ISRCTN54805841 https://doi.org/10.1186/ISRCTN54805841

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

Submission date	Recruitment status	[X] Prospectively registered
15/02/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/02/2017	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
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)

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

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 phaeocromocytoma
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
United Kingdom

England

Study participating centre
The University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

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

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?
Results article	results	17/02/2017		Yes	No
Protocol article	protocol	12/03/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes