National Institute for Health and Care Excellence

Final

Tobacco: preventing uptake, promoting quitting and treating dependence

[P] Effectiveness and cost-effectiveness of Allen Carr's Easyway

NICE guideline NG209

Evidence reviews underpinning recommendation 1.12.2 and research recommendations in the NICE guideline

August 2022

Final

National Institute for Health and Care Excellence

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1.1 Review question

In adults who smoke, what is the effectiveness and cost-effectiveness of the Allen Carr Easyway for smoking cessation?

1.1.1 Introduction

NICE was notified of the publication of 2 randomised controlled trials (RCT) (Keogan S et al 2019 and Frings D et al 2020) assessing the effectiveness of Allen Carr's Easyway (ACE) to Stop Smoking in person group seminars. This intervention is not currently considered as a stop smoking intervention in the NICE guideline on tobacco: preventing uptake, promoting quitting and treating dependence (NICE guideline NG209). The current guideline recommends that commissioners and providers of SSS should ensure that evidence-based interventions such as behavioural support (individual and group), bupropion, NRT, varenicline and very brief advice are available for adults who smoke.

The aim of this review is to investigate the effectiveness and cost-effectiveness of the Allen Carr's Easyway for smoking cessation. This review identified studies that fulfilled the conditions specified in Table 1. For full details of the review protocol, see appendix A.

1.1.2 Summary of the protocol

Table 1: PICOS inclusion criteria

Eligibility criterion	Content
Population	Adults (aged over 18) who smoke tobacco and want to stop.
Interventions	Allen Carr Easyway seminar programme (multicomponent programme that includes group cognitive behavioural and relaxation therapies without pharmacotherapy).
Comparator	Any comparator
Outcomes	Primary outcomes: • Smoking status at 26 week or longer timepoints (biochemically validated) • Cost-utility Secondary outcomes: • Smoking status at earlier (<26 weeks) timepoints (biochemically validated) • Relapse rates • Pharmacotherapy usage • Adverse events • Health Related Quality of Life (validated measures only)
Study type	• Randomised controlled trials (RCTs) • Cost-effectiveness studies • (Systematic reviews of RCTs included for reference checking)

For the full protocol see appendix A.

1.1.3 Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A and the methods document.

Declarations of interest were recorded according to NICE's conflicts of interest policy.

1.1.3.1 Search methods – effectiveness evidence

The searches for the effectiveness evidence were run on 25 January 2022. The following databases were searched: Allied and Complementary Medicine (Ovid), Applied Social Science Index and Abstracts (ProQuest), Cochrane Central Register of Controlled Trials (Wiley), Cochrane Database of Systematic Reviews (Wiley), Database of Abstracts of Reviews of Effects (CRD), EconLit (Ovid), Embase (Ovid), Emcare (Ovid), Health Management Information Consortium (Ovid), International HTA Database (INAHTA), MEDLINE (Ovid), NICE Evidence Search (evidence.nhs.uk), PsycINFO (Ovid), Social Policy and Practice (Ovid) and Web of Science (Clarivate). Full search strategies for each database are provided in appendix B.

The database searches were supplemented with additional search methods. Reference checking and forwards citation searching were conducted on Citationchaser. Searches of clinical trial registries were undertaken on ClinicalTrials.gov, EU Clinical Trials Register, ISRCTN Registry, ScanMedicine and World Health Organization International Clinical Trials Registry Platform. Searches for grey literature were also undertaken on the Allen Carr website and using Google.com. Full details for each method are provided in appendix B.

A NICE information specialist conducted the searches. The MEDLINE strategy was quality assured by a trained NICE information specialist and all translated search strategies were peer reviewed to ensure their accuracy. Both procedures were adapted from the 2016 PRESS Checklist.

1.1.3.2 Search methods – cost-effectiveness evidence

The searches for the cost effectiveness evidence were run on 26 January 2022. The following databases were searched: Allied and Complementary Medicine (Ovid), Applied Social Science Index and Abstracts (ProQuest), EconLit (Ovid), Embase (Ovid), Emcare (Ovid), Health Management Information Consortium (Ovid), International HTA Database (INAHTA), MEDLINE (Ovid), NHS Economic Evaluation Database (CRD) and Social Policy and Practice (Ovid). Full search strategies for each database are provided in appendix B.

The database searches were supplemented with additional search methods. Searches of clinical trial registries were undertaken on ClinicalTrials.gov, EU Clinical Trials Register, ISRCTN Registry, ScanMedicine and World Health Organization International Clinical Trials Registry Platform. Searches for grey literature were also undertaken on the Allen Carr website and using Google.com. Full details for each method are provided in appendix B.

A NICE information specialist conducted the searches. The MEDLINE strategy was quality assured by a trained NICE information specialist and all translated search strategies were peer reviewed to ensure their accuracy. Both procedures were adapted from the 2016 PRESS Checklist.

1.1.3.3 Protocol deviations

1. An outcome not specified in the protocol was found in the included papers (self-reported abstinence at 4, 12, 26 and 52 weeks). This outcome was included because it provided evidence on an additional way to measure abstinence. These data were extracted and presented to the committee but the confidence in the evidence was downgraded once for indirectness to reflect that self-reported abstinence was not biochemically validated.
2. Separate searches were run for effectiveness and cost-effectiveness evidence. The same key terms were used with appropriate terms for cost utility and cost effectiveness studies applied (making the cost-effectiveness results a subset of the effectiveness results).
3. Several sources were added during the search as the numbers being obtained were relatively low and it was feasible within the time and resources available to expand the list of sources beyond those specified in the protocol. This accounts for AMED, Emcare and Web of Science being searched. This was to ensure comprehensive coverage of the potential literature.

1.1.4 Effectiveness evidence

1.1.4.1 Included studies

A systematic search carried out to identify randomised controlled trials (RCTs) found 283 references (see appendix B for the literature search strategy).

These 283 references were screened at title and abstract level against the review protocol, with 281 excluded at this level. Screening was undertaken separately by two reviewers with 99% agreement (280 out of 283). Discrepancies were resolved by discussion.

The full texts of 2 RCTs were ordered for closer inspection by two reviewers independently. Both reviewers agreed that both studies met the criteria specified in the review protocol (appendix A). For a summary of the 2 included studies see table 2.

The clinical evidence study selection is presented as a PRISMA diagram in appendix C.

See section 1.1.14 References – included studies for the full references of the included studies.

Data extraction for the 2 included studies was done by one reviewer and checked by another reviewer.

1.1.4.2 Excluded studies

No effectiveness studies were excluded at full text.

1.1.5 Summary of studies included in the effectiveness evidence

Table 2: Summary of studies included in the effectiveness evidence review

Study	Setting	Population	Intervention	Comparator	Outcome(s)
Frings (2020)	London, UK	Adult (>18) smokers wanting to quit.	Allen Carr Easyway in-person group seminar:	NHS Specialist Stop Smoking Service: 1 to 1 30 min CBT/MI in-person session	Primary outcome Biochemically verified abstinence at 26 weeks

Study	Setting	Population	Intervention	Comparator	Outcome(s)
		N = 620 Mean age: 40.8 years %male = 53.4	4.5 – 6 hour seminar 6 follow up SMS Up to 2 top up sessions	Up to 4 weekly follow up sessions Final appointment at 4 weeks 12 weeks medication via voucher or letter to GP.	Secondary outcomes Verified abstinence at 4 and 12 weeks Pharmacotherapy usage
Keogan (2018)	Republic of Ireland	Adult (>18) smokers of at least 5 cigarettes a day N = 300 Median age: 44 %male = 55.6 (int), 54.4 (control)	Allen Carr Easyway in-person group seminar: 4.5 – 6 hour seminar 6 follow up SMS Up to 2 top up sessions	Quit.ie phone, text and web based stop smoking service: Daily support texts/emails for 1 month 2 follow up communications 1 counselling call Medication advice but users have to organise own medication.	Primary outcome Biochemically verified abstinence at 26 and 52 weeks Secondary outcomes Verified abstinence at 4 and 12 weeks Self-reported abstinence at 4, 12, 26 and 52 weeks.

See appendix D for full evidence tables.

1.1.6 Summary of the effectiveness evidence

The evidence is presented with the studies combined and separately.

Allen Carr's Easyway for smoking cessation compared with usual practice (Quit.ie and 1 to 1 NHS stop smoking services for smoking cessation combined)

Patient or population: people who smoke and want to give up
Settings: Any setting
Intervention: Allen Carr's Easyway in-person group seminar
Comparison: usual practice (Quit.ie or 1 to 1 in-person NHS stop smoking services for smoking cessation)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Interpretation
	Assumed risk **Usual practice**	Corresponding risk **Allen Carr's Easyway**				
Allen Carr's Easyway in-person group seminar compared with usual practice (Quit.ie or 1 to 1 in-person NHS stop smoking services for smoking cessation)						
Verified abstinence self-report plus CO validation Follow-up: 4 weeks	**29 per 100**	**36 per 100** (16 to 80)	**RR 1.23** (0.55 to 2.74)	920 (2 studies[1])	⊕⊖⊖⊖ **very low**[2,3,4]	Evidence could not differentiate between arms
Allen Carr's Easyway in-person group seminar compared with 1- to 1 in-person NHS stop smoking services for smoking cessation						

Verified abstinence self report plus CO validation Follow-up: 4 weeks	**34 per 100**	**28 per 100** (22 to 35)	**RR 0.83** (0.65 to 1.05)	620 (1 study[5])	⊕⊕⊖⊖ **low**[6,7]	Evidence could not differentiate between arms

Allen Carr's Easyway in-person group seminar compared with Quit.ie

Verified abstinence self report plus CO validation Follow-up: 4 weeks	**20 per 100**	**38 per 100** (26 to 55)	**RR 1.87** (1.28 to 2.74)	300 (1 study[8])	⊕⊕⊕⊖ **moderate**[9]	Allen Carr's Easyway seminar better than usual practice

Allen Carr's Easyway in-person group seminar compared with usual practice (Quit.ie or 1 to 1 in-person NHS stop smoking services for smoking cessation)

Verified abstinence self-report plus CO validation Follow-up: 12 weeks	**20 per 100**	**25 per 100** (14 to 45)	**RR 1.29** (0.72 to 2.32)	920 (2 studies[1])	⊕⊖⊖⊖ **very low**[2,3,4]	Evidence could not differentiate between arms

Allen Carr's Easyway in-person group seminar compared with 1 to 1 in-person NHS stop smoking services for smoking cessation

Verified abstinence self report plus CO validation Follow-up: 12 weeks	**22 per 100**	**22 per 100** (16 to 29)	**RR 0.99** (0.73 to 1.33)	620 (1 study[5])	⊕⊕⊖⊖ **low**[6,7]	Evidence could not differentiate between arms

Allen Carr's Easyway in-person group seminar compared with Quit.ie

Verified abstinence self report plus CO validation Follow-up: 12 weeks	**15 per 100**	**26 per 100** (17 to 42)	**RR 1.79** (1.12 to 2.87)	300 (1 study[8])	⊕⊕⊕⊖ **moderate**[9]	Allen Carr's Easyway seminar better than usual practice

Allen Carr's Easyway in-person group seminar compared with usual practice (Quit.ie or 1 to 1 in-person NHS stop smoking services for smoking cessation)

Verified abstinence self-report plus CO validation Follow-up: 26 weeks	**15 per 100**	**21 per 100** (15 to 27)	**RR 1.37** (1.03 to 1.82)	920 (2 studies[1])	⊕⊕⊕⊖ **moderate**[2]	Allen Carr's Easyway seminar better than usual practice

Allen Carr's Easyway in-person group seminar compared with 1- to 1 in-person NHS stop smoking services for smoking cessation

Verified abstinence self report plus CO validation Follow-up: 26 weeks	**15 per 100**	**19 per 100** (14 to 27)	**RR 1.30** (0.92 to 1.85)	620 (1 study[5])	⊕⊕⊖⊖ **low**[6,7]	Evidence could not differentiate between arms

Allen Carr's Easyway in-person group seminar compared with Quit.ie

Verified abstinence self report plus CO validation Follow-up: 26 weeks	**15 per 100**	**23 per 100** (14 to 37)	**RR 1.50** (0.93 to 2.41)	300 (1 study[8])	⊕⊕⊖⊖ **low**[7,9]	Evidence could not differentiate between arms

*The basis for the **assumed risk** is the median control group risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Frings (2020), Keogan (2018)
[2] Keogan (2018) did not report information on concealment of allocation sequence; information on deviations from the intended interventions; a pre-specified analysis plan; and there was differential attrition with around 10% more participants lost to follow-up at 3 and 6 months in the Quit.ie arm. Frings (2020) reported that more than half of participants (51.3%) were lost to follow-up; reasons for dropouts were not reported. Moderate risk of bias. Downgraded once.
[3] I2 value >66.7%. Downgraded twice.
[4] Pooled effect estimate crosses line of no effect. Downgraded once.
[5] Frings (2020)
[6] More than half of participants (51.3%) were lost to follow-up; reasons for dropouts were not reported. Moderate risk of bias. Downgraded once.
[7] Effect estimate crosses line of no effect. Downgraded once.
[8] Keogan (2018)
[9] Information was not reported on concealment of allocation sequence; deviations from the intended interventions; a pre-specified analysis plan; and there was differential attrition with around 10% more participants lost to follow-up at 3 and 6 months in the Quit.ie arm. Moderate risk of bias. Downgraded once.

Allen Carr's Easyway compared to Quit.ie for smoking cessation

Patient or population: people who smoke and want to give up
Settings: Any
Intervention: Allen Carr's Easyway seminar
Comparison: Quit.ie

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Interpretation
	Assumed risk **Quit.ie**	Corresponding risk **Allen Carr's Easyway**				
Verified abstinence self-report plus CO validation Follow-up: 52 weeks	**11 per 100**	**22 per 100** (13 to 38)	**RR 1.92** (1.12 to 3.29)	300 (1 study[1])	⊕⊕⊕⊖ **moderate**[2,3]	Allen Carr's Easyway seminar better than Quit.ie
Self-reported abstinence self-report only Follow-up: 4 weeks	**24 per 100**	**42 per 100** (30 to 59)	**RR 1.73** (1.23 to 2.43)	300 (1 study[1])	⊕⊕⊖⊖ **low**[2,3]	Allen Carr's Easyway seminar better than Quit.ie
Self-reported abstinence self-report only Follow-up: 12 weeks	**17 per 100**	**32 per 100** (21 to 48)	**RR 1.82** (1.2 to 2.77)	300 (1 study)	⊕⊕⊖⊖ **low**[2,3]	Allen Carr's Easyway seminar better than Quit.ie
Self-reported abstinence self-report only Follow-up: 26 weeks	**17 per 100**	**28 per 100** (18 to 43)	**RR 1.66** (1.07 to 2.57)	300 (1 study[1])	⊕⊕⊖⊖ **low**[2,3]	Allen Carr's Easyway seminar better than Quit.ie
Self-reported abstinence self-report only Follow-up: 52 weeks	**14 per 100**	**24 per 100** (15 to 39)	**RR 1.69** (1.04 to 2.76)	300 (1 study[1])	⊕⊕⊖⊖ **low**[2,3]	Allen Carr's Easyway seminar better than Quit.ie

* The basis for the **assumed risk** is the median control group risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the

intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Keogan (2018)
[2] Keogan (2018) did not report information on concealment of allocation sequence; information on deviations from the intended interventions; a pre-specified analysis plan; and there was differential attrition with around 10% more participants lost to follow-up at 3 and 6 months in the Quit.ie arm. Moderate risk of bias. Downgraded once.
[3] Outcome not in protocol. Indirect outcome (self-reported abstinence was not biochemically validated). Downgraded once.

Allen Carrs Easyway compared to NHS 1 to 1 in-person stop smoking services for smoking cessation

Patient or population: people who smoke and want to give up
Settings: Any
Intervention: Allen Carr's Easyway
Comparison: 1 to 1 in-person NHS stop smoking services

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Interpretation
	Assumed risk	Corresponding risk				
	1 to 1 in-person NHS stop smoking services	**Allen Carr's Easyway**				
Pharma usage: Completed study self-report	**96 per 100**	**48 per 100** (40 to 57)	**RR 0.5** (0.42 to 0.6)	295 (1 study[1])	⊕⊕⊕⊕ **high**[2]	Allen Carr's Easyway seminar better than 1 to 1 in-person NHS stop smoking services
Pharma usage: Completed study & treatment self-report	**98 per 100**	**47 per 100** (39 to 57)	**RR 0.48** (0.4 to 0.58)	275 (1 study[1])	⊕⊕⊕⊕ **high**[2]	Allen Carr's Easyway seminar better than 1 to 1 in-person NHS stop smoking services
Pharma usage self-reported pharmacology free Follow-up: 26 weeks	**40 per 100**	**83 per 100** (64 to 100)	**RR 2.06** (1.58 to 2.7)	180 (1 study[1])	⊕⊕⊕⊕ **high**[2]	Allen Carr's Easyway seminar better than 1 to 1 in-person NHS stop smoking services

* The basis for the **assumed risk** is the median control group risk across studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Frings (2020)
[2] More than half of participants (51.3%) were lost to follow-up; reasons for dropouts were not reported. Moderate risk of bias. Downgraded once. Outcome reported only by those participants for whom pharmacotherapy usage was known at follow-up.

See appendix F for full GRADE tables.

1.1.7 Economic evidence

A search of published cost-effectiveness evidence was carried out for the question: In adults who smoke, what is the effectiveness and cost-effectiveness of the Allen Carr Easyway for smoking cessation?. Seventeen studies were identified. There were no eligible studies for this question.

1.1.7.1 Included studies

17 records were identified and assessed against eligibility criteria.

14 records were excluded based on information in the title and abstract (mostly not smoking cessation interventions; one book review; one obituary; and two were not RCTs or a cost-effectiveness study).

The full-text papers of 3 documents were retrieved and assessed; none met the inclusion criteria.

1.1.7.2 Excluded studies

Three full text documents were excluded. The documents and the reasons for their exclusion are listed in Appendix J – Excluded studies.

1.1.8 Summary of included economic evidence

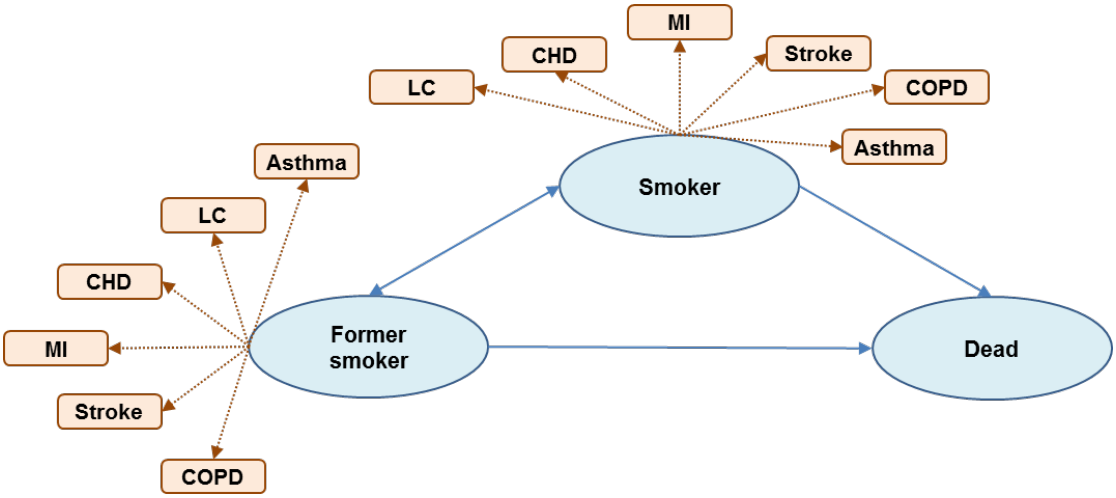
No economic studies were included in this review.

1.1.9 Economic model

The cost-effectiveness of Allen Carr's Easyway to Stop Smoking (ACE) intervention was evaluated through economic modelling. The evaluation used methods described in previous NICE guidance[1]. A similar model structure has been used in past cost-effectiveness models for smoking interventions (PHG10, PHG45, NG92[1] Taylor et al. 2011[2]). The model tracks a hypothetical cohort of 1,000 smokers, and estimates their smoking status at annual timepoints based on the effectiveness of interventions and the natural quit and relapse rates for the general population. For each smoking status (smoker or former smoker) mortality rates are assigned by age and gender and, in addition, epidemiological data are used to estimate the prevalence (by age and gender) of 6 different conditions (see Figure 1).

