Comparison of Allen Carr’s Easyway programme with a specialist behavioural and pharmacological smoking cessation support service: a randomised controlled trial.

Running head: Comparison of Allen Carr’s Easyway programme

Frings Da, Albery IPa, Moss ACa, Brunger Ha, Burghela Ma, White Sb, Wood KVa

a Centre for Addictive Behaviours Research, London South Bank University, London, UK

b Population Health Research Institute, St George’s University of London, London, UK

Corresponding author: KV Wood email: [woodk6@lsbu.ac.uk](mailto:woodk6@lsbu.ac.uk). Tel.: 02078155888

**Conflicts of interest** The specialist behavioural and pharmacological smoking cessation support service was provided by Lambeth NHS Stop Smoking Service. The design, conduct, data collection, analyses and interpretation of the trial are conducted by London South Bank University, independent from Allen Carr’s Easyway (International) Ltd. Based on the findings, papers for publication were prepared by the research team at LSBU who had ultimate authority over these activities. The research team are contractually free to publish whatever findings the study produces, Allen Carr’s Easyway has no veto over publication, but were given advanced notice of the findings prior to publication. The authors have no other conflicts to declare.

**Trial Registration** This trial was registered with ClinicalTrials.gov (ClinicalTrials.gov (NCT02855255), the ISRCTN (ISRCTN23584477) and the Open Science Framework (OSF: t6vgs).

**Word count:** 4387

**ABSTRACT**

**Background and Aims** A combination of behavioural and pharmacological support is judged to be the optimal approach for assisting smoking cessation. Allen Carr’s Easyway (ACE) is a single-session pharmacotherapy-free programme that has been in operation internationally for 38 years. We compared the effectiveness of ACE with specialist behavioural and pharmacological support delivered to the national standard in England.

**Design** A two-arm, parallel-group, single blind, randomised controlled trial.

**Setting** London, UK, between February 2017 and May 2018.

**Participants** 620 participants (310 in ACE and 310 in the combined behavioural and pharmacological support condition) were included in the analysis. Adult (≥ 18 years) smokers wanting to quit were randomised in a 1:1 ratio. Mean age for the total sample was 40.8 years, with 53.4% being male. Participant baseline characteristics (ethnicity, educational level, number of previous quit attempts, nicotine dependence) were evenly balanced between treatment groups.

**Intervention and comparator** The intervention was the ACE method of stopping smoking. This centres on a 4.5-6 hour session of group-based support, alongside subsequent text messages and top-up sessions if needed. It aims to make it easy to stop smoking by convincing smokers that smoking provides no benefits for them. The comparator was a specialist stop smoking service (SSS) providing behavioural and pharmacological support in accordance with national standards.

**Measurements** The primary outcome was self-reported continuous abstinence for 26 weeks from the quit/quit reset date verified by exhaled breath carbon monoxide measurement <10 ppm. Primary analysis was by intention to treat. Secondary outcomes were: use of pharmacotherapy, adverse events and continuous abstinence up to 4 and 12 weeks.

**Findings** 152 participants did not attend treatment (55 ACE vs 97 SSS, p<0.05). Of those who did attend treatment, 100 completed 6-month measures (23.7% ACE vs 20.7% SSS). Continuous abstinence to 26 weeks was 19.4% (60 out of 310) in the ACE intervention and 14.8% (46 out of 310) in the SSS intervention (risk difference for ACE vs SSS 4.5% [95% CI -1.4% to 10.4%, OR = 1.38]). The Bayes factor for superiority of the ACE condition was 1.24.

**Conclusion** There was no clear evidence of a difference in the efficacies of the Allen Carr’s Easyway (ACE) and specialist smoking cessation support involving behavioural support and pharmacotherapy.

**Keywords** Smoking, Cessation, Allen Carr, NHS, Randomised Controlled Trial.

**INTRODUCTION**

Although the WHO1 report that the prevalence of tobacco smoking is declining worldwide, in England alone in 2017 14.9% of adults were classified as smokers, with 77,900 deaths attributed to smoking.2 Many smokers want to quit and often make several attempts to do so, but the majority fail due to both physiological and psychological factors.3 Over the years, researchers have sought to develop effective cessation treatments (psychological and pharmacological) in an effort to provide education and support. Although evidence suggests these types of intervention are cost-effective from a public health perspective, a recent report showed that 37% of smokers made an attempt to quit but only 19% were successful in the short term.4 In addition, many people fail to maintain smoking cessation in the longer term.5,6

It is important to understand and continually evaluate the relative efficacies of various interventions designed to help people quit smoking, and to develop the evidence base for methods which, while well-established, have not been tested systematically. One such treatment, offered in the UK, is the Allen Carr’s Easyway (ACE) method of stopping smoking. While the ACE method is well established and its efficacy has received some empirical support,7,8 there has not to date been a full trial testing the efficacy of this method using the Russell Standard as the outcome measure (the benchmark cessation measure) or a comparison against a specialist stop smoking service (SSS) providing behavioural and pharmacological support in accordance with national standards (a highly effective stop smoking intervention offered in the UK).9,10 Evaluating the efficacy of the ACE method is important as it offers a pharmacotherapy free method of smoking cessation which can be delivered in group therapy sessions. As such, it may offer a viable cost-effective additional treatment option in public/funded healthcare settings. In the current study, we conducted a parallel group, randomised controlled trial to compare the efficacy of the ACE method and a specialist stop smoking service (SSS) providing behavioural and pharmacological support.

