

Consultation on draft guideline - Stakeholder comments table 11/05/2022 - 07/06/2022

ID	Stakeho Ider	Docu ment	Page No	Line No	Comments	Developer's response
	Action on Smokin g and Health	Guideli ne	006	020	Recommendation 1.12.2 This recommendation requires that behavioural interventions, licensed products and nicotine-containing ecigarettes are <u>all</u> made accessible to adults who smoke. This is based on a significant evidence base, both in terms of RCTs and NHS stop smoking service outcomes over the last two decades that a combination of behavioural and pharmacological interventions is the most effective approach. [1]] The Allen Carr method specifically excludes the use of medications and e-cigarettes so including it as a first-line intervention by definition undermines the general approach set out in the guidance that smokers should be offered a combination of behavioural and pharmacological treatment. [1] Hartmann-Boyce J, Hong B, Livingstone-Banks J, Wheat H, Fanshawe TR. Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation. Cochrane Database Syst Rev. 2019 Jun 5;6(6):CD009670. doi:	Thank you. The amount of evidence for Allen Carr's Easyway (ACE) was comparable to the amount of evidence the committee considered for e-cigarettes (for example). The committee agreed that the evidence demonstrated that ACE was not inferior to NHS stop smoking services that use a combination of behavioural and pharmacological treatment. The committee agreed that it was an important addition to the range of services that could help people give up smoking. The update of this guideline was triggered by new evidence related to a research recommendation in the PH10 (Stop smoking services) guideline on the effectiveness of Allen Carr's Easyway. Allen Carr's Easyway is a unique approach because it has a combination of components such as elements of cognitive behavioural therapy and relaxation. Therefore it is not considered to be behavioural support.



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					10.1002/14651858.CD009670.pub4. PMID: 31166007; PMCID: PMC6549450.	We have clarified that behavioural support does not include Allen Carr's Easyway in-person group seminar (see the definition of behavioural support in the section of 'Terms used in this guideline'). This has been also clarified in recommendation 1.12.5 adding that behavioural support should not be offered to people who have chosen Allen Carr Easyway inperson group seminar.
						The rationale and impact section of the guideline has an explanation on the differences between Allen Carr's Easyway and other recommended interventions and how these differences prevented the committee to position Allen Carr's Easyway within the hierarchy of effectiveness of interventions recommended in recommendations 1.12.7 or 1.12.8.
2	Action on Smokin g and Health	Guideli ne	007	002	Recommendation 1.12.2 The rationale for citing Allen Carr's Easyway in-person group seminar as a specific intervention appears faulty. The Allen Carr Easyway seminar is one of many behavioural interventions, and therefore as a matter of taxonomical classification it should not be identified separately, but at most cited	Thank you. This update looked specifically at the Allen Carr's Easyway (ACE) and did not look at behavioural support more broadly. Surveillance by NICE did not indicate significant new evidence that would change the recommendations for behavioural support, however it did highlight 2 randomised controlled trials that compared the Allen Carr's



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					as one example under the classification "behavioural support".	Easyway to a control intervention. Allen Carr's Easyway is primarily a cognitive intervention with additional components which makes it different to 'behavioural support'. Additionally, in PH10 Stop Smoking Services, the committee agreed that ACE was not comparable to other behavioural support, which was part of the rationale for not recommending it at that time. Allen Carr's Easyway is a unique approach because it has a combination of components such as elements of cognitive behavioural therapy and relaxation.
3	Action on Smokin g and Health	Guideli ne	007	002	Recommendation 1.12.2 We are concerned that by recommending a single commercial provider, in this case Allen Carr, over others NICE is giving unwarranted advantage to one commercial entity. This is not the practice NICE has followed elsewhere in this and other guidance, NICE recommends NRT not branded products, and digital and mobile interventions rather than specific apps. Furthermore, we are concerned that NICE does not seem to have considered the longer-term implications for future guidance. Adopting this recommendation sets a precedent. Any other provider of a behavioural intervention, whether a seminar or digital and mobile health interventions, who can	Thank you. It is not correct to say that NICE has not looked at branded products before. Within the broader field of public health there are a range of commercially protected interventions that have been evaluated. See for example forthcoming NICE guidelines on Social, emotional and mental wellbeing in primary and secondary education. Allen Carr's Easyway is a unique approach because it has a combination of components such as elements of cognitive behavioural therapy and relaxation. We looked at evidence for Allen Carr's Easyway as there were two clinical trials that surveillance by NICE identified as relevant and with the



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					show similar evidence of effectiveness for their method would be justified in believing that it should be entitled to a specific NICE recommendation.	potential to impact recommendations. Should evidence of effectiveness and cost-effectiveness become available for other interventions then NICE would need to consider whether they should be the subject of a recommendation or update of the guideline.
4	Action on Smokin g and Health	Guideli ne	007	002	Smoking is highly addictive and tobacco dependence is recognised as a chronic relapsing disorder. On average it takes a smoker 30 attempts to quit successfully. [1] The unaided quit rate for smokers is around 5% each year [2] It has been estimated that 1-year cessation rates are 3 times higher among smokers using NHS stop smoking services [3] The relapse rate for those abstinent at 6 months is estimated to be 51.25% and for those abstinent at 12 months 35%.[4] The recommendation is based on 2 RCTs. Of particular relevance to the English context was Frings 2020 [5] the RCT which compared outcomes from Allen Carr's Easyway seminar (ACE) with that of a stop smoking service (SSS). The conclusion was that there was no evidence of a statistically significant difference in rates of verified continuous abstinence at 26 weeks between the ACE and SSS groups, (19.4 versus	Thank you. The committee agreed that there was not a significant difference between NHS SSS and the Allen Carr's Easyway and because Allen Carr's Easyway was no worse than NHS SSS and was cost-effective then it should be recommended alongside NHS SSS. NICE is not responsible for the content of the Allen Carr organisation's media and communications, howeverit is expected that healthcare professionals will provide accurate information to people wanting to stop smoking about available interventions including Allen Carr's Easyway so there is an obligation on healthcare professionals not to use materials that are inaccurate.



