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Allen Carr’s Easyway to Stop Smoking - A Randomised Clinical Trial

L. Clancy
Dublin Institute of Technology, lclancy@tri.ie

Sheila Keogan
Dublin Institute of Technology

Shasha Li
Dublin Institute of Technology

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Allen Carr’s Easyway to Stop Smoking - A randomised clinical trial

Sheila Keogan, Shasha Li, Luke Clancy

ABSTRACT

Objective To determine if Allen Carr’s Easyway to Stop Smoking (AC) was superior to Quit.ie in a randomised clinical trial (RCT).

Setting Single centre, open RCT, general population based.

Participants 300 adult smokers, 18 years plus, minimum 5 cigarettes daily, and English speaking. AC, 151 (females 44.4%) and Quit.ie, 149 (females 45.6%), mean age 44 years. outcomes for all 300 were analysed (intention-to-treat). Recruited through advertisement from July 2015 to February 2016.

Intervention Randomly assigned to AC (n=151) and Quit.ie (n=149), matched for age, sex and education. Block randomisation, enrolment and follow-up at 1, 3, 6 and 12 months. Primary aim was to determine if AC had higher quit rates than Quit.ie service at 3 months. Secondary aims: quit rates at 1, 6 and 12 months and analysis of associated factors including weight. AC consisted of a 5-hour seminar, in a group setting. Quit.ie is an online portal for smoking cessation.

Results AC had higher quit rates at 1, 3, 6 and 12 months. AC: 38%, (n=57), 27% (n=40), 23% (n=35), 22% (n=33) vs Quit.ie: 20% (n=30), 15% (n=22), 15% (n=23), 11% (n=17), respectively (all p values <0.05). Logistic regression AC vs Quit.ie, OR 2.26 (95% CI 1.22 to 4.21) p value=0.01. Weight gain 3.8 kg in AC vs 1.8 kg in Quit.ie (p value <0.05).

Conclusions All AC quit rates were superior to Quit.ie outcomes were comparable with established interventions.


INTRODUCTION

Established, effective and cost-effective treatments for tobacco dependence include brief intervention, psychological support and pharmacotherapy, including nicotine replacement therapy (NRT), varenicline and bupropion, which have a high level of proven success in previous scientific studies.

The success rates achieved are variable but are of the order of 7%–31% quit at 12 months.

Recently, efforts have been made to improve the reach and impact of smoking cessation services in Ireland including the implementation of mobile phone, internet and social media-based interventions.

The Allen Carr method has been used for over 30 years and is available in 150 centres in over 50 different countries. The method claims to have helped more than 30 million smokers quit, with a 90% quit rate advertised on its website.

There has been very little empirical research on the efficacy of the AC method. The scientific basis of the method is also unclear. AC does not include pharmacotherapy, and the behavioural intervention does not seem to be based on the transtheoretical model of behaviour change.

In this study, we compare Allen Carr’s Easyway to Stop Smoking (AC) with the National Online Smoking Cessation Service, Quit.ie, in a randomised clinical trial (RCT).

STUDY OBJECTIVES

The objectives were: to assess the relative effectiveness of AC and Quit.ie, using carbon monoxide (CO) validated Quit status at 1, 3, 6 and 12 months for each treatment condition, and to measure the continuous abstinence rate using Russell standard, to consider non-quit outcomes and factors associated with successful quitting.

STUDY GOALS

To provide an evidence base with regard to the efficacy of the AC method for smoking cessation for smokers wishing to quit and also to inform policy-makers regarding its possible suitability for inclusion in publicly recommended smoking cessation treatment services.

METHODS

This is an open, single-centre, randomised, superiority clinical trial with parallel group design using Consolidated Standards of Reporting Trials guidelines (online supplementary file 1). Patients (n=300) were randomly assigned to either AC condition or registered on the online Health Service Executive (HSE) National Smoking Cessation Service (https://www.quit.ie/).

The study protocol (online supplementary file 2) was registered on the ISRCTN registry.

RECRUITMENT

Smokers were recruited through public advertisement in an Irish national newspaper, and on national and local radio in July 2015. Those responding were directed to TobaccoFree Research Institute Ireland (TFRI) website (www.tri.ie) and asked to complete a study questionnaire on inclusion and exclusion criteria and a readiness to quit score (online supplementary file 3).

The inclusion criteria were that participants be 18 years or older, smoking a minimum of 5 cigarettes per day, have a good knowledge of the English language, as AC was delivered in English, and agree to attend all five study visits in TFRI, Dublin. Exclusion criteria were doctor-diagnosed, acute cardiac or respiratory illness or serious psychiatric illness.
Table 1  Baseline characteristics of participants by treatment groups

<table>
<thead>
<tr>
<th></th>
<th>Quit.ie (n=149)</th>
<th>AC (n=151)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>68 (45.6)</td>
<td>67 (44.4)</td>
</tr>
<tr>
<td>Age, median (IQR)</td>
<td>44.0 (38.0–51.0)</td>
<td>44.0 (36.0–52.0)</td>
</tr>
<tr>
<td>Initial weight, median (IQR), kg</td>
<td>80.8 (69.0–93.9)</td>
<td>79.8 (69.4–91.7)</td>
</tr>
<tr>
<td>Postsecondary and higher education, n (%)</td>
<td>104 (69.8)</td>
<td>105 (69.5)</td>
</tr>
<tr>
<td>Baseline CO reading, mean (SD), ppm</td>
<td>20.4 (10.5)</td>
<td>22.1 (11.6)</td>
</tr>
<tr>
<td>Time to first cigarette, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤5 min</td>
<td>42 (28.2)</td>
<td>56 (37.1)</td>
</tr>
<tr>
<td>6–30 min</td>
<td>66 (44.3)</td>
<td>61 (40.4)</td>
</tr>
<tr>
<td>&gt;31 min</td>
<td>41 (27.5)</td>
<td>34 (22.5)</td>
</tr>
<tr>
<td>Prior use of e-cigarettes, n (%)</td>
<td>72 (48.3)</td>
<td>75 (49.7)</td>
</tr>
<tr>
<td>Previous quit attempts, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>6 (4.2)</td>
<td>4 (2.7)</td>
</tr>
<tr>
<td>1–3</td>
<td>63 (43.8)</td>
<td>69 (46.3)</td>
</tr>
<tr>
<td>4–9</td>
<td>61 (42.4)</td>
<td>59 (39.6)</td>
</tr>
<tr>
<td>10 and over</td>
<td>14 (9.7)</td>
<td>17 (11.4)</td>
</tr>
<tr>
<td>No of cigarettes smoked per day, median (IQR)</td>
<td>20.0 (15.0–22.0)</td>
<td>20.0 (15.0–25.0)</td>
</tr>
<tr>
<td>How many years are you smoking, median (IQR)</td>
<td>28.0 (22.0–34.0)</td>
<td>26.0 (20.0–35.0)</td>
</tr>
<tr>
<td>Readiness to quit score, median (IQR)</td>
<td>27.0 (24.5–29.0)</td>
<td>27.0 (25.0–29.0)</td>
</tr>
</tbody>
</table>

AC, Allen Carr’s Easyway to Stop Smoking; CO, carbon monoxide.

Participants completed a 5-hour, group AC seminar, maximum 20 participants, in a routine seminar session. Participants smoke during smoking breaks until there is a ritualistic final cigarette followed by a 20 min relaxation exercise. Follow-up was arranged at TFRI research centre for months 1, 3, 6 and 12. Two free AC follow-ups were also available.

**Quit.ie service**

Quit.ie is an online portal for HSE smoking cessation services, and it is delivered free of charge. Quit.ie has a team of accredited National Centre for Smoking Cessation and Training (NCSCCT, UK) Tobacco Cessation Practitioners. They give smokers information and behavioural support on the phone, by text and online through their website and Facebook community. As part of the Quit.ie quit plan, participants set their quit date, requested daily support texts and or emails for 1 month and at least two further follow-up communications and arranged to have a counselling phone call from the quit team specialist. The decision to use medication rested with the client, who was also responsible for arranging the purchase or prescription of any NRT or other medication that they used.

Participants were registered on Quit.ie during their first TFRI visit, and an agreed quit date was set. An appointment for follow-up was arranged at the TFRI research centre at months 1, 3, 6 and 12 following their target quit date. All registered clients are sent an email from Quit.ie at 3 months requesting confirmation of quit status.

