ISRCTN03732457 https://doi.org/10.1186/ISRCTN03732457

A study on implementing a smoking reduction programme through General Practices

Submission date	Recruitment status	[X] Prospectively registered
29/09/2010	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/10/2010	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/05/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Taina Taskila

Contact details
Primary Care Clinical Sciences
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1

Study information

Scientific Title
A randomised controlled trial testing the feasibility of nicotine assisted reduction to stop in General Practice

Acronym
RedGP

Study objectives
1. General Practices can successfully implement smoking reduction programme as part of their stop smoking service
2. Reducing smoking gradually will help people with chronic conditions to stop smoking

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands REC Centre, ref: 10/H1208/67

Study design
2-arm cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Smoking reduction

Interventions
Participants will be randomised into either an intervention group receiving a smoking reduction service or a control group receiving the standard NHS care.

Participants in the intervention group will be encouraged to use both a nicotine patch and a short acting form of NRT. Patients who agree to behavioural support, will be in the trial for a minimum of 2 weeks and maximum of 20 weeks.

The programme will be evaluated using qualitative methods. Semi structured interviews with a sample of GPs and their medical staff as well as trial participants.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Number of people within the populations of interest that are offered smoking reduction programmes
2. Number that take up the offer
3. Number of behavioural support visits made
4. Amount of NRT used
5. Number that complete reduction programmes
6. All episodes where a GP records that a patient stopped NRT due to adverse events

Secondary outcome measures
1. Number of people within the population of interest that try to quit smoking
2. Number that succeed in quitting: Success defined as a self-report of at least four weeks of complete cessation verified by at least one CO reading of <10ppm, which is in line with the NHS standard
3. Proportion of people that meet the GCP criteria for serious adverse events and the occurrence of any events of interest e.g. hospitalisation for acute coronary syndrome in those with ischaemic heart disease. These are events where smoking cessation might be expected to reduce the incidence.
4. All hospitalisations and visits to the GP, classifying the latter as scheduled for chronic care and incidental events
5. Number of people that reduce their smoking: Smoking reduction defined as smoking <50% of baseline cigarettes per day accompanied by a fall of at least 1ppm in exhaled carbon monoxide

Overall study start date
01/12/2010

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Males and females 18 years or older
2. People with one or more of the following chronic conditions:
2.1. Ischaemic heart disease
2.2. Hypertension
2.3. Diabetes mellitus
2.4. Stroke
2.5. Asthma
2.6. Chronic Obstructive Pulmonary Disease (COPD)
2.7. Chronic kidney disease
2.8. Schizophrenia
2.9. Bipolar disorder
3. For the intervention arms only: Daily smokers with either a carbon monoxide (CO) of at least

10 parts per million (ppm) at least 15 minutes after last smoking or smoke at least 10 cigarettes or 8g of loose tobacco as roll your own cigarettes daily
4. As the programme will be offered as a part of normal follow-up care, consent will not be required.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
Does not match inclusion criteria.
All smokers, regardless of interest are included in the denominator population. Some smokers might not be offered NRT if, in the judgement of their GP, it would be unsafe to do so. The situations where this might occur include:
1. Has had severe reactions to NRT previously
2. Unstable angina pectoris, myocardial infarction, acute coronary syndrome, or cerebrovascular accident during the last 3 weeks
3. Severe cardiac arrhythmia
4. Currently uncontrolled hyperthyroidism
5. Active phaeocromocytoma
6. Pregnancy or lactation

Date of first enrolment
01/12/2010

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Care Clinical Sciences
Birmingham

United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham

Sponsor details
c/o Dr Brendan Laverty
Edgbaston
Birmingham
England
United Kingdom
B15 2TT

Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Heart of Birmingham Teaching Primary Care Trust (UK) - (REF: 114000391)

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