# Trial of muscle relaxation as an aid to stopping smoking

Submission date 31/03/2008	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 09/05/2008	<b>Overall study status</b> Completed	
Last Edited 24/10/2008	<b>Condition category</b> Mental and Behavioural Disorders	[] 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**

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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

Urge to smoke: measured using the Mood and Physical Symptoms Score (MPSS) questionnaire
 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

## 51/05/2007

# 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 United Kingdom B15 2TT

## Sponsor information

**Organisation** University of Birmingham (UK)

## Sponsor details

Edgbaston Birmingham England United Kingdom B15 2TT +44 (0)121 414 3344 b.laverty@bham.ac.uk

**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