

Trial of muscle relaxation as an aid to stopping smoking

Submission date 31/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/10/2008	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul Aveyard

Contact details
Department of Primary Care & General Practice
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 8529
p.n.aveyard@bham.ac.uk

Additional identifiers

Protocol serial number
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).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Prolonged biochemically confirmed smoking abstinence at four weeks.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre
Department of Primary Care & General Practice
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (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

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