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					14.8%), and further relapse would be expected for both interventions.[5]	
					We are concerned that healthcare professionals have contacted ASH forwarding us emails they have been sent by Allen Carr representatives promoting Easyway which includes a link to a two minute video which claims that the method has "more than a 90% success rate".[6] This claim is not substantiated by the RCTs.[5] [7] Allen Carr says this claim is "based on our unique moneyback guarantee" going on to say that "We're so sure of our method that we offer a full moneyback guarantee. If you don't succeed in quitting smoking, your money is refunded in full." (see 1 minute 19 seconds to 1 minute 34 seconds) [6] However, the online information about the "unique moneyback guarantee" suggests to us that the onerous limitations on this guarantee do not justify the claim of a "more than 90% success rate". First if you relapse after 3 months you do not qualify. Secondly you can only get your money back if you "attend at least two free back-up seminars within three months of the date of your first seminar (the second and third seminars are not a repeat of the	



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					first seminar and last approximately 2-4 hours each)." [8]	
					We also draw attention to the claim (see at 54 seconds in) that smokers will not gain weight using the method as a further example of the need for caution in taking this commercial entity's claims at face value.[6] The evidence for this claim is not included in the video but it is not substantiated by the Keogan 2019 RCT [7] which found that, "Absolute weight gains: The mean weight gain for quitters at 3 months in AC [Allen Carr's Easyway] was 3.8 kg vs 1.8 kg in Quit.ie, the mean weight gain at 12 months in the AC was 5.02 kg vs 3.18 kg in Quit.ie". Weight gain was not assessed in Frings 2020.	
					[1] Chaiton, Michael et al. "Estimating the number of quit attempts it takes to quit smoking successfully in a longitudinal cohort of smokers." BMJ open vol. 6,6 e011045. 9 Jun. 2016, doi:10.1136/bmjopen-2016-011045. [2] Jackson, S. E., Kotz, D., West, R., & Brown, J. (2019). Moderators of real-world effectiveness of smoking cessation aids: a population study. Addiction, 114(9), 1627-1638. Doi:https://doi.org/10.1111/add.14656.	



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	Idei	IIICIIC	110	110	[3] Stead, L. F., Buitrago, D., Preciado, N.,	
					Sanchez, G., Hartmann-Boyce, J., & Lancaster,	
					T. (2013). Physician advice for smoking	
					cessation. Cochrane database of systematic	
					reviews(5).	
					[4] Stapleton, J. A., & West, R. (2012). A direct	
					method and ICER tables for the estimation of	
					the cost-effectiveness of smoking cessation	
					interventions in general populations: application	
					to a new cytisine trial and other examples.	
					Nicotine Tob Res, 14(4), 463-471.	
					Doi:10.1093/ntr/ntr236.	
					[5] Frings D, Albery IP, Moss AC, Brunger H,	
					Burghelea M, White S, Wood KV. Comparison	
					of Allen Carr's Easyway programme with a	
					specialist behavioural and pharmacological	
					smoking cessation support service: a	
					randomized controlled trial. Addiction. 2020	
					May;115(5):977-85.	
					[6]	
					https://www.youtube.com/watch?v=JMoDpoN	
					JQ3s accessed 5 th June 2022	
					[7] Keogan S, Li S, Clancy L. Allen Carr's	
					Easyway to Stop Smoking-A randomised clinical	
					trial. Tobacco control. 2019 Jul 1;28(4):414-9.	
					[8] Allen Carr's Easyway Money-Back	
					Guarantee	



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					https://www.allencarr.com/moneyback- guarantee/ accessed 5 th June 2022	
5	Action on Smokin g and Health	Guideli ne	General	General	This consultation was launched on 11 May and closes on 5pm, Tuesday 7 June 2022 with publication of the revised guidance expected on 4 th August. This update, which has significant implications for commissioning and practice for the Stop Smoking Services will only have been out for consultation for 27 days, which is less than four weeks, and is expected to be turned round for publication in 8 weeks by the committee after they receive comments. ASH has done its best to make a considered response, but we would like more time to enable us to submit a more detailed consultation response and to allow others to do the same, and for the Committee to consider those responses. We therefore recommend that the consultation length should be extended to 12 weeks, and 12 weeks for the Committee to consider responses, both of which are good practice for public consultations. It is particularly important for this consultation, for although the additional recommendation may seem limited, it potentially has very significant implications for the commissioning of smoking cessation treatment, that could impact on	Thank you. A 12 week consultation was not considered for this guideline because this would not be aligned with Developing NICE guidelines: the manual (see section 10.1). In this case, because the update was very small, a 4-week consultation was agreed to be appropriate. This ran from 11 May 2022 to 7 June 2022. These dates were advertised in advance.



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					service delivery, and affect service outcomes, access, and attitudes and behaviour towards the using of stop smoking medications and ecigarettes. All these issues need detailed consideration and that will take more time than has currently been allowed.	
6	Allen Carrs Easywa y (interna tional) Ltd	Guideli ne	007	002	The guideline refers to "Allen Carr's Easyway inperson group seminar" but it should be "Allen Carr's Easyway live group seminar" or "Allen Carr's Easyway seminar to stop smoking" which is used elsewhere in the guideline. This is because the RCTs the RCTs included in-person at a centre or live online via zoom seminars with a facilitator. The guidance should therefore include both seminar types and the easiest way is to replace the word in-person with live to avoid any confusion.	Thank you. 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. One study offered an online follow-up but every participant in the study had the initial session in person. Therefore, they were unable to generalise from this evidence and only recommended the in-person group seminar. The committee agreed that because the evidence was limited, more research would be useful to look at the effectiveness of the online and book versions of the programme and they made a research recommendation to cover this gap in the evidence. This discussion was added to the rationale and impact section of the guideline.
7	Allen Carrs Easywa y	Guideli ne	009	005	The heading should be "Allen Carr's Easyway live group seminar" or "Allen Carr's Easyway seminar to stop smoking" which is used elsewhere in the guideline rather than "Allen	Thank you. 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. One study



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	(interna tional) Ltd				Carr's Easyway in-person group seminar". This is because the RCTs the RCTs included inperson at a centre or live online via zoom seminars with a facilitator. The guidance should therefore include both seminar types and the easiest way is to replace the word in-person with live to avoid any confusion	offered an online follow-up but every participant in the study had the initial session in person. Therefore, they were unable to generalise from this evidence and only recommended the in-person group seminar. The committee agreed that because the evidence was limited, more research would be useful to look at the effectiveness of the online and book versions of the programme and they made a research recommendation to cover this gap in the evidence. This discussion was added to the rationale and impact section of the guideline.
8	Allen Carrs Easywa y (interna tional) Ltd	Guideli ne	012	020 - 021	This should be slightly amended to say "effectiveness of Allen Carr's Easyway programme delivered in formats other than live group seminars (for example online videos or using the self-help book) compared". This is because the online seminars were part of the RCT and should therefore be approved in this guidance.	Thank you. 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. One study offered an online follow-up but every participant in the study had the initial session in person. Therefore, they were unable to generalise from this evidence and only recommended the in-person group seminar. The committee agreed that because the evidence was limited, more research would be useful to look at the effectiveness of the online and book versions of the programme and they made a research recommendation to cover this