Figure 1: Model structure

[1] For more details on the model see supporting documentation Model Q.
[2] Taylor M, Leonardi-Bee J, Agboola S, McNeill A, Coleman T. Cost effectiveness of interventions to reduce relapse to smoking following smoking cessation. *Addiction*. 2011 Oct;106(10):1819-1826.



* *LC = lung cancer, CHD = coronary heart disease, MI = myocardial infarction, COPD = chronic obstructive pulmonary disease, asthma = asthma exacerbation.*

Costs and quality of life scores are assigned to each of the health conditions (as well as for those people who are free from those conditions). These are combined with the intervention costs in order to estimate the lifetime costs and quality-adjusted life years (QALYs) associated with different interventions.

For the analysis of ACE, effectiveness data were drawn from two randomised controlled trials[3,4]. Table 3, outlines the key data from those studies. In Keogan et al (2019), ACE is compared with 'Quit.ie', whilst in Frings et al (2020) ACE is compared with 1 to 1 Stop Smoking Services (SSS). The costs of the interventions are also outlined in Table 3.

Table 3: Intervention effectiveness and costs

Keogan et al (2019)	**ACE**	**Quit.ie**
Quit rate at 12 months[a]	21.9%	11.4%
Cost of intervention	£299.00[b]	£44.00[c]
Frings et al (2020)	**ACE**	**1-1 SSS**
Quit rate at 12 months	16.6%[d]	12.7%[e]
Cost of intervention	£299.00[b]	£79.06[f]

a Intention to treat, Russell Standard method.
b List price.
c Assumes 4x 15-minute nurse calls, at a cost of £44 per hour[5].
d Intention to treat. 6-month quite rate was 19.4%. Converted to 12-month rate using relapse rates from Coleman et al (2014)[6].
e Intention to treat. 6-month quite rate was 14.8%. Converted to 12-month rate using relapse rates from Coleman et al (2014)[5].

[3] Keogan S, Li S, Clancy L. Allen Carr's Easyway to Stop Smoking - A randomised clinical trial *Tobacco Control* 2019;28:414–419.
[4] Frings D, Albery IP, Moss AC et al. Comparison of Allen Carr's Easyway programme with a specialist behavioural and pharmacological smoking cessation support service: a randomized controlled trial. *Addiction* 2020.
[5] PSSRU *Unit Costs* 2021.
[6] Coleman T, Agboola S, Leonardi-Bee J, Taylor M, McEwen A, McNeill A. Relapse prevention in UK Stop Smoking Services: current practice, systematic reviews of effectiveness and cost-effectiveness analysis. *Health Technol Assess.* 2010 Oct;14(49):1-152, iii-iv.

f	*Assumes 1x 30-minute nurse call, followed by 4x 15-minute nurse calls, plus 50% of people using NRT (average price of 7-day supply from Boots, standard patches only) and 50% of people using varenicline (0.5 mg for 3 days, 0.5 mg twice per day for 4 days, 11 weeks of 1mg twice daily. British National Formulary[7]).*

Probabilistic sensitivity analysis (PSA) was also undertaken in order to assess the overall uncertainty associated with the conclusions. The approach follows that used in the previous modelling work. For the effectiveness (quit rate) inputs, a Beta distribution was used, with the Alpha and Beta parameters being represented by the *number* of people that quit and did not quit, respectively. This approach is potentially conservative from the point of view of ACE, since it assumes that each intervention's effectiveness is varied independently.

RESULTS

ACE vs Quit.ie (Keogan et al 2019)

Table 4, shows the cost-effectiveness results for ACE compared with Quit.ie.

Table 4: Cost-effectiveness results, ACE vs Quit.ie

Discounted per patient results	**ACE**	**Quit.ie**	**Incremental**
Intervention costs	£299	£44	£255
Stroke	£5,121	£5,261	-£140
Lung cancer	£1,080	£1,146	-£66
MI	£1,166	£1,215	-£49
CHD	£2,288	£2,317	-£29
COPD	£1,345	£1,431	-£86
Asthma exacerbations	£15.39	£15.49	-£0.10
Total costs	**£11,314**	**£11,429**	**-£115**
QALYs	**15.12**	**15.11**	**0.02**
ICER			**Dominant**
Net monetary benefit			**£2,329**

This shows that, when ACE is compared with Quit.ie, it is both cost saving (saving £115 per person) and more effective (generating an additional 0.02 QALYs per smoker). Although the *intervention* costs are higher for ACE, this is more than offset through the reduction in comorbidities. When a monetary value of £20,000 is assigned to each QALY gained, the 'net monetary benefit' of ACE is estimated to be £2,329 per smoker.

[7] *British National Formulary* 2022.

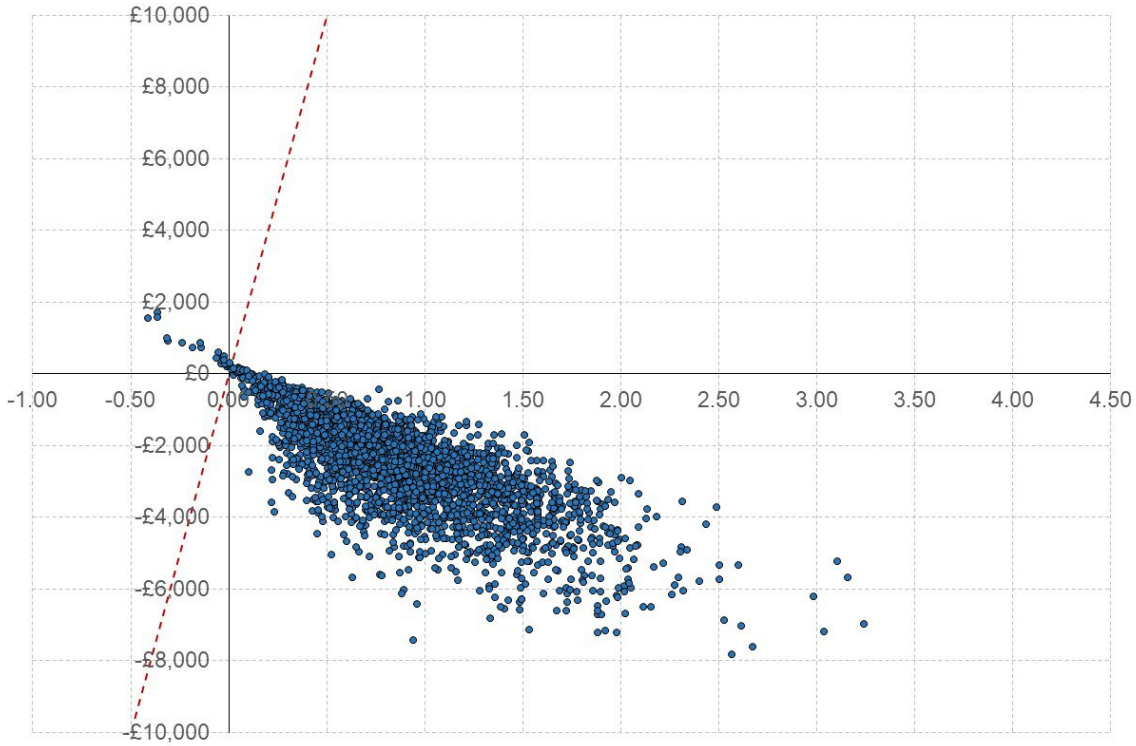
Because many of the model's inputs and assumptions may be uncertain, it is important to consider a range of alternative scenarios. Table 5, shows the results for a range of sensitivity analyses.

Table 5: Sensitivity analysis, ACE vs Quit.ie

Scenario	Incremental costs	Incremental QALYs	ICER	Net monetary benefit
Time horizon limited to 5 years	£170	0.01	£11,677	£121
Time horizon limited to 10 years	£91	0.03	£2,765	£566
Time horizon limited to 20 years	-£10	0.06	Dominant	£1,290
Cost of ACE = £200[a]	-£214	0.11	Dominant	£2,428
Cost of Quit.ie = £0[b]	-£71	0.11	Dominant	£2,285
Cost of Quit.ie = £0[c] and effectiveness = 2%	-£126	0.13	Dominant	£2,669
Cost of pharmacotherapy added to Quit.ie arm[d]	-£208	0.11	Dominant	£2,422

a Correspondence with ACE identified that a volume-related discount is sometimes applied in cases where ACE does not need to recruit smokers. The average price in such cases was quoted as £200.
b To simulate a comparison against 'no intervention', where 'no intervention' has an effectiveness equivalent to Quit.ie.
c To simulate a comparison against 'no intervention', where 'no intervention' has an effectiveness equivalent to the natural quit rate.
d Keogan (2019) reports that 60% of people in the Quit.ie arm received NRT and 20% used varenicline.

The PSA indicates that ACE has a 98.87% chance of being cost-effective at a threshold of £20,000. The figure below shows the results of the PSA. As can be seen, the vast majority of the iterations fall within the south-east quadrant (i.e. ACE dominates Quit.ie).



ACE vs 1 to 1 Stop Smoking Services (Frings et al 2020)

Table 6, shows the cost-effectiveness results for ACE compared with 1 to 1SSS.

Table 6: Cost-effectiveness results, ACE vs 1 to 1 SSS

Discounted per patient results	**ACE**	**1 to 1 SSS**	**Incremental**
Intervention costs	£299	£197	£102
Stroke	£5,192	£5,244	-£52
Lung cancer	£1,113	£1,138	-£25
MI	£1,190	£1,209	-£18
CHD	£2,303	£2,314	-£11
COPD	£1,388	£1,421	-£32
Asthma exacerbations	£15.44	£15.48	-£0.04
Total costs	**£11,501**	**£11,538**	**-£37**
QALYs	**15.18**	**15.14**	**0.04**
ICER			**Dominant**
Net monetary benefit			**£868**

This shows that, when ACE is compared with 1-1 SSS, it is both marginally cost saving and more effective (generating an additional 0.04 QALYs per smoker). Although the *intervention* costs are higher for ACE, this is offset through the reduction in comorbidities. When a monetary value of £20,000 is assigned to each QALY gained, the 'net monetary benefit' of ACE is estimated to be £868 per smoker.

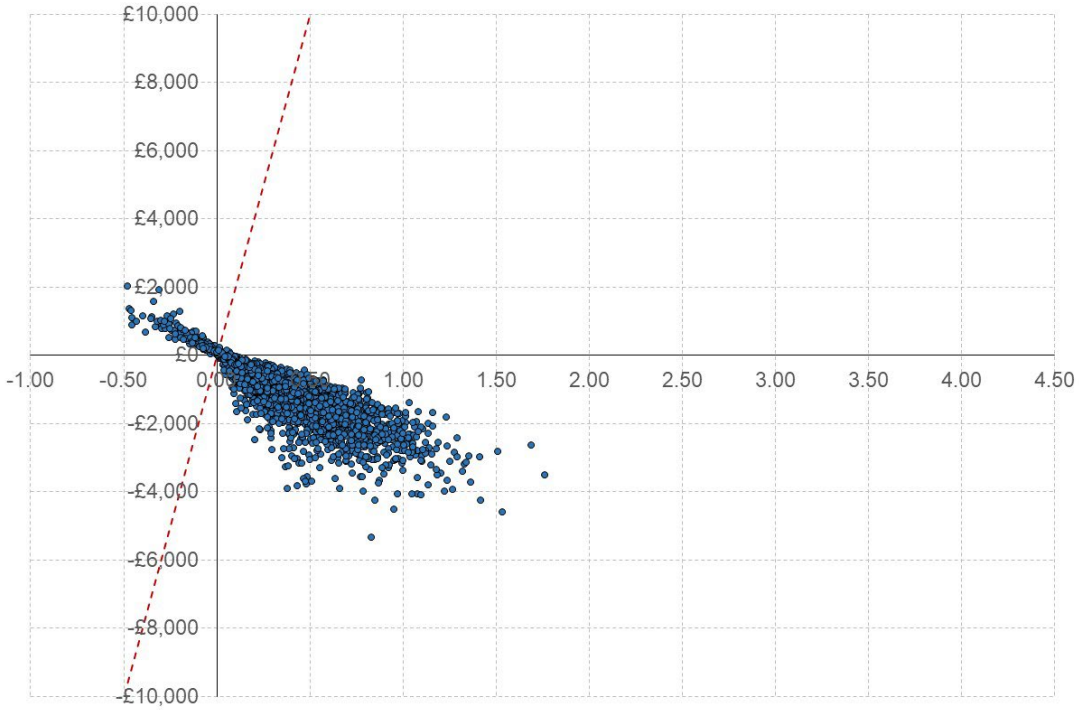
Because many of the model's inputs and assumptions may be uncertain, it is important to consider a range of alternative scenarios. Table 7, shows the results for a range of sensitivity analyses.

Table 7: Sensitivity analysis, ACE vs 1 to 1 SSS

Scenario	Incremental costs	Incremental QALYs	ICER	Net monetary benefit
Time horizon limited to 5 years	£70	0.01	£12,773	£40
Time horizon limited to 10 years	£40	0.01	£3,252	£206
Time horizon limited to 20 years	£2	0.02	£86	£478
Cost of ACE = £200[a]	-£136	0.04	Dominant	£967
Cost of 1-1 SSS = £0b	£160	0.04	£3,860	£670
Cost of 1-1 SSS = £0b and effectiveness = 2%	-£216	0.15	Dominant	£3,296
Additional pharmacotherapy costs for ACE arm[d]	£26	0.04	£619	£805

a Correspondence with ACE identified that a volume-related discount is sometimes applied in cases where ACE does not need to recruit smokers. The average price in such cases was quoted as £200.
b To simulate a 1-1 comparison against 'no intervention', where 'no intervention' has an effectiveness equivalent to SSS.
c To simulate a comparison against 'no intervention', where 'no intervention' has an effectiveness equivalent to the natural quit rate.
d Assumes 47.8% of population use pharmacotherapy (Frings, 2020) and use of pharmacotherapy is split equally between NRT and varenicline.

Probabilistic sensitivity analysis shows that ACE has a 92.8% chance of being cost-effective compared with 1 to 1 SSS. The output from the PSA is shown below. Again, the vast majority of iterations fall within the south-east quadrant (i.e. ACE dominates 1 to 1 SSS).



DISCUSSION

The economic analysis found that Allen Carr's Easy Way to Stop Smoking method is cost effective. The findings are consistent with previous economic evaluations for NICE guidance in smoking cessation in that *effective* interventions also tend to be *cost-effective* interventions, because the benefits (increased life expectancy, improved quality of life and reduced healthcare costs) associated with reducing tobacco use are substantial and generally outweigh the cost of the intervention.

The analysis showed that, even if the NHS pays the full cost of the intervention, the cost savings along would quickly outweigh the cost of the intervention (in less than five years based on the Keogan 2019 study and after around seven years based on the Frings 2020 study). In addition, the QALY gains (estimated to be 0.02 and 0.04 based on the Keogan and Frings studies respectively) would be substantial when aggregated over larger populations.

As with any modelling study that relies on published data and makes extrapolations, this analysis has limitations. These are outlined in detail in the previous report for the model[8]. The limitations include the following considerations:

- The same rates for relapse and 'natural (future) quitting' were applied to all interventions in the model, meaning that any benefits associated with longer term abstinence were not captured in full.
- The model's cost and quality of life outcomes were restricted to the six comorbidities outlined in Figure 1. Whilst it is suspected that tobacco use is linked to many more conditions, data were not available by age and gender cohorts in order to include them in the model.
- The model does not consider multiple quit attempts, nor does it consider the specific *sequence* of quit attempts.

[8] For more details on the model see supporting documentation Model Q.

- The model does not differentiate between different *levels* of tobacco use (i.e. all smokers are considered to carry the same risk of comorbidities, regardless of their duration or frequency of tobacco use), meaning that any benefits derived from *reducing* intake of tobacco are not captured.

In general, these limitations tend to mean that the model underestimate the benefits associated with the more effective treatments and can, as such, be considered to be conservative. The limitations are, therefore, unlikely to change the direction of the conclusions and may actually mean that the true benefits have been underestimated.

1.1.10 Economic evidence statements

- One directly applicable cost utility analysis with minor limitations found that ACE was dominant (i.e. less costly and more effective than the comparator). The time horizon and costs were varied in a series of sensitivity analyses which found the intervention remained highly cost effective with the exception of a 5-year time horizon for the comparison between ACE and the stop smoking services.

1.1.11 The committee's discussion and interpretation of the evidence

1.1.11.1. The outcomes that matter most

The committee agreed that the critical outcome for adult smokers wanting to quit was biochemically validated smoking status at 26 weeks or longer and that pharmacotherapy usage was an important outcome. There were other important outcomes such as relapse rates, adverse events and health related quality of life but the included studies did not report on any of these outcomes.

The committee agreed that any reduction in smoking has a measurable health impact. Therefore, they agreed to use the line of no effect as the decision threshold for an important difference. This means that results were interpreted as clinically significant when 95% confidence intervals did not cross the line of no effect (for relative risk the line of no effect being 1.0). For the other outcome reported in this update (pharmacotherapy usage), the committee agreed to use a default decision threshold (for relative risk: 0.8 to 1.25) as no other decision threshold was identified. Minimal important differences (MIDs) and decision thresholds are described in the methods document.

1.1.11.2 The quality of the evidence

Overall, the quality of the evidence varied from high to very low. One of the main reasons for downgrading the evidence was due to imprecision of the relative effectiveness of the stop smoking interventions. The other reason for downgrading the evidence was due to the risk of bias of one of the included RCTs (lack of reporting information on concealment of allocation sequence; lack of reporting information on deviations from the intended interventions; differential attrition (around 10% more participants were lost to follow-up at 3 and 6 months in the Quit.ie arm [Keogan 2018]) and lack of a pre-specified analysis plan). Quit.ie was a comparator only available in the Republic of Ireland. Quit.ie is an online and phone smoking cessation service supported by the TobaccoFree Research Institute Ireland, however the committee agreed that it was a useful comparator.

The committee raised concerns regarding the differential attrition at follow-up in one of the included RCTs (Keogan 2018) with more participants lost to follow-up at 3 and

6 months (around 10% more) in the Quit.ie arm compared to the Allen Carr's Easyway in-person group seminar. This differential attrition was considered as a concern for the risk of bias of Keogan 2018. There was high attrition in the RCT published by Frings in 2020 (around 30% of participants were available for assessments at 6 months). Intention to treat analyses were used to deal with attrition problems for the primary outcome (biochemically validated smoking status). Pharmacotherapy usage was downgraded because this outcome was reported only by those participants for whom pharmacotherapy usage was known at follow-up.

1.1.11.3 Benefits and harms

The evidence showed that the Allen Carr's Easyway in-person group seminar was more effective compared to usual care (Quit.ie or 1 to 1 in-person NHS stop smoking services session) at 6 months on biochemically verified abstinence:

- pooled effect estimate: RR 1.37, 95% CI 1.03 to 1.82

However this difference was not statistically significant when Allen Carr's Easyway in-person group seminar was compared individually to each of the comparators Quit.ie or NHS stop smoking services at 6 months:

- Allen Carr's Easyway in-person group seminar compared to 1 to 1 in-person NHS stop smoking services (RR 1.30, 95% CI 0.92 to 1.85)
- Allen Carr's Easyway in-person group seminar compared to Quit.ie (RR 1.50, 95% CI 0.93 to 2.41)

At 12 months, evidence was only reported for Quit.ie (Keogan 2018). There were significantly more participants in the Allen Carr's Easyway in-person group seminar with biochemically verified abstinence compared to Quit.ie at 12 months follow-up:

- Allen Carr's Easyway in-person group seminar compared to Quit.ie (RR 1.92, 95% CI 1.12 to 3.29)

Allen Carr's Easyway in-person group seminar is an approach that uses cognitive behavioural therapy and relaxation methods without pharmacotherapy. However, participants in the included RCTs were not prevented from using pharmacotherapy. Frings 2020 collected information about pharmacotherapy usage and reported that fewer participants in the Allen Carr's Easyway in-person group seminar used pharmacotherapy compared to participants receiving 1 to 1 in-person NHS stop smoking services support. The Allen Carr's Easyway in-person group seminar and the NHS stop smoking services include elements of cognitive behavioural therapy. The 1 to 1 in-person NHS stop smoking services also includes motivational interviewing and the Allen Carr's Easyway in-person group seminar includes relaxation. In addition, participants in the latter are encouraged to carry on smoking as normal right up until they attend the session during which they are encouraged to smoke as normal during scheduled smoking breaks (around every 45-60mins) until a final ritual cigarette at the end of the session. The committee noted there are differences between people who smoke and the way they respond to therapy and that the Allen Carr's Easyway in-person group seminar might be more suitable for a particular cohort of people wanting to stop smoking. Although it was not possible to identify who these people might be.