**METHODS**

**Study design**

A two-arm, parallel group, single blind, randomised controlled trial, conducted in London, UK. First randomisation was on 3rd February, 2017, and the last follow up on 25th May, 2018. The published protocol describes procedures in detail.11

**Participants**

People were eligible if aged 18 years or older, were current smokers wanting to quit, were open to being randomly assigned to one of two treatment conditions, and who could provide consent. We excluded pregnant women; those reporting a mental health condition or respiratory disease such as asthma or emphysema; people who were currently enrolled on a similar clinical trial; and people who were not willing to undertake a stop smoking service which is neither endorsed by the NHS, nor NICE approved.

**Procedure**

We recruited via social media channels, newspaper and radio advertisements, and targeted emails to local businesses and organisations asking people to contact the study centre for more information and eligibility pre-screening. This was undertaken by research assistants, who also performed follow-up assessments. The research team made an initial contact attempt within two days to arrange a suitable time for pre-screening (with subsequent attempts over the next three weeks, unless the participant withdrew). They were not told at the point of pre-screening which two interventions were being compared, just that the study aimed to compare the efficacy of two stop smoking interventions. If eligible, participants were asked about demographics, nicotine dependence and prior quit attempts to allow for stratified randomisation into the trial. Eligible participants were sent a consent form immediately after pre-screening and asked to return it within a week. On gaining written consent, participant’s details were immediately sent to the independent randomiser for allocation. Once randomised, participant details were emailed to the allocated intervention arm, for them to make contact to schedule treatment, which was recorded on a blind shared file. Treatment arms attempted to make contact with participants within the first week of receiving the allocation. Research assistants checked this file daily, and contacted participants to arrange a face-to-face appointment to collect baseline data (no more than one week before the treatment date). Tests were administered by research assistants at LSBU and participants were paid £15 for attending each appointment. In addition, all participants who completed the final wave were entered into a raffle for a holiday and other (low value) prizes. Data collection continued as scheduled if participants discontinued treatments.

The Fulham Research Ethics Committee approved the research protocol (ref: 16/LO/1657) as did the London South Bank University (LSBU) ethics panel (UEP0516).

**Randomisation and Masking**

Participants who met the inclusion criteria and gave details about demographics and nicotine dependence (Fagerstrom Test for Nicotine Dependence [FTND12]) were randomised by the study statistician (SW) in a 1:1 ratio to either the ACE or NHS treatments, with computerised block randomisation stratified by age (18-37 or >38), sex (male or female), number of previous quit attempts (none made over past year or attempts reported over past year), and level of nicotine dependence (>5 or ≤5 FTND). The stratification variables were selected as they have been shown to influence treatment success, and our aim was to investigate the unique effects of treatment across a demographically heterogeneous sample. Participants were blind to both treatments until randomised and once allocated were blind to the treatment not being received. Treatment staff were not blind to participants taking part in the trial. Members of the trial steering committee, management committee, and other team members (with the exception of the statistician/randomiser), remained blind to treatment allocation until the final follow-up was completed and the analysis undertaken recorded. The analysis protocol and syntax were prepared and lodged with the OSF before the statistician was provided with the dataset.

**Interventions**

*Allen Carr’s Easyway Programme*

Participants randomised to the ACE treatment arm attended a single group session at their choice of either LSBU (2 days a week) or Allen Carr’s London treatment centre (6 days a week, afternoon only). The session lasted five to six hours and comprised elements of cognitive behavioural therapy (CBT) with a brief relaxation exercise at the end that serves to reinforce the main points covered. Participants were encouraged to carry on smoking as usual prior to attending the session and to take advantage of scheduled smoking breaks (every 45-60 minutes) before finishing with a final ‘ritual’ cigarette. A trained facilitator worked with participants to help them recognise the positive expectancies they associate with smoking (e.g. pleasure, support, a crutch) before moving towards the conclusion that any beliefs about smoking being of benefit to the individual are harmful. Participants were also taught how the psychological and pharmacological mechanisms of nicotine addiction facilitate the maintenance of a problematic belief system. Following the session, participants were sent regular SMS messages from the clinical team, standard procedure for this intervention, reminding them to touch base with any questions they might have (for a fuller description see the published protocol11 and Appendix below). One therapist delivered each group session (7 therapists in total delivered group sessions). The mean number of participants per group was 8.95 (SD=4.08, range = 1-19). Participants could select which site to attend - 197 attended their initial treatment session at LSBU and 58 at ACE’s London treatment centre. There was no difference in the primary outcome measure between sites (x2 = 0.87, p = 0.351).