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						gap in the evidence. This discussion was added to the rationale and impact section of the guideline.
9	Allen Carrs Easywa y (interna tional) Ltd	Guideli ne	014	001	The copy should be "Allen Carr's Easyway live group seminars" or "Allen Carr's Easyway seminar to stop smoking" which is used elsewhere in the guideline rather than "Allen Carr's Easyway in-person group seminars". This is because the RCTs the RCTs included inperson at a centre or live online via zoom seminars with a facilitator. The guidance should therefore include both seminar types and the easiest way is to replace the word in-person with live to avoid any confusion	Thank you. 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. One study offered an online follow-up but every participant in the study had the initial session in person. Therefore, they were unable to generalise from this evidence and only recommended the in-person group seminar. The committee agreed that because the evidence was limited, more research would be useful to look at the effectiveness of the online and book versions of the programme and they made a research recommendation to cover this gap in the evidence. This discussion was added to the rationale and impact section of the guideline.
10	Allen Carrs Easywa Y (interna tional) Ltd	Guideli ne	014	007	The copy should be "Allen Carr's Easyway live group seminars" or "Allen Carr's Easyway seminar to stop smoking" which is used elsewhere in the guideline rather than "Allen Carr's Easyway in-person group seminars". This is because the RCTs the RCTs included inperson at a centre or live online via zoom	Thank you. 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. One study offered an online follow-up but every participant in the study had the initial session in person. Therefore they were unable to



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					seminars with a facilitator. The guidance should therefore include both seminar types and the easiest way is to replace the word in-person with live to avoid any confusion	generalise from this evidence and only recommended the in-person group seminar. The committee agreed that because the evidence was limited, more research would be useful to look at the effectiveness of the online and book versions of the programme and they made a research recommendation to cover this gap in the evidence. This discussion was added to the rationale and impact section of the guideline.
11	Allen Carrs Easywa y (interna tional) Ltd	Guideli ne	015	011	The copy should be "Allen Carr's Easyway live group seminars" or "Allen Carr's Easyway seminar to stop smoking" which is used elsewhere in the guideline rather than "Allen Carr's Easyway in-person group seminars". This is because the RCTs the RCTs included inperson at a centre or live online via zoom seminars with a facilitator. The guidance should therefore include both seminar types and the easiest way is to replace the word in-person with live to avoid any confusion	Thank you. 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. One study offered an online follow-up but every participant in the study had the initial session in person. Therefore, they were unable to generalise from this evidence and only recommended the in-person group seminar. The committee agreed that because the evidence was limited, more research would be useful to look at the effectiveness of the online and book versions of the programme and they made a research recommendation to cover this gap in the evidence. This discussion was added to the rationale and impact section of the guideline.



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12	Allen Carrs Easywa y (interna tional) Ltd	Guideli ne	015	017 - 018	The statement is correct but it omits the online seminars that were part of the RCT so we would recommend this line says "The committee noted that some people living in rural areas may need help with travel costs if they need to travel long distances to attend the in-person seminar but that there are also live online seminars that people can attend remotely providing they have access to good broadband and a smart phone or computer. The method is pharmacological free and so there are no ongoing costs, the online seminars eradicate travel costs, childcare costs childcare costs (a parent can take the seminar from home while minding their children), disabilities/people who are housebound - all of which helps with levelling up and health inequalities". There is therefore ease of access for anyone even by phone, tablet or computer as well as via attending a centre	Thank you. 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. One study offered an online follow-up but every participant in the study had the initial session in person. Therefore, they were unable to generalise from this evidence and only recommended the in-person group seminar. The committee agreed that because the evidence was limited, more research would be useful to look at the effectiveness of the online and book versions of the programme and they made a research recommendation to cover this gap in the evidence. This discussion was added to the rationale and impact section of the guideline.
13	Associat ion of Respirat ory Nurse	Guideli ne	800	003 - 004	What is the relevance of the lack of availability of Verenicline in Nov 2021 for future guidance? If Verenicline is still not available, it should be stated as such.	Thank you. We have updated the date as August 2022 because varenicline is still unavailable in the UK.



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	Speciali sts					
14	Associat ion of Respirat ory Nurse Speciali sts	Guideli ne	009	006	A group seminar of 6 hours seems very long.	Thank you. The committee noted that the length of the seminar (4.5 to 6 hours) might be a burden for some people. This discussion was added to the rationale and impact section of the guideline.
15	Associat ion of Respirat ory Nurse Speciali sts	Guideli ne	009	007 - 010	Is the use of the word "encourage" intentional? We feel it reinforces smoking rather than is a prelude to smoking cessation. Should it perhaps be considered to read: "Participants may carry on smoking" and "during the session they are advised they can smoke"	Thank you. Encourage is the correct term. It conveys the expectation that people will smoke as they normally would until the ritual final cigarette.
16	Associat ion of Respirat ory Nurse Speciali sts	Guideli ne	011	023 - 024	What is the relevance of the lack of availability of Verenicline in Nov 2021 for future guidance? If Verenicline is still not available, it should be stated as such.	Thank you. The recommendations about varenicline are in the greyed out section of the recommendation and are not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation. The date of November 2021 refers to the time that the varenicline recommendations were last updated. At that time the committee were led to



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						believe that varenicline was likely to be unavailable for some time.
17	Associat ion of Respirat ory Nurse Speciali sts	Guideli ne	015	025 - 027	contains a future date with annotation that the evidence was reviewed by then, was it meant to read: future updates/reviews planned?	Thank you for noticing this error. August 2022 is the planned publication date for this guideline and was mistakenly added to the consultation version.
18	Associat ion of Respirat ory Nurse Speciali sts	Guideli ne	Gen eral	Gen eral	We like to concept of the inclusion of a group therapy/Allen Carr session.	Thank you for your support.
19	Associat ion of Respirat ory Nurse Speciali sts	Guideli ne	Gen eral	Gen eral	Brief intervention advice should be forefront in the document – even prior to referral and suggesting interventions.	Thank you. Brief interventions are in the greyed out section of the recommendation and are not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation .
20	Associat ion of Respirat ory	Guideli ne	Gen eral	Gen eral	We are concerned around the limitations in relation to the evidence around the effectiveness of the Allen Carr method in relation to other smoking cessation methods	Thank you. The committee were content that the evidence was sufficient to demonstrate that the Allen Carr's Easyway was not inferior to other methods of stopping smoking. If any new



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	Nurse Speciali sts				and would like to have seen more prior to adding this into the guidance.	evidence is published this will be examined for any impact on the recommendation.
21	Associat ion of Respirat ory Nurse Speciali sts	Guideli ne	Gen eral	Gen eral	We have some concerns about the ICS's (CCG's) adding the Allen Carr method into their budgets. Will this widen the gap with some adding it and others not? The impact of this will be putting some smokers at more of a disadvantage than others who are being offered the method.	Thank you. Local commissioning arrangements are outside of NICE's remit, however the expectation is that commissioners of smoking cessation services will commission the range of services outlined by the NICE guideline. You raise important points that will need to be considered by those commissioning the services. The committee discussed the potential of Allen Carr's Easyway to increase inequalities in health. They agreed commissioners would need to know and understand the needs of their local populations to be able to commission it in a way that would mitigate against worsening health inequalities. This could include measures to facilitate access to and use of the services. This discussion was added to the rationale and impact section of the guideline.
22	British Thoraci c Society	Guideli ne	007	028	Should this read regrading VARENECLINE when available (currently this is not available and we are not sure when it will be	Thank you. The recommendations about varenicline are in the greyed out section of the recommendation and are not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for



