

# Improving behavioural support for reducing smoking among those who want to cut down

<b>Submission date</b> 05/07/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/05/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

NHS smoking cessation treatment aims to help people to remain abstinent after a quit attempt, but even with the best available support as few as 22% are abstinent at 12 months. Studies have shown that during smoking abstinence, a short period of physical activity (e.g., a brisk walk, seated exercise) reduces cravings and withdrawal symptoms, and delays the time between smoking cigarettes. Physical activity has the potential to increase cessation rates. In this study we wish to examine whether physical activity enhances quit attempts and successful quitting among 'hard-to-reach' smokers from lower socio-economic groups.

### Who can participate?

Heavy smokers (more than 15 cigarettes per day) aged 18 and over who wish to cut down but who have not yet quit.

### What does the study involve?

Participants are randomly allocated to one of two groups. One group receives brief advice on cutting down. The other group receives brief advice and also a physical activity intervention (Health Trainer counselling, use of pedometers and guidance into free physical activity options). Both groups are offered support by the Plymouth NHS Stop Smoking Service for up to 6 weeks. The smoking status of all participants is assessed at 8 and 16 weeks after the start of the study, and at 4 weeks after any quit attempt. We also assess the number of quit attempts, quality of life, withdrawal symptoms, cravings, readiness to quit, confidence to quit and stay quit, use of NHS Stop Smoking Service; physical activity and weight. Taped interviews are conducted with GPs, stop smoking advisors and smokers to assess the feasibility and acceptability of the study procedures.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

University of Exeter (UK)

When is the study starting and how long is it expected to run for?  
September 2010 to November 2012

Who is funding the study?  
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?  
Prof Adrian Taylor  
a.h.taylor@ex.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Adrian Taylor

**Contact details**  
School of Sport & Health Sciences  
University of Exeter  
St. Luke's Campus  
Heavitree Road  
Exeter  
United Kingdom  
EX1 2LU  
+44 (0)1392 264 747  
a.h.taylor@ex.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HTA 07/78/02

## Study information

**Scientific Title**  
An exploratory trial to evaluate the effects of a physical activity intervention as a smoking cessation induction and cessation aid among the 'hard to reach'

**Acronym**  
EARS (Exercise Assisted Reduction then Stop)

**Study objectives**

**Primary objective:**

To develop a multi-component physical activity (PA) intervention aimed at helping smokers (not intending to quit in the next month), among 'hard to reach' groups, to cut down.

**Secondary objectives:**

1. To assess via interview the acceptability of such a PA intervention as an aid to cutting down, among 'hard to reach' smokers
2. To assess via interview the acceptability of recruitment, assessment and randomisation procedures within a pilot pragmatic randomised controlled trial to compare the effects of a PA intervention versus brief advice (usual care) on quitting, among 'hard to reach' smokers
3. To obtain an estimate of the intervention (PA versus brief advice) effect size, relative risk and its precision to inform sample size calculations for a fully powered trial, from a pilot randomised trial to assess carbon monoxide confirmed abstinence at 4 weeks post-quit date
4. To assess process measures at 4, 8 and 16 weeks post-baseline including:
  - 4.1. Self-reported cigarettes smoked
  - 4.2. Number of quit attempts
  - 4.3. Self-reported quality of life
  - 4.4. Mood and physical symptoms
  - 4.5. Cravings
  - 4.6. PA by self-report and accelerometer (in a sub-sample)
  - 4.7. Pharmacological and behavioural support used
  - 4.8. Weight
5. To estimate the resource use and costs associated with delivery of the intervention, and to pilot methods for determining future cost-effectiveness analyses

More details can be found at <http://www.nets.nihr.ac.uk/projects/hta/077802>

Protocol can be found at [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0018/51921/PRO-07-78-02.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/51921/PRO-07-78-02.pdf)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Pilot randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Smoking reduction and cessation

## **Interventions**

Brief advice:

Written and verbal information on NHS Stop Smoking Service (SSS) with information on the benefits of quitting and how to quit provided at baseline. Those expressing a desire to make a quit attempt will subsequently be referred to NHS SSS.

PA intervention:

Written and verbal information on NHS SSS with information on the benefits of quitting and how to quit provided at baseline. Smokers will select one of three strategies for smoking reduction and receive weekly support to attain this. Face to face physical activity support sessions will be conducted at weeks 1, 4, and 8 along with supportive phone calls in each intermediate week. The communications will involve tailored physical activity counselling, guidance on using a free pedometer to achieve SMART goals, and signposting to local exercise opportunities with subsidised access as required, with the aim of increasing the amount of regular physical activity completed by each participant for both implicit and explicit purposes as an aid to quit. Those expressing a desire to make a quit attempt will subsequently be referred to NHS SSS.

Added 14/07/2010:

Please note that this trial is recruiting only in Plymouth, specifically in Stonehouse and Devonport areas of the city, where smoking prevalence is more than twice the national, regional and citywide average.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Prolonged abstinence at 4 weeks post-quit

## **Secondary outcome measures**

1. Weight and height (body mass index [BMI]), measured at baseline, 8 weeks and 16 weeks
2. Self reported cigarettes, pipes, and cigars smoked, measured at baseline and weekly thereafter
3. Readiness to quit smoking, measured at baseline
4. Cigarettes smoked in past week, measured at baseline and weekly thereafter
5. Urge to smoke (single item), measured at baseline and weekly thereafter
6. Mood and Physical Symptom Scores (MPSS, 7 items), measured at baseline and weekly thereafter
7. Physical Symptom Scores (PSS), measured at baseline and weekly thereafter
8. Self reported and accelerometer assessed PA, measured at baseline and weekly thereafter
9. Alcohol consumption
10. 36-item short form health survey (SF36), measured at baseline, 8 weeks and 16 weeks
11. Self reported use of nicotine replacement therapy (NRT) products or smoking related aids, measured at baseline and weekly thereafter

## **Overall study start date**

01/09/2010

**Completion date**

01/11/2012

## Eligibility

**Key inclusion criteria**

1. Written informed consent
2. People who are currently smoking at least 15 cigarettes a day and have done for a minimum of 3 years
3. Are at least 18 years of age, either sex
4. Are not motivated to quit smoking in the next month but do wish to cut down the number of cigarettes they do smoke

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

120

**Key exclusion criteria**

1. Contra-indicated for moderate physical activity
2. Have an injury or illness that might be exacerbated by exercise
3. Pregnant

**Date of first enrolment**

01/09/2010

**Date of final enrolment**

01/11/2012

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**University of Exeter**  
Exeter  
United Kingdom  
EX1 2LU

## **Sponsor information**

**Organisation**  
University of Exeter (UK)

**Sponsor details**  
c/o Helen Loughlin  
Innovation Centre  
Streatham Campus  
Exeter  
England  
United Kingdom  
EX4 4QJ

**Sponsor type**  
University/education

**Website**  
<http://www.exeter.ac.uk/>

**ROR**  
<https://ror.org/03yghzc09>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

**Alternative Name(s)**  
NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**  
Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results	01/01/2014		Yes	No
<a href="#">Results article</a>	results	12/02/2015		Yes	No