*Specialist stop smoking service (SSS)*

Participants who received the SSS treatment attended a single 30-minute session, which combined motivational interviewing and CBT approaches and up to four follow up sessions (their standard treatment protocol). Sessions took place at LSBU and were delivered by four SSS therapists. Sessions were available 5 days a week in the morning or afternoon. This constitutes the local NHS stop smoking service currently offered at Guy’s and St Thomas’ NHS Foundation Trust and Lambeth Public Health. In the first session, a therapist assessed current smoking, readiness to quit and past quit attempts. Participants were then advised about nicotine dependence and withdrawal and the pros and cons of pharmacotherapy discussed. Participants were asked to set a quit date (within two weeks of attending the first session) and assisted to recognise and plan for any upcoming high-risk situations which may lead to relapse. NRT was provided using a voucher redeemable at local pharmacies in Lambeth and Southwark and for Champix, they were provided with a letter of recommendation to take to their GP in order to request the prescribed medication. The intervention allowed for medications for up to 12 weeks in total. After the 4 week follow up, participants were prescribed 4 weeks supply and asked to contact the SSS team to arrange the final prescription (should one be required). One, two and three weeks post-quit date, participants could return for a brief 10-minute progress check including a review of cessation coping mechanisms and pharmacotherapy supplies, and an opportunity to reflect on and plan for any challenging situations encountered. At four weeks post-quit date, participants could return for a final 10-minute meeting where they were advised about the continued use of pharmacotherapy and techniques for coping with urges and cravings. At each appointment, participants had their carbon monoxide levels measured and feedback was provided by the clinician. Participants were also urged to remain completely abstinent from cigarettes (for a fuller description see the published protocol11).

*Top-ups and Resets*

Both treatments contained, as standard, options to reset quit dates. The ACE provision allowed participants to ‘top-up’ their treatment through one or two additional sessions that broadly followed the same format as the main seminar, but were shorter at approximately 3.5 hours and could be attended either face-to-face or online. Participants receiving the SSS treatment were able to reset their quit date at the suggestion of the clinician. Participants across both treatment arms were permitted a total of two top-up sessions or opportunities to reset within 12 weeks of their original quit date. Any top-ups or resets were recorded by clinicians on a central shared file (containing no condition data) and all follow-up assessments were calculated according to the reset date rather than the original quit date (i.e. if a participant reset a month after their original quit date, all follow-ups moved to a month later). This design decision is addressed in more detail in our protocol11. In the ACE arm, 36 attended a first top-up session at LSBU, 32 at the treatment centre and 22 received the top-up online (via an online webinar replicating the content of face to face sessions). Fifteen attended a third session at LSBU, 6 at the treatment centre and 12 received the session online.

**Measures**

*Baseline*

Quit efficacy was measured using four 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’. A scale of 1 (strongly disagree) to 7 (strongly agree) was used.

Use of support mechanisms (NRT, e-cigarettes, Champix). Participants were asked ‘Have you regularly used any of the following in the past few months?’ and ‘’Are you planning on using any of the following when you quit smoking?’ Yes/No answers.

Continuous smoking abstinence. This was biochemically verified by exhaled breath carbon monoxide measurement (<10 ppm), using Bedfont Micro Smokerlyzers. This is in line with the standard assessment of smoking cessation used in research and practice in the UK.10

Nicotine dependence. This was measured using the Fagerstrom Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker and Fagerstrom, 1991).

*4, 12 and 26 weeks*

Quit efficacy and continuous smoking abstinence were measured as above.

Use of support mechanisms (NRT, e-cigarettes, Champix). Participants were asked ‘Since we last met, have you regularly used any of the following?’ and ‘’Are you planning on using any of the following when you quit smoking?’ Yes/No answers., 1991).

Self-reported continuous abstinence from the quit/quit reset date. This was measured using 5-items: ‘Are you still an ex-smoker?’; ‘Since we last met, have you had any cigarettes? If so, how many?’; ‘How many cigarettes have you had in the last week?’; ‘How many cigarettes in the last month?’; ‘In total, how many cigarettes have you had since your quit date?’

Nicotine dependence. This was measured using the Fagerstrom Test for Nicotine Dependence (Heatherton, Kozlowski, Frecker and Fagerstrom, 1991).

Adverse events. Participants were asked ‘Have you had any new medical issues which may be due to your quit?’

**Funding**

Funding was provided by Allen Carr’s Easyway International Ltd. They had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication. The research team recognise the need for a high level of accountability to avoid systematic bias in all studies, and in particular those which are commercially funded. To minimize the chance of bias, we took a number of steps. Specifically, we (i) had expert peer review of our protocol prior to and during our protocol registration, (ii) appointed and stayed in close contact with an independent steering committee to monitor the trial and advise on design issues and (iii) pre-registered our analysis, including syntax, on the OSF.

**Sample Size**

The trial was designed to test for superiority on an Intention to treat (ITT) basis. In the Cochrane review of combined pharmacotherapy and behavioural interventions for smoking cessation9, a pooled quit rate of 17% was found for interventions provided by specialist services. This study was powered to detect, with 85% power, a 10% advantage for ACE over the SSS (assuming it would perform as the specialist service providers) at a 5% significance level. Therefore, an initial sample of 620 participants was sought (310 per intervention group).

**Statistical Analysis**

Statistical analyses were carried out using SPSS version 25. The primary analyses used the ITT approach at the point of randomisation (participants with unknown smoking status were assumed to be smoking).

