trained community smoking cessation workers to deliver smoking cessation services (Phase 1)
2. Conduct a pilot randomised controlled trial comparing the likely uptake and effectiveness of these models of care with standard care (Phase II of the complex interventions framework)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from South Staffordshire LREC in April 2007 (ref: 06/Q2602/57).

Study design

Pilot randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

Please note that as of 02/07/2007 the start date of this trial was changed to 01/10/2006, and the anticipated end date of this trial has been changed to 30/09/2008.

Current interventions as of 02/07/2007:

'The interventions to be tested in this two arm pilot trial are:

1. Trained community smoking cessation officer based in smoking cessation clinic ('clinic only')
2. Trained smoking cessation facilitator working in the clinic and also in an outreach capacity with clients in a location of their choosing ('clinic + outreach')

Previous interventions:

The interventions to be tested in this three arm pilot trial are:

1. Standard care (control)
2. Trained community smoking cessation officer based in smoking cessation clinic ('clinic only')
3. Trained smoking cessation facilitator working in the clinic and also in an outreach capacity with clients in a location of their choosing ('clinic + outreach')

Intervention Type

Other

Phase

Phase I/II

Primary outcome(s)

Our main overall outcome of interest for this work is to refine, pilot and have the data needed to inform sample size calculations for a definitive trial evaluating these interventions.

Key secondary outcome(s)

Added as of 02/07/2007:

1. Patient adherence to pharmacotherapy
2. Patient satisfaction with the stop smoking service accessed

Completion date

28/02/2008

Eligibility**Key inclusion criteria**

1. All consenting self-assigned (using Census 2001 categories) Pakistani and Bangladeshi adults (18 years or older)
2. Regular smokers (defined as self-declared usage of on average more than or equal to one cigarette/day) who want to quit

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

Key exclusion criteria

Those unwilling or unable to give informed consent will be excluded.

Date of first enrolment

01/03/2006

Date of final enrolment

28/02/2008

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre

Professor of Primary Care Research & Development

Edinburgh

United Kingdom

EH8 9DX

Sponsor information

Organisation

University of Edinburgh (UK)

ROR

<https://ror.org/01nrxf90>

Funder(s)

Funder type

Government

Funder Name

National Prevention Research Initiative (NPRI) (UK) (ref: G0501288)

Results and Publications

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				

[Results article](#)

[Protocol article](#)

protocol

19/08/2011

14/08/2009

Yes

Yes

No

No