The committee had some concerns that there were only 2 studies, and because of concerns about the quality of the evidence outlined in section 1.1.11.2, they agreed that there was not enough effectiveness evidence to conclude whether Allen Carr's Easyway in-person group seminar was better than Quit.ie or 1 to 1 in-person NHS stop smoking services. But the committee agreed the evidence showed Allen Carr's

Easyway in-person group seminar was as good as Quit.ie or 1 to 1 in-person NHS stop smoking services.

The evidence considered by the committee compared Allen Carr's Easyway in-person group seminar with 1-to-1 support provided by an NHS stop smoking service (which includes behavioural support and the use of medicinally licensed products) and with a remote stop smoking service (which included behavioural support and information about how to access medicinally licensed products). The committee agreed the evidence showed it was as good as other methods such as 1-to-1 support provided by local stop-smoking services but there was not enough evidence to position Allen Carr's Easyway in-person group seminar within the hierarchy of effectiveness of interventions in recommendations 1.12.7 or 1.12.8.

The committee also noted that cost-effectiveness evidence found that Allen Carr's Easyway in-person group seminar is cost effective when compared with Quit.ie or 1-1 in person NHS stop smoking services. They also agreed that making it available alongside other interventions would broaden people's choice, and that the more choice people had, the more likely they were to find the right intervention for them. Allen Carr's Easyway in-person group seminar would be an alternative approach without pharmacotherapy which might be more suitable for people wanting to stop smoking without using any nicotine replacement substances. For this reason the committee thought it might encourage a new (additional) cohort of smokers to attempt to quit.

The committee discussed various ways of providing the seminar, including online, but noted that the evidence they saw was only for the in-person group seminar (although in 1 study an online follow up was offered). Therefore, they were unable to generalise from this evidence to formats other than the in-person group seminar.

The committee discussed the funding of studies of the intervention. One was funded by Allen Carr's Easyway, but the committee agreed that the methods used to conduct the study minimised any risk of bias associated with this.

The committee discussed the potential effect of Allen Carr's Easyway on inequalities in health. They noted that the length of the seminar (4.5 to 6 hours) and any travel costs to attend the seminar might be difficult for some people, and that people who are housebound would not be able to attend an in-person group seminar at all. They also noted that the evidence did not include any analysis by age, family background, pregnancy. The committee were unaware whether the in-person group seminars were available in languages other than English, and agreed this was a potential barrier for some people. The evidence also showed that the quit rate was greater in people with higher education in the Allen Carr Easyway in-person group seminar arm. The committee discussed that commissioners would need to know and understand the needs of their local populations to be able to commission Allen Carr's Easyway in a way that would maximise access and use of the service.

The committee agreed that more research would be useful on the effects of Allen Carr's Easyway in different population groups, and on the effectiveness and cost effectiveness of different formats of Allen Carr's Easyway stopping smoking programmes (including online group seminars and the self-help book as well as research comparing the different delivery modes with each other including with in-person group seminars).

1.1.11.4 Cost effectiveness and resource use

The cost-effectiveness of Allen Carr's Easyway to Stop Smoking (ACE) intervention was evaluated through economic modelling. The evaluation used the same methods

as the evaluation for the updated tobacco guideline (NG209) to ensure that this update was consistent with that economic evaluation.

The committee noted that the economic analysis found that Allen Carr's Easy Way to Stop Smoking method is cost-effective. The findings are consistent with previous economic evaluations for NICE guidance in smoking cessation in that *effective* interventions also tend to be *cost-effective* interventions, because the benefits (increased life expectancy, improved quality of life and reduced healthcare costs) associated with reducing tobacco use are substantial and generally outweigh the cost of the intervention.

The analyses showed that, even if the NHS (or local authority) pays the full cost of the intervention, the cost savings would quickly outweigh the cost of the intervention (in less than five years based on the Keogan 2019 study and after around seven years based on the Frings 2020 study). In addition, the QALY gains (estimated to be 0.02 and 0.04 based on the Keogan and Frings studies respectively) would be substantial when aggregated over larger populations.

They agreed that in all likelihood the model underestimates the benefits of the treatment. They were also informed that ACE offers volume related discounts so thought it likely that the NHS or other publicly funded bodies would be able to negotiate a lower price for the intervention. Therefore, they agreed that the true benefits are likely to have been underestimated.

1.1.11.5 Other factors the committee took into account

The committee noted that as a commercial enterprise, people would normally be expected to pay for the Allen Carr's in-person group seminar and that this meant that the seminar was probably accessed by people who were able to afford to pay for it, and that this could cause inequalities in health. They agreed that making the method available through the NHS could potentially reduce these inequalities and widen the range of people who had access to the seminars. For people living in rural areas, support should be provided when they need to travel long distances to attend Allen Carr's in-person group seminar.

1.1.12 Recommendations supported by this evidence review

This evidence review supports recommendation 1.12.2 and the research recommendations on the effects of Allen Carr's Easyway in different population groups and on stopping smoking of Allen Carr's Easyway in different formats, including online group seminars and the self-help book.

1.1.13 References – included studies

1.1.13.1 Effectiveness

Frings, Daniel, Albery, Ian P, Moss, Antony C et al. (2020) Comparison of Allen Carr's Easyway programme with a specialist behavioural and pharmacological smoking cessation support service: a randomized controlled trial. Addiction (Abingdon, England) 115(5): 977-985

Keogan, Sheila; Li, Shasha; Clancy, Luke (2019) Allen Carr's Easyway to Stop Smoking - A randomised clinical trial. Tobacco control 28(4): 414-419

1.1.13.2 Economic

No included economic studies.

Appendices

Appendix A – Review protocol

Review protocol for the effectiveness and cost effectiveness of the Allen Carr Easyway to stop smoking in adults who smoke tobacco.

ID	Field	Content
0.	PROSPERO registration number	CRD42022301554
1.	Review title	The effectiveness of the Allen Carr Easyway for smoking cessation.
2.	Review question	In adults who smoke, what is the effectiveness and cost-effectiveness of the Allen Carr Easyway for smoking cessation?
3.	Objective	To determine the comparative effectiveness and cost effectiveness of the Allen Carr Easyway programme for smoking cessation.
4.	Searches	**Systematic reviews** Relevant systematic reviews will be identified during the screening of database search results and the studies included in those systematic reviews will be checked for potential inclusion in this review. **Database searches** There will be a single search covering the effectiveness and cost effectiveness evidence. The principal search strategy will be developed in MEDLINE (Ovid interface) and then adapted, as appropriate, for use in the other sources listed, taking into account their size, search functionality and subject coverage. The databases will be: • Applied Social Science Index and Abstracts (ASSIA) via ProQuest • Cochrane Central Register of Controlled Trials (CENTRAL) via Wiley • Cochrane Database of Systematic Reviews (CDSR) via Wiley • Database of Abstracts of Reviews of Effects (DARE) legacy database via CRD https://www.crd.york.ac.uk/CRDWeb • EconLit via Ovid • Embase via Ovid • Health Management Information Consortium (HMIC) via Ovid • International HTA Database via INAHTA https://database.inahta.org/ • MEDLINE ALL (including In-Process and Epub-Ahead-of-Print) via Ovid

ID	Field	Content
		• NICE Evidence Search via https://www.evidence.nhs.uk • PsycINFO via Ovid • Social Policy and Practice (SPP) via Ovid **Database search limits** Database functionality will be used, where available, to exclude: • animal studies • editorials, letters and commentaries • conference abstracts and posters • registry entries for ongoing or unpublished clinical trials • duplicates • theses and dissertations. Sources will be searched from January 1998 to the current date. The database search strategies will not use any search filters for specific study types. Searches will not be limited by language in the first instance unless the number of records retrieved is deemed to be unmanageable (>3000) in which case an English language filter will be added. **Additional search sources** The reference lists of potentially relevant references identified from the scoping searches and exceptional surveillance review will be checked. Citation searching will be done using the same set of base papers as the reference list checking to identify any later references that cite the potentially relevant references. The reference checking and citation searching will be done using "Citationchaser: an R package and Shiny app for forward and backward citations chasing in academic searching" via https://estech.shinyapps.io/citationchaser/. Note that the underlying data is derived from Lens.org. The Allen Carr Easyway website will also be checked for any additional trial reports or other evaluations via https://www.allencarr.com/. **Quality assurance** The Information Services team at NICE will quality assure the principal search strategy and peer review the strategies for the other databases. Any revisions or additional steps will be agreed by the review team before being implemented. Any deviations

ID	Field	Content
		and a rationale for them will be recorded alongside the search strategies. **Search results** The database search results will be downloaded to EPPI-Reviewer version 5 for deduplication followed by data screening. The full search strategies for all databases will be published in the final review.
5.	Condition or domain being studied	Smoking tobacco
6.	Population	Inclusion: Adults (aged over 18) who smoke tobacco and want to stop.
7.	Intervention/Exposure/Test	Allen Carr Easyway seminar programme (multicomponent programme that includes group cognitive behavioural and relaxation therapies without pharmacotherapy).
8.	Comparator/Reference standard/Confounding factors	Any comparator
9.	Types of study to be included	• RCTs • RCT components of mixed methods studies • Cost-effectiveness studies
10.	Other exclusion criteria	Evaluations of Allen Carr self-help book without seminars for smoking cessation.
11.	Context	Evidence has been highlighted to NICE during the update of its tobacco guideline that RCT evidence has become available for the Allen Carr Easyway to stop smoking. Preliminary examination suggests that the method may be as effective as specialist stop smoking services in the UK and therefore NICE will do a more thorough analysis of its effectiveness and cost effectiveness.
12.	Primary outcomes (critical outcomes)	• Smoking status at 26 week or longer timepoints (biochemically validated) • Cost-utility
13.	Secondary outcomes (important outcomes)	• Smoking status at earlier (<26 weeks) timepoints (biochemically validated) • Relapse rates • Pharmacotherapy usage • Adverse events • HRQoL (validated measures only)
14.	Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI reviewer 5 and de-duplicated. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria

ID	Field	Content
		outlined above. A standardised form will be used to extract data from studies (see Developing NICE guidelines: the manual section 6.4. This review will make use of the priority screening functionality within the EPPI-reviewer software.
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using Cochrane Risk of Bias v.2.0 as described in Developing NICE guidelines: the manual.
16.	Strategy for data synthesis	Where possible, meta-analyses of outcome data will be conducted for all comparators that are reported by more than one study, with reference to the Cochrane Handbook for Systematic Reviews of Interventions. Where data can be disambiguated it will be separated into the subgroups identified in section 17 (below). Continuous outcomes will be analysed as mean differences, unless multiple scales are used to measure the same factor. In these cases, standardised mean differences will be used instead. Pooled relative risks will be calculated for dichotomous outcomes (using the Mantel–Haenszel method) reporting numbers of people having an event. Absolute risks will be presented where possible. Fixed- and random-effects models (der Simonian and Laird) will be fitted for all comparators, with the presented analysis dependent on the degree of heterogeneity in the assembled evidence. Fixed-effects models will be deemed to be inappropriate if one or both of the following conditions is met: Significant between study heterogeneity in methodology, population, intervention or comparator was identified by the reviewer in advance of data analysis. The presence of significant statistical heterogeneity in the meta-analysis, defined as I2≥50%. In any meta-analyses where some (but not all) of the data comes from studies at high risk of bias, a sensitivity analysis will be conducted, excluding those studies from the analysis. Results from both the full and restricted meta-analyses will be reported. Similarly, in any meta-analyses where some (but not all) of the data comes from indirect studies, a sensitivity analysis will be conducted, excluding those studies from the analysis. GRADE will be used to assess the quality of the outcomes. All outcomes in this review will come from RCTs and will be rated as high quality initially and downgraded from this point. Where 10 or more studies are included as part of a single meta-analysis, a funnel plot will be produced to graphically (visually) assess the potential for publication bias.

ID	Field	Content		
		Meta-analyses will be carried out separately for each study type per outcome, but the similarities and differences between the results obtained from the different study types will be noted. Since this review aims to evaluate the effectiveness of a single intervention, no network meta-analysis will be considered.		
17.	Analysis of sub-groups	Where data are presented by subgroup, or can be disaggregated into sub-groups, the following stratifications will be used: • Age • Gender • SES • People in prison • Homeless people • Geographical area of the participants • People with mental ill-health		
18.	Type and method of review	☒	Intervention	
		☐	Diagnostic	
		☐	Prognostic	
		☐	Qualitative	
		☐	Epidemiologic	
		☐	Service Delivery	
		☐	Other (please specify)	
19.	Language	English		
20.	Country	England		
21.	Anticipated or actual start date	16 February 2022.		
22.	Anticipated completion date	Consultation on draft guideline (including publication of draft review: 11 May 2022. Publication of final guideline (including final review): 4 August 2022.		
23.	Stage of review at time of this submission	Review stage	Started	Completed
		Preliminary searches	☑	☑
		Piloting of the study selection process	☑	☐
		Formal screening of search results against eligibility criteria	☐	☐
		Data extraction	☐	☐
		Risk of bias (quality) assessment	☐	☐
		Data analysis	☐	☐

ID	Field	Content
24.	Named contact	**Named contact** NICE Guideline Development Team **Named contact e-mail** PHAC@nice.org.uk **Organisational affiliation of the review** National Institute for Health and Care Excellence (NICE) Guideline Development Team.
25.	Review team members	From the NICE Guideline Development Team: Mr Chris Carmona, technical lead Dr Yolanda Martinez, technical analyst Dr Lesley Owen, health economic adviser Mr Paul Levay, information specialist Mr Adam O'Keefe, project manager From the University of York, York Health Economic Consortium (YHEC): Dr Matthew Taylor, Director
26.	Funding sources/sponsor	This systematic review is being completed by the NICE Guideline Development Team which is an internal team at NICE.
27.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
28.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10271.
29.	Other registration details	No other registrations of this protocol.
30.	Reference/URL for published protocol	https://www.crd.york.ac.uk/prospero/
31.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as:

ID	Field	Content	
		notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.	
32.	Keywords	Tobacco; smoking; smoking cessation; stop smoking interventions; Allen Carr Easyway.	
33.	Details of existing review of same topic by same authors	This is a new review and does not update a previous review of this intervention.	
34.	Current review status	☒	Ongoing
		☐	Completed but not published
		☐	Completed and published
		☐	Completed, published and being updated
		☐	Discontinued
35.	Additional information	This review will be used to update the NICE guideline on Tobacco: preventing uptake, promoting quitting and treating dependence.	
36.	Details of final publication	www.nice.org.uk	

Appendix B – Literature search strategies

Effectiveness searches

Search design and peer review

A NICE information specialist conducted the literature searches for the evidence review. The searches were run on 25 January 2022. This search report is compliant with the requirements of PRISMA-S.

The MEDLINE strategy below was quality assured (QA) by a trained NICE information specialist. All translated search strategies were peer reviewed to ensure their accuracy. Both procedures were adapted from the 2016 PRESS Checklist.

The principal search strategy was developed in MEDLINE (Ovid interface) and adapted, as appropriate, for use in the other sources listed in the protocol, taking into account their size, search functionality and subject coverage.

Review management

The search results were managed in EPPI-Reviewer v5. Duplicates were removed in EPPI-R5 using a two-step process. First, automated deduplication is performed using a high-value algorithm. Second, manual deduplication is used to assess 'low-probability' matches. All decisions made for the review can be accessed via the deduplication history.

Prior work

The search for the 2020 exceptional surveillance of stop smoking interventions and services (NICE guideline NG92) and the scoping search for this review (January 2021) were consulted.

The free-text terms for smoking were derived from the searches for NICE guideline 209 Tobacco: preventing uptake, promoting quitting and treating dependence.

Limits and restrictions

No limits were applied to the searches.

Search filters

No search filters were used.

Key decisions

Purpose

This search was for the key named intervention only, as agreed with the technical team.

Test papers

Six test papers were identified for testing. Two were from the surveillance review:

Frings, Daniel, et al. "Comparison of Allen Carr's Easyway Programme with a Specialist Behavioural and Pharmacological Smoking Cessation Support Service: A Randomized Controlled Trial." *Addiction*, vol. 115, no. 5, 2020, pp. 977–85, doi:https://doi.org/10.1111/add.14897.

Keogan, Sheila, et al. “Allen Carr’s Easyway to Stop Smoking - A Randomised Clinical Trial.” *Tobacco Control*, vol. 28, no. 4, July 2019, pp. 414–19, doi:10.1136/tobaccocontrol-2018-054243.

Four were from the January 2021 scoping searches, during which over 2800 references were manually screened.

Dijkstra A., Zuidema R., Vos D., van Kalken M. (2014) The effectiveness of the Allen Carr smoking cessation training in companies tested in a quasi-experimental design. *BMC Public Health*, 14: 952. 10.1186/1471-2458-14-952
25218267

Hutter H, Moshammer H, Neuberger M. (2006) Smoking cessation at the workplace: 1 year success of short seminars. *Int Arch Occup Environ Health*, 79: 42. 10.1007/s00420-005-0034-y

Moshammer H, Neuberger M. (2007) Long term success of short smoking cessation seminars supported by occupational health care. *Addict Behav*, 32: 1486-93. 10.1016/j.addbeh.2006.10.002

Wood, Kerry V; Albery, Ian P; Moss, Antony C et al. (2017) Study protocol for a randomised controlled trial of Allen Carr's Easyway programme versus Lambeth and Southwark NHS for smoking cessation. *BMJ Open*, 7, 12, e016867. 10.1136/bmjopen-2017-016867

Free-text terms

There is no obvious MeSH term used to describe Allen Carr Easyway, established by running the test papers through the Yale MeSH Analyzer. The papers were checked manually in Embase. Therefore, no subject headings were used.

All six test papers were retrieved by the MEDLINE and Embase searches in Ovid.

The abbreviation ACE was not used as it returned a high number of irrelevant results, as it is used to abbreviate other concepts (e.g. angiotensin-converting enzyme-2 (ACE-2); Adverse Childhood Experiences).

The term "Easyway" returned a small number of potentially relevant results. The phrase "easy way" can be used in many different contexts and so was combined with free text for smoking, which was derived from the NG209 searches.

The number of results was low enough for some parts of the search to be used in all fields. This was not possible for "Allen Carr" as it returns authors with similar names and so this term was searched in titles, abstracts and the available keyword fields.

Searches were conducted in clinical trial registries (see below for details) to identify clinical trials. The identity numbers of the trials that mentioned Allen Carr were added to the database searches.

Notes on translations

ASSIA - NOFT means "Anywhere except full text" and is equivalent to using all fields.

Econlit – there is a kw but not a kf field.

HMIC and SPP – the heading word (hw) field is the equivalent to using subject headings from the uncontrolled vocabulary.

PsycINFO – there is no kw,kf field and so replaced with key concepts (ID) and Sponsorship (GS)

Deviations from the protocol

The searches were conducted to cover effectiveness and cost effectiveness, before these were separated. This document is therefore for the effectiveness review.

There was also a deviation in that several sources were added during the search as the numbers being obtained were relatively low and it was feasible within the time and resources available to expand the list of sources beyond those specified in the protocol. This accounts for AMED, Emcare and Web of Science being searched. This was to ensure comprehensive coverage of the potential literature.

The results from each search were relatively low and so no limits were applied so that the full results could be screened manually.