*Primary outcome analysis.* The primary outcome was continuous smoking abstinence (self-reported abstinence over the whole follow-up period, allowing ≤5 cigarettes in total since quit date), for 26 weeks from the quit/quit reset date. Participants for whom smoking cessation could not be confirmed (i.e. are lost to follow-up) were included in the analysis as failed quits in line with the Russell Standard.10 Absolute risk differences are presented with 95% confidence intervals (CI). Pearson χ2 analysis was used to test whether the risk difference differed significantly from 0 or not, exact p-values are reported. Odds ratios with 95% CIs are also reported, calculated using logistic regression.

A series of sensitivity analyses were conducted to assess the robustness of primary results with regards to definition of the primary outcome. To investigate if the differential effects of interventions are present at each time point (4 and 12 weeks), the primary analysis was repeated twice, the dependent variable being smoking cessation confirmed at 4 and 12 weeks. The primary analysis was repeated on smoking cessation outcomes at both 12 and 26 weeks using only participants who did not ‘reset’ their quit dates (SSS arm) or did not attend a top-up session (ACE arm). For this analysis, this approach is preferable to including top-ups/resets as failed quits, as many may in fact be successful cessations. Estimates of effectiveness at 4, 12 and 26 weeks are also reported for only participants who attended treatment. Stratification variables were included as covariates in logistic regression models when the full sample (n=620) was not used.

*Secondary outcomes.* Use of any NRT/e-cigarettes/Champix was analysed in the same manner as the primary outcome using risk differences and adjusted odds ratios. Treatment arm and treatment success were included as independent variables along with stratification variables in the logistic regression. These analyses were completed for a) those participants for whom NRT usage was known at 26 weeks and those who had reported NRT use at 4 or 12 weeks, b) as in a) but restricted to those who had attended treatment, and c) those participants followed up at 26 weeks (ignoring previous NRT use). A further secondary outcome was completion of treatment (operationalised as attendance at the ACE session or attendance at a minimum of one SSS session).

**RESULTS**

Of 2,115 people who were assessed, 133 did not meet the eligibility criteria, 1358 declined to participate, and 620 (29%) were randomised for inclusion into the study (Figure 1). 310 people were assigned to each treatment arm. At 4 weeks 49% of ACE participants completed follow-ups, 43% for SSS, at 12 weeks the respective values are 46% and 38%, for 26 weeks 29% and 28%. Thus, assumed smoking rates (due to loss to follow up) at 26 weeks were 148 vs 170 - a difference of 7.1% (95% CI -1.0%, 14.8%) *p* = 0.077. Participants’ baseline characteristics were evenly balanced between treatment groups (Table 1). 82 participants reset their quit date, 33 in the SSS group (three reset twice, see Table 4 in appendix for number of sessions attended) and 49 in the ACE group (17 of them twice). 468 (75.5%) participants attended treatment. Treatment attendance was significantly higher in the ACE group compared to the SSS group, *p* <0.001 (see Table 2 for number of sessions attended by treatment arm).

Insert Figure 1

Insert Table 1

Insert Table 2

There was no evidence of a difference in rates of verified continuous abstinence at 26 weeks between the ACE and SSS groups, 19.4% vs 14.8% (risk difference=4·5%; 95% CI: -1.4%, 10.4%; Table 3). This difference is not statistically significant, *p* = 0.165. Given the non-significant finding a Bayes factor (B) was calculated, B=1.24, indicating nonconclusive evidence for the null hypothesis of no difference. Risk differences for the 4 and 12 week abstinence rates are also non statistically significant (risk difference; 95% CI; -5.8%; -13.0%, 1.5%; and -0.3%; -6.8%, 6.2%; respectively).

Among self-reported quitters, 3 who self-reported at 4 weeks failed verification, 3 at 12 weeks and none at 26 weeks. Similar estimates of treatment benefit were found in the sensitivity analyses.

No significant difference was found when those who reset were classed as non-abstainers at 12 and 26 weeks. In the SSS arm, 6 people who reset were successful quits at 26 weeks. In the ACE arm, 9 were successful at 26 weeks. The SSS group had statistically significant higher rates of verified abstinence at 4 weeks when only analysing those participants who had attended treatment.

Use of pharmacotherapy was significantly higher in the SSS group, with 47.9% less participants in the ACE group using any aids throughout the study. In the NHS arm, 71 participants self-reported use of nicotine patches (25 quits), 23 used varenicline (4 quits), 35 used nicotine gum (11 quits), 51 used e-cigarettes (15 quits), and 73 other forms of pharmacotherapy (22 quits). In the ACE arm, 4 participants self-reported use of nicotine patches (1 successful quit), 4 used varenicline (1 quit), 5 used nicotine gum (1 quit), 19 used e-cigarettes (3 quits) and 10 used other forms (3 quits). At 26 weeks 83.3% of ACE participants were not using pharmacotherapy in comparison to 40.1% of SSS participants, risk difference=43.1% (29.4%, -54.5%).

Although non-inferiority testing was not planned, exploration via post hoc analyses using a 5% non-inferiority limit for the risk difference (see Siemer et al.14 for a detailed rationale of a 5% limit in this context) suggest the ACE method was at least as effective as the SSS intervention (the absolute risk difference for the primary outcome was 4.5 [95% CI -1.4 – 10.4]; -1.4 is within the margin of -5). This suggests that among smokers wanting to quit, the ACE method is neither superior nor inferior to the SSS for achieving cessation at 26 weeks.

