

# Study comparing two stop smoking intervention efficacies

<b>Submission date</b> 30/08/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/02/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Smoking continues to be a major health problem in the UK. Every year around 100,000 people in the UK die from smoking, with many more living with debilitating smoking-related illnesses. Smoking increases your risk of developing more than 50 serious health conditions, including cancer, heart disease and lung disease. It is important to understand the effectiveness of the various interventions designed to help people quit. The aim of this study is to compare the effectiveness of two stop smoking interventions amongst people living and working in the Lambeth and Southwark boroughs of London.

### Who can participate?

Current smokers aged over 18 living and working in the Lambeth and Southwark boroughs of London.

### What does the study involve?

Participants are randomly allocated to one of two groups. Participants in one group attend Allen Carr's Easyway to stop smoking programme, which consists of one 5/6-hour group session, plus one or two 3-hour booster sessions over the following 3 months for those who require them. Participants in the other group attend a 1-1 counselling service available via the NHS, consisting of one 30-minute session and four weekly follow-ups of 10-15 minutes. The effectiveness of both treatments is followed up at 4, 12 and 24 weeks after treatment. Participants' success at stopping smoking is confirmed by breath testing. Participants' continued use of nicotine-containing products (e.g. e-cigarettes, nicotine replacement products) and life satisfaction are also assessed.

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

The results of this study will add to the evidence around the use of the Allen Carr method. The Allen Carr method has yet to be NICE approved. We ensure that participants are aware of this and offer them NHS treatment before joining the study, and also offer them an NHS referral if they fail to quit during the study. Participants need to attend treatment and follow-up sessions, which may be an inconvenience. We ensure participants can schedule appointments at evenings and weekends, and are compensated for travel costs and time.

Where is the study run from?  
London South Bank University (UK)

When is the study starting and how long is it expected to run for?  
June 2016 to January 2018

Who is funding the study?  
Allen Carr's Easyway (International) Ltd

Who is the main contact?  
Dr Daniel Frings

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Daniel Frings

**ORCID ID**  
<https://orcid.org/0000-0002-0183-9516>

**Contact details**  
London South Bank University  
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SE1 0AA.

## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT02855255

**Protocol serial number**  
RC7697

## Study information

**Scientific Title**  
Comparing the 24-week efficacy of Allen Carr's Easyway to stop smoking and NHS 1-1 counselling provision amongst people living and working in the Lambeth and Southwark boroughs of London

**Study objectives**  
By comparing the Allen Carr's Easyway (ACE) method to a NHS-delivered treatment program, an estimate of the relative effectiveness of both methods (and associated costs) can be made. This will potentially inform future judgements about the use of this method by private and public healthcare providers.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Submitted to Fulham Research Ethics Committee, London - pending

**Study design**

Single-centre, blinded between subjects, two-armed randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Other

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

Smoking

**Interventions**

Participants are randomly allocated to either Allen Carr's Easyway to stop smoking programme or NHS 1-1 counselling service, using an adaptive randomisation programme to balance levels of prior smoking, number of prior quit attempts, age and gender.

1. Allen Carr's Easyway to stop smoking programme comprises one 5/6 hour group session (plus one or two 3 hour booster sessions over the following 3 months for those who require them)
2. The 1-1 counselling service available via the NHS comprises one 30-minute session and four weekly follow-ups of 10-15 minutes.

The efficacy of both treatments will be followed up at 4, 12 and 24 weeks after treatment. The evaluation will be compliant with the Russell 6 Standard (which requires, amongst other things, a double blind, randomised design, chemical verification of quit outcomes, and the inclusion of all participants who received treatment in the final analysis). The research team will also be blinded to participants' condition.

**Intervention Type**

Behavioural

**Primary outcome(s)**

Cessation of smoking 24 weeks post treatment commencement, measured in line with the Russell 6 standard (i.e. fewer than 5 incidents of smoking from the quit date, including all participants lost to follow-up as failed treatment, and confirming all successful quits via breath carbon monoxide testing). The intention to treat principle will be followed and those lost to follow-up will be considered failed quit.

**Key secondary outcome(s)**

1. Self-reported maintenance of smoking cessation questions, measured at 4, 12, 24 weeks post treatment commencement; current cessation, number of slips, number of cigarettes in past week /month/since last session.
2. The Satisfaction with Life Scale (Diener, Emmons, Larsen, & Griffin, 1985), measured at baseline and 4, 12, 24 weeks post treatment commencement

3. Survey assessing use of nicotine replacement therapy/nicotine containing products, measured at 4, 12, 24 weeks post treatment commencement. Participants will be asked to answer Yes/No to the following: 'Since we last met, have you regularly used any of the following?' and 'Are you planning on using any of the following in the future?' E-cigarettes, nicotine patches, nicotine gum, other

4. Quit efficacy measured at baseline, 4, 12, 24 weeks post treatment commencement. Measured on a scale of 1-7 (strongly disagree - strongly agree), to the following items: 'I can achieve my aims to quit smoking', 'I can cope with the demands of quitting smoking', 'It is unlikely that I will do well at quitting smoking', 'I think I can perform well at quitting smoking'

5. Perceived value of being nicotine free measured at 4, 12, 24 weeks post treatment commencement. Measured on a scale of 1-7 (strongly disagree - strongly agree), to the following items: 'Being nicotine free is of value to me', 'I value being nicotine free', 'Having no nicotine in my system is/would be beneficial to me'

### **Completion date**

31/07/2018

## **Eligibility**

### **Key inclusion criteria**

1. Current smoker aged over 18
2. Resident or work in Lambeth/Southwark areas
3. Prepared to be assigned randomly to one of two treatment conditions (NHS standard provision or Allen Carr's Easyway)
4. Intend to quit smoking cigarettes

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

620

### **Key exclusion criteria**

1. Individuals who would prefer an NHS-provided treatment
2. Currently in another RCT or similar research project
3. Have a mental health condition
4. Are pregnant
5. Have a respiratory disease (such as chronic obstructive pulmonary disease or emphysema)

6. Unable to reach the treatment locations (London South Bank Universities Southwark Campus or SW20)

**Date of first enrolment**

01/01/2017

**Date of final enrolment**

01/01/2018

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**London South Bank University**

103 Borough Road

London

United Kingdom

SE1 0AA

## **Sponsor information**

**Organisation**

London South Bank University

**Organisation**

Allen Carr's Easyway (International) Ltd

**Organisation**

London South Bank University

**ROR**

<https://ror.org/02vwnat91>

## **Funder(s)**

## Funder type

Industry

## Funder Name

Allen Carr's Easyway (International) Ltd

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2020	12/02/2020	Yes	No
<a href="#">Protocol article</a>	protocol	14/12/2017		Yes	No