**FOLLOW-UP VISITS**

All randomised smokers were invited to attend an initial and four other visits at TFRI. Self-reported quitting was recorded and validation by CO Breath test was carried out at each visit using a CO monitor. The monitor used in this study was the Care fusion CO monitor. Other data collected included weight, relapse information, medication used, motivational contacts received by phone, text and email or at face-to-face meetings, if any, or attendance at AC at each visit.

**SAMPLE SIZE CALCULATION**

The quit rates at 3 months were predicted as 25% for AC and 12% for Quit.ie. An allocation of 1:1 was selected. With 80% power and two-sided significance level of 5%, a sample size of 139 for each group would be needed to detect superiority between AC and Quit.ie.

An ‘intention-to-treat’ (ITT) approach, where only CO-validated quitting, as per Russell standard is accepted as valid was used to determine the numerator in both conditions and data from all 300 randomised smokers (149 Quit.ie and 151 Allen Carr) were included in the denominators for the analysis. Participants who were consented, randomised, set a quit date, attended for follow-up visits and or made an appointment for an AC seminar were included in the ITT analysis. All missing quit data were regarded as being due to failure to quit smoking even if the participants were lost to follow-up.

A complete case analysis (CCA) approach based on both CO-validated quitting (Russell Standard) and self-reported quitting was subsequently used to examine the difference in the retention rate in the two conditions and reassure that failure to return for follow-up in person was indicative of failure to quit in this trial. Subjects who did not attend for follow-up in person, but responded to contact by email/text/phone and self-reported on their quit status were combined with those who had attended in person to form the CCA samples.

and must not be currently undergoing treatment for alcohol or illicit drug use. A total of 3065 smokers responded, 112 did not leave contact details, 918 were excluded on exclusion criteria. The remaining 2035 were contacted by email on a first-come-first-served basis; 1414 did not respond and 631 responded positively. Appointments were sent to 551 yielding 300 who met the criteria, and were randomised; 251 did not attend as requested and 70 were not contacted once recruitment was completed in February 2016. Follow-up was completed in March 2017. Irish and UK white nationals made up 90% of the sample, nine other nationalities were represented and there was equal ethnic distribution for both conditions.

**RANDOMISATION**

Block randomisation was used to reduce bias and achieve balance in the allocation of participants to the treatment arms. Randomisation was performed by TFRI from July 2015 to February 2016. Participants were randomised by submitting details of their gender, age and highest education level reached that is, primary, secondary or third level, resulting in eight blocks and consented participants within each block were then randomly assigned to either the AC or the Quit.ie condition.

Participants were told that those who attended all four follow-up visits would be entered into a prize draw for 2-week holiday, a weekend holiday and an iPad.

Randomised participants were given a unique participant identifier code. All participant and project data were deidentified and stored on a secured password-protected server. Of the 300 enrolled, 151 smokers were allocated to AC arm and 149 to Quit.ie (table 1).

**DETAILS OF TREATMENT CONDITIONS**

**Allen Carr’s Easyway to Stop Smoking**

The AC condition was delivered, free of charge, by experienced AC therapists.

Participants were registered on Quit.ie after their first TFRI visit, and an agreed quit date was set. An appointment for follow-up was arranged at the TFRI research centre at months 1, 3, 6 and 12 following their target quit date. All registered clients are sent an email from Quit.ie at 3 months requesting confirmation of quit status.
The CCA numerators for quit rates, when accepting self-report as quit, were the sums of self-reported quit data collected from those who attended in person and quit data from non-attenders who responded to electronic contact. The CCA numerator, when using CO-validated quitting, can only be based on those who attended in person. This may be clinically misleading as it demands omitting self-reported quitting but is included for completeness. The denominators in CCA consisted of those for whom data were furnished in contrast to the ITT approach where all subjects in the trial were retained in the denominator even if lost to follow-up. For comparison, an ITT analysis using self-report quit rates was also performed.

