

A study on implementing a smoking reduction programme through General Practices

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Primary Care Clinical Sciences

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham

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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration