ISRCTN70036823 https://doi.org/10.1186/ISRCTN70036823

Trial of muscle relaxation as an aid to stopping smoking

Submission date	Recruitment status	[ ] Prospectively registered
31/03/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/10/2008	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
A pilot randomised controlled trial of the value of bodyscan and isometric exercises in reducing urge to smoke in smokers attempting to quit

Study objectives
1. To examine the uptake and use of isometric exercises and bodyscan sent by email to smokers trying to stop
2. To examine the effects of the exercises on the urge to smoke and withdrawal
3. To examine the effects of the exercises on abstinence

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the South Birmingham NHS Local Research Ethics Committee on the 21st December 2006 (ref: RD/52574/1).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Intervention:
Email of instruction sheets and mp3 files giving instructions for use when the urge to smoke strikes. Participants will be followed weekly for four weeks after quit day and asked to do the exercises as often as they can during the four weeks when the urge to smoke strikes.

Control:
Control participants will have no exercises.

Both groups receive standard smoking cessation treatment (nicotine replacement therapy plus behavioural support at the weekly sessions).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Primary outcomes measured and analysed on a week by week basis:
1. Reported use of exercises and helpfulness: the proportion of people that used either bodyscan or isometric exercises to deal with the urge to smoke
2. Urge to smoke: measured using the Mood and Physical Symptoms Score (MPSS) questionnaire
3. Withdrawal severity: measured using the Mood and Physical Symptoms Score (MPSS) questionnaire

Prolonged abstinence at 4 weeks measured according to the Russell standard means that lapses in the first two weeks of attempted quitting do not count against abstinence, but total abstinence must be maintained for weeks 3 - 4 and that abstinence is confirmed by exhaled carbon monoxide less than 10 ppm. Participants lost to follow up would be counted as smokers.

Secondary outcome measures
Prolonged biochemically confirmed smoking abstinence at four weeks.

Overall study start date
01/01/2007

Completion date
31/03/2007

Eligibility

Key inclusion criteria
Smokers:
1. Aged 18 years and older, either sex
2. Wanting to quit
3. Attending the smoking cessation clinic
4. Prepared to do the exercise interventions if randomised to them
5. Who have an active email address to receive the intervention material

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
Does not comply with the above inclusion criteria.

Date of first enrolment
01/01/2007

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Care & General Practice
Birmingham
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Sponsor information

Organisation
University of Birmingham (UK)

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Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
University/education

Funder Name
University of Birmingham (UK) - covering the costs of the project

Funder Name
NHS will pay for the treatment costs

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?
Results article	Results	06/10/2008		Yes	No