Insert Table 3

**DISCUSSION**

The SSS and Allen Carr’s Easyway (ACE) method to quit smoking both achieved good outcomes on an intention-to-treat basis at 26 weeks, comparable with other trials of methods (including NRT and behavioural interventions with combined pharmacotherapy).9,13 The pattern of findings was consistent when considering covariates such as age, gender, nicotine dependence, previous quit attempts and across a range of analyses (comparing participants who attended the treatment versus intention-to-treat and participants who reset their quit date) and when a complete case analysis was undertaken. As such, these findings support and broaden the evidence base in support of the use of such interventions in public health settings.

Treatment initiation was significantly higher in the ACE arm (83%) relative to the SSS arm (69%). Without qualitative data it is difficult to conclusively interpret this finding. However, candidate factors could include participants preferring a single, longer session, preferring a nicotine free approach and/or perceived novelty or perceived efficacy of the ACE arm. These could be explored in future research. In relation to this, it should be noted that participants in the ACE treatment arm were offered treatment at two sites (in contrast to the SSS condition, where only one was offered) to avoid a significant imbalance in days/times available (ACE sessions were only available on Wednesdays and Thursdays at LSBU, in contrast to am or pm five days per week in the SSS). This may have influenced treatment uptake.   
A key and noteworthy difference between treatment arms is their focus on the use of stop smoking aids (pharmacotherapy). The SSS approach has a strong focus on the selection and usage of nicotine replacement therapy (NRT), Champix and other medicinal supports. E-cigarettes are also increasingly being promoted as a stop smoking aid (although not explicitly in the current study). In contrast, the ACE method emphasises a nicotine free approach to cessation and cessation maintenance. These differences were reflected in our results; amongst our sample, 91.3% of SSS participants who successfully quit used NRT, Champix or an e-cigarette. In contrast, in the ACE condition, significantly fewer people (13.3%) who successfully quit used these forms of support.

The strengths of our study include the measurement of smoking cessation using a continuous abstinence criterion. Results from a recent study comparing the ACE method to Ireland’s Quit.ie service found demonstrably superior quit rates for the ACE method, however they adopted a point prevalence method.7 We also compared the ACE method against a single intervention with high recorded efficacy, in contrast to the Quit.ie. service which features interventions of varying intensity and efficacy.

Our study had several limitations. In line with the Russell Standard, we verified successful quits using exhaled breath carbon monoxide measurement. Although this is considered a superior measure to self-report, other forms of chemical verification of being nicotine free (i.e. cotinine testing) are able to detect levels of nicotine consumed further in the past. Such methods were precluded in the current study as participants in the SSS condition were provided with the option of using funded NRT, and both treatment arms were free to purchase these independently along with other quit aids such as e-cigarettes. As such, the limitations surrounding carbon monoxide testing (i.e. the duration one needs to be nicotine free for, sensitivity to detect very low levels of smoking versus passive smoking versus environmental effects, and measurement error associated with the devices themselves) limit our findings. One way future research could disambiguate tobacco based nicotine levels from others (such as from NRT and e-cigarettes) would be through the use of tests of anabasine or antabine15.

Our study excluded vulnerable patients (e.g. pregnancy, mental illness and respiratory illness), meaning results are generalizable to a relatively healthy population and may not be a true reflection of each service’s everyday operation or treatment priorities.

Attrition between contacting the study and consent was high. This may have been due to the nature of incentives offered (i.e. a chance to win a holiday). It could also reflect that most participants had engaged in quit attempts before, with prior experience with one or both treatment arms which they perceived as being unsuccessful. On a similar note, 48.70% of participants randomised were accounted for at the 6-month point, leaving 51.29% as lost to follow-up. This presents a caveat in the confident assessments of equivalence between arms, although the potential impact of this is mitigated slightly by equal attrition between arms.

Finally, significantly more participants completed treatment when randomised to the ACE intervention. This could reflect a preference for the mode of delivery offered by ACE, but could also reflect prior experience with SSS which did not result in success, or were perceived as less novel.

Our study provides evidence that the ACE method for stopping smoking was neither superior or inferior to leading stop smoking interventions.6,9 Given the significantly lower usage of stop smoking aids in participants undergoing the ACE intervention, higher treatment completion rates, and possible cost-savings resulting from group-based delivery, findings support the use of this intervention in a public health setting.

**Contributors**

DF, IPA, ACM and KVW conceived the design of the trial and conducted the literature search. KVW and DF wrote the study protocol with input from IPA and ACM. KVW managed the day-to-day running of the trial, including all participant follow-up. HB and MB recruited participants and conducted data collection. SW conducted the data analyses. SW, DF, KVW, IPA and ACM interpreted the data. This article was written by KVW with input from all co-authors. DF is guarantor for this paper. All authors read and approved the final manuscript. The advisory panel consisted Professor Robert West, Professor Lynne Dawkins, Jacqui Leslie and Dr Rachel Taylor. The SSS intervention was provided by Lambeth Stop Smoking Service.

