

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

Submission date 08/06/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/11/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

Added as of 02/07/2007:

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

Overall study start date

01/03/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

180

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**

Scotland

United Kingdom

Study participating centre

Professor of Primary Care Research & Development

Edinburgh

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Sponsor information**Organisation**

University of Edinburgh (UK)

Sponsor details

College of Medicine and Veterinary Medicine Office

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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Government

Funder Name

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

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?
Protocol article	protocol	14/08/2009		Yes	No
Results article	results	19/08/2011		Yes	No