STATISTICAL ANALYSIS

Analysis of variance test was used to test if participants’ categorical characteristics were balanced between the two conditions. Two-sided two-sample mean tests were carried out for continuous characteristics. In addition, as it was a superiority clinical trial, two-sample one-tailed proportion tests were carried out when comparing quit rates and retention rates between the two trial groups, and when comparing treatment effects in Quit.ie. Two-sample mean tests were used to compare weight gain.

The dichotomous primary outcomes were analysed via multivariable logistic regression. The independent variables included were trial group, gender, education, age, prior use of e-cigarettes, baseline CO reading, time to first cigarette, readiness to quit score and previous quit attempt. Univariable logistic regressions were carried out to measure the impact on quit outcome of taking cigarette puffs between visits. Significance level of all tests was set to 0.05. All analyses were performed using IBM SPSS Statistics for Windows V.24.

RESULTS

χ² test and two-sample proportion z test showed that AC was superior to Quit.ie. At each visit, the quit rate in the AC group is significantly greater than that of the Quit.ie group using ITT Co-validated quitting (table 2). The difference between the two groups was strongest at the 1-month follow-up visit and remained statistically significant at 3, 6 and 12-month follow-ups, in each of which, quit rates in the AC group were almost twice that of the Quit.ie. Table 2 shows that in the AC condition, the quit rate decreased from 37.7% (n=57) at 1 month to 21.9% (n=33) at 12 months (p=0.001) while in Quit.ie, the quit rate decreased from 20% (n=30) at 1 month to 11.4% (n=17) at the 12 months (p=0.02).

Using CCA and CO-validated quitting, where the quitting rate in AC was nearly twice as great as Quit.ie, the difference was not statistically significant.

It was assumed in ITT that non-attenders had mainly failed to quit, no such assumption was made for CCA and that seemed to account for the difference in attendance in this trial.

However, using data collected from non-attenders and accepting self-report as quit for ITT and CCA, the results were similar to CO-validated quitting ITT with an even greater superiority for AC and suggesting that failure to attend was not attributable to the condition (table 2) and that the worst case assumption of CO-validated quitting was not misleading.

The relapse rates were not significantly different between Quit.ie and AC condition at the 1, 3, 6 or 12 month visits.

Multivariate logistic regression of 3-month outcomes included: trial group, gender, education, age, prior use of E-cigarettes, baseline CO reading, time to first cigarette, readiness to quit score and previous quit attempts. Three significant variables were found: trial group, education and baseline CO.

Being in the AC condition increased the odds of quitting by 2.3 (95% CI 1.2 to 4.2) compared with being in Quit.ie condition. Education and baseline CO level were also significant factors associated with an increased likelihood of quitting at 3-month follow-up (table 3).

In sensitivity analysis, CO readings were replaced by the number of cigarettes smoked per day; this was not found to be significant. The number of years’ participants were smoking was not included as the correlation of number of years smoking with age was too strong. Time to first cigarette variable had two missing values, and previous quit attempt variable had seven missing values. Therefore, the total number of observations used

<table>
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<tr>
<th>Method</th>
<th>Quitting definition</th>
<th>Month</th>
<th>No of quitters</th>
<th>Sample size</th>
<th>Quit rate</th>
<th>No of quitters</th>
<th>Sample size</th>
<th>Quit rate</th>
<th>P values*</th>
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<td>30</td>
<td>149</td>
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<td>151</td>
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<td>22</td>
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<td>40</td>
<td>151</td>
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<td>151</td>
<td>23.2%</td>
<td>0.045†</td>
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<td></td>
<td></td>
<td>12</td>
<td>17</td>
<td>149</td>
<td>11.4%</td>
<td>33</td>
<td>151</td>
<td>21.9%</td>
<td>0.008†</td>
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<td>Self-report</td>
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<td>149</td>
<td>24.2%</td>
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<td>151</td>
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<td>151</td>
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<td>110</td>
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<td>63</td>
<td>52.4%</td>
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<td>134</td>
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<td>130</td>
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<td>36</td>
<td>107</td>
<td>33.6%</td>
<td>0.013†</td>
</tr>
</tbody>
</table>

*The alternative hypothesis is that AC has a higher quit rate than Quit.ie.
†The test is significant at 0.05 level.
AC, Allen Carr’s Easyway to Stop Smoking; CCA, complete case analysis; CO, carbon monoxide; ITT, intention-to-treat.

