

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

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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, randomized controlled trial. **Setting** London, UK, between February 2017 and May 2018. **Participants** A total of 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 randomized 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 re-set date verified by exhaled breath carbon monoxide measurement < 10 parts per million (p.p.m.). 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** A total of 468 participants attended treatment (255 ACE versus 213 SSS, $P < 0.05$). Of those who did attend treatment, 100 completed 6-month measures (23.7% ACE versus 20.7% SSS). Continuous abstinence to 26 weeks was 19.4% (60 of 310) in the ACE intervention and 14.8% (46 of 310) in the SSS intervention [risk difference for ACE versus SSS 4.5% (95% confidence interval (CI) = -1.4 to 10.4%, odds ratio (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 Allen Carr, cessation, NHS, randomised controlled trial, smoking.

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Submitted 15 March 2019; initial review completed 16 May 2019; final version accepted 8 November 2019

INTRODUCTION

Although the World Health Organization (WHO) [1] report that the prevalence of tobacco smoking is declining world-wide, in 2017 in England alone 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 that 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 United Kingdom 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 been a full trial to date 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 United Kingdom) [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 health-care settings. In the current study, we conducted a parallel group, randomized 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, randomized controlled trial, conducted in London, UK. First randomization was on 3 February 2017, and the last follow up on 25 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 National Health Service (NHS) nor National Institute for Health and Care Excellence (NICE)-approved.

Procedure

We recruited via social media channels, newspaper and radio advertisements, and targeted e-mails to local businesses and organizations 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 2 days to arrange a suitable time for pre-screening (with subsequent attempts over the next 3 weeks, unless the participant withdrew). Participants 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 randomization 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, participants' details were immediately sent to the independent randomizer for allocation. Once randomized, participant details were e-mailed to the allocated intervention arm for them to make contact with 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 1 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).

Randomization and masking

Participants who met the inclusion criteria and gave details about demographics and nicotine dependence [Fagerstrom Test for Nicotine Dependence (FTND[12])] were randomized by the study statistician (S.W.) in a 1 : 1 ratio to either the ACE or NHS treatments, with computerized block randomization stratified by age (18–37 or > 38 years), sex (male or female), number of previous quit attempts (none made over the past year or attempts reported over the 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 randomized, 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/randomizer) 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 Open Science Framework (OSF) before the statistician was provided with the data set.

Interventions

Allen Carr's Easyway programme

Participants randomized 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 4.5–6 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 recognize the positive expectancies they associate with smoking (e.g. pleasure, support) as 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 protocol [11] and Supporting information Appendix). One therapist delivered each group session (seven therapists in total delivered group sessions). The mean number of participants per group was 8.95 [standard deviation (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 ($\chi^2 = 0.87$, $P = 0.351$).

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 2 weeks of attending the first session) and assisted to recognize and plan for any upcoming high-risk situations which may lead to relapse. Nicotine replacement therapy (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 general practitioner (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, 2 and 3 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 4 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 protocol [11]).

Top-ups and re-sets

Both treatments contained, as standard, options to re-set 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 re-set 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 re-set within 12 weeks of their original quit date. Any top-ups or re-sets were recorded by clinicians on a central shared file (containing no condition data) and all follow-up assessments were calculated according to the re-set date rather than the original quit date (i.e. if a participant re-set 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 protocol [11]. 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.

For 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 was biochemically verified by exhaled breath carbon monoxide measurement [< 10 parts per million (p.p.m.)], using Bedfont Micro Smokerlyzers. This is in line with the standard assessment of smoking cessation used in research and practice in the United Kingdom [10].

Nicotine dependence was measured using the Fagerstrom Test for Nicotine Dependence [12].

Follow-ups at 4, 12 and 26 weeks

Quit efficacy and continuous smoking abstinence were measured as above.

For 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).

Self-reported continuous abstinence from the quit/quit re-set date was measured using five 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?'; and 'How many cigarettes in the last month?'; 'In total, how many cigarettes have you had since your quit date?'

Nicotine dependence was measured using the Fagerstrom Test for Nicotine Dependence [12].

For adverse events, participants were asked: 'Have you had any new medical issues which may be due to your quit?'