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						this update and pages 1 to 3 of the draft guideline for consultation. The date of November 2021 refers to the time that the varenicline recommendations were last updated. At that time the committee were led to believe that varenicline was likely to be unavailable for some time.
23	British Thoraci c Society	Guideli ne	009	006	Further context would be helpful. E.g. the history/background of Allen Carr (or link to said information), and what its current availability in the UK setting is. Are there any examples of its current use in the NHS setting.	Thank you. The job of the committee was to evaluate the evidence on effectiveness and cost-effectiveness of the Allen Carr's Easyway and to make a recommendation based on that evaluation. NICE is not aware of the history or background of Allen Carr's Easyway, or of its availability in the UK. The committee were not aware of examples of the current use of Allen Carr's Easyway inperson group seminar in the NHS setting.
24	British Thoraci c Society	Guideli ne	009	Gen eral	IF the availability is limited (I can only find availability through the Allen Carr website - \$500 for 6 hour session), do commissioners have a means of franchising – i.e. is this specific guidance relevant to the NHS setting? Is it accessible in its current form	Thank you. Decisions about how best to commission the service will need to be made at a local level to reflect the local commissioning landscape. The committee was also informed that Allen Carr's Easyway offers volume related discounts and it is likely that the NHS or other publicly funded bodies would be able to negotiate a lower price for the intervention.



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25	British Thoraci c Society	Guideli ne	014	003	ACE contradicts the tried and trusted approach of getting people to use enough medication/products to successfully quit, and could lead to confusion among those we are trying to reach	Thank you. The evidence showed that the Allen Carr's Easyway is as effective as NHS SSS which routinely use medication alongside behavioural interventions. The committee thought Allen Carr's Easyway was effective and cost-effective and added an additional choice to people who smoke and want to stop smoking.
26	British Thoraci c Society	Guideli ne	014	003	Many people trying to quit are 'nicotine-phobic' and try to quit without products, resulting in many unsuccessful attempts, often leading to a loss of confidence that they will ever succeed	Thank you for this information. The Allen Carr's Easyway might appeal to people who want to give up smoking without nicotine containing products. Allen Carr's Easyway in-person group seminar has a combination of components such as elements of cognitive behavioural therapy and relaxation which is not the same as someone trying to stop smoking by themselves without medication.
27	British Thoraci c Society	Guideli ne	All page s	First line	DFAFT should be DRAFT	Thank you. This will be replaced with FINAL when the document is finalised.
28	British Thoraci c Society	Guideli ne	Gen eral	Gen eral	The guideline should re iterate that lack of behavioural support should not preclude prescription of NRT (CCG and Primary care declining to prescribe if no behavioural support is available)	Thank you. The recommendations about behavioural support and NRT are in the greyed out section of the recommendation and are not part of this consultation, which only covers the Allen Carr's Easyway. Please see



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						the <u>scope</u> document for this update and pages 1 to 3 of the <u>draft guideline for consultation</u> .
29	Cancer Researc h UK	Guideli ne	007	002	Due to a significant lack of independently funded research into the Allen Carr Easy seminars demonstrating its efficacy in smoking cessation, Cancer Research UK do not believe this intervention should be included in NICE guidance. Please see the rationale and impact section for a full explanation of this position.	Thank you. The committee considered the provenance of funding, but were content that the research was robust and clearly reported. The Keogan study was funded by the Irish Dept of Health and approved by a University Research Ethics Committee. The Frings study 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 (e.g., the study was peer reviewed and the protocol was pre-published on an established trial register).
30	Cancer Researc h UK	Guideli ne	007	002 - 003	We are unsure why the Allen Carr in person group seminar is not mentioned under the 'behaviour interventions' subpoint. It is also unclear how the Allen Carr Easyway programme would interact with existing local stop smoking services - i.e whether the method would be provided in addition to existing services or whether it could be commissioned as the sole provider. If there was a situation whereby the Allen Carr Easyway programme was the sole provider, we would be concerned with the impact of this on the rest of the	Thank you. This update looked specifically at the Allen Carr's Easyway (ACE) and did not look at behavioural support more broadly. Surveillance by NICE did not indicate significant new evidence that would change the recommendations for behavioural support, however it did highlight 2 randomised controlled trials that compared the Allen Carr's Easyway to a control intervention. Allen Carr's Easyway is primarily a cognitive intervention with additional components which makes it different to 'behaviour support'. Additionally, in PH10 Stop Smoking Services, the committee



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					guidance. For example, the need to ensure that medically licensed products are accessible to all adults who want to stop smoking, given the Allen Carr seminar does not promote or use medically licensed products or nicotine containing cigarettes. Local stop smoking services already provide a combination of behavioural support and pharmacotherapy ^{i,ii,iii} and provide people with the best chance of stopping successfully. People who attempt to stop smoking using prescription medication and support from local stop services are around three times more likely to stop smoking successfully than those attempting to quit unaided. ^{i,ii,iii} The latest complete figures suggest that 51% of those using these services reported being smoke-free after 4 weeks; 62% of the people who had successfully quit had their results confirmed by carbon monoxide verification (which equates to a verified quit rate of around 32% for those using the service). ^{iv} The verified quit rate for people using these services has remained relatively stable between 2009/10 and 2019/20. ^{iv}	agreed that ACE was not comparable to other behavioural support, which was part of the rationale for not recommending it at that time. Recommendation 1.12.2 begins "Ensure the following are available to people who smoke". The list remains unchanged other than having Allen Carr's Easyway added to it. The expectation is that all of the services would be provided. Medicinally licensed products will still be available to people who want to stop smoking. People who smoke and want to stop smoking have the choice to use Allen Carr's Easyway which excludes medicinally licensed products. Thank you for providing information on validated quit rates.