**Data Sharing**

Disidentified data will be made available on publication. Data will be hosted on the Open Science Framework (on the project page associated with the trial - https://osf.io/9kj8d/) on a CC BY-NC 4.0 basis. Study materials such as consent forms and questionnaire will also be available.

**Acknowledgements**

We thank Lambeth Public Health for their support with this study.

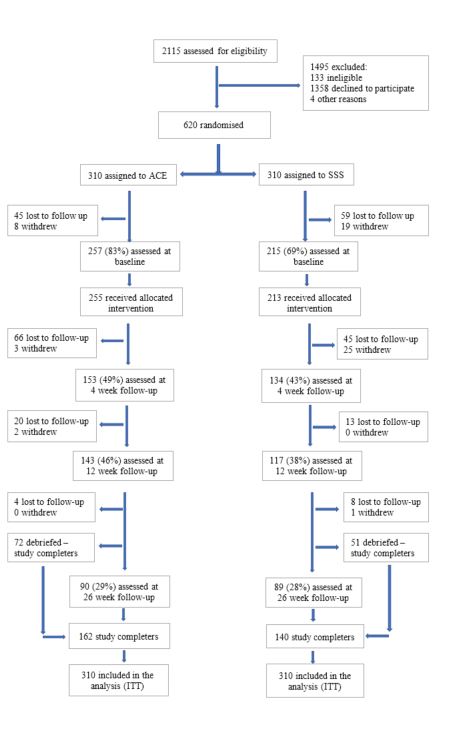
**References**

1. World Health Organisation. Global report on trends in prevalence of tobacco smoking.2015.http://www.who.int/tobacco/publications/surveillance/reportontrendstobaccosmoking/en/ (accessed November 2018)
2. Statistics on smoking. England: 2018. https://files.digital.nhs.uk/0C/95F481/stat-smok-eng-2018-rep.pdf (accessed January 2019)
3. Bucchalter AR, Acosta MC, Evans SE, Breland AB, Eissenberg T. (2015). Tobacco abstinence symptom suppression: the role played by the smoking-related stimuli that are delivered by denicotinized cigarettes. *Addiction,* 2015; **100:**550-559.
4. Public Health England (2016). Health matters: Smoking and quitting in England. https://www.gov.uk/government/publications/health-matters-smoking-and-quitting-in-england/smoking-and-quitting-in-england (accessed December 2018)
5. Ronckers ET, Groot W, Ament AJ. Systematic review of economic evaluations of smoking cessation: standardizing the cost-effectiveness. *Medical Decision Making.* 2005; **25**:437-448.
6. Stead LF, Perera R, Bullen C, et al. Nicotine replacement therapy for smoking cessation. *Cochrane Database of Systematic Reviews.* 2012; **11***.* Doi:10.1002/14651858.CD000146.pub4.
7. Keogan S, Li S, Clancy L. Allen Carr’s Easyway to stop smoking – A randomized clinical trial. *Tobacco Control.* 2018; **0**:1-6. Doi: 10.1136/tobaccocontrol-2018-054243
8. Dijkstra A, Zuidema. R, Vos D, van Kalken M. The effectiveness of the Allen Carr smoking cessation training in companies tested in quasi experimental design. *BMC Public Health.* 2014; **14:**952.
9. Stead LF, Koilpillai P, Fanshawe TR, Lancaster T. Combined pharmacotherapy and behavioural interventions for smoking cessation.

Cochrane Database of Systematic Reviews. 2016; **3**. DOI: 10.1002/14651858.CD008286.pub3.

1. West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. *Addiction*. 2005; **100:** 299-303.
2. Wood KV, Albery IP, Moss AC, White S, Frings D. Study protocol for a randomised controlled trial of Allen Carr’s Easyway programme versus Lambeth and Southwark NHS for smoking cessation. *BMJOpen*. 2017; **7.** doi: 10.1136/bmjopen-2017-016867
3. Heatherton TF, Kozlowski LT, Frecker RC, Fagerstrom KO. The Fagerstrom Test for Nicotine Dependence: a revision of the Fagerstrom Tolerance Questionnaire. *Br J Addict.* 1991. **86**:1119-27.
4. Hartmann‐Boyce  J, Chepkin  SC, Ye  W, Bullen  C, Lancaster  T. Nicotine replacement therapy versus control for smoking cessation. *Cochrane Database of Systematic Reviews.* 2018; **5.** DOI: 10.1002/14651858.CD000146.pub5.
5. Siemer L, Pieterse ME, Brusse-Keizer MG, Postel MG, Allouch SB, Sanderman R. Study protocol for a non-inferiority trial of a blended smoking cessation treatment versus face-to-face treatment (LiveSmokefree-Study). *BMC Public Health.* 2016; **16(1),** 1187.
6. Jacob P, Hatsukami D, Severson H, Hall S, Yu L, Benowitz NL. Anabasine and anatabine as biomarkers for tobacco use during nicotine replacement therapy. C*ancer Epidemiology and Prevention Biomarkers*. 2002;**11**:1668-73.

Figure 1: Participant flow



Note: Treatment completion = operationalised as attendance at the ACE session or attendance at a minimum of one SSS session. Study completers = operationalised as completing all follow-up measures. Debriefed study completers = failed quits at 12 weeks who were debriefed and not required to attend for 6-month follow-up.