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 cessation [9] 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 randomization (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 re-set 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's χ^2 analysis was used to test whether the risk difference differed significantly from zero or not; exact *P*-values are reported. ORs 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 're-set' 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/re-sets 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 ORs. Treatment arm and treatment success were included as independent variables together 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 (operationalized as attendance at the ACE session or attendance at a minimum of one SSS session).

RESULTS

Of 2115 people who were assessed, 133 did not meet the eligibility criteria, 1358 declined to participate and 620 (29%) were randomized for inclusion into the study (Fig. 1).

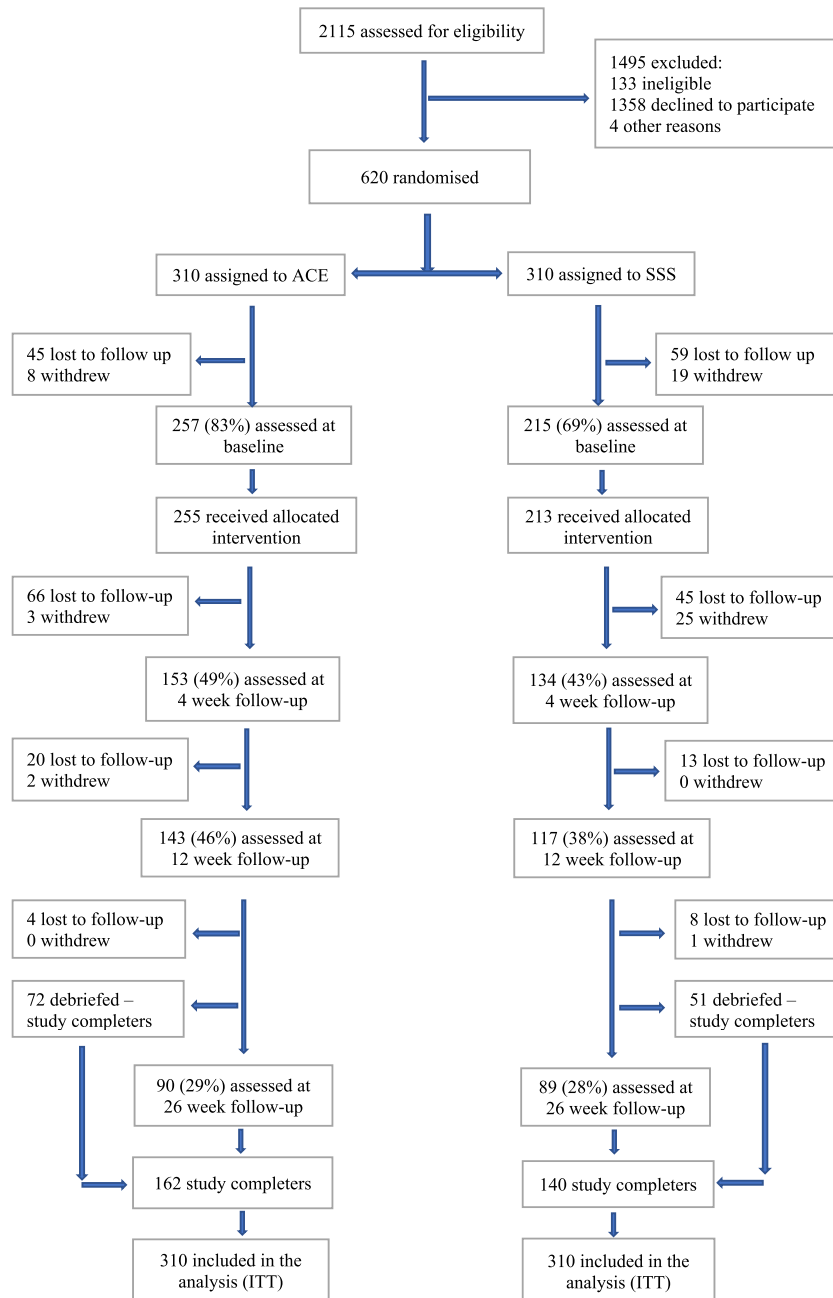


Figure 1 Participant flow [Colour figure can be viewed at wileyonlinelibrary.com]