Keogan S, et al. Tob Control 2018;0:1–6. doi:10.1136/tobaccocontrol-2018-054243
The relationship between having taken a ‘single puff’ between quit date and 1 month and quit outcome at subsequent visits was also examined combining both trial groups. Univariable logistic regressions were carried out and were significant at both 3-month and 6-month visits. People who had quit at 1 month who had not taken a single puff (n=65) between quit date and 1 month had a 3.9 (95% CI 1.4 to 11.2) times greater odds of quitting at 3 months (n=47) than those who had taken a puff at 1 month (n=20) and had quit at 3 months (n=10).

All participants attending the AC condition were instructed not to take any form of pharmacotherapy to aid quitting. Therefore, when considering the pharmacotherapeutic agents used for quitting, other than e-cigarettes, we examined only Quit.ie. This showed: NRT (n=42, various formulations), varenicline (n=14) and none (n=14). Those who took varenicline between quit date and 3 months had a significantly higher quit rate at 3 months than both those who took nothing (p=0.003) and those who took NRT (p=0.005). There was no statistically significant difference in quit outcome at 3 months between those using none and those using NRT (p=0.36).

A number of participants used e-cigarettes at some stage between quit date and 3 months, (n=15) in Quit.ie and (n=12) in the AC condition. E-cigarettes were not found to significantly affect the quit outcome at 3 months in AC group. In Quit.ie condition, people who used e-cigarettes before the 3-month visit achieved a lower quit rate at 3 months (3 out of 15) than those who did not use e-cigarettes (19 out of 35) (p=0.01). This result may be due to the small number of observations in Quit.ie.

Successful quitters gained weight in both study conditions. There were three pregnant women in the study, two in AC group and one in Quit.ie. There were two participants who had serious illnesses and received medical intervention during the study. As fluctuations in weight could not be attributed to quitting, all five were removed from the weight analysis.

Absolute weight gains: The mean weight gain for quitters at 3 months in AC was 3.8 kg vs 1.8 kg in Quit.ie, the mean weight gain at 12 months in the AC was 5.02 kg vs 3.18 kg in Quit.ie. The mean weight gain was statistically greater in AC than Quit.ie at 1, 3 and 6 months (p=0.003 for 1 month, p=0.008 for 3 months, p=0.02 for 6 months), but not at 12 months (p=0.15).

Of the 300 participants randomised, the numbers retained at 1, 3, 6 and 12 months were 179, 127, 113 and 101 participants, respectively. The retention rate was significantly higher in the AC group than that in the Quit.ie group at each follow-up visit (p=0.001 at 1, 3 and 6 months, p=0.002 at 12 months). To get further information on the quit rates including non-attenders at clinic follow-up, all participants who did not attend at each month were contacted by email or by phone, if no email address was available. A CCA was then performed on the total sample with quit data at 1 month, 258 total (124 Quit.ie vs 134 AC), at 3 months 244 (114 Quit.ie vs 130 AC), at 6 months 228 (108 Quit.ie vs 120 AC) and at 12 months 212 (105 Quit.ie vs 107 AC). This analysis showed that AC was statistically superior at each month, with p value at 0.002, 0.008, 0.025 and 0.013 at 1, 3, 6 and 12 months, respectively (see online supplementary file 4).

The only reported adverse effect was one person in the AC treatment who went to see her doctor because of withdrawal symptoms.

**DISCUSSION**

In this RCT, AC—a non-pharmacotherapeutic one-off seminar-based intervention—had a quit rate which was superior to...
an online comprehensive national smoking cessation service consisting of advice by telephone, texts and email, supported by a dedicated website and Facebook community.