**Table 1: Baseline characteristics of participants**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **ACE**  **n=310** | **SSS**  **n=310** | **Total**  **n=620** |
| Age in years M(SD) |  | 41·3 (11·1) | 40·3 (11·8) | 40·8 (11·5) |
| Male |  | 170 (54·8%) | 161 (51·9%) | 331 (53·4%) |
| Ethnicity, n=617 | Indian | 14 (4·5%) | 13 (4·2%) | 27 (4·4%) |
| Pakistani | 5 (1·6%) | 4 (1·3%) | 9 (1·5%) |
| Bangladeshi | 2 (0·6%) | 3 (1·0%) | 5 (0·8%) |
| Asian(other) | 10 (3·2%) | 10 (3·2%) | 20 (3·2%) |
| Black-African | 3 (1·0%) | 10 (3·2%) | 13 (2·1%) |
| Black-Caribbean | 11 (3·6%) | 21 (6·8%) | 32 (5·2%) |
| Black-Other | 8 (2·6%) | 6 (1·9%) | 14 (2·3%) |
| Mixed race | 14 (4·5%) | 20 (6·5%) | 34 (5·5%) |
| White-UK or Irish | 178 (57·8%) | 157 (50·8%) | 335 (54·3%) |
| White - Other European | 41 (13·3%) | 43 (13·9%) | 84 (13·8%) |
| White - other | 13 (4·2%) | 16 (5·2%) | 29 (4·7%) |
| Other | 9 (2·9%) | 6 (1·9%) | 15 (2·4%) |
| Education achieved n=616 | GCSE, CSE or equivalent | 30 (9·7%) | 24 (7·8%) | 54 (8·8%) |
| A Level | 45 (14·6%) | 43 (14·0%) | 88 (14·3%) |
| Vocational qualification | 23 (7·4%) | 23 (7·5%) | 46 (7·5%) |
| Degree BA, BSc | 116 (37·5%) | 127 (41·4%) | 243 (39·4%) |
| Postgraduate degree | 69 (22·3%) | 59 (19·2%) | 128 (20·8%) |
| Other | 26 (8·4%) | 31 (10·1%) | 57 (9·3%) |
| Number of cigarettes smoked / day n=619 | 10 or less | 102 (32·9%) | 135 (43·7%) | 237 (38·3%) |
| 11 – 20 | 163 (52·6%) | 142 (46·0%) | 305 (49·3%) |
| 21 – 30 | 37 (11·9%) | 27 (8·7%) | 64 (10·3%) |
| more than 30 | 8 (2·6%) | 5 (1·6%) | 13 (2·1%) |
| Age started smoking (years) n=617 |  | 17·1 (4·3) | 16·6 (3·7) | 16·9 (4·0) |
| Lives with other smokers n=617 |  | 105 (34·0%) | 104 (33·8%) | 209 (33·9%) |
| At least 1 quit attempt in past 12 months |  | 196 (63·2%) | 196 (63·2%) | 392 (63·2%) |
| FTND score 5-8 |  | 129 (41·6%) | 112 (36·1%) | 241 (38·9%) |
| Quit efficacy n=473 |  | 20·7 (4·3) | 20·8 (4·1) | 20·8 (4·2) |
| Baseline CO reading n=473 |  | 17.5 (9.8) | 15.1 (10.2) | 16.4 (10.1) |

**Note.** ACE: Allen Carr’s Easyway method. SSS: specialist stop smoking service (SSS) providing behavioural and pharmacological support in accordance with national standards FTND: Fagerstrom Test for Nicotine dependence.All measures were taken before randomisation, n=620 unless otherwise stated

**Table 2: Participant flow and data summary**

|  |  |  |
| --- | --- | --- |
|  | *ACE* | *SSS* |
| Randomised | 310 | 310 |
| Eligible for inclusion in outcome analysis | 310 | 310 |
| Attended allocated treatment | 255 | 213 |
| RS smoking |  |  |
| Self-report of smoking at 26 weeks (>5 cigarettes) | 24 | 31 |
| Self-report of smoking at 12 weeks and debriefed (>5 cigarettes) | 58 | 29 |
| Self-report of abstinence throughout FU, attended and failed at least one biochemical validation session | 5 | 0 |
| Self-report of abstinence throughout FU, did not attend for a biochemical validation session at final FU | 0 | 0 |
| No contact at final FU | 220 | 221 |
| RS abstinent |  |  |
| Self-report of abstinence (<5 cigarettes) throughout FU, passed biochemical validation session at final FU | 60 | 46 |
| RS abstinence rate | 60/310 | 46/310 |