Searches

Main search – Databases

Database	Date searched	Database platform	Database segment or version	No. of results downloaded
Allied and Complementary Medicine (AMED)	25/01/2022	Ovid	Allied and Complementary Medicine) <1985 to January 2022>	0
Applied Social Science Index and Abstracts (ASSIA)	25/01/2022	ProQuest	1987 - current Last date of update not stated	1
Cochrane Central Register of Controlled Trials (CENTRAL)	25/01/2022	Wiley	Cochrane Central Register of Controlled Trials Issue 12 of 12, December 2021	9
Cochrane Database of Systematic Reviews (CDSR)	25/01/2022	Wiley	Cochrane Database of Systematic Reviews Issue 1 of 12, January 2022	0
Database of Abstracts of Reviews of Effects (DARE)	25/01/2022	CRD	Legacy database - last updated on 31 March 2015 with content up to 31 December 2014.	0
EconLit	25/01/2022	Ovid	Econlit <1886 to January 13, 2022>	3
Embase	25/01/2022	Ovid	Embase <1974 to 2022 January 24>	71
Emcare	25/01/2022	Ovid	Ovid Emcare <1995 to 2022 Week 3>	20
Health Management Information Consortium (HMIC)	25/01/2022	Ovid	HMIC Health Management Information Consortium <1979 to November 2021>	2
International HTA Database (INAHTA)	25/01/2022	INAHTA	Last date of update not stated, searched on 25/01/2022	1

Database	Date searched	Database platform	Database segment or version	No. of results downloaded
MEDLINE	25/01/2022	Ovid	Ovid MEDLINE(R) ALL <1946 to January 24, 2022>	36
NICE Evidence Search	25/01/2022	www.evidence.nhs.uk	Last date of update not stated, searched on 25/01/2022	8
PsycINFO	25/01/2022	Ovid	APA PsycInfo <1806 to January Week 3 2022>	115
Social Policy and Practice (SPP)	25/01/2022	Ovid	Social Policy and Practice <202201>	0
Web of Science (WOS)	25/01/2022	Clarivate	Web of Science Core Collection (1990-present) Science Citation Index Expanded (1990-present) Social Sciences Citation Index (1990-present) Arts & Humanities Citation Index (1990-present) Emerging Sources Citation Index (2017-present) Data last updated 24/01/2022	39

Main search – Additional methods

Additional method	Date searched	No. of results downloaded
Forwards citation searching	25/01/2022	39
Reference checking	25/01/2022	50
Scoping searches	24/01/2022	9
Clinical trial registries	24/01/2022	1
Web searching	25/01/2022	0

Search strategy history

Database name: Allied and Complementary Medicine

AMED (Allied and Complementary Medicine) <1985 to January 2022>

1 (allen* adj2 carr*).ti,ab. or (allen* and carr*).hw. or (allencarr* or easyway*).af. 0
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 0
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 0
4 or/1-3 0

Database name: Applied Social Sciences Index & Abstracts

S1	TIABSU(allen* near/2 carr*)	1
S2	NOFT(allencarr* or easyway*)	0
S3	NOFT("easy way*") AND NOFT(nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)	0
S4	NOFT(NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771)	0
S5	s1 or s2 or s3 or s4	1

Database name: Cochrane Database of Systematic Reviews

#1 (allencarr* or easyway*) 6
#2 (allen* near/2 carr*):ti,ab,kw 11
#3 ((easy NEXT way*) AND (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or (hand NEXT roll*) or handroll* or rollies or (roll NEXT up*) or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)) 8
#4 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771) 8
#5 {OR #1-#4} 15
#6 {OR #1-#4} in Cochrane Reviews, Cochrane Protocols 0
Note: Where not stated, the field searched was All Fields

Database name: Cochrane Central Register of Controlled Trials

#1 (allencarr* or easyway*) 6
#2 (allen* near/2 carr*):ti,ab,kw 11
#3 ((easy NEXT way*) AND (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or (hand NEXT roll*) or handroll* or rollies or (roll NEXT up*) or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)) 8
#4 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771) 8
#5 {OR #1-#4} 15
#6 {OR #1-#4} in Trials 15
#7 (clinicaltrials or trialsearch):so 388528
#8 #6 not #7 9
Note: Where not stated, the field searched was All Fields

Database name: Database of Abstracts of Reviews of Effects

Line	Search	Hits
1	(allen* adj2 carr*)	0
2	(allencarr* or easyway*)	0
3	("easy way*")	4
4	(nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)	1641
5	#3 AND #4	0
6	(NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771)	0
7	#1 OR #2 OR #5 OR #6	0

Note: Where not stated, the field searched was All Fields
Bibliographic records were published on DARE until 31st March 2015. Searches of MEDLINE, Embase, CINAHL, PsycINFO and PubMed for DARE were continued until the end of 2014.

Database name: EconLit

Econlit <1886 to January 13, 2022>

1 (allen* adj2 carr*).ti,ab,kw. or (allencarr* or easyway*).af. 2
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 1
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 0
4 or/1-3 3

Database name: Embase

Embase <1974 to 2022 January 24>

1 (allen* adj2 carr*).ti,ab,kw,kf. or (allencarr* or easyway*).af. 21
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 50
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 5
4 or/1-3 71

Database name: Emcare

Ovid Emcare <1995 to 2022 Week 3>

1 (allen* adj2 carr*).ti,ab,kw,kf. or (allencarr* or easyway*).af. 9
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 10
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 3
4 or/1-3 20

Database name: Health Management Information Consortium

HMIC Health Management Information Consortium <1979 to November 2021>

1 (allen* adj2 carr*).ti,ab. or (allen* and carr*).hw. or (allencarr* or easyway*).af. 1
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 1
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 0
4 or/1-3 2

Database name: International HTA Database

1	allencarr* or easyway*	0
2	Allen* AND Carr*	1
3	NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771	0
4	(("easy way" or "easy ways") and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll" or "hand rolling" or "hand rolls" or "hand rolled" or handroll* or rollies or "roll up" or "roll ups" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)	0
5	1 OR #2 OR #3 OR #4	1

Note: Where not stated, the field searched was All Fields

Database name: MEDLINE

Ovid MEDLINE(R) ALL <1946 to January 24, 2022>

1 (allen* adj2 carr*).ti,ab,kw,kf. or (allencarr* or easyway*).af. 16
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 19
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 5
4 or/1-3 36

Database name: NICE Evidence Search

Searched on 25 January 2022

1 result for allencarr* or easyway*

Your search for NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771 returned no results.

7 results for "allen carr" or "allen carr's" or "allen carrs"

80 results for ("easy way") and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)

These results were reviewed manually on screen for relevance. "Easy way" did not occur in any of the titles. One item was relevant but this was already contained in the 7 results from the ACE search and was not downloaded again. No other results were relevant.

Database name: PsycINFO

APA PsycInfo <1806 to January Week 3 2022>

1 (allen* adj2 carr*).ti,ab,id,gs. or (allencarr* or easyway*).af. 13
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 105
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 1
4 or/1-3 115

Database name: Social Policy and Practice

Social Policy and Practice <202201>

1 (allen* adj2 carr*).ti,ab. or (allen* and carr*).hw. or (allencarr* or easyway*).af. 0
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 0
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 0
4 or/1-3 0

Database name: Web of Science

1 TI=(Allen$ NEAR/2 Carr$) or AB=(Allen$ NEAR/2 Carr$) or AK=(Allen$ NEAR/2 Carr$) 16
2 ALL=(allencarr$ or easyway$) 10
3 ALL=(NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771) 1
4 ALL=(("easy way$" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*))) 22
5 #1 OR #2 OR #3 OR #4 39

Additional search methods

Source name: forwards citation searching

Date of search	25 January 2022
How the base papers were identified	There were 2 results in the 2020 exceptional surveillance of stop smoking interventions and services (NICE guideline NG92) plus selected another 5 from those marked as relevant in the January 2021 scoping searches.
Databases used	Haddaway NR, Grainger MJ, Gray CT (2021) Citationchaser: An R package and Shiny app for forward and backward citations chasing in academic searching. doi: 10.5281/zenodo.4543513. https://estech.shinyapps.io/citationchaser/ Note that this package uses reference data from Lens.org.
Date of last update	Not stated but searches use the live Lens.org API.
How results were managed	Only those references that could be accessed through Citationchaser were added to the search results. Duplicates were removed automatically by Citationchaser.
How the results were selected	All results were downloaded, without any further processing.
Total no. of records downloaded	39
List of base papers used	Dijkstra A., Zuidema R., Vos D., van Kalken M. (2014) The effectiveness of the Allen Carr smoking cessation training in companies tested in a quasi-experimental design. *BMC Public Health*, 14: 952. doi: 10.1186/1471-2458-14-952 Frings, Daniel, et al. "Comparison of Allen Carr's Easyway Programme with a Specialist Behavioural and Pharmacological Smoking Cessation Support Service: A Randomized Controlled Trial." *Addiction*, vol. 115, no. 5, 2020, pp. 977–85, doi: 10.1111/add.14897. Hutter H, Moshammer H, Neuberger M. (2006) Smoking cessation at the workplace: 1 year success of short seminars. *Int Arch Occup Environ Health*, 79: 42-8. doi: 10.1007/s00420-005-0034-y Keogan, Sheila, et al. "Allen Carr's Easyway to Stop Smoking - A Randomised Clinical Trial." *Tobacco Control*, vol. 28, no. 4, July 2019, pp. 414–19, doi:10.1136/tobaccocontrol-2018-054243. Marron, Donncha (2019) Stop smoking the Easyway: Addiction, self-help, and tobacco cessation. *Contemporary Drug Problems: An Interdisciplinary Quarterly,* 46(2), 198-214. doi: 10.1177/0091450919843344 Moshammer H, Neuberger M. (2007) Long term success of short smoking cessation seminars supported by occupational health care. *Addict Behav*, 32: 1486-93. doi: 10.1016/j.addbeh.2006.10.002 Wood, Kerry V; Albery, Ian P; Moss, Antony C et al. (2017) Study protocol for a randomised controlled trial of Allen Carr's Easyway programme versus Lambeth and Southwark NHS for smoking cessation. BMJ Open, 7, 12, e016867. doi: 10.1136/bmjopen-2017-016867

Additional notes	The articles were cited a total of 54 times, comprising 39 unique papers.

Source name: reference checking

Date of search	25 January 2022
How the base papers were identified and the types of references examined	There were 2 results in the 2020 exceptional surveillance of stop smoking interventions and services (NICE guideline NG92). Also added the Wood et al. protocol identified at scoping identified the protocol. These were the most recent papers and so would be expected to cite any earlier papers of relevance.
Databases used	Haddaway NR, Grainger MJ, Gray CT (2021) Citationchaser: An R package and Shiny app for forward and backward citations chasing in academic searching. doi: 10.5281/zenodo.4543513. https://estech.shinyapps.io/citationchaser/ Note that this package uses reference data from Lens.org.
Date of last update	Not stated but searches use the live Lens.org API.
How results were managed	Only those references that could be accessed through Citationchaser were added to the search results. Duplicates were removed automatically by Citationchaser.
How the results were selected	All results were downloaded, without any further processing.
Total no. of records downloaded	50
List of base papers used	Frings, Daniel, et al. “Comparison of Allen Carr’s Easyway Programme with a Specialist Behavioural and Pharmacological Smoking Cessation Support Service: A Randomized Controlled Trial.” Addiction, vol. 115, no. 5, 2020, pp. 977–85, doi: 10.1111/add.14897. Keogan, Sheila, et al. “Allen Carr’s Easyway to Stop Smoking - A Randomised Clinical Trial.” Tobacco Control, vol. 28, no. 4, July 2019, pp. 414–19, doi:10.1136/tobaccocontrol-2018-054243. Wood, Kerry V; Albery, Ian P; Moss, Antony C et al. (2017) Study protocol for a randomised controlled trial of Allen Carr's Easyway programme versus Lambeth and Southwark NHS for smoking cessation. BMJ Open, 7, 12, e016867. doi: 10.1136/bmjopen-2017-016867
Additional notes	The articles had a total of 60 references, comprising 50 unique papers.

Source name: scoping searches

Date of search	Original search conducted 14 January 2021. Records extracted for this search on 24 January 2022
No. of results added	9
How the results were selected	There were 2 results in the 2020 exceptional surveillance of stop smoking interventions and services (NICE guideline NG92). A further 7 had been selected at full text in the January 2021 scoping searches.
List of results added	There were 2 results in the 2020 exceptional surveillance of stop smoking interventions and services (NICE guideline NG92) Frings, Daniel, et al. "Comparison of Allen Carr's Easyway Programme with a Specialist Behavioural and Pharmacological Smoking Cessation Support Service: A Randomized Controlled Trial." *Addiction*, vol. 115, no. 5, 2020, pp. 977–85, doi:https://doi.org/10.1111/add.14897. Keogan, Sheila, et al. "Allen Carr's Easyway to Stop Smoking - A Randomised Clinical Trial." *Tobacco Control*, vol. 28, no. 4, July 2019, pp. 414–19, doi:10.1136/tobaccocontrol-2018-054243. There were another 6 from the January 2021 scoping searches. Dijkstra A., Zuidema R., Vos D., van Kalken M. (2014) The effectiveness of the Allen Carr smoking cessation training in companies tested in a quasi-experimental design. *BMC Public Health*, 14: 952. Foshee JP; Oh A; Luginbuhl A; Curry J; Keane W; Cognetti D. (2017) Prospective, randomized, controlled trial using best-selling smoking-cessation book. *Ear, Nose, & Throat Journal*, 96(7): 258-262. Hutter H, Moshammer H, Neuberger M. (2006) Smoking cessation at the workplace: 1 year success of short seminars. *Int Arch Occup Environ Health*, 79: 42-8. 10.1007/s00420-005-0034-y Marron, Donncha (2019) Stop smoking the Easyway: Addiction, self-help, and tobacco cessation. *Contemporary Drug Problems: An Interdisciplinary Quarterly,* 46(2), 198-214. Moshammer H, Neuberger M. (2007) Long term success of short smoking cessation seminars supported by occupational health care. *Addict Behav*, 32: 1486-93. 10.1016/j.addbeh.2006.10.002 Wood, Kerry V; Albery, Ian P; Moss, Antony C et al. (2017) Study protocol for a randomised controlled trial of Allen Carr's Easyway programme versus Lambeth and Southwark NHS for smoking cessation. *BMJ Open*, 7, 12, e016867 There was also a conference abstract from the scoping searches, which was added. Keogan, S Li, SS Clancy, L (2018) A 12 month smoking cessation outcome-Allen Carr's Easyway to Stop Smoking-a randomised clinical trial *European Respiratory Journal*, 52 (Suppl 62): OA5227. This is an ERS International Congress abstract. No full-text version is available.

Source name: clinical trial registries

Name	ClinicalTrials.gov
URL	https://clinicaltrials.gov/ct2/home
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	Not stated
Search terms	(Allen Carr) OR AllenCarr OR Easyway ("easy way") AND (nicotine OR smoker OR smoking OR tobacco OR cigar OR cigarette)
Any limitations used	None
How the results were selected	1 registry entry - reviewed for posted results and links to published results
No. of results	0
List of results	-
Notes	1 registry entry: NCT02855255 is Frings "Comparison of Allen Carr's Easyway Programme with a Specialist Behavioural and Pharmacological Smoking Cessation Support Service: A Randomized Controlled Trial." *Addiction*, vol. 115, no. 5, 2020, pp. 977–85, No results posted, just a link to the protocol published as Wood et al. 2017 *BMJ Open*.

Name	ISRCTN Registry
URL	https://www.isrctn.com/
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	Updated 24/01/2022
Search terms	(Allen Carr) OR AllenCarr OR Easyway ("easy way") AND (nicotine OR smoker OR smoking OR tobacco OR cigar OR cigarette)
Any limitations used	None
How the results were selected	Reviewed registry entries for posted results and links to published results
No. of results	1
List of results	ISRCTN12951013 has basic results
Notes	4 registry entries: ISRCTN23584477 is NCT0285525 (Frings et al.) - links to the Frings paper, does not provide further results.

	ISRCTN12951013 is Keogan, Sheila, et al. “Allen Carr’s Easyway to Stop Smoking - A Randomised Clinical Trial.” *Tobacco Control*, vol. 28, no. 4, July 2019, pp. 414–19. - includes link to basic results data ISRCTN16006023 : Promoting smoking abstinence through Virtual Reality - no results available ISRCTN15690771 : Retraining automatic action tendencies for smoking using mobile phone-based approach-avoidance bias training

Name	ScanMedicine
URL	https://scanmedicine.com/
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	Jan 2022
Search terms	allencarr | easyway | "allen carr" "easy way" + (nicotine | smoker | smoking | tobacco | cigar | cigarette)
Any limitations used	None
How the results were selected	Reviewed registry entries for posted results and links to published results
No. of results	0
List of results	-
Notes	5 registry entries, which had all been identified already: NCT02855255 ISRCTN23584477 ISRCTN12951013 ISRCTN15690771 ISRCTN16006023

Name	World Health Organization International Clinical Trials Registry Platform (ICTRP)
URL	https://trialsearch.who.int
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	Updates range from 29/11/2021 to 07/12/2021
Search terms	(Allen Carr) OR AllenCarr OR Easyway ("easy way") AND (nicotine OR smoker OR smoking OR tobacco OR cigar OR cigarette)
Any limitations used	None
How the results were selected	Reviewed registry entries for posted results and links to published results

No. of results	0
List of results	-
Notes	5 registry entries, which had all been identified already: NCT02855255 ISRCTN23584477 ISRCTN12951013 ISRCTN15690771 ISRCTN16006023

Name	EU Clinical Trials Register
URL	https://www.clinicaltrialsregister.eu/ctr-search/search/
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	The EU Clinical Trials Register currently displays 41472 clinical trials with a EudraCT protocol
Search terms	(Allen Carr) OR AllenCarr OR Easyway ("easy way") AND (nicotine OR smoker OR smoking OR tobacco OR cigar OR cigarette)
Any limitations used	None
How the results were selected	Reviewed registry entries for posted results and links to published results
No. of results	0
List of results	-
Notes	Query did not match any clinical trials

Source name: website searching

Name	Allen Carr
URL	https://www.allencarr.com/
Date searched	25 January 2022
Segment or dates covered by search, including any specific sections browsed	On the front page there is a note saying ACE is "Clinically Proven1" and this leads to 5 citations which have all been identified in the search results already (Frings, Keogan, Moshammer, Dijkstra and Hutter). <https://www.allencarr.com/#ref> Browsed sections: Success stories https://www.allencarr.com/success-stories/ About Us https://www.allencarr.com/about-allen-carrs-easyway/ - again refers back to Frings and Keogan.
Search terms	Also used Google.com to see if there were any pdf documents (e.g. for evaluative reports) using: site:https://www.allencarr.com filetype:pdf Your search - site:https://www.allencarr.com filetype:pdf - did not match any documents.

How the results were selected	Looking for any reports or data, rather than personal testimonials.
No. of results	0

Name	Google search
URL	https://www.google.com/
Date searched	25 January 2022
Search terms	"allen carr" filetype:pdf - 76 results "allencarr" filetype:pdf - 79 results "easyway" smoking filetype:pdf - 68 results "easyway" cigarettes filetype:pdf - 44 results "easyway" tobacco filetype:pdf - 48 results
How the results were selected	Searched for anything in English that was not already in EPPI that contained data, an evaluation or clinical trial. NHS Education for Scotland Acupuncture, Acupressure, Laser Therapy and Electrostimulation - cites Hutter and Moshammer, which are already in EPPI, and it seems to be based on an ASH letter from 2006.
No. of results	0

Cost-effectiveness searches

Search design and peer review

A NICE information specialist conducted the literature searches for the evidence review. The searches were run on 25 January 2022. This search report is compliant with the requirements of PRISMA-S.

The MEDLINE strategy below was quality assured (QA) by a trained NICE information specialist. All translated search strategies were peer reviewed to ensure their accuracy. Both procedures were adapted from the 2016 PRESS Checklist.

The principal search strategy was developed in MEDLINE (Ovid interface) and adapted, as appropriate, for use in the other sources listed in the protocol, taking into account their size, search functionality and subject coverage.

Review management

The search results were managed in EPPI-Reviewer v5. Duplicates were removed in EPPI-R5 using a two-step process. First, automated deduplication is performed using a high-value algorithm. Second, manual deduplication is used to assess 'low-probability' matches. All decisions made for the review can be accessed via the deduplication history.

