

Testing the feasibility of nicotine-assisted reduction to stop in pharmacies

Submission date 15/02/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/02/2017	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
G0802135

Study information

Scientific Title

Testing the feasibility of nicotine-assisted reduction to stop in pharmacies: a 2x2 factorial trial

Acronym

RedPharm

Study objectives

This pilot study aims to examine the feasibility of nicotine-assisted reduction to stop (NARS) in pharmacies and also to see if behavioural support and the length of the trial affects the success rate for cessation. The trial will test how well pharmacists can be trained to implement NARS and how this is received by smokers and by pharmacists.

Primary aims:

To test the processes, examine implementation issues, and reactions to the programme of those involved

Secondary aims:

1. Investigate whether behavioural support is more effective than no support
2. Investigate whether shorter reduction programmes are more effective

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval pending from South Birmingham REC on 16/03/2010

Study design

Multicentre randomised 2x2 factorial design controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Public Health

Interventions

This trial has a 2x2 factorial design. The pharmacists will recruit 16 patients per pharmacy; 160 smokers altogether. Participants will be randomised in sealed envelopes to receive:

1. Behavioural support
- 1.1. 52 weeks

1.2. 4 weeks

The pharmacist will give support for 52 weeks by inviting participants to set a treatment goal and provide advice on how to reduce cigarettes. Participants in the 4-week supported programme will be given the same advice with the reduction but with a different schedule. Participants will be provided with a weeks worth of Nicotine Replacement Therapy every week for the duration of their participation in the trial.

2. No support

2.1. 52 weeks

2.2. 4 weeks

Participants in the no support arms will not be given advice or support. Instead they will be given a leaflet that describes the reduction programmes, and encourages use of Nicotine Replacement Therapy (NRT) to support the reduction.

The trial will run for 52 weeks regardless of the trial arm, it is only the way they reduce the amount they smoke that will differ. The NRT will be given by the recruiting pharmacist. The participants will also be asked to provide a CO2 reading at their first appointment, at the last appointment and also after every time they have gone smoke free for a month.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Hospital Anxiety Depression Scale (HADS) measured at baseline and the end of follow up (52 weeks)
2. Smoking behaviour measured at baseline
3. Service satisfaction questionnaire at end of follow up (52 weeks)

Secondary outcome measures

Cessation activity: at 4 wks, 8 wks, 12, 16, 20, 24 etc. every month until the end of the trial (52 weeks) (11 measures)

Overall study start date

02/06/2010

Completion date

01/07/2012

Eligibility

Key inclusion criteria

1. Male or female, 18 years or older
2. Smokes at least 10 cigarettes or 12.5g of loose tobacco daily as roll your own cigarettes, or blows 15ppm or above on CO recording
3. Do not intend to stop in the next month, but are prepared to reduce their consumption with any of the programmes offered
4. Evidence of a personally signed and dated informed consent document indicating that the subject has been informed of all pertinent aspects of the study and consents to participate and be randomised to either arm and have either a telephone or email for follow-up

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

320

Key exclusion criteria

1. Currently using other NRT, bupropion, nortriptyline, mecamylamine, reserpine, or varenicline, or undergoing any treatment for tobacco dependence (e.g. acupuncture),
2. Unstable angina pectoris, myocardial infarction, or cerebrovascular accident during the last 3 weeks,
3. Severe cardiac arrhythmia
4. Currently uncontrolled hyperthyroidism
5. Active pheochromocytoma
6. Pregnancy, lactation or intended pregnancy
7. Participation in other medicinal trials within the last three months and during study participation,
8. Previously had severe skin reactions to nicotine patches or severe eczema or other skin diseases that make patch use hazardous or undesirable
9. Severe acute or chronic medical or psychiatric condition or previously diagnosed clinically important renal or hepatic disease, that may increase the risk associated with study participation or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the subject inappropriate for entry into this study

Date of first enrolment

02/06/2010

Date of final enrolment

01/07/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The University of Birmingham
Birmingham
United Kingdom
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Sponsor information

Organisation

University of Birmingham (UK)

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) - National Prevention Research Initiative (NPRI) (ref: G0802135)

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	12/03/2012		Yes	No
Results article	results	17/02/2017		Yes	No