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

Submission date
08/06/2006

Recruitment status
No longer recruiting

Registration date
11/09/2006

Overall study status
Completed

Last Edited
22/11/2011

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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Sponsor information

Organisation
University of Edinburgh (UK)

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College of Medicine and Veterinary Medicine Office
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Sponsor type
University/education

ROR
https://ror.org/01nrxwf90

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