Prior work

The search for the 2020 exceptional surveillance of stop smoking interventions and services (NICE guideline NG92) and the scoping search for this review (January 2021) were consulted.

The free-text terms for smoking were derived from the searches for NICE guideline 209 Tobacco: preventing uptake, promoting quitting and treating dependence.

Limits and restrictions

No limits were applied to the searches.

Search filters

A modified version of Glanville was use. Several modifications have been made to this filter over the years that are standard NICE practice.

> Glanville J et al. (2009) Development and Testing of Search Filters to Identify Economic Evaluations in MEDLINE and EMBASE. Alberta: Canadian Agency for Drugs and Technologies in Health (CADTH)

The standard NICE cost utility filter was also used. This is more recent (2020, unpublished) and so was used as well as Glanville to ensure comprehensive coverage.

Key decisions

Purpose

This search was for the key named intervention only, as agreed with the technical team.

Test papers

Six test papers were identified for testing. Two were from the surveillance review:

> Frings, Daniel, et al. "Comparison of Allen Carr's Easyway Programme with a Specialist Behavioural and Pharmacological Smoking Cessation Support Service: A Randomized

Controlled Trial." *Addiction*, vol. 115, no. 5, 2020, pp. 977–85, doi:https://doi.org/10.1111/add.14897.

Keogan, Sheila, et al. "Allen Carr's Easyway to Stop Smoking - A Randomised Clinical Trial." *Tobacco Control*, vol. 28, no. 4, July 2019, pp. 414–19, doi:10.1136/tobaccocontrol-2018-054243.

Four were from the January 2021 scoping searches, during which over 2800 references were manually screened.

Dijkstra A., Zuidema R., Vos D., van Kalken M. (2014) The effectiveness of the Allen Carr smoking cessation training in companies tested in a quasi-experimental design. *BMC Public Health*, 14: 952. 10.1186/1471-2458-14-952
25218267

Hutter H, Moshammer H, Neuberger M. (2006) Smoking cessation at the workplace: 1 year success of short seminars. *Int Arch Occup Environ Health*, 79: 42. 10.1007/s00420-005-0034-y

Moshammer H, Neuberger M. (2007) Long term success of short smoking cessation seminars supported by occupational health care. *Addict Behav*, 32: 1486-93. 10.1016/j.addbeh.2006.10.002

Wood, Kerry V; Albery, Ian P; Moss, Antony C et al. (2017) Study protocol for a randomised controlled trial of Allen Carr's Easyway programme versus Lambeth and Southwark NHS for smoking cessation. *BMJ Open*, 7, 12, e016867. 10.1136/bmjopen-2017-016867

Free-text terms

There is no obvious MeSH term used to describe Allen Carr Easyway, established by running the test papers through the Yale MeSH Analyzer. The papers were checked manually in Embase. Therefore, no subject headings were used for the intervention component of the search..

The abbreviation ACE was not used as it returned a high number of irrelevant results, as it is used to abbreviate other concepts (e.g. angiotensin-converting enzyme-2 (ACE-2); Adverse Childhood Experiences).

The term "Easyway" returned a small number of potentially relevant results. The phrase "easy way" can be used in many different contexts and so was combined with free text for smoking, which was derived from the NG209 searches.

The number of results was low enough for some parts of the search to be used in all fields. This was not possible for "Allen Carr" as it returns authors with similar names and so this term was searched in titles, abstracts and the available keyword fields.

Searches were conducted in clinical trial registries (see below for details) to identify clinical trials. The identity numbers of the trials that mentioned Allen Carr were added to the database searches. These were re-screened to identify any results data relating to cost effectiveness but none was identified.

Notes on translations

ASSIA - NOFT means "Anywhere except full text" and is equivalent to using all fields.

Econlit – there is a kw but not a kf field.

HMIC and SPP – the heading word (hw) field is the equivalent to using subject headings from the uncontrolled vocabulary.

Deviations from the protocol

The results from each search were relatively low and no limits were applied so that the full results could be screened manually.

The protocol had set out that there would be a single search covering effectiveness and cost effectiveness. A change was made to do separate searches so that the results could be processed separately. The MEDLINE and Embase searches were re-run with appropriate filters applied for cost effectiveness; these were peer reviewed again. There are no filters for AMED, ASSIA, HMIC, INAHTA or SPP but the results were so low that the same search as the effectiveness review could be used. A new search was done for the legacy database NHS EED. No filter is necessary in Econlit and the same search as the effectiveness review could be used.

This document just covers the cost effectiveness review and a separate search history is available for the effectiveness review.

Cost effectiveness searches

Main search – Databases

Database	Date searched	Database platform	Database segment or version	No. of results downloaded
Allied and Complementary Medicine (AMED)	26/01/2022	Ovid	Allied and Complementary Medicine) <1985 to January 2022>	0
Applied Social Science Index and Abstracts (ASSIA)	25/01/2022	ProQuest	1987 - current Last date of update not stated	1
EconLit	26/01/2022	Ovid	Econlit <1886 to January 13, 2022>	3
Embase	26/01/2022	Ovid	Embase <1974 to 2022 January 25>	10
Emcare	26/01/2022	Ovid	Ovid Emcare <1995 to 2022 Week 3>	2
Health Management Information Consortium (HMIC)	26/01/2022	Ovid	HMIC Health Management Information Consortium <1979 to November 2021>	2
International HTA Database (INAHTA)	25/01/2022	INAHTA	Last date of update not stated, searched on 25/01/2022	1
MEDLINE	26/01/2022	Ovid	Ovid MEDLINE(R) ALL <1946 to January 25, 2022>	7
NHS Economic Evaluation Database (NHS EED)	26/01/2022	CRD	Legacy database - last updated on 31 March 2015 with content up to 31 December 2014	0
Social Policy and Practice (SPP)	26/01/2022	Ovid	Social Policy and Practice <202201>	0

Main search – Additional methods

Additional method	Date searched	No. of results downloaded
Clinical trial registries	24/01/2022	0
Web searching	25/01/2022	0

Search strategy history

Database name: Allied and Complementary Medicine

AMED (Allied and Complementary Medicine) <1985 to January 2022>

1 (allen* adj2 carr*).ti,ab. or (allen* and carr*).hw. or (allencarr* or easyway*).af. 0
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 0
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 0

4 or/1-3 0

Database name: Applied Social Sciences Index & Abstracts

S1	TIABSU(allen* near/2 carr*)	1
S2	NOFT(allencarr* or easyway*)	0
S3	NOFT("easy way*") AND NOFT(nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)	0
S4	NOFT(NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771)	0
S5	s1 or s2 or s3 or s4	1

Database name: EconLit

Econlit <1886 to January 13, 2022>

1 (allen* adj2 carr*).ti,ab,kw. or (allencarr* or easyway*).af. 2
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 1
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 0
4 or/1-3 3

Database name: Embase

Embase <1974 to 2022 January 25>

1 (allen* adj2 carr*).ti,ab,kw,kf. or (allencarr* or easyway*).af. 21
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 50
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 5
4 or/1-3 71
5 cost utility analysis/ 10881
6 quality adjusted life year/ 30707
7 cost*.ti. 176172
8 (cost* adj2 utilit*).tw. 11063
9 (cost* adj2 (effective* or assess* or evaluat* or analys* or model* or benefit* or threshold* or quality or expens* or saving* or reduc*)).tw. 337535
10 (economic* adj2 (evaluat* or assess* or analys* or model* or outcome* or benefit* or threshold* or expens* or saving* or reduc*)).tw. 57380
11 (qualit* adj2 adjust* adj2 life*).tw. 23510
12 QALY*.tw. 23069
13 (incremental* adj2 cost*).tw. 24745
14 ICER.tw. 10910
15 utilities.tw. 13229
16 markov*.tw. 34752
17 (dollar* or USD or cents or pound or pounds or GBP or sterling* or pence or euro or euros or yen or JPY).tw. 63815
18 ((utility or effective*) adj2 analys*).tw. 32680
19 (willing* adj2 pay*).tw. 12179
20 (EQ5D* or EQ-5D*).tw. 21204

21 ((euroqol or euro-qol or euroquol or euro-quol or eurocol or euro-col) adj3 ("5" or five)).tw. 4037
22 (european* adj2 quality adj3 ("5" or five)).tw. 756
23 or/5-22 556716
24 4 and 23 3
25 health-economics/ or exp economic-evaluation/ or exp health-care-cost/ or pharmacoeconomics/ or Monte Carlo Method/ or Decision Tree/ 633185
26 (Economic* or cost or costs or costly or costing or costed or price or prices or pricing or pharmacoeconomic* or pharmaco economic* or budget*).ti,ab. 1212271
27 ((monte adj carlo) or markov or (decision adj2 (tree* or analys*))).ti,ab. 105736
28 (value adj2 (money or monetary)).ti,ab. 3665
29 Quality of Life/ or Quality Adjusted Life Year/ or Quality of Life Index/ or Short Form 36/ or Health Status/ 688488
30 (quality of life or quality adjusted life or qaly* or qald* or qale* or qtime* or quality of wellbeing or quality of well-being or willingness to pay or standard gamble* or time trade off* or time tradeoff* or qol or hql or hqol or hrqol or disutili* or rosser*).ti,ab. 529813
31 (disability adjusted life or daly).ti,ab. 5768
32 (health* year* equivalent* or hye or hyes).ti,ab. 165
33 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six or sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six or sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve or sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen or sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty or euroqol or euro qol or eq5d or eq 5d).ti,ab. 80647
34 or/25-33 2240994
35 4 and 34 10
36 24 or 35 10

Database name: Emcare

Ovid Emcare <1995 to 2022 Week 3>

1 (allen* adj2 carr*).ti,ab,kw,kf. or (allencarr* or easyway*).af. 9
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 10
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 3
4 or/1-3 20
5 cost utility analysis/ 4802
6 quality adjusted life year/ 11160
7 cost*.ti. 52928
8 (cost* adj2 utilit*).tw. 3642
9 (cost* adj2 (effective* or assess* or evaluat* or analys* or model* or benefit* or threshold* or quality or expens* or saving* or reduc*)).tw. 95302
10 (economic* adj2 (evaluat* or assess* or analys* or model* or outcome* or benefit* or threshold* or expens* or saving* or reduc*)).tw. 19284
11 (qualit* adj2 adjust* adj2 life*).tw. 8491
12 QALY*.tw. 6827
13 (incremental* adj2 cost*).tw. 8332
14 ICER.tw. 2428
15 utilities.tw. 3530
16 markov*.tw. 8484
17 (dollar* or USD or cents or pound or pounds or GBP or sterling* or pence or euro or euros or yen or JPY).tw. 16549
18 ((utility or effective*) adj2 analys*).tw. 10724
19 (willing* adj2 pay*).tw. 4415
20 (EQ5D* or EQ-5D*).tw. 6172
21 ((euroqol or euro-qol or euroquol or euro-quol or eurocol or euro-col) adj3 ("5" or five)).tw. 1585
22 (european* adj2 quality adj3 ("5" or five)).tw. 266

23 or/5-22 156202
24 4 and 23 2
25 health-economics/ or exp economic-evaluation/ or exp health-care-cost/ or pharmacoeconomics/ or Monte Carlo Method/ or Decision Tree/ 223980
26 (Economic* or cost or costs or costly or costing or costed or price or prices or pricing or pharmacoeconomic* or pharmaco economic* or budget*).ti,ab. 345748
27 ((monte adj carlo) or markov or (decision adj2 (tree* or analys*))).ti,ab. 25605
28 (value adj2 (money or monetary)).ti,ab. 1559
29 Quality of Life/ or Quality Adjusted Life Year/ or Quality of Life Index/ or Short Form 36/ or Health Status/ 238658
30 (quality of life or quality adjusted life or qaly* or qald* or qale* or qtime* or quality of wellbeing or quality of well-being or willingness to pay or standard gamble* or time trade off* or time tradeoff* or qol or hql or hqol or hrqol or disutili* or rosser*).ti,ab. 159695
31 (disability adjusted life or daly).ti,ab. 2152
32 (health* year* equivalent* or hye or hyes).ti,ab. 69
33 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six or sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six or sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve or sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen or sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty or euroqol or euro qol or eq5d or eq 5d).ti,ab. 26092
34 or/25-33 688899
35 4 and 34 2
36 24 or 35 2

Database name: Health Management Information Consortium

HMIC Health Management Information Consortium <1979 to November 2021>

1 (allen* adj2 carr*).ti,ab. or (allen* and carr*).hw. or (allencarr* or easyway*).af. 1
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 1
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 0
4 or/1-3 2

Database name: International HTA Database

1	allencarr* or easyway*	0
2	Allen* AND Carr*	1
3	NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771	0
4	(("easy way" or "easy ways") and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll" or "hand rolling" or "hand rolls" or "hand rolled" or handroll* or rollies or "roll up" or "roll ups" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)	0
5	1 OR #2 OR #3 OR #4	1

Note: Where not stated, the field searched was All Fields

Database name: MEDLINE

Ovid MEDLINE(R) ALL <1946 to January 25, 2022>

1 (allen* adj2 carr*).ti,ab,kw,kf. or (allencarr* or easyway*).af. 16

2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 19
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 5
4 or/1-3 36
5 Cost-Benefit Analysis/ 88168
6 Quality-Adjusted Life Years/ 14307
7 Markov Chains/ 15553
8 exp Models, Economic/ 16020
9 cost*.ti. 132510
10 (cost* adj2 utilit*).tw. 6728
11 (cost* adj2 (effective* or assess* or evaluat* or analys* or model* or benefit* or threshold* or quality or expens* or saving* or reduc*)).tw. 242475
12 (economic* adj2 (evaluat* or assess* or analys* or model* or outcome* or benefit* or threshold* or expens* or saving* or reduc*)).tw. 40361
13 (qualit* adj2 adjust* adj2 life*).tw. 15413
14 QALY*.tw. 12382
15 (incremental* adj2 cost*).tw. 14988
16 ICER.tw. 4941
17 utilities.tw. 8202
18 markov*.tw. 27909
19 (dollar* or USD or cents or pound or pounds or GBP or sterling* or pence or euro or euros or yen or JPY).tw. 49024
20 ((utility or effective*) adj2 analys*).tw. 21770
21 (willing* adj2 pay*).tw. 8060
22 (EQ5D* or EQ-5D*).tw. 10830
23 ((euroqol or euro-qol or euroquol or euro-quol or eurocol or euro-col) adj3 ("5" or five)).tw. 2985
24 (european* adj2 quality adj3 ("5" or five)).tw. 541
25 or/5-24 445688
26 4 and 25 3
27 Economics/ or exp "Costs and Cost Analysis"/ or Economics, Dental/ or exp Economics, Hospital/ or exp Economics, Medical/ or Economics, Nursing/ or Economics, Pharmaceutical/ or Budgets/ or exp Models, Economic/ or Markov Chains/ or Monte Carlo Method/ or Decision Trees/ 366703
28 (Economic* or cost or costs or costly or costing or costed or price or prices or pricing or pharmacoeconomic* or pharmaco economic* or budget*).ti,ab. 938071
29 ((monte adj carlo) or markov or (decision adj2 (tree* or analys*))).ti,ab. 91553
30 (value adj2 (money or monetary)).ti,ab. 2712
31 Quality of Life/ or Health Status Indicators/ or Quality-Adjusted Life Years/ or Value of Life/ 266491
32 (quality of life or quality adjusted life or qaly* or qald* or qale* or qtime* or quality of wellbeing or quality of well-being or willingness to pay or standard gamble* or time trade off* or time tradeoff* or qol or hql or hqol or hrqol or disutili* or rosser*).ti,ab. 332156
33 (disability adjusted life or daly).ti,ab. 4671
34 (health* year* equivalent* or hye or hyes).ti,ab. 84
35 (sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).ti,ab. 28133
36 (sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).ti,ab. 2378
37 (sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).ti,ab. 6721
38 (sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).ti,ab. 35
39 (sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).ti,ab. 431
40 (euroqol or euro qol or eq5d or eq 5d).ti,ab. 13764
41 or/27-40 1537647
42 4 and 41 7
43 26 or 42 7

Database name: NHS Economic Evaluation Database

Line	Search	Hits
1	(allen* adj2 carr*)	0
2	(allencarr* or easyway*)	0
3	("easy way*")	4
4	(nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)	1641
5	#3 AND #4	0
6	(NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771)	0
7	#1 OR #2 OR #5 OR #6	0

Note: Where not stated, the field searched was All Fields
Bibliographic records were published on NHS EED until 31st March 2015. Searches of MEDLINE, Embase, CINAHL, PsycINFO and PubMed for DARE were continued until the end of 2014.

Database name: Social Policy and Practice

Social Policy and Practice <202201>

1 (allen* adj2 carr*).ti,ab. or (allen* and carr*).hw. or (allencarr* or easyway*).af. 0
2 ("easy way*" and (nicotin* or smoker* or smoking* or tobacco* or cigar* or cigs or "hand roll*" or handroll* or rollies or "roll up*" or rollup* or antismok* or exsmoker* or polytobacco* or multitobacco*)).af. 0
3 (NCT02855255 or ISRCTN23584477 or ISRCTN12951013 or ISRCTN16006023 or ISRCTN15690771).af. 0
4 or/1-3 0

Additional search methods

Source name: clinical trial registries

Name	ClinicalTrials.gov
URL	https://clinicaltrials.gov/ct2/home
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	Not stated
Search terms	(Allen Carr) OR AllenCarr OR Easyway ("easy way") AND (nicotine OR smoker OR smoking OR tobacco OR cigar OR cigarette)
Any limitations used	None
How the results were selected	1 registry entry - reviewed for posted results and links to published results
No. of results	0
List of results	-
Notes	1 registry entry: NCT02855255 is Frings "Comparison of Allen Carr's Easyway Programme with a Specialist Behavioural and Pharmacological Smoking Cessation Support Service: A Randomized Controlled Trial." *Addiction*, vol. 115, no. 5, 2020, pp. 977–85, No results posted, just a link to the protocol published as Wood et al. 2017 *BMJ Open*.