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31	Cancer Researc h UK	Guideli ne	012	021	Evidence is limited for alternative formats. In both studies referred to, the main seminar was conducted in person, although in the Fring et al study participants had the option to receive their subsequent sessions online. 22 received a second session online and 15 attended a third session online. The Keogan et al paper references a small US study by Foshee et al, in which reading the self-help book was not associated with higher quit rates among patients attending an otolaryngology clinic. Therefore, further research is needed to determine the effectiveness of the Allen Carr Easyway programme in formats other than group seminars.	Thank you for supporting the research recommendation.
32	Cancer Researc h UK	Guideli ne	014	001 - 015	Cancer Research UK supports the introduction of new stop smoking interventions provided that they are clinically and cost effective. Cancer Research UK projections indicate that England will not reach its target of achieving Smokefree 2030 (where less than 5% of the adult population smoke), if current smoking trends continue. Therefore, novel interventions to help people who smoke to stop should be made accessible on the NHS without delay ^{v.}	Thank you. This update looked specifically at the Allen Carr's Easyway seminar and did not look at other methods (for example the one you mention that was reported by Dijkstra et al.). Regarding your comment about research funding, the committee considered the provenance of funding, but were content that the research was robust and clearly reported. The committee were content that the evidence was sufficient to demonstrate that the Allen Carr's Easyway was not inferior to other



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	Ider	ment	No	No	However, Cancer Research UK have a number of concerns on the proposal to include Allen Carr's Easyway in NICE guidelines for smoking cessation. The evidence review on the clinical effectiveness of Allen Carr's in-person group seminars finds two studies demonstrating that it is as, or more effective than the standard offering of behavioural support (NHS England Stop smoking services or the equivalent offered in the Republic of Ireland). Our evidence search using (Allen[Title] AND Carr[Title]) AND (tobacco[Title/Abstract] or cigarette*[Title/Abstract]	methods of stopping smoking. The Frings study 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 (e.g., the study was peer reviewed and the protocol was pre-published on an established trial register). Regarding your comment about lack of published research into this intervention, the amount of evidence for Allen Carr's Easyway (ACE) was comparable to the amount of evidence the committee considered for e-
					smok*[Title/Abstract]) AND (stop*[Title/Abstract] OR cessation[Title/Abstract]) terms yielded similar results, however also included the study protocol for the Frings et al paper and a study by Dijkstra et al which investigated an Allen Carr programme delivered in a company setting but does not appear to be the 'EasyWay' method. In the NICE evidence review, one study was funded by Allen Carr's EasyWay International and the other by a grant from the Irish Department of Health. Cancer Research UK notes that the one independently funded study	cigarettes with 4 RCTs included (for example). Regarding your comment about standard of care, recommendation 1.12.2 begins "Ensure the following are available to people who smoke". The list remains unchanged other than having Allen Carr's Easyway added to it. This list broadens people's choices to find the right intervention for them. Therefore, Allen Carr's Easyway is an addition rather than a divergence. Regarding your comment about health inequalities in giving up smoking, you raise



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	luci	ment	INO	INO	was GRADE rated as moderate for examining the primary outcome of the study (long term cessation) - biologically verified abstinence at 12 weeks. The sample sizes were small, as 300 participants were enrolled, but only 127 remained at 3 months and 101 at 12 months. Retention was significantly higher in the group who received the Allen Carr intervention. 12 participants in the Allen Carr arm reported using e-cigarettes and the use of cessation aids other than e-cigarettes was only investigated in the control arm. This contamination in the study arm may limit the ability to disentangle the effects of the Allen Carr seminars with e-cigarette use. The trial population may not be representative of the wider population, including people who smoke, as participants were primarily middle-aged and people with certain health conditions were excluded. The authors note that the study was limited to 'well' people. Although participants were matched on ethnicity, no information about the ethnic backgrounds of participants is provided, and sexual orientation does not appear to have been recorded. Therefore, Cancer Research UK believes that	important points that will need to be considered by those commissioning the services. The committee discussed the potential of Allen Carr's Easyway to increase inequalities in health. They agreed commissioners would need to know and understand the needs of their local populations to be able to commission it in a way that would mitigate against worsening health inequalities. This could include measures to facilitate access to and use of the services. This discussion was added to the rationale and impact section of the guideline. The committee further discussed the issue of health inequalities and have made an additional research recommendation to determine the effectiveness and cost effectiveness of Allen Carr's Easyway in different subgroups including people from more deprived backgrounds, pregnant women, traveller communities, and others There is also a section in the guideline with recommendations on support to stop smoking for people with mental health problems (section 1.14 Support to stop smoking in secondary care services).
					there is a significant lack of independently	



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					funded research demonstrating the efficacy of this intervention. The lack of published research into this intervention also suggests that available studies may be vulnerable to publication bias.	
					People from more deprived groups are more likely to smoke ^{vi} and smoking is responsible for twice as many cancer cases in the most deprived groups compared with the least deprived groups ^{vii.} Therefore, it is important that the impact of new stop smoking interventions on health inequalities are considered. Stop smoking services have been proven to be effective when tested specifically in the most deprived groups ^{viii} . However, the evidence on effectiveness of the Allen Carr EasyWay method in more deprived groups is unclear. Most participants in the studies referred to in the evidence review were relatively highly educated and no other measures of deprivation were collected. The paper by Keogan <i>et al</i> also found a positive association between a higher level of education and quit rate. In addition, NICE guidance suggests that stop smoking services be targeted specifically to groups at high risk of tobacco-	



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					related harm, including people with mental health problems, people who misuse substances, people with health conditions linked to smoking, people from more deprived backgrounds, pregnant women who smoke, people who are more likely to smoke (including manual workers, travellers, and people in gender or sexual minority groups) and people living in custodial settings. It is unclear how the Allen Carr EasyWay method might be tailored towards these groups.	
					The Allen Carr EasyWay method does not recommend the use of pharmacotherapy, nicotine replacement therapy or e-cigarettes, but uses behavioural methods to help people to break their nicotine addiction. The former are the typical standard of care recommended in NICE guidance (alongside behavioural support). Therefore, this approach represents a significant divergence from the usual advice given to people who smoke and want to stop. It is important that participants are not discouraged from using these tools, as they are proven to be clinically and cost effective. It usually takes people several attempts to stop	



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					smoking for good ^{ix} and different methods work for different people. Therefore, it is important that no method included in NICE guidance has the potential to dissuade someone from trying other methods they may find effective on subsequent quit attempts, including pharmacotherapy, NRT or e-cigarettes.	
					As outlined above, the Allen Carr EasyWay approach is a significant divergence from the approaches doctors, pharmacists and stop smoking service staff are trained to counsel patients in. Details of the exact methods used by Allen Carr EasyWay are not easily available publicly, so further training of healthcare professionals in advising their patients on this method would likely be necessary to ensure they are able to effectively advise on this method.	
					Given the above considerations on the evidence base on the efficacy of the Allen Carr EasyWay method for smoking cessation, Cancer Research UK do not believe this intervention should be included in NICE guidance. We welcome further independently funded research into this intervention to	



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					determine its efficacy compared to other standards of care.	
33	Cancer Researc h UK	Guideli ne	015	011 - 018	Implementation of any stop smoking intervention has resource implications that need long term and sustainable funding to be mitigated against. Funding for local, regional and national tobacco control activities in England has been significantly cut in recent years.* These funding pressures mean local authorities are not only unable to deliver smoking cessation services as they should,*i but this also threatens the delivery of local stop smoking campaigns and enforcement activity aimed at preventing underage tobacco sales and tackling illicit tobacco: Only 67% of local authorities in England commissioned a specialist service open to all local people who smoke in 2021.*ii Furthermore, from 2013/14 to 2019/20, total local authority spending on stop smoking services and tobacco control in England fell by 43.3% from £148.5 million to £84.2 million.**iii	Thank you. Decisions about how best to commission the service will need to be made at a local level to reflect the local commissioning landscape.