**Table 3: Efficacy of treatment, pharmacotherapy usage and treatment completion.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **n** | **ACE** | **SSS** | **χ2 p-value** | **Odds ratio (95% CI)** | **Risk difference (95% CI)** |
| **Treatment acceptability** |  |  |  |  |  |  |
| Attended treatment | 310/310 | 255 (82.3%) | 213 (68.7%) | <0.001 | 2.11 (1.45, 3.08) | 13.6% (6.6%%, 20.4%) |
| **Verified abstinence: (ITT) analyses** | | | | | | |
| 4 weeks | 310/310 | 86 (27·7%) | 104 (33·5%) | 0·139 | 0·76 (0·54, 1·07) | -5·8% (-13·0%, 1·5%) |
| 12 weeks | 310/310 | 67 (21·6%) | 68 (21·9%) | 1·0 | 0·98 (0·67, 1·44) | -0·3% (-6·8%, 6·2%) |
| 26 weeks (PO) | 310/310 | 60 (19·4%) | 46 (14·8%) | 0·165 | 1·38 (0·90, 2·10) | 4·5% (-1·4%, 10·4%) |
| **Verified abstinence: Participants who attended treatment analyses\*** | | | | | | |
| 4 weeks | 255/213 | 86 (33.7%) | 104 (48·8%) | 0·001 | 0·54, (0·37, 0·79) | -15.1% (-24.1%, 5.9%) |
| 12 weeks | 255/213 | 67 (26·3%) | 68 (31·9%) | 0·185 | 0·75 (0·50, 1·13) | -5·7% (-14·9%, 2·9%) |
| 26 weeks | 255/213 | 60 (23·5%) | 44 (20·7%) | 0·503 | 1·18 (0·75, 1·85) | 2.9% (-5.1%, 10·6%) |
| **Pharmacotherapy usage** | | | | | | |
| Completed study | 134/161 | 64 (47·8%) | 154 (95·7%) | <0·001 | 0·01 (0·00, 0·07) | -47·9% (-56·5%, -38·4%) |
| Completed study and treatment | 131/144 | 62 (47.3%) | 141 (97·9%) | <0·001 | 0·01 (0·00, 0·05) | -50·6% (-59·4%, -40·7%) |
| Pharmacotherapy free at 26 weeks | 91/89 | 76 (83·5%) | 36 (40·4%) | <0·001 | 7·59 (3·71, 15·52) | 43·1% (29·4%, -54·5%) |

**Note.** ITT: Intention to Treat.PO: Primary Outcome. \* Non-attenders are treated as non-abstainers

**Table 4. Number of sessions attended by SSS arm participants**

|  |  |
| --- | --- |
| SSS sessions attended | n participants (%) |
| 1 | 42 (13.5%) |
| 2 | 25 (8.1%) |
| 3 | 18 (5.8%) |
| 4 | 21 (6.8%) |
| 5 | 31 (10.0%) |
| 6 | 57 (18.4%) |
| 7 | 9 (2.9%) |
| 8 | 8 (2.6%) |
| 9 | 1 (0.3%) |
| 10 | 1 (0.3%) |

**Appendix**

*Brief summary of the ACE perspective and method.*

The Allen Carr’s Easyway method combines elements cognitive restructuring and a brief relaxation phase. Initially, clients are invited to relax, and encouraged to smoke during breaks in the session. They are encouraged to be sceptical of the method and query elements as the session proceeds. The session then outlines arguments from the perspective that (i) the client has not always been a smoker, (ii) that smoking is not a pleasurable activity, (iii) that quitting is not a loss, but a gain (or a loss of a burden/negative need) and (iv) that, given the above, quitting does not require immense willpower or involve unpleasant feelings or experiences v) most unpleasant feelings experienced in previous attempts to quit were mainly caused by negative and skewed thought processes (and the physical reaction caused by those thought processes) rather than nicotine withdrawal, (vi) therefore once (i), (ii), (iii), (iv), (v) have been explained and understood using everyday examples of the smoker’s own experience – the process of stopping smoking is not unpleasant or arduous – but relatively easy and enjoyable. Towards the end of the session, clients are given an expectation of what quitting will be like. They are also encouraged to avoid suppressing thoughts about smoking but to reframe such thoughts positively, and the main points of discussion are re-iterated. Following this, clients have a final ritual cigarette in silence, then discard their remaining cigarettes. There is then a short relaxation session (similar to a guided hypnotherapy session in which the main arguments are restated). Finally, clients are encouraged to think of themselves as non-smokers, asked to make a written record of what it was about their life as a smoker that made them want to stop smoking, and warned against relapse. They are also invited to contact the treatment team if they need advice.

Following the session, SMS messages are sent to clients (accompanied by the ACE contact number) on days 1, 3, 10, 18, 45, 70, as follows;

Day 1: Good luck today! Please save our number on your phone in case you have any questions afterwards

Day 3: (Name), Hope all is well with you :). Do give us a call if you have any questions or need some support

Day 10: (Name), How are you doing? Don’t forget you can give us a call for support

Day 18: (Name) Happy non-smoker? Yay! If not please do give us a call for support

Day 45: (Name), Happy non-smoker? YIPPEE! If not please do give us a call for support

Day 70: (Name), Are you a happy non-smoker? If so YAY – if not please do give us a call for help.

If clients contact the ACE team for additional support standard responses to those who had smoked was to recommend they attend back-up session and offered dates to attend. Clients who had not smoked was to be offered a call back. Call-backs involved discussing the smokers experience since attending the session, checking that the client had made a written record of what life was like for them as a smoker in line with advice given in the session, and given guidance on how to react to thoughts about cigarettes or smoking so that the experience ceased to be difficult or negative.