The short-term and long-term cessation CO-validated quit rates of AC exceeded those of Quit.ie by a factor of nearly two at all the time points tested on an ITT basis. The mechanism of this effect is unclear. There is some suggestion that the seminar is based on an expectancy challenge as has been used in alcohol treatment and consideration of these types of interventions seem to be similar to the AC approach.10–21 Being told that all AC therapists have used the method to stop smoking themselves, the widespread celebrity endorsements, and the popularity of the Allen Carr book may also be factors. The recent RCT of the Allen Carr book does not seem to support this latter suggestion.32 It specifically does not seem to be based on motivational behavioural change, and smoking cessation pharmacotherapy is not allowed or suggested even for control of withdrawal symptoms. No apps, texts or phone calls or social media community are prescribed in AC. The results achieved with AC, 26% quit at 12 months, are similar to the estimates for UK national smoking cessation service for varenicline with specialist individual behavioural support at a specialist clinic.123 The results achieved with Quit.ie at 11% at 12 months are similar to UK national smoking cessation service with Mono NRT with specialist drop-in behavioural support.113

The outcomes in Quit.ie are comparable with results observed with individual elements of successful interventions of internet, telephone support, emails and social media. Perhaps Quit.ie may be improved by increased use of proven evidence-based medication and face to face consultations.17,33

This RCT was limited to well people and although there was no age restriction in the protocol, it did not have very many young adults or older people who may have a lower quit rate but this did not seem to increase the quit rate in the well-matched Quit.ie condition. Our inability to explore possible mechanisms of action of AC and the training of AC therapists and not to be able to tailor Quit.ie content precisely creates a limitation to full understanding of the conditions but does not account for the superiority of the AC condition. For instance, face-to-face interactions were possible in the Quit.ie service but must be requested by the participant and they were not requested. Also pharmacotherapy was recommended in Quit.ie but was underused within the programme by trial participants. Changes have been made to formalise the interventions in the Quit.ie service.

The retention rate was low, particularly in the Quit.ie condition and may have been partially influenced by the absence of personal contact. Electronic follow-up of clinic defaulters confirmed a lower self-reported quit rate in Quit.ie. The resulting CCA analysis gave similar results to the ITT approach suggesting that the poor retention rate was not particular to either condition and did not materially affect the results.

One person in the AC condition developed significant withdrawal symptoms which led her to visit her doctor. Otherwise, AC was very well tolerated, making it particularly suitable for smokers unwilling or unable to tolerate pharmacotherapy. Pregnancy is also a condition where AC would seem particularly suitable, where reluctance to take medication is very strong.14,35 Young people who also have a low uptake of present services may be interested in the AC method.16–21 These are populations not addressed in this trial but would seem worthy of further exploration. It is clear however that it is suitable for well, middle-aged smokers of both sexes.

There is widespread acceptance by the public of the efficacy of AC as evidenced by the numbers who have used the service at their own expense and its widespread use in corporate settings for smoking cessation but, to the best of our understanding, it is not employed by any public health agency providing a smoking cessation service.19 The previous lack of RCT evidence showing efficacy may be the reason funding authorities both public and private seem reluctant to offer AC. The present RCT is positive and should encourage further trials and increase the likelihood that AC will take its place as a valid, effective and needed addition to available smoking cessation interventions.

What this paper adds

- The Allen Carr book is said to have sold some 13 million copies and has helped people stop smoking.
- There are a large number of celebrity endorsements testifying to the merits of Allen Carr's method but very few trials of any kind and very few publications of outcomes.
- No randomised clinical trials of Allen Carr's Easyway to Stop Smoking were published before this trial.
- This study shows that Allen Carr's Easyway to Stop Smoking was superior to a standard online National Smoking Cessation in a Randomised Clinical Trial.
- It was free of any serious side effects.
- As a once-off seminar, where pharmacotherapy is not used, it seems highly appropriate to consider it as an acceptable method for smoking cessation.

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Contributors LC conceived the study, SK and LC designed the study and were responsible for the conduct of the study. SK was mainly responsible for the conduct of the trial with LC as principal investigator. SL and SK did the literature search and were involved in analysis of the data. SK drafted the first version of the manuscript with input from LC. LC and SL had input into all redrafts. All authors read and approved the final version.

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Competing interests LC was involved in the Cease of NRT conducted on behalf of the ERS by the Occupational and Epidemiology Assembly and with the sponsorship of Pharmacia & Upjohn, Helsingborg, Sweden. He has served on advisory Boards for Pfizer and has in the past received research grants from Pfizer for Tobacco Control projects but none for smoking cessation. SK and SL declare no competing interest.

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