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					 National spending in England on public education campaigns has also dropped from a peak of £23.38 million in 2008/9 to just £1.99 million in 2017/18.xiv,xv 	
					Tobacco kills up to half of all users in the long term whilst being highly profitable for its manufacturers: the four largest tobacco manufacturers make around £900 million of profits in the UK each year. We smoking is also estimated by Action on Smoking and Health (ASH) to cost society £17 billion annually in England. We only £265.5 million of additional funding would be needed to pay for national, regional and local tobacco control activity in England, which increases to £315.2 million for UK-wide measures.	
					That's why CRUK are calling for additional funding – for example, through a Smokefree Fund: a fixed annual charge on the tobacco industry that would use their funds, without their interference, to pay for tobacco control measures across the UK. This investment could significantly help reduce smoking prevalence,	
					address a leading driver of health disparities across the UK, and ultimately support the vital	



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					mission of the UK Government to level up (more <u>here</u>).	
34	Cardiff and Vale Universi ty Health Board	Guideli ne	007	011	Also add in offer behavioural support to people who are addicted to nicotine based products (e.g. vapers wanting to stop vaping)	Thank you. Behavioural support is in the greyed out section of the recommendations and is not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation .
35	Cardiff and Vale Universi ty Health Board	Guideli ne	008	020	Add in additional comment – For harm reduction, ensure combination of cigarettes smoked and use of NRT product are equivalent to their current nicotine addiction levels.	Thank you. The recommendation about NRT is in the greyed out section of the recommendations and is not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation.
36	Cardiff and Vale Universi ty Health Board	Guideli ne	009	024	Add in additional comment – flexible, longer term follow on support should be available for secondary care and mental health smokers.	Thank you. The additional comment is not part of what the guideline update covers. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation.
37	Cardiff and	Guideli ne	010	025	Add in additional comment – both behavioural and pharmacological products should be	Thank you. Harm reduction definition is in the greyed out section of the guideline and is not



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	Vale Universi ty Health Board				offered to ensure the smoker continues reducing their cigarettes in a controlled empowered manner.	part of this consultation, which only covers the Allen Carr's Easyway. Behavioural interventions and pharmacological products remain unchanged in recommendation 1.12.2. The expectation is that all of the services would be provided. People who smoke and want to stop smoking will have the choice to use any of the interventions listed in recommendation 1.12.2. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation .
38	Cardiff and Vale Universi ty Health Board	Guideli ne	012	012	Add in secondary care specific paragraph – for community smokers the person's priority is to stop smoking. For secondary care smokers they are told they have to stop smoking, they do not choose to stop. Giving up smoking is low on their priority list. Secondary care smokers require a holistic approach to stopping smoking. The treatment plan should be flexible, longer term and tailored to individual needs to fit around their presenting physical and psychological issues. Support tailored around hospital appointments and any medical intervention.	Thank you. Level of care is not part of this consultation. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation.
39	Cardiff and Vale	Guideli ne	012	012	Add in additional comment – for any smoker who is not confident in their ability to immediately stop smoking, discuss a controlled	Thank you. Stop in one go definition is in the greyed out section of the guideline and is not part of this consultation, which only covers the



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	Universi ty Health Board				harm reduction approach with behavioural and pharmacological support.	Allen Carr's Easyway. Please see the <u>scope</u> document for this update and pages 1 to 3 of the <u>draft guideline for consultation</u> .
40	Clinical Standar ds Commit tee, Faculty of Dental Surgery, Royal College of Surgeon s	Q1 confid entialit y form	002	Gen eral	The introduction of the Allen Carr's Easyway Programme has the potential to widen the accessibility of smoking cessation to smokers in the general population. The expertise and manpower resource required and its availability across the country at a consistent level/standard would be one of the potential challenges. Evaluation of the efficacy of this new intervention could be resource intensive as there is the potential of losing patients to follow-up and/or the lack of response following completion of therapy.	Thank you. You raise important points that will need to be considered by those commissioning the services. The committee discussed the potential of Allen Carr's Easyway to increase inequalities in health. They agreed commissioners would need to know and understand the needs of their local populations to be able to commission it in a way that would mitigate against worsening health inequalities. This could include measures to facilitate access to and use of the services. This discussion was added to the rationale and impact section of the guideline.
41	Clinical Standar ds Commit tee, Faculty of Dental Surgery,	Q2 confid entialit y form	002	Gen eral	The initial cost outlay is reported to be higher than current services available, however in the long term it has been reported that this intervention should cost neutral. Funding organisations/services will need to consider this in their resource allocation and planning.	Thank you. Economic modelling suggests that the intervention is likely to be cost-saving in 5-7 years rather than cost-neutral.



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	Royal College of Surgeon					
42	Clinical Standar ds Commit tee, Faculty of Dental Surgery, Royal College of Surgeon s	Q3 confid entialit y form	002	Gen eral	The group setting for the Allen Carr's Easyway Programme could suit users who prefer to interact within such a setting. In communication with users of the service and/or the clients, there should be a clear and simple message about the nature of each of the options of intervention on offer. Ideally the interventions available should cater to the various settings i.e., individualised or group, which should support the widest user population possible.	Thank you. This is reflected elsewhere in the guideline, particularly in recommendations 1.12.1 and 1.12.6.
43	Clinical Standar ds Commit tee, Faculty of Dental	Guideli ne	Gen eral	Gen eral	Based on the summary of evidence presented, the inclusion of the Allen Carr's Easyway Programme as part of a smoking cessation intervention will be supported and potentially might be beneficial as it adds to the diversity of interventions available within the NHS. Prospective evaluation of its efficacy and accessibility across all parts of the country to all	Thank you for your support for the addition of the Allen Carr's Easyway as another tool to support people who want to stop smoking.



