ISRCTN12951013 https://doi.org/10.1186/ISRCTN12951013

Is Allen Carr's Easyway to Stop Smoking Programme superior to the smoking cessation service delivered by Quit.ie?

Submission date
12/09/2016

Recruitment status
No longer recruiting

Registration date
15/09/2016

Overall study status
Completed

Last Edited
01/11/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Minister for Health Dr James Reilly has declared that Ireland will be Tobacco Free by the year 2025. Helping people to stop smoking is key if the number of smokers is to be reduced to less than 5% by 2025. There are many proven treatments that help people stop smoking including help from a doctor or another healthcare professional, psychological support, and drug treatment such as nicotine replacement therapy (NRT), varenicline and bupropion. Varenicline and bupropion are approved prescription medications. NRT is a medically-approved way to take nicotine by means other than tobacco, such as patches, gum, lozenges, inhalers and nasal sprays. They have been shown to increase the odds of successful quitting. Recent efforts have been made to improve the reach and impact of smoking cessation services including the implementation of web and social-media based interventions (e.g. Quit.ie). Allen Carr's "Easyway To Stop Smoking" method has become increasingly popular since 1985, advertising a 90% 3-month success rate and 51% 12-month success rate and claiming to have "cured at least 10 million smokers". The basis of the method is still unclear. It does not include pharmacotherapy. It is delivered at a 5-hour workshop session, during which participants are encouraged to smoke in order to reflect on their reasons for smoking. While numerous celebrity endorsements advertise the success of the programme, it has yet to be independently tested. In Ireland, the AC programme has treated 12,000 over the past decade. Despite its widespread popularity and use, there has been virtually no research on the effectiveness of the Allen Carr Easyway method. The aim of this study is to assess the effectiveness of Allen Carr's Easyway to Stop Smoking programme.

Who can participate?
Otherwise healthy daily smoking adults (aged over 18)

What does the study involve?
Participants are randomly allocated to one of two groups. Group 1 participants attend a 1-day Allen Carr's Easy Way to stop smoking seminar. Group 2 participants are registered on the Quit. ie service and an agreed quit date is set. A follow-up phone call is requested from a Quit.ie smoking cessation specialist, along with daily motivational texts and emails. They are given

treatment options for their quit attempt but the choice of treatment is entirely theirs. Varenicline and NRT may be prescribed to some of the participants in the Quit.ie group. These treatments are usually for a 3-month period and a combination of delivery methods and strengths can be used. Appointments are made with all participants at 1, 3, 6 and 12 months after their target quit date to check whether they have quit using a breath test.

What are the possible benefits and risks of participating?
Within three weeks of stopping smoking, participants will be able to exercise and perform physical activities without feeling winded, and their blood circulation and heart function will improve significantly. Their lungs may also begin to clear, allowing them to breathe more easily. After 5 years their risk of heart attack falls to that of a non-smoker, and after 10 years their risk of lung cancer falls to about half that of a non-smoker. Early smoking withdrawal symptoms may include intense cravings, anxiety, tension, or frustration, drowsiness or trouble sleeping, and increased appetite. For most smokers, withdrawal symptoms start to subside about two weeks after quitting, and go away completely within 9 months after quitting.

Where is the study run from?
This study is conducted by the TobaccoFree Research Institute of Ireland and study visits take place at the Dublin Institute of Technology. The Allen Carr Programme takes place at the Moran Hotel in Dublin.

When is the study starting and how long is it expected to run for?
October 2014 to April 2017

Who is funding the study?
The study is funded by the Department of Health Lottery Fund and TobaccoFree Research Institute Ireland with Allen Carr funding their treatment sessions.

Who is the main contact?
Sheila Keogan

Contact information

Type(s)
Public

Contact name
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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14-94

Study information

Scientific Title
Is Allen Carr's Easyway to Stop Smoking Programme superior to the smoking cessation service delivered by Quit.ie? A randomised controlled trial

Acronym
ACESCQ

Study objectives
The aim of this trial is to compare the 12-month smoking cessation success rate of the Allen Carr Easyway to Stop Smoking method against the standardised smoking cessation service with the use of standard care treatment for tobacco dependence

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dublin Institute of Technology Research Ethics Committee, 18/06/2015 , ref: 14-94

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
After determining eligibility, establishing willingness to take part, and receiving active consent, a researcher will arrange an appointment where subjects will be randomised to one of two conditions:
1. Allen Carr Easyway to Stop Smoking: An appointment will be made to participate in a full day Allen Carr Easyway treatment programme. Follow up appointments will be required at 1, 3, 6, and 12 month intervals in order to verify smoking status. TFRI staff members will contact subjects to arrange these appointments. Attendance is expected and subjects will be reimbursed for any travel costs incurred.
2. Quit.ie service: Subjects will receive information on how to access and best utilise the Quit.ie service. Quit.ie is an online smoking cessation support service and will be provided as per HSE guidelines and materials. If assigned to this group, subjects will be reviewed at 1, 3, 6, and 12 month intervals following the treatment to verify their smoking status at these time points. TFRI staff members will contact subjects to arrange these appointments. Attendance is expected and they will be reimbursed for any travel costs incurred.