A total of 310 people were assigned to each treatment arm. At 4 weeks, 49% of ACE participants completed follow-ups and 43% for SSS; at 12 weeks the respective values are 46 and 38%; and for 26 weeks 29 and 28%. Thus, assumed smoking rates (due to loss to follow up) at 26 weeks were 148 versus 170: a difference of 7.1% (95% CI = -1.0, 14.8%; $P = 0.077$). Of those attended treatment, 100 completed 6-month follow-up measures (23.7% ACE versus 20.7% SSS); participants who had previously indicated they had returned to smoking were not eligible to complete these measures as their outcome status was already known, see Fig. 1 for full participant flow details. Participants' baseline characteristics were evenly balanced between treatment groups (Table 1). Eighty-two participants re-set their quit date, 33 in the SSS group (three re-set twice, see Table S1 in Supporting information 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).

There was no evidence of a difference in rates of verified continuous abstinence at 26 weeks between the ACE and SSS groups, 19.4 versus 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 non-conclusive 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% CIs = -5.8; -13.0 and 1.5%; and -0.3, -6.8 and 6.2%, respectively).

Among self-reported quitters, three who self-reported at 4 weeks failed verification, three 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 re-set were classed as non-abstainers at 12 and 26 weeks. In the SSS arm, six people who re-set were successful

Table 1 Baseline characteristics of participants.

	ACE $n = 310$	SSS $n = 310$	Total $n = 620$
Age in years, mean (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)

ACE = Allen Carr's Easyway method. SSS = specialist stop smoking service (SSS) providing behavioural and pharmacological support in accordance with national standards; CO = carbon monoxide; FTND = Fagerstrom Test for Nicotine Dependence; SD = standard deviation. All measures were taken before randomization, $n = 620$ unless otherwise stated.

Table 2 Participant flow and data summary.

	ACE	SSS
Randomized	310	310
Eligible for inclusion in outcome analysis	310	310
Attended allocated treatment	255	213
<i>RS smoking</i>		
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
<i>RS abstinent</i>		
Self-report of abstinence (< 5 cigarettes) throughout FU, passed biochemical validation session at final FU	60	46
RS abstinence rate	60 of 310	46 of 310

RS = Russell Standard; FU = follow-up.

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

	n	ACE	SSS	χ^2 P-value	Odds ratio (95% CI)	Risk difference (95% CI)
<i>Treatment acceptability</i>						
Attended treatment	310/310	255 (82.3%)	213 (68.7%)	< 0.001	2.11 (1.45, 3.08)	13.6% (6.6%, 20.4%)
<i>Verified abstinence: (ITT) analyses</i>						
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%)
<i>Verified abstinence: participants who attended treatment analyses*</i>						
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%)
<i>Pharmacotherapy usage</i>						
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%)

ITT = intention-to-treat; PO = primary outcome; CI = confidence interval; ACE = Allen Carr's Easyway; SSS = stop smoking services. *Non-attenders are treated as non-abstainers

quits at 26 weeks. In the ACE arm, nine 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% fewer 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 (four 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 (one successful quit), 4 used varenicline (one quit), 5 used nicotine gum (one quit), 19 used e-cigarettes (three quits) and 10 used other forms (three 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.* [13] for a detailed rationale of a 5% limit in this context) suggest that 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 to 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.

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 stop smoking methods (including NRT and behavioural interventions with combined pharmacotherapy) [9,14]. 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 ITT and participants who re-set 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 a.m. or p.m. 5 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 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 emphasizes a nicotine-free approach to cessation and cessation maintenance. These differences were reflected in our results; among 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 for which one needs to be nicotine-free, 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 in which 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 antabine [15].

Our study excluded vulnerable patients (e.g. pregnancy, mental illness and respiratory illness), meaning that 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 randomized were accounted for at the 6-month point, leaving 51.30% 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 randomized 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, the findings support the use of this intervention in a public health setting.

Clinical trial registration

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

Declaration of interests

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. 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.

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 recognize 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.

Acknowledgements

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

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Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix Brief summary of the ACE perspective and method.

Table S1 Number of sessions attended by SSS arm participants.