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	Surgery, Royal College of Surgeon s				population groups will need to be incorporated into the package through which this service will be introduced and resourced.	
44	Compan y Chemist s Associat ion Ltd	Guideli ne	007	General	1.12.5The guidelines recommend that behaviour support is offered to people who smoke regardless of which option they choose. Evidence shows smoking cessation services delivered by community pharmacy are effective and cost-effective, particularly for vulnerable or deprived communities. A systematic review and meta-analysis by Brown et al. (2016) showed that delivering smoking cessation services through community pharmacy is both effective and cost-effective when compared with usual care. The guidelines should reflect that smoking cessation support already exists in community settings and ensure that pharmacy-led interventions are promoted as an option for patients. As of March 2022, the Smoking Cessation Service has been introduced as an	Thank you. Behavioural support is in the greyed out section of the recommendations and is not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation.



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					advanced service in the CPCF. This service will enable NHS trusts to refer patients discharged from hospital to a community pharmacy of their choice to continue their smoking cessation care pathway, including providing medication and behavioural support as required, in line with the NHS Long Term Plan care model for tobacco addiction.	
					Recently available data suggests that more than 2,000 pharmacies have signed up to deliver the service. There should be greater promotion of the service within secondary care settings to ensure a continuity of support for patients in hospital and upon discharge into the community.	
45	Compan y Chemist s Associat ion Ltd	Guideli ne	007	Gen eral	1.12.3 The guidelines suggest that NRT should be considered for smokers under the age of 16. Under a framework of Gillick competence, patients who smoke and are under 16 should be reassured that clinicians will not inform their parents or guardians. Adolescents in particular may need this reassurance so that they are not deterred from seeking and/or adhering to smoking cessation support	Thank you. The recommendation about NRT for young people is in the greyed out section of the recommendations and are not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation.



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46	Johnson & Johnson	Guideli ne	007	002	We welcome NICE's draft decision to include specific reference to branded smoking cessation products and services that satisfy its threshold for clinical evidence. We look forward to this approach being adopted for other smoking cessation products and services for which companies are able to demonstrate a similar level of clinical evidence.	Thank you. Should evidence of effectiveness and cost-effectiveness become available for other interventions then NICE would need to consider whether they should be the subject of a recommendation or update of the guideline. Allen Carr's Easyway is a unique approach because it has a combination of components such as elements of cognitive behavioural therapy and relaxation. This is why it was not listed as a 'behavioural intervention'. NICE is not suggesting it will always refer to branded products separately in the future. This will only happen when there is a product that is clearly different from other products that are or could be available.
47	NHS England and Improve ment	Guideli ne	006	007	Highlights that pregnant woman are "mainly" covered in a separate section which has not been included for consultation. Does this mean that the Allen Carr's Easyway is recommended for adults, but is excluding pregnant women? Where is it recommended 1.12.2, other pharmacotherapy is listed that is not appropriate for pregnant women. Clarification is required as this is unclear and will confuse front line staff.	Thank you. The committee discussed that the evidence did not include any analysis on pregnant women. Therefore, they were unable to generalise from this evidence and did not make a specific recommendation for pregnant women. The committee agreed that because the evidence was limited, more research would be useful to look at the effects of Allen Carr's Easyway in different population groups including pregnant women and they made a research recommendation to cover this gap in



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					Indeed, this method is not necessarily appropriate for consideration in pregnancy given the time critical nature of the need for smoking cessation in this cohort (evidence that quitting needs to be before 15/40 to reverse outcomes, and the need for cessation whilst pregnant to reduce risk). Encouragement of smoking as normal until attendance, smoking in breaks etc entailed in this method present a challenge for pregnancy	the evidence. This discussion was added to the rationale and impact section of the guideline.
48	NHS England and Improve ment	Guideli ne	006- 007	020 - 002	In the evidence document, the group did not find that the Allen Carr's Easyway method is more effective that Quit or 1-1 in-person NHS sessions (compared individually), and it is stated that the group had concerns about the quality of the evidence, have deemed that the 'evidence was limited', and that it is 'highly likely' rather than proven to be cost-effective. Given this, and the fact that there are resource implications related to this method, perhaps the word 'consider' rather than 'ensure' should used in relation to access to this intervention in this section (or consideration given to the wording on page 7 line 002).	Thank you for your comment. The term 'highly likely' relates to the probabilistic sensitivity analysis which looks at the probability of an intervention being cost effective using the NICE decision threshold of £20K/QALY. In both studies the probability of the intervention being cost effective was very high: Allen Carr's Easyway vs Quit.ie = 98.87%, Quit.ie vs 1 to 1 in-person NHS stop smoking services 92.8%. The base case analyses, which use estimates and costs based on the studies, show both are cost effective – when Allen Carr's Easyway is compared with Quit.ie, it is both cost saving (saving £115 per person) and more effective (generating an additional 0.02 QALYs per



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						smoker) and when Allen Carr's Easyway is compared with 1 to 1 in-person NHS stop smoking services, it is both marginally cost saving and more effective (generating an additional 0.04 QALYs per smoker). Based on the evidence from these analyses the committee considered a strong recommendation was justified.
49	NHS England and Improve ment	Guideli ne	014	004 - 006 and 010 - 011	NICE have previously listed the range of effectiveness of other interventions. Can NICE be more specific about which "other methods" the Allen Carr's Easyway is expected to be as good as? This will be key information for helping advise potential quitters about the pros and cons of different interventions. On page 14, the committee make reference to this product "would broaden people's choice" (line 10), however to allow informed patient choice specific evidence and comparable data on effectiveness would be needed - the current drafting does not support this.	Thank you. The committee agreed that the evidence demonstrated that the Allen Carr's Easyway was not inferior to other methods of stopping smoking such as the NHS stop smoking services. The committee agreed that it was an important addition to the range of services that could help people give up smoking. The data on effectiveness is available in the accompanying evidence review.
50	NHS England and	Guideli ne	015	013	On page 014 line 007, it is stated that Allen Carr's Easyway in-person group seminars are "highly likely to be cost effective", however, this	Thank you for the comment. The difference in terminology relates to the probabilistic sensitivity analysis and the base case analysis.



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	Improve ment				changes on page 15 line 013 to being "highly cost effective". Should page 015 be updated to reflect the fact the intervention is highly likely to be cost effective and have the potential to offset increased costs?	We have amended the document to ensure consistency and to avoid confusion.
51	NHS England and Improve ment	Guideli ne	Gen eral	Gen eral	For other interventions, branded products are not specifically listed. Is the evidence suggesting that in-person group seminars including cognitive behavioural therapy and a brief relaxation exercise is an appropriate smoking cessation intervention – or does it specifically have to be this specific branded intervention (which would be more in line with a review of technology)? Limiting to one provider will potentially limit other parties from developing services which could increase capacity, value and support innovation.	This update looked specifically at the Allen Carr's Easyway (ACE) and did not look at behavioural support more broadly. Surveillance by NICE did not indicate significant new evidence that would change the recommendations for behavioural support, however it did highlight 2 randomised controlled trials that compared the Allen Carr's Easyway to a control intervention. Allen Carr's Easyway is primarily a cognitive intervention with additional components which makes it different to 'behaviour support'. Additionally, in PH10 Stop Smoking Services, the committee agreed that ACE was not comparable to other behavioural support, which was part of the rationale for not recommending it at that time.
52	NHS	Guideli	Gen	Gen	The other interventions listed within the	Thank you. The network meta-analysis focused
	England and	ne	eral	eral	guideline and evidence review were included as part of a network meta-analysis. Should a	on pharmacological interventions and there are other interventions recommended in the
	Improve				consistent level of analytical scrutiny be applied	guideline that were not subject to network
	ment				to the Allen Carr's Easyway in-person group	meta-analysis.