Name	ISRCTN Registry
URL	https://www.isrctn.com/
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	Updated 24/01/2022
Search terms	(Allen Carr) OR AllenCarr OR Easyway ("easy way") AND (nicotine OR smoker OR smoking OR tobacco OR cigar OR cigarette)
Any limitations used	None
How the results were selected	Reviewed registry entries for posted results and links to published results
No. of results	0
List of results	-
Notes	4 registry entries:

	ISRCTN23584477 is NCT0285525 (Frings et al.) - links to the Frings paper, does not provide further results. ISRCTN12951013 is Keogan, Sheila, et al. “Allen Carr’s Easyway to Stop Smoking - A Randomised Clinical Trial.” *Tobacco Control*, vol. 28, no. 4, July 2019, pp. 414–19. - includes link to basic results data ISRCTN12951013 has basic results but not related to cost effectiveness ISRCTN16006023 : Promoting smoking abstinence through Virtual Reality - no results available ISRCTN15690771 : Retraining automatic action tendencies for smoking using mobile phone-based approach-avoidance bias training

Name	ScanMedicine
URL	https://scanmedicine.com/
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	Jan 2022
Search terms	allencarr | easyway | "allen carr" "easy way" + (nicotine | smoker | smoking | tobacco | cigar | cigarette)
Any limitations used	None
How the results were selected	Reviewed registry entries for posted results and links to published results
No. of results	0
List of results	-
Notes	5 registry entries, which had all been identified already: NCT02855255 ISRCTN23584477 ISRCTN12951013 ISRCTN15690771 ISRCTN16006023

Name	World Health Organization International Clinical Trials Registry Platform (ICTRP)
URL	https://trialsearch.who.int
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	Updates range from 29/11/2021 to 07/12/2021
Search terms	(Allen Carr) OR AllenCarr OR Easyway ("easy way") AND (nicotine OR smoker OR smoking OR tobacco OR cigar OR cigarette)
Any limitations used	None

How the results were selected	Reviewed registry entries for posted results and links to published results
No. of results	0
List of results	-
Notes	5 registry entries, which had all been identified already: NCT02855255 ISRCTN23584477 ISRCTN12951013 ISRCTN15690771 ISRCTN16006023

Name	EU Clinical Trials Register
URL	https://www.clinicaltrialsregister.eu/ctr-search/search/
Date searched	25/01/2022
Segment or dates covered by search (if stated on the site)	The EU Clinical Trials Register currently displays 41472 clinical trials with a EudraCT protocol
Search terms	(Allen Carr) OR AllenCarr OR Easyway ("easy way") AND (nicotine OR smoker OR smoking OR tobacco OR cigar OR cigarette)
Any limitations used	None
How the results were selected	Reviewed registry entries for posted results and links to published results
No. of results	0
List of results	-
Notes	Query did not match any clinical trials

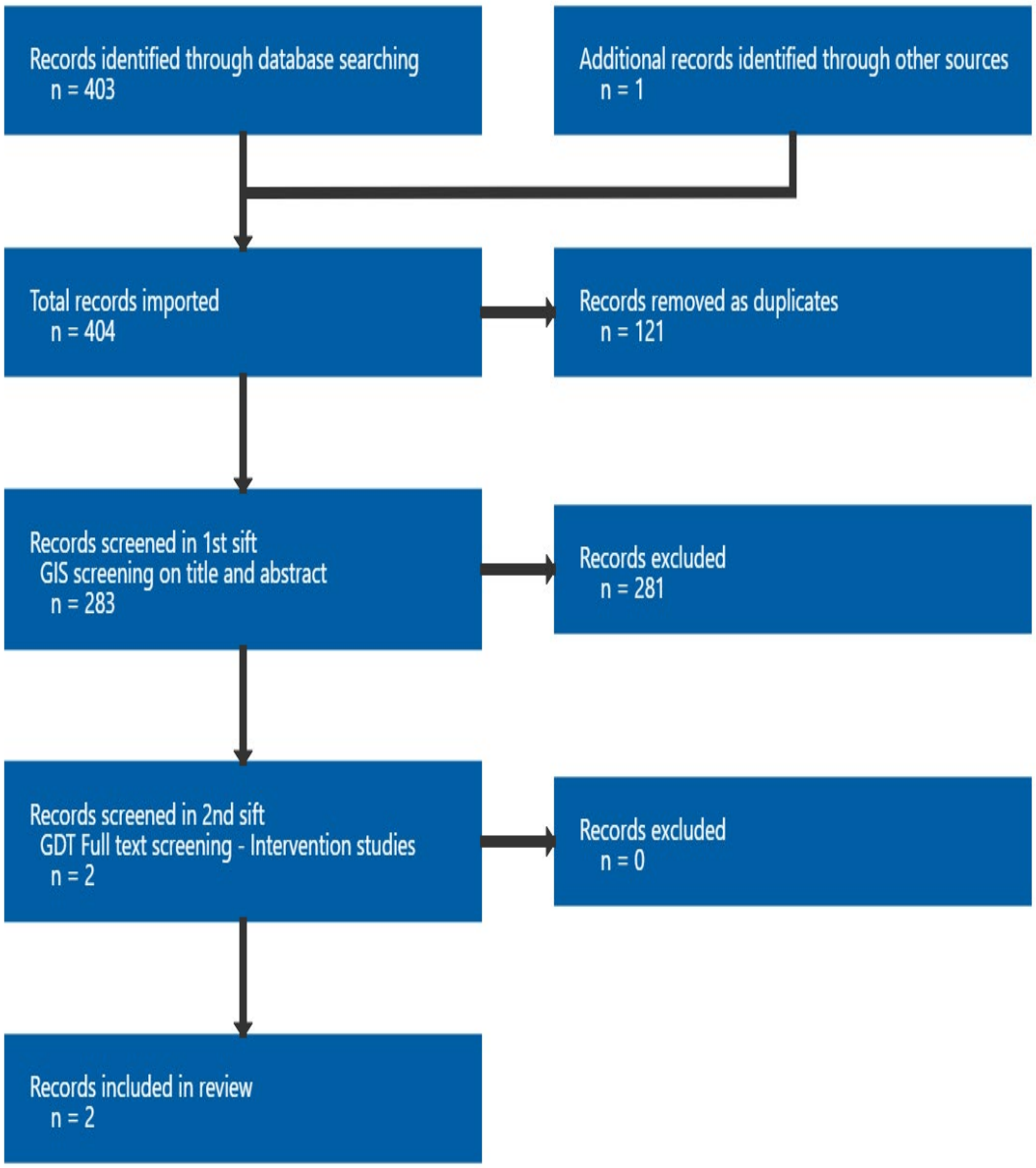
Source name: website searching

Name	Allen Carr
URL	https://www.allencarr.com/
Date searched	25 January 2022
Segment or dates covered by search, including any specific sections browsed	On the front page there is a note saying ACE is "Clinically Proven1" and this leads to 5 citations which have all been identified in the search results already (Frings, Keogan, Moshammer, Dijkstra and Hutter). <https://www.allencarr.com/#ref> Browsed sections: Success stories https://www.allencarr.com/success-stories/ About Us https://www.allencarr.com/about-allen-carrs-easyway/ - again refers back to Frings and Keogan.
Search terms	Also used Google.com to see if there were any pdf documents (e.g. for evaluative reports) using: site:https://www.allencarr.com filetype:pdf

	Your search - site:https://www.allencarr.com filetype:pdf - did not match any documents.
How the results were selected	Looking for any reports or data, rather than personal testimonials.
No. of results	0

Name	Google search
URL	https://www.google.com/
Date searched	25 January 2022
Search terms	"allen carr" filetype:pdf - 76 results "allencarr" filetype:pdf - 79 results "easyway" smoking filetype:pdf - 68 results "easyway" cigarettes filetype:pdf - 44 results "easyway" tobacco filetype:pdf - 48 results
How the results were selected	Searched for anything in English that was not already in EPPI that contained data, an evaluation or clinical trial. NHS Education for Scotland Acupuncture, Acupressure, Laser Therapy and Electrostimulation - cites Hutter and Moshammer, which are already in EPPI, and it seems to be based on an ASH letter from 2006.
No. of results	0

Appendix C – Effectiveness evidence study selection



Appendix D – Effectiveness evidence tables

Frings, 2020

Bibliographic Reference	Frings, Daniel; Albery, Ian P; Moss, Antony C; Brunger, Helen; Burghelea, Meda; White, Sarah; Wood, Kerry V; Comparison of Allen Carr's Easyway programme with a specialist behavioural and pharmacological smoking cessation support service: a randomized controlled trial.; Addiction (Abingdon, England); 2020; vol. 115 (no. 5); 977-985

Study details

Trial registration number and/or trial name	This trial was registered with ClinicalTrials.gov (NCT02855255), the ISRCTN (ISRCTN23584477) and the Open Science Framework (OSF: t6vgs).
Study type	Randomised controlled trial (RCT)
Study location	UK
Study setting	Community recruitment
Study dates	February 2017 to May 2018
Sources of funding	Funding was provided by Allen Carr’s Easyway International Ltd.
Inclusion criteria	• 18 years or older • Current smoker wanting to quit smoking • Open to being randomly assigned to one of the 2 interventions • Who could provide consent
Exclusion criteria	• Pregnant women • Reporting a mental health condition • Reporting a respiratory disease such as asthma or emphysema • Currently enrolled on a similar clinical trial

	• Not willing to undertake a stop smoking service which is neither endorsed by the NHS nor NICE-approved
Intervention(s)	**Allen Carr's Easyway (ACE) seminar programme** Participants attended a single group session at their choice of either London South Bank University (2 days a week) or Allen Carr's London treatment centre (6 days a week, afternoon only). The session lasted 4.5 to 6 hours and comprised elements of cognitive-behavioural therapy (CBT) with a brief relaxation exercise at the end that served 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 to 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) 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. One therapist delivered each group session (seven therapists in total delivered group sessions).
Comparator	**1 to 1 in-person specialist stop smoking service (SSS)** Participants attended a single 1 to 1 30-minute in-person session, which combined motivational interviewing and CBT approaches and up to four follow up sessions (their standard treatment protocol). Sessions took place at London South Bank University 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 recognise 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.
Outcome measures	**Verified abstinence** 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 UK. **Pharmacotherapy usage** For use of support mechanisms (NRT, e-cigarettes, Champix), participants were asked: • 'Since we last met, have you regularly used any of the following?' • 'Are you planning on using any of the following when you quit smoking?' (yes/no answers). **Self-reported abstinence** 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?' • 'How many cigarettes in the last month?' • 'In total, how many cigarettes have you had since your quit date?'
Number of participants	N=620 • Allen Carr Easyway seminar programme (N=310)

	• Specialist stop smoking service (N=310)
Duration of follow-up	Follow-ups were at 4, 12 and 26 weeks
Additional comments	**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). In the ACE arm, 36 attended a first top-up session at London South Bank University, 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 London South Bank University, 6 at the treatment centre, and 12 received the session online.

Study arms

Allen Carr Easyway seminar programme (N = 310)

Loss to follow-up	148 participants were lost to follow-up (47.7%)

Specialist stop smoking service (N = 310)

Loss to follow-up	170 participants were lost to follow-up (54.8%)

Characteristics

Arm-level characteristics

Characteristic	Allen Carr Easyway seminar programme (N = 310)	Specialist stop smoking service (N = 310)
% Female Sample size	n = 140 ; % = 45.2	n = 149 ; % = 48.1
Mean age (SD) (years) Mean (SD)	41.3 (11.1)	40.3 (11.8)
Ethnicity N=617 Sample size		
Indian Sample size	n = 14 ; % = 4.5	n = 13 ; % = 4.2
Pakistani Sample size	n = 5 ; % = 1.6	n = 4 ; % = 1.3
Bangladeshi Sample size	n = 2 ; % = 0.6	n = 3 ; % = 1
Asian (other) Sample size	n = 10 ; % = 3.2	n = 10 ; % = 3.2
Black African Sample size	n = 3 ; % = 1	n = 10 ; % = 3.2

Characteristic	Allen Carr Easyway seminar programme (N = 310)	Specialist stop smoking service (N = 310)
Black Caribbean Sample size	n = 11 ; % = 3.6	n = 21 ; % = 6.8
Black: Other Sample size	n = 8 ; % = 2.6	n = 6 ; % = 1.9
Mixed Race Sample size	n = 14 ; % = 4.5	n = 20 ; % = 6.5
White: UK or Irish Sample size	n = 178 ; % = 57.8	n = 157 ; % = 50.8
White: other European Sample size	n = 41 ; % = 13.3	n = 43 ; % = 13.9
White Other Sample size	n = 13 ; % = 4.2	n = 16 ; % = 5.2
Other Sample size	n = 9 ; % = 2.9	n = 6 ; % = 1.9
Education achieved N=616 Sample size		
GCSE, CSE or equivalent	n = 30 ; % = 9.7	n = 24 ; % = 7.8

Characteristic	Allen Carr Easyway seminar programme (N = 310)	Specialist stop smoking service (N = 310)
Sample size		
A-level Sample size	n = 45 ; % = 14.6	n = 43 ; % = 14
Vocational qualification Sample size	n = 23 ; % = 7.4	n = 23 ; % = 7.5
Degree BA, BSc Sample size	n = 116 ; % = 37.5	n = 127 ; % = 41.4
Post-graduate degree Sample size	n = 69 ; % = 22.3	n = 59 ; % = 19.2
Other Sample size	n = 26 ; % = 8.4	n = 31 ; % = 10.1
Number of cigarettes smoked/day N=619 Sample size		
10 or less Sample size	n = 102 ; % = 32.9	n = 135 ; % = 43.7
11 to 20 Sample size	n = 163 ; % = 52.6	n = 142 ; % = 46

Characteristic	Allen Carr Easyway seminar programme (N = 310)	Specialist stop smoking service (N = 310)
21 to 30 Sample size	n = 37 ; % = 11.9	n = 27 ; % = 8.7
More than 30 Sample size	n = 8 ; % = 2.6	n = 5 ; % = 1.6
Age started smoking (years) N=617 Mean (SD)	17.1 (4.3)	16.6 (3.7)
Lives with other smokers N=617 Sample size	n = 105 ; % = 34	n = 104 ; % = 33.8
At least 1 quit attempt in the past 12 months Sample size	n = 196 ; % = 63.2	n = 196 ; % = 63.2
Fagerstrom Test for Nicotine Dependence (FTND) score 5 to 8 Sample size	n = 129 ; % = 41.6	n = 112 ; % = 36.1
Quit efficacy (N=473) 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. Mean (SD)	20.7 (4.3)	20.8 (4.1)

Characteristic	Allen Carr Easyway seminar programme (N = 310)	Specialist stop smoking service (N = 310)
Baseline carbon monoxide reading N=473 Mean (SD)	17.5 (9.8)	15.1 (10.2)

Critical appraisal - GDT Crit App - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Question	Answer
Risk of bias judgement	Moderate *(More than half of participants (51.3%) were lost to follow-up; reasons for dropouts were not reported.)*
Overall Directness	Directly applicable

Keogan, 2019

Bibliographic Reference	Keogan, Sheila; Li, Shasha; Clancy, Luke; Allen Carr's Easyway to Stop Smoking - A randomised clinical trial.; Tobacco control; 2019; vol. 28 (no. 4); 414-419

Study details

Trial registration number and/or trial name	Trial registration number ISRCTN12951013.
Study type	Randomised controlled trial (RCT)

Study location	Republic of Ireland
Study setting	Community recruitment
Study dates	July 2015 to March 2017
Sources of funding	DOH Ireland Grant: NL14/1.
Inclusion criteria	• 18 years or older • Smoking a minimum of 5 cigarettes per day • Having a good knowledge of the English language • Agreeing to attend all 5 study visits in TobaccoFree Research Institute Ireland, Dublin
Exclusion criteria	• Doctor-diagnosed, acute cardiac or respiratory illness or serious psychiatric illness • Undergoing treatment for alcohol or illicit drug use
Intervention(s)	**Allen Carr Easyway (ACE) seminar programme** The ACE intervention was delivered, free of charge, by experienced ACE therapists. Participants completed a 5-hour, group ACE seminar, maximum 20 participants, in a routine seminar session. Participants smoked during smoking breaks until there was a ritualistic final cigarette followed by a 20 min relaxation exercise. Follow-up was arranged at TobaccoFree Research Institute Ireland (TFRI) research centre for months 1, 3, 6 and 12. Two free ACE follow-ups were also available.
Comparator	**Quit. ie service** Quit. ie is an online portal for Health Service Executive (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 (NCSCT, 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.

Outcome measures	**Verified abstinence** • Carbon monoxide validated **Self-reported abstinence** • Self-reported quitting
Number of participants	N=300 • Allen Carr Easyway seminar programme (N=151) • Quit. ie service (N=149)
Duration of follow-up	1, 3, 6 and 12 months

Study arms

Allen Carr Easyway seminar programme (N = 151)

Loss to follow-up	44 participants were lost to follow-up (29.1%)

Quit.ie service (N = 149)

Loss to follow-up	44 participants were lost to follow-up (29.5%)

Characteristics

Arm-level characteristics

Characteristic	Allen Carr Easyway seminar programme (N = 151)	Quit.ie service (N = 149)
% Female	n = 67 ; % = 44.4	n = 68 ; % = 45.6

Characteristic	Allen Carr Easyway seminar programme (N = 151)	Quit.ie service (N = 149)
Sample size		
Age (years) Median (IQR)	44 (36 to 52)	44 (38 to 51)
Postsecondary and higher education Sample size	n = 105 ; % = 69.5	n = 104 ; % = 69.8
Baseline carbon monoxide reading (parts per million (p.p.m.)) Mean (SD)	22.1 (11.6)	20.4 (10.5)
Time to first cigarette Sample size		
≤5 min Sample size	n = 56 ; % = 37.1	n = 42 ; % = 28.2
6 to 30 min Sample size	n = 61 ; % = 40.4	n = 66 ; % = 44.3
>31 min Sample size	n = 34 ; % = 22.5	n = 41 ; % = 27.5
Prior use of e-cigarettes Sample size	n = 75 ; % = 49.7	n = 72 ; % = 48.3
Previous quit attempts		

Characteristic	Allen Carr Easyway seminar programme (N = 151)	Quit.ie service (N = 149)
Sample size		
None Sample size	n = 4 ; % = 2.7	n = 6 ; % = 4.2
1 to 3 Sample size	n = 69 ; % = 46.3	n = 63 ; % = 43.8
4 to 9 Sample size	n = 59 ; % = 39.6	n = 61 ; % = 42.4
10 or over Sample size	n = 17 ; % = 11.4	n = 14 ; % = 9.7
No of cigarettes smoked per day Median (IQR)	20 (15 to 25)	20 (15 to 22)
How many years are you smoking? Median (IQR)	26 (20 to 35)	28 (22 to 34)
Readiness to quit score Median (IQR)	27 (25 to 29)	27 (24.5 to 29)

Critical appraisal - GDT Crit App - Cochrane Risk of Bias tool (RoB 2.0) Normal RCT

Question	Answer
Risk of bias judgement	Moderate *(There was no information on concealment of allocation sequence and no information on deviations from the intended interventions. A pre-specified analysis plan was not reported. There was differential attrition with around 10% more participants lost to follow-up at 3 and 6 months in the Quit.ie arm.)*
Overall Directness	Directly applicable

Appendix E – Forest plots

E.1.1.1 Comparison: Allen Carr Easyway seminar programme vs usual care

Figure 2: Allen Carr Easyway seminar programme vs usual care; Outcome: Verified abstinence (follow-up 4 weeks; assessed with: self-report plus carbon monoxide validation)

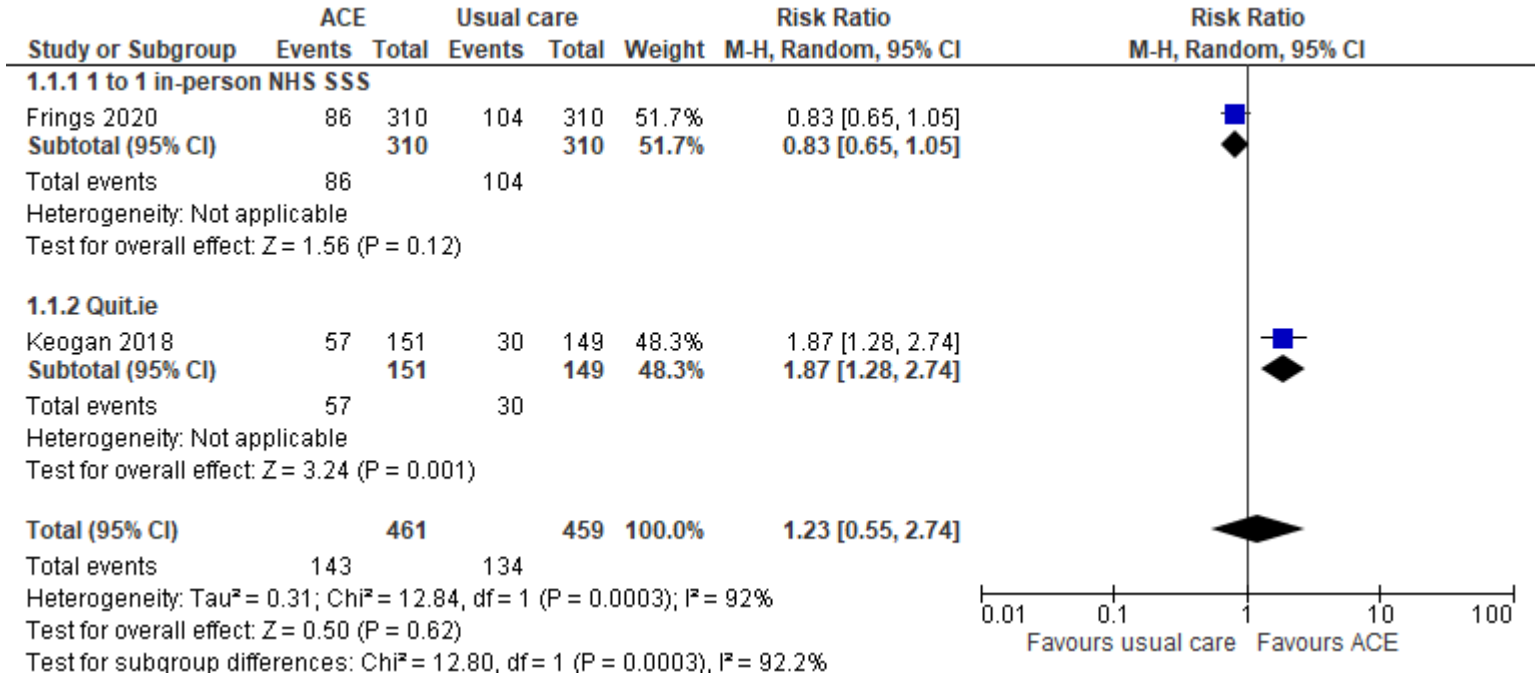


Figure 3: Allen Carr Easyway seminar programme vs usual care; Outcome: Verified abstinence (follow-up 12 weeks; assessed with: self-report plus carbon monoxide validation)