Group allocation will be done completely at random based on a series of demographic questions. We want to make sure that we have equal groups based on age, gender, and smoking habits. We do not base our grouping on any other factors and we cannot honour any individual requests for grouping. Once subjects are assigned a group, they cannot be reassigned. Participation is 100% voluntary. No one will be included in any stage of the research unless they have given consent. Participants can revoke consent at any stage of the process.

All information that is gathered in this study remains 100% confidential. Subjects information will be stored in a de-identified form on a secure computer that is only used by members of the research team. No one will have access to the information gathered in this study aside from the researchers and it will only be used for research purposes. There will be no identifiable information stored in the computer at any stage during this research.

Intervention Type
Behavioural

Primary outcome measure
Self-reported quit rates at 3 months, verified by exhaled breath carbon monoxide measurement, at 3 months post setting of a quit date or attending Allen Carr Easyway to stop smoking session.

Secondary outcome measures
1. Self-reported quit rates at 1 month, verified by breath carbon monoxide measurement at 1 month post setting of a quit date or attending Allen Carr Easyway to stop smoking session

2. Self-reported quit rates at 6 months, verified by breath carbon monoxide measurement at 6 months post setting of a quit date or attending Allen Carr Easyway to stop smoking session
3. Self-reported quit rates at 12 months, verified by breath carbon monoxide measurement at 12 months post setting of a quit date or attending Allen Carr Easyway to stop smoking session
4. Weight: subjects are weighed at baseline/randomisation visit and at 1 3 6 and 12 months post setting of a quit date or attending Allen Carr Easyway to stop smoking session
5. Cigarette consumption: recorded at baseline/randomisation and at 1 3 6 and 12 months post setting of a quit date or attending Allen Carr Easyway to stop smoking session

Overall study start date
01/10/2014

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Smokers over 18 years of age
2. Smokes 5 or more cigarettes a day
3. Is able and willing to attend all workshops and clinics as set out in the protocol
4. All subjects will give informed consent
5. Have good knowledge of English, because the Allen Carr treatment is delivered in English

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The numbers needed to treat have been estimated at 279 (i.e. 139 in each treatment arm)

Key exclusion criteria
1. Participants undergoing treatment for alcohol or illicit drug abuse
2. Participants diagnosed with acute cardiac or respiratory conditions
3. Participants with a diagnosed serious psychiatric illness
4. Participants under the age of 18 years
5. Participants with a poor knowledge of English

Date of first enrolment
12/07/2015

Date of final enrolment

28/02/2016

Locations

Countries of recruitment
Ireland

Study participating centre
TobaccoFree Research Institute
Ireland
Dublin 8

Sponsor information

Organisation
Department of Health

Sponsor details
Hawkins House
Hawkins Street
Dublin
Ireland
2

Sponsor type
Government

Organisation
TobaccoFree Research Institute

Sponsor details
Focus Research Institute
DIT Kevin Street
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8

Sponsor type
Charity

Website
www.tri.ie

Organisation
Department of Health

Sponsor details

Sponsor type
Government

ROR
https://ror.org/03k6fqn53

Funder(s)

Funder type
Government

Funder Name
Department of Health Lottery Fund (Ireland)

Funder Name
TobaccoFree Research Institute (Ireland)

Results and Publications

Publication and dissemination plan
TFRI will prepare the relevant reports and a full report will be furnished to the Department of Health. Scientific research papers and presentations with recommendations based on the outcomes achieved will be produced. The results will also be propagated through different media channels. For instance, summaries can be posted on more than one webpage (TFRI, Dublin Institute of Technology (DIT), the Health Service Executive (HSE), Asthma Society of Ireland and relevant NGOs e.g. ICS, IHF, ASH Ireland), including more European centred venues such as the European Network for Smoking Prevention (ENSP). These websites will reach different audiences and it is likely that the focus of each summary or paper will be individually tailored. Collaboration with ASH Ireland advocacy group will bolster dissemination for the current study. Findings from the study will be submitted for publication in peer-reviewed journals in the corresponding disciplines (environmental and respiratory health, clinical and Tobacco Control journals). In addition, poster and/or oral presentations of the results will be presented at scientific, policy and advocacy meetings in Ireland and internationally.

Intention to publish date
30/04/2018

Individual participant data (IPD) sharing plan

The anonymised datasets generated during and/or analysed during the current study will be available upon request from Sheila Keogan.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		15/09/2016	16/09/2016	No	Yes
Basic results		17/09/2018	17/09/2018	No	No
Results article	results	01/07/2019		Yes	No