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Study comparing two stop smoking intervention efficacies

Submission date
30/08/2016

Recruitment status
No longer recruiting

Registration date
28/09/2016

Overall study status
Completed

Last Edited
12/02/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02855255

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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

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 measure
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.

Secondary outcome measures
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'

Overall study start date
01/06/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
620

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
England

United Kingdom

Study participating centre
London South Bank University
103 Borough Road
London
United Kingdom
SE1 0AA

Sponsor information

Organisation
London South Bank University

Sponsor details

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Sponsor type
University/education

Organisation
Allen Carr's Easyway (International) Ltd

Sponsor details
Park House
14 Pepys Road
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London
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SW20 8NH

Sponsor type
Industry

Organisation
London South Bank University

Sponsor details

Sponsor type
Not defined

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

ROR
https://ror.org/02vwnat91

Funder(s)

Funder type
Industry

Funder Name
Allen Carr's Easyway (International) Ltd

Results and Publications

Publication and dissemination plan
A study protocol is currently being prepared. At the end of the study, a non-technical summary of the results will be prepared for participants. Manuscripts will be prepared for publication in peer-reviewed journals and conference presentations prepared and delivered at relevant conferences.

Intention to publish date
31/08/2019

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?
Protocol article	protocol	14/12/2017		Yes	No
Results article	results	01/05/2020	12/02/2020	Yes	No