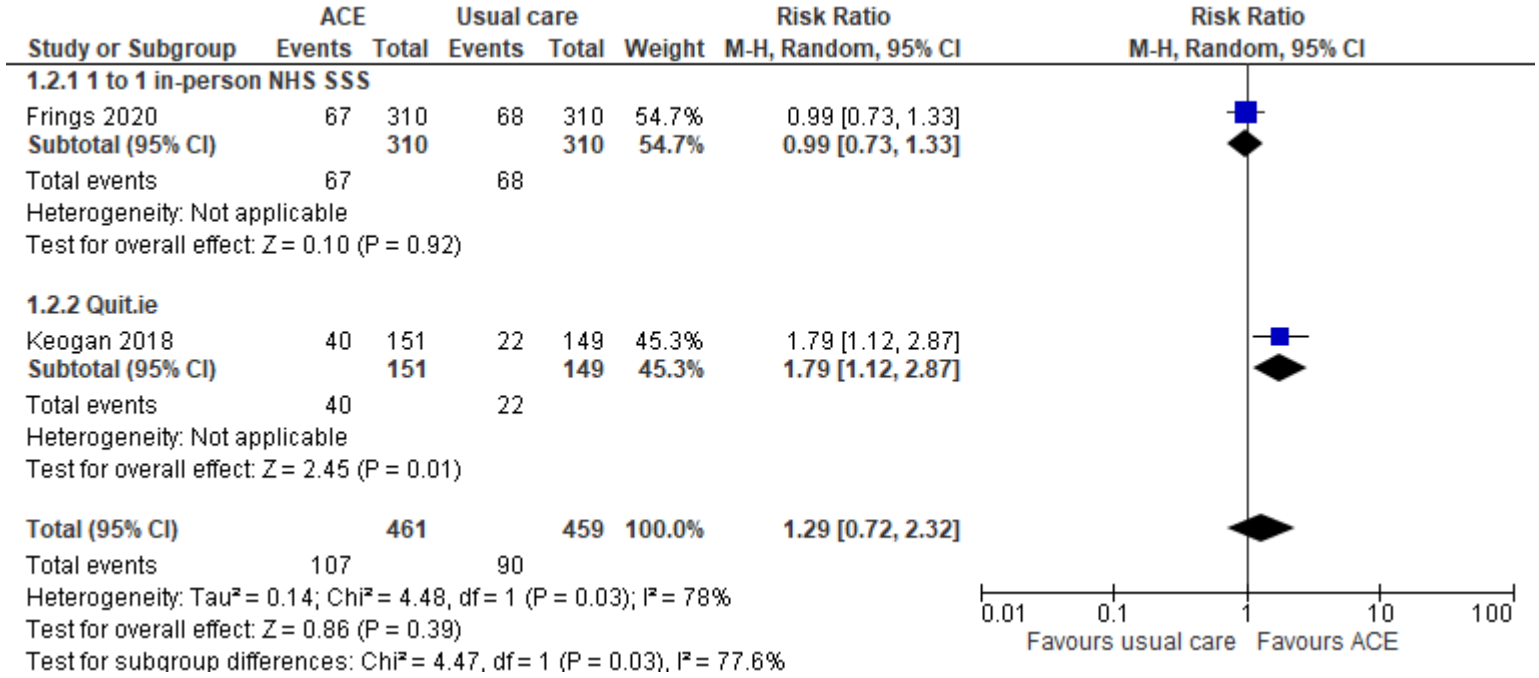
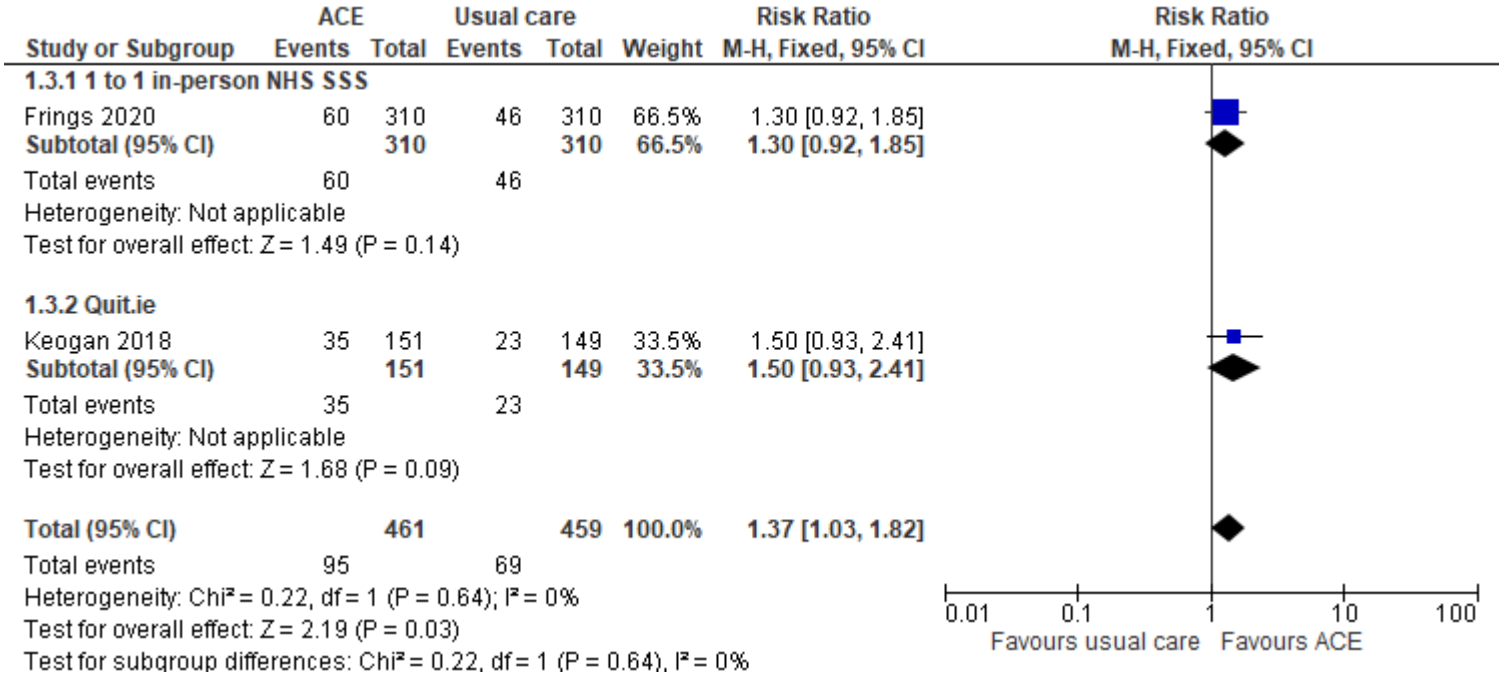


Figure 4: Allen Carr Easyway seminar programme vs usual care; Outcome: Verified abstinence (follow-up 26 weeks; assessed with: self-report plus carbon monoxide validation)



Appendix F – GRADE tables

F.1.1.1 Comparison: Allen Carr Easyway seminar programme vs usual care

The evidence is presented with the studies combined and separately.

Outcome: Verified abstinence (assessed with: self-report plus carbon monoxide validation)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Allen Carr's Easyway	Usual practice	Relative (95% CI)	Absolute		
Allen Carr's Easyway in-person group seminar compared with usual practice (Quit.ie or 1 to 1 in-person NHS stop smoking services for smoking cessation) **Verified abstinence (follow-up 4 weeks; assessed with: self-report plus CO validation)**												
2[1]	randomised trials	serious[2]	very serious[3]	no serious indirectness	serious[4]	none	143/461 (31%)	134/459 (29.2%)	RR 1.23 (0.55 to 2.74)	7 more per 100 (from 13 fewer to 51 more)	⊕OOO VERY LOW	IMPORTANT[5]
Allen Carr's Easyway in-person group seminar compared with 1- to 1 in-person NHS stop smoking services for smoking cessation **Verified abstinence (follow-up 4 weeks; assessed with: self report plus CO validation)**												
1[6]	randomised trials	serious[7]	NA[8]	no serious indirectness	serious[9]	none	86/310 (27.7%)	104/310 (33.5%)	RR 0.83 (0.65 to 1.05)	6 fewer per 100 (from 12 fewer to 2 more)	⊕⊕OO LOW	IMPORTANT[5]
Allen Carr's Easyway in-person group seminar compared with Quit.ie **Verified abstinence (follow-up 4 weeks; assessed with: self report plus CO validation)**												
1[10]	randomised trials	serious[11]	NA[8]	no serious indirectness	no serious imprecision	none	57/151 (37.7%)	30/149 (20.1%)	RR 1.87 (1.28 to 2.74)	18 more per 100 (from 6 more to 35 more)	⊕⊕⊕O MODERATE	IMPORTANT[5]
Allen Carr's Easyway in-person group seminar compared with usual practice (Quit.ie or 1 to 1 in-person NHS stop smoking services for smoking cessation) **Verified abstinence (follow-up 12 weeks; assessed with: self-report plus CO validation)**												

2[1]	randomised trials	serious[2]	very serious[3]	no serious indirectness	serious[4]	none	107/461 (23.2%)	90/459 (19.6%)	RR 1.29 (0.72 to 2.32)	6 more per 100 (from 5 fewer to 26 more)	⊕OOO VERY LOW	IMPORTANT[5]
Allen Carr's Easyway in-person group seminar compared with 1- to 1 in-person NHS stop smoking services for smoking cessation **Verified abstinence (follow-up 12 weeks; assessed with: self report plus CO validation)**												
1[6]	randomised trials	serious[7]	NA[8]	no serious indirectness	serious[9]	none	67/310 (21.6%)	68/310 (21.9%)	RR 0.99 (0.73 to 1.33)	0 fewer per 100 (from 6 fewer to 7 more)	⊕⊕OO LOW	IMPORTANT[5]
Allen Carr's Easyway in-person group seminar compared with Quit.ie **Verified abstinence (follow-up 12 weeks; assessed with: self report plus CO validation)**												
1[10]	randomised trials	serious[11]	NA[8]	no serious indirectness	no serious imprecision	none	40/151 (26.5%)	22/149 (14.8%)	RR 1.79 (1.12 to 2.87)	12 more per 100 (from 2 more to 28 more)	⊕⊕⊕O MODERATE	IMPORTANT[5]
Allen Carr's Easyway in-person group seminar compared with usual practice (Quit.ie or 1 to 1 in-person NHS stop smoking services for smoking cessation) **Verified abstinence (follow-up 26 weeks; assessed with: self-report plus CO validation)**												
2[1]	randomised trials	serious[2]	no serious inconsistency	no serious indirectness	no serious imprecision	none	95/461 (20.6%)	69/459 (15%)	RR 1.37 (1.03 to 1.82)	6 more per 100 (from 0 more to 12 more)	⊕⊕⊕O MODERATE	CRITICAL[6]
Allen Carr's Easyway in-person group seminar compared with 1- to 1 in-person NHS stop smoking services for smoking cessation **Verified abstinence (follow-up 26 weeks; assessed with: self report plus CO validation)**												
1[6]	randomised trials	serious[7]	NA[8]	no serious indirectness	serious[9]	none	60/310 (19.4%)	46/310 (14.8%)	RR 1.30 (0.92 to 1.85)	4 more per 100 (from 1 fewer to 13 more)	⊕⊕OO LOW	CRITICAL[12]
Allen Carr's Easyway in-person group seminar compared with Quit.ie **Verified abstinence (follow-up 26 weeks; assessed with: self report plus CO validation)**												
1[10]	randomised trials	serious[11]	NA[8]	no serious indirectness	serious[9]	none	35/151 (23.2%)	23/149 (15.4%)	RR 1.50 (0.93 to 2.41)	8 more per 100 (from 1 fewer to 22 more)	⊕⊕OO LOW	CRITICAL[12]

[1] Frings (2020), Keogan (2018)
[2] Keogan (2018) did not report information on concealment of allocation sequence; information on deviations from the intended interventions; a pre-specified analysis plan; and there was differential attrition with around 10% more participants lost to follow-up at 3 and 6 months in the Quit.ie arm. Frings (2020) reported that more than half of participants (51.3%) were lost to follow-up; reasons for dropouts were not reported. Moderate risk of bias. Downgraded once.
[3] I2 value >66.7%. Downgraded twice.
[4] Pooled effect estimate crosses line of no effect. Downgraded once.

[5] Secondary outcome in protocol
[6] Frings (2020)
[7] More than half of participants (51.3%) were lost to follow-up; reasons for dropouts were not reported. Moderate risk of bias. Downgraded once.
[8] Not applicable - single study
[9] Effect estimate crosses line of no effect. Downgraded once.
[10] Keogan (2018)
[11] Information was not reported on concealment of allocation sequence; deviations from the intended interventions; a pre-specified analysis plan; and there was differential attrition with around 10% more participants lost to follow-up at 3 and 6 months in the Quit.ie arm. Moderate risk of bias. Downgraded once.
[12] Primary outcome in protocol

Outcome: Verified abstinence (assessed with: self-report plus carbon monoxide validation or with self-report only)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Allen Carr's Easyway	Quit.ie	Relative (95% CI)	Absolute		
Verified abstinence (follow-up 52 weeks; assessed with: self-report plus CO validation)												
1[1]	randomised trials	serious[2]	NA[3]	no serious indirectness	no serious imprecision	none	33/151 (21.9%)	17/149 (11.4%)	RR 1.92 (1.12 to 3.29)	10 more per 100 (from 1 more to 26 more)	⊕⊕⊕O MODERATE	CRITICAL[4]
Self reported abstinence (follow-up 4 weeks; assessed with: self-report only)												
1[1]	randomised trials	serious[2]	NA[3]	serious[5]	no serious imprecision	none	63/151 (41.7%)	36/149 (24.2%)	RR 1.73 (1.23 to 2.43)	18 more per 100 (from 6 more to 35 more)	⊕⊕OO LOW	NOT IMPORTANT[6]
Self reported abstinence (follow-up 12 weeks; assessed with: self-report only)												
1	randomised trials	serious[2]	NA[3]	serious[5]	no serious imprecision	none	48/151 (31.8%)	26/149 (17.4%)	RR 1.82 (1.2 to 2.77)	14 more per 100 (from 3 more to 31 more)	⊕⊕OO LOW	NOT IMPORTANT[6]
Self reported abstinence (follow-up 26 weeks; assessed with: self-report only)												
1[1]	randomised trials	serious[2]	NA[3]	serious[5]	no serious imprecision	none	42/151 (27.8%)	25/149 (16.8%)	RR 1.66 (1.07 to 2.57)	11 more per 100 (from 1 more to 26 more)	⊕⊕OO LOW	NOT IMPORTANT[6]
Self reported abstinence (follow-up 52 weeks; assessed with: self-report only)												
1[1]	randomised trials	serious[2]	NA[3]	serious[5]	no serious imprecision	none	36/151 (23.8%)	21/149 (14.1%)	RR 1.69 (1.04 to 2.76)	10 more per 100 (from 1 more to 25 more)	⊕⊕OO LOW	NOT IMPORTANT[6]

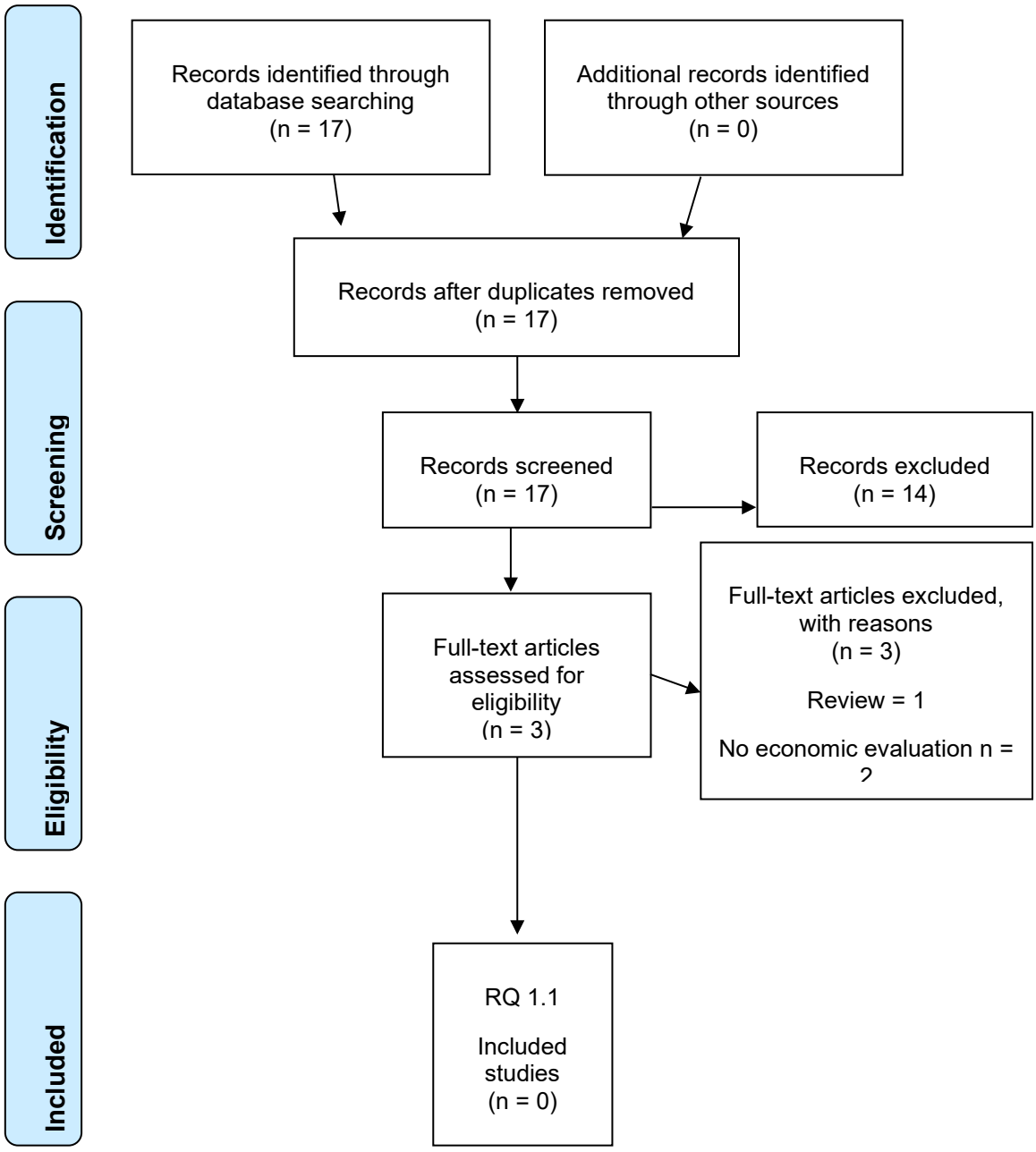
[1] Keogan (2018)
[2] Keogan (2018) did not report information on concealment of allocation sequence; information on deviations from the intended interventions; a pre-specified analysis plan; and there was differential attrition with around 10% more participants lost to follow-up at 3 and 6 months in the Quit.ie arm. Moderate risk of bias. Downgraded once.
[3] Not applicable - single study
[4] Primary outcome in protocol
[5] Outcome not in protocol
[6] Indirect outcome (self-reported abstinence was not biochemically validated). Downgraded once.