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					seminars prior to being compared in terms of effectiveness in relation to the other cessation methodologies?	
53	NHS England and Improve ment	Guideli ne	Gen eral	Gen eral	Endorsing the continuation of smoking until people engage with the Allen Carr's Easyway in-person group seminars and that nicotine is not required produces potential misconceptions about the effectiveness and validity of other proven cessation methods and potentially perpetuates harm whilst people await access to the in-person seminar.	Thank you. The inclusion of Allen Carr's Easyway increases the choice of interventions available to people who want to stop smoking. It does not prevent people from choosing an alternative intervention that includes a pharmacotherapy containing nicotine.
54	NHS England and Improve ment	Guideli ne	Gen eral	Gen eral	Acknowledging the evidence review assertation that making this available on the NHS will reduce individual costs and therefore close some of the health inequality gaps currently seen, the recommendation to exacerbate some of the starkest health inequalities those from the poorest backgrounds who may struggle to engage with the in-person seminars.	Thank you. You raise important points that will need to be considered by those commissioning the services. The committee discussed the potential of Allen Carr's Easyway to increase inequalities in health. They agreed commissioners would need to know and understand the needs of their local populations to be able to commission it in a way that would mitigate against worsening health inequalities. This could include measures to facilitate access to and use of the services. They agreed that because the evidence was limited, more research would be useful to look at the effects of Allen Carr's Easyway in different population



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						groups including people from poorer socio- economic backgrounds. Therefore, they made a research recommendation to cover this gap in the evidence. This discussion was added to the rationale and impact section of the guideline.
55	NHS England and Improve ment	Guideli ne	Gen eral	Gen eral	From a primary care perspective, we can see no impact from this guidance as either: - Practices are not offering this – other community services are in place, or - Those practices that are doing so will be under a Local Enhanced Service The recommendations – discussion, choice of behaviour and pharmacological treatment - are already common practice and present no additional workload for general practice.	Thank you for your comment.
56	North Central London Joint Formula ry Commit tee	Guideli ne	Gen eral	Gen eral	Regarding stop-smoking interventions (1.12): When varenicline was available, several areas in the country used a combination of varenicline with NRT (particularly for initiation in hospitals where the patient is engaging with stop smoking services and wishes to set a quit date, but cannot smoke on the hospital grounds – and hence uses NRT until they are able to quit). This hasn't been discussed in the current update of the guideline, and I cannot see that it has been discussed in previous versions. There	Thank you. The recommendations about varenicline are in the greyed out section of the recommendations and are not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.



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					has been evidence generated in this space (e.g. the meta-analysis by Chang et al, doi:10.1186/s12889-015-2055-0) and is used in practice. Acknowledging information on varenicline in the NICE guidance is based on the NICE TA (2007) and this has not been reviewed since 2014, can varenicline + NRT combination therapy be considered within scope of NICE guidance?	
57	Royal College of General Practitio ners	Guideli ne	006	023	We find it interesting that so few colleagues in the health service (many working in a health care setting managing the problems associated with tobacco dependency) have not heard of, nor use Very Brief Advise – and would suggest more emphasis be placed on this as a fundamental trigger to encourage a quit attempt	Thank you. The recommendation about very brief advice is in the greyed out recommendations and is not part of this consultation, which only covers the Allen Carr's Easyway. The expectation is that all of the interventions listed in recommendation 1.12.2 would be provided (including very brief advice). People who smoke and want to stop smoking will have the choice to use any of the interventions listed in recommendation 1.12.2. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation .
58	Royal College	Guideli ne	007	002	We note that the evidence review associated with this recommendation was extensive based	Thank you. The committee agreed that because the evidence was limited, more research would
	of				on two published papers where concerned	be useful and made a research recommendation
	General				expressed about the quality of the research.	on the effectiveness and cost effectiveness of



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	Practitio ners				The addition and economic analysis on the basis of this we would assume will be challenged as expected. Would this be suitable for a carefully constructed NIHR funded trial – as the implications are significant.	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).
59	Royal College of General Practitio ners	Guideli ne	Gen eral	Gen eral	We wonder if the cost economics of training in VBA for the health care professional workforce would have a bigger impact on life years saved and QALY in comparison to say the training of the workforce on CPR (not that we would suggest that CPR updating is discontinued – but we wonder if this impact of Very Brief Advise would be greater?	Thank you. The recommendation about very brief advice is in the greyed out recommendations and is not part of this consultation, which only covers the Allen Carr's Easyway. Please see the scope document for this update and pages 1 to 3 of the draft guideline for consultation. The committee highlighted the importance of having effective and cost-effective interventions as choices for people who smoke and want to stop smoking.
60	Sheffiel d Teachin g Hospital s NHS Foundat ion Trust	Eviden ce review	020	009	1.1.11.3: benefits & harms – this should include burden of treatment to the individual (i.e. 4.5 – 6 hour session + follow-up sessions) and potentially cost (e.g. travel)	Thank you. This is an important consideration and we have added it to the rationale and impact section of the guideline as well as to section 1.1.11.3 of the evidence review.



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61	Sheffiel d Teachin g Hospital s NHS Foundat ion Trust	Comm ents form	Q1	Gen eral	Group sessions would be difficult to implement in secondary care settings, partly due to space, but also the potential for Covid disruption. They would require more training as group dynamics are very different to working in 1:1 settings. Also, participants wouldn't be able to have smoking breaks and a final 'ritual' cigarette, as hospital grounds are smoke-free.	Thank you. The committee agreed that it seems unlikely that the Allen Carr's Easyway seminar would be delivered in secondary care settings.
62	Sheffiel d Teachin g Hospital s NHS Foundat ion Trust	Comm ents form	Q2	Gen eral	Providing the Allen Carr Easyway as an NHS intervention would require a 1:1 intervention to assess for suitability for the programme and a clear description of what to expect etc., which would need to be factored into the cost; may be a higher drop out rate for an NHS service compared with 'private', which was described in the evidence.	Thank you. The recommendations in section 1.12 of the guideline all require a 1:1 intervention to help people decide which form of smoking cessation would be best suited to them and to provide them with advice and information. The committee did not see any data on dropout rates but the effectiveness was comparable with existing interventions recommended by NICE