Outcome: Pharmacological usage (assessed with: self-report)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Allen Carr's Easyway	1 to 1 in-person NHS stop smoking services	Relative (95% CI)	Absolute		
Pharma usage: Completed study (assessed with: self-report)												
1[1]	randomised trials	serious[2]	NA[3]	no serious indirectness	no serious imprecision	none	64/134 (47.8%)	154/161 (95.7%)	RR 0.5 (0.42 to 0.6)	48 fewer per 100 (from 38 fewer to 55 fewer)	⊕⊕⊕O MODERATE	IMPORTANT[4]
Pharma usage: Completed study & treatment (assessed with: self-report)												
1[1]	randomised trials	serious[2]	NA[3]	no serious indirectness	no serious imprecision	none	62/131 (47.3%)	141/144 (97.9%)	RR 0.48 (0.4 to 0.58)	51 fewer per 100 (from 41 fewer to 59 fewer)	⊕⊕⊕O MODERATE	IMPORTANT[4]
Pharma usage (follow-up 26 weeks; assessed with: self-reported pharmacology free)												
1[1]	randomised trials	serious[2]	NA[3]	no serious indirectness	no serious imprecision	none	76/91 (83.5%)	36/89 (40.4%)	RR 2.06 (1.58 to 2.7)	43 more per 100 (from 23 more to 69 more)	⊕⊕⊕O MODERATE	IMPORTANT[4]

[1] Frings (2020)
[2] More than half of participants (51.3%) were lost to follow-up; reasons for dropouts were not reported. Moderate risk of bias. Downgraded once. Outcome reported by those participants for whom pharmacotherapy usage was known at follow-up.
[3] Not applicable - single study
[4] Secondary outcome in protocol

Appendix G – Economic evidence study selection



Appendix H – Economic evidence tables

No studies were included

Appendix I – Health economic model

See Section 1.1.9 for details of the model.

Appendix J – Excluded economic studies

	Reference	Reason for exclusion
1.	Frings D, Albery IP, Moss AC, Brunger H, Burghelea M, White S, et al. Comparison of Allen Carr's Easyway programme with a specialist behavioural and pharmacological smoking cessation support service: a randomized controlled trial. Addiction (Abingdon, England). 2020;115(5):977-85.	No economic evaluation
2.	Rasch A, Greiner W. [Efficacy and cost-effectiveness of smoking cessation courses in the statutory health insurance: a review]. Gesundheitswesen (Bundesverband der Arzte des Offentlichen Gesundheitsdienstes (Germany)). 2009;71(11):732-8.	Systematic review (checked and no relevant references cited)
3.	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. BMJ open. 2017;7(12):e016867.	No economic evaluation (protocol for the Frings 2020 study)

Appendix K Research recommendations – full details

K.1.1 Research recommendation

For adults who want to stop smoking, What is the effectiveness and cost effectiveness of the Allen Carr's Easyway programme delivered in formats other than in-person group seminars (for example online or via the self-help book), compared to other methods of smoking cessation?

K.1.2 Why this is important

There was evidence from 2 RCTs of the Allen Carr's Easyway in-person group seminar for stopping smoking during the update of the guideline in 2022. The evidence was limited to the in-person group seminar format of the programme. There might be people who could benefit from other formats of the Allen Carr's Easyway programme including online group seminars and the self-help book.

K.1.3 Rationale for research recommendation

Importance to 'patients' or the population	There was little evidence of the Allen Carr's Easyway in-person group seminar for stopping smoking and no evidence on other formats of the programme. Smoking is a public health problem.
Relevance to NICE guidance	Allen Carr's Easyway in-person group seminar has been considered in this guideline and there is a lack of data on other formats of the programme.
Relevance to the NHS	The outcome would affect the types of stopping smoking interventions provided by the NHS.
National priorities	High
Current evidence base	Minimal
Equality considerations	None known

K.1.4 Modified PICO table

Population	Adults (aged over 18) who smoke tobacco and want to stop.
Intervention	Allen Carr Easyway programme including online group seminars and the self-help book
Comparator	Any comparator (including Allen Carr's Easyway in-person group seminar)
Outcome	Primary outcomes: • Smoking status at 26 week or longer timepoints (biochemically validated) • Cost-utility • Secondary outcomes:

	• Smoking status at earlier (<26 weeks) timepoints (biochemically validated) • Relapse rates • Pharmacotherapy usage • Adverse events • Health Related Quality of Life (validated measures only)
Study design	Randomised controlled trial
Timeframe	26 weeks or longer
Additional information	None

K.1.5 Research recommendation

For specific groups who are at risk of health inequalities, for example pregnant women, people from lower socioeconomic backgrounds or people who do not speak English well:

- What is the differential effectiveness and cost-effectiveness of Allen Carr's Easyway (including the in-person group seminar and other formats)?
- What strategies or interventions are effective in minimising those differences?

K.1.6 Why this is important

There was evidence from 2 RCTs of the Allen Carr's Easyway in-person group seminar for stopping smoking during the update of the guideline in 2022. The evidence did not include any analysis by age, socioeconomic background, pregnancy, or in people who do not speak English well.

K.1.7 Rationale for research recommendation

Importance to 'patients' or the population	There was little evidence of the Allen Carr's Easyway in-person group seminar for stopping smoking and no data on the use of Allen Carr's Easyway by groups at risk of health inequalities. Smoking is a public health problem.
Relevance to NICE guidance	Allen Carr's Easyway in-person group seminar has been considered in this guideline and there is a lack of data on the use of Allen Carr's Easyway by groups at risk of health inequalities.
Relevance to the NHS	The outcome would affect the types of stopping smoking interventions provided by the NHS.
National priorities	High
Current evidence base	Minimal
Equality considerations	No data

K.1.8 Modified PICO table

Population	Adults (aged over 18) who smoke tobacco and want to stop.
Intervention	Allen Carr's Easyway in-person group seminar

Comparator	Any comparator (including other formats of Allen Carr's Easyway programme)
Outcome	Primary outcomes: • Smoking status at 26 week or longer timepoints (biochemically validated) • Secondary outcomes: • Smoking status at earlier (<26 weeks) timepoints (biochemically validated) • Relapse rates • Pharmacotherapy usage • Adverse events • Health Related Quality of Life (validated measures only)
Study design	Randomised controlled trial
Timeframe	26 weeks or longer
Additional information	Subgroups by: • Age • Ethnicity • Socioeconomic background • Pregnancy

Appendix L Methods

This guideline was developed in accordance with the process set out in 'Developing NICE guidelines: the manual (2020)'. Where the guidelines manual does not provide advice, additional methods are described below.

Developing the review questions and outcomes

The single review question developed for this update was based on the key areas identified in the guideline scope. The review question was developed by the NICE Guideline Development Team (GDT) and refined, validated and signed off by the Public Health Advisory Committee (PHAC) and NICE quality assurance team.

The review question was based on the Population, Intervention, Comparator, Outcome and Study type (PICOS) framework for reviews of interventions.

Full literature searches, critical appraisals and evidence reviews were completed for the review question.

Details of these elements are found in the review protocol in Appendix A. Where protocol deviations have been made, these are reported in section 1.1.3.3 Protocol deviations.

Reviewing research evidence

Review protocols

Review protocols were developed with the guideline committee to outline the inclusion and exclusion criteria used to select studies for each evidence review. Where possible, review protocols were prospectively registered in the PROSPERO register of systematic reviews. Protocols are reproduced in each evidence review along with the PROPSERO registration number.

Table 8: PROSPERO registration numbers

Review	Registration number
[A] The effectiveness and cost-effectiveness of the Allen Carr Easyway for smoking cessation.	CRD42022301554

Searching for evidence

Evidence was searched for each review question using the methods specified in the 2020 NICE guidelines manual. Full details of search strategies, databases searched and numbers of studies identified can be found in Appendix B.

Selecting studies for inclusion

All references identified by the literature searches and from other sources (for example, previous versions of the guideline or studies identified by committee members) were uploaded into EPPI reviewer software (version 5) and de-duplicated. All titles and abstracts were assessed for possible inclusion using the criteria specified in the review protocol. 10% of the abstracts were reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer.

As an additional check to ensure this approach did not miss relevant studies, systematic reviews were included in the review protocol and search strategy. Relevant systematic

reviews were used to identify any papers not found through the primary search. Committee members were also consulted to identify studies that were missed.

The decision not to use EPPI reviewer's inbuilt priority screening tool to limit screening was taken by the reviewing team based on the size of the database and predicted number of includes.

The full text of potentially eligible studies was retrieved and assessed according to the criteria specified in the review protocol. A standardised form was used to extract data from included studies into the EPPI reviewer software. Study investigators were contacted for missing data when time and resources allowed (when this occurred, this was noted in the evidence review and relevant data was included).

Incorporating published evidence syntheses

For all review questions where a literature search was undertaken looking for a particular study design, published evidence syntheses (quantitative systematic reviews) containing studies of that design were also included. All included studies from those syntheses were screened to identify any additional relevant primary studies not found as part of the initial search. Evidence syntheses that were used solely as a source of primary studies were not formally included in the evidence review (as they did not provide additional data) and were not quality assessed.

Methods of combining evidence

Data synthesis for intervention studies

Where possible, meta-analyses were conducted to combine the results of quantitative studies for each outcome.

Pairwise meta-analysis

Pairwise meta-analyses were performed in Cochrane Review Manager V5.3 where possible. A pooled relative risk was calculated for dichotomous outcomes (using the Mantel–Haenszel method) reporting numbers of people having an event. Both relative and absolute risks were presented, with absolute risks calculated by applying the relative risk to the risk in the comparator arm of the meta-analysis (calculated as the total number events in the comparator arms of studies in the meta-analysis divided by the total number of participants in the comparator arms of studies in the meta-analysis).

A pooled mean difference was calculated for continuous outcomes (using the inverse variance method) when the same scale was used to measure an outcome across different studies. Where different studies presented continuous data measuring the same outcome but using different numerical scales (e.g. a 0-10 and a 0-100 visual analogue scale), these outcomes were all converted to the same scale before meta-analysis was conducted on the mean differences. Where outcomes measured the same underlying construct but used different instruments/metrics, data were analysed using standardised mean differences (SMDs, Hedges' g).

For continuous outcomes analysed as mean differences, change from baseline values were used in the meta-analysis if they were accompanied by a measure of spread (for example standard deviation). Where change from baseline (accompanied by a measure of spread) were not reported, the corresponding values at the timepoint of interest were used. If only a subset of trials reported change from baseline data, final timepoint values were combined with change from baseline values to produce summary estimates of effect. For continuous outcomes analysed as standardised mean differences this was not possible. In this case, if

all studies reported final timepoint data, this was used in the analysis. If some studies only reported data as a change from baseline, analysis was done on these data, and for studies where only baseline and final time point values were available, change from baseline standard deviations were estimated, assuming a correlation coefficient derived from studies reporting both baseline and endpoint data, or if no such studies were available, assuming a correlation of 0.5 as a conservative estimate (Follman et al., 1992; Fu et al., 2013).. In cases where SMDs were used they were back converted to a single scale to aid interpretation by the committee where possible.

Random effects models were fitted when significant between-study heterogeneity in methodology, population, intervention or comparator was identified by the reviewer in advance of data analysis. This decision was made and recorded before any data analysis was undertaken.

For all other syntheses, fixed- and random-effects models were fitted, with the presented analysis dependent on the degree of heterogeneity in the assembled evidence. Fixed-effects models were the preferred choice to report, but in situations where the assumption of a shared mean for fixed-effects model were clearly not met, even after appropriate pre-specified subgroup analyses were conducted, random-effects results are presented. Fixed-effects models were deemed to be inappropriate if there was significant statistical heterogeneity in the meta-analysis, defined as $I^2 \geq 50\%$.

However, in cases where the results from individual pre-specified subgroup analyses were less heterogeneous (with $I^2 < 50\%$) the results from these subgroups were reported using fixed effects models. This may have led to situations where pooled results were reported from random-effects models and subgroup results were reported from fixed-effects models.

Where sufficient studies were available, meta-regression was considered to explore the effect of study level covariates.

Appraising the quality of evidence

Intervention studies (relative effect estimates)

RCTs were quality assessed using the Cochrane Risk of Bias Tool v.2.0. Evidence on each outcome for each individual study was classified into one of the following groups:

- **Low risk of bias** – The true effect size for the study is likely to be close to the estimated effect size.
- **Moderate risk of bias** – There is a possibility the true effect size for the study is substantially different to the estimated effect size.
- **High risk of bias** – It is likely the true effect size for the study is substantially different to the estimated effect size.

Each individual study was also classified into one of three groups for directness, based on if there were concerns about the population, intervention, comparator and/or outcomes in the study and how directly these variables could address the specified review question. Studies were rated as follows:

- **Direct** – No important deviations from the protocol in population, intervention, comparator and/or outcomes.
- **Partially indirect** – Important deviations from the protocol in one of the following areas: population, intervention, comparator and/or outcomes.
- **Indirect** – Important deviations from the protocol in at least two of the following areas: population, intervention, comparator and/or outcomes.

Minimally important differences (MIDs) and decision thresholds

The Core Outcome Measures in Effectiveness Trials (COMET) database was searched to identify published minimal important difference thresholds relevant to this guideline that might aid the committee in identifying decision thresholds for the purpose of GRADE. Identified MIDs were assessed to ensure they had been developed and validated in a methodologically rigorous way, and were applicable to the populations, interventions and outcomes specified in this guideline. In addition, PHAC members were asked to prospectively specify any outcomes where they felt a consensus decision threshold could be defined from their experience.

Decision thresholds were used to assess imprecision using GRADE and aid interpretation of the size of effects for different outcomes. Decision thresholds that were used in the guideline are given in Table 9 and also reported in the evidence review.

Table 9: Agreed decision thresholds

Outcome	Decision threshold
Abstinence from smoking	95% confidence intervals do not cross the line of no effect
Adverse events of mortality	95% confidence intervals do not cross the line of no effect
All other adverse events	Default (RR 0.8 - 1.25, (S)MD 0.5 SDs – see below)
Health-related quality of life (HRQoL) measures	Published MIDs if available for individual measure if available, otherwise default.

For continuous outcomes expressed as a mean difference where no other decision threshold was available, a decision threshold of 0.5 of the median standard deviations of the comparison group arms was used (Norman et al. 2003). For continuous outcomes expressed as a standardised mean difference where no other decision threshold was available, a decision threshold of 0.5 standard deviations was used. For SMDs that were back converted to one of the original scales to aid interpretation, rating of imprecision was carried out before back calculation. For relative risks and hazard ratios, where no other decision threshold was available, a default decision threshold for dichotomous outcomes of 0.8 to 1.25 was used. Odds ratios were converted to risk ratios before presentation to the committee to aid interpretation.

GRADE for pairwise meta-analyses of interventional evidence

GRADE was used to assess the quality of evidence for the outcomes specified in the review protocol. Data from randomised controlled trials were initially rated as high quality. The quality of the evidence for each outcome was downgraded or not from this initial point, based on the criteria given in Table 10.

Table 10: Rationale for downgrading quality of evidence for intervention studies

GRADE criteria	Reasons for downgrading quality
Risk of bias	Not serious: If less than 33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias, the overall outcome was not downgraded. Serious: If greater than 33.3% of the weight in a meta-analysis came from studies at moderate or high risk of bias, the outcome was downgraded one level. Very serious: If greater than 33.3% of the weight in a meta-analysis came from studies at high risk of bias, the outcome was downgraded two levels.

GRADE criteria	Reasons for downgrading quality
	Extremely serious: If greater than 33.3% of the weight in a meta-analysis came from studies at critical risk of bias, the outcome was downgraded three levels
Indirectness	Only directly applicable studies (in terms of the population, intervention and comparator) were included in this review. Outcomes not identified as primary or secondary outcomes in the protocol that were reported in included studies were downgraded one level for indirectness and included in the review.
Inconsistency	Concerns about inconsistency of effects across studies, occurring when there is unexplained variability in the treatment effect demonstrated across studies (heterogeneity), after appropriate pre-specified subgroup analyses have been conducted. This was assessed using the I^2 statistic. N/A: Inconsistency was marked as not applicable if data on the outcome was only available from one study. Not serious: If the I^2 was less than 33.3%, the outcome was not downgraded. Serious: If the I^2 was between 33.3% and 66.7%, the outcome was downgraded one level. Very serious: If the I^2 was greater than 66.7%, the outcome was downgraded two levels.
Imprecision	If an MID other than the line of no effect was defined for the outcome, the outcome was downgraded once if the 95% confidence interval for the effect size crossed one line of the MID, and twice if it crosses both lines of the MID. If the line of no effect was defined as an MID for the outcome, it was downgraded once if the 95% confidence interval for the effect size crossed the line of no effect (i.e. the outcome was not statistically significant), and twice if the 95% confidence interval crossed both upper and lower MIDs.
Publication bias	Where 10 or more studies were included as part of a single meta-analysis, a funnel plot was produced to graphically assess the potential for publication bias. When a funnel plot showed convincing evidence of publication bias, or the review team became aware of other evidence of publication bias (for example, evidence of unpublished trials where there was evidence that the effect estimate differed in published and unpublished data), the outcome was downgraded once. If no evidence of publication bias was found for any outcomes in a review (as was often the case), this domain was excluded from GRADE profiles to improve readability.

Reviewing economic evidence

Inclusion and exclusion of economic studies

Literature reviews seeking to identify published cost–utility analyses of relevance to the issues under consideration were conducted for all questions. In each case, the search undertaken for the public health review was modified, retaining population and intervention descriptors, but removing any study-design filter and adding a filter designed to identify relevant health economic analyses. In assessing studies for inclusion, population, intervention and comparator, criteria were always identical to those used in the parallel public health search; only cost–utility analyses were included. Economic evidence profiles, including critical appraisal according to the Guidelines manual, were completed for included studies.

Appraising the quality of economic evidence

Economic studies identified through a systematic search of the literature were appraised using a methodology checklist designed for economic evaluations (Developing NICE guidelines: the manual [2020]). This checklist is not intended to judge the quality of a study per se, but to determine whether an existing economic evaluation is useful to inform the decision-making of the committee for a specific topic within the guideline.

There are 2 parts of the appraisal process. The first step is to assess applicability (that is, the relevance of the study to the specific guideline topic and the NICE reference case); evaluations are categorised according to the criteria in Table 11.

Table 11: Applicability criteria

Level	Explanation
Directly applicable	The study meets all applicability criteria, or fails to meet one or more applicability criteria but this is unlikely to change the conclusions about cost effectiveness
Partially applicable	The study fails to meet one or more applicability criteria, and this could change the conclusions about cost effectiveness
Not applicable	The study fails to meet one or more applicability criteria, and this is likely to change the conclusions about cost effectiveness. These studies are excluded from further consideration

In the second step, only those studies deemed directly or partially applicable are further assessed for limitations (that is, methodological quality); see categorisation criteria in Table 12.

Table 12: Methodological criteria

Level	Explanation
Minor limitations	Meets all quality criteria, or fails to meet one or more quality criteria but this is unlikely to change the conclusions about cost effectiveness
Potentially serious limitations	Fails to meet one or more quality criteria and this could change the conclusions about cost effectiveness
Very serious limitations	Fails to meet one or more quality criteria and this is highly likely to change the conclusions about cost effectiveness. Such studies should usually be excluded from further consideration

Where relevant, a summary of the main findings from the systematic search, review and appraisal of economic evidence is presented in an economic evidence profile alongside the public health evidence.

Health economic modelling

As well as reviewing the published economic literature for each review question, as described above, de novo economic analysis was undertaken in selected areas. Priority areas for new health economic analysis were agreed by the committee.

The following general principles were adhered to in developing the analysis:

- Methods were consistent with the NICE reference case.
- The design of the model, selection of inputs and interpretation of the results was discussed and agreed with the committee.

- Where possible, model inputs were based on the systematic review of the public health literature, supplemented with other published data sources identified by the committee as required.
- When published data were not available committee expert opinion was used to populate the model.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.

Full methods for the de novo cost-effectiveness analysis are described in the HE report.

Resource impact assessment

The resource impact team used the methods outlined in the in Assessing resource impact process manual: guidelines

The resource impact team worked with the guideline committee from an early stage to identify recommendations that either individually or cumulatively would a substantial impact on resources. The aim was to ensure that a recommendation would not introduce a cost pressure into the health and social care system unless the committee was convinced of the benefits and cost effectiveness of the recommendation. The team gave advice to the committee on issues related to the workforce, capacity and demand, training, facilities and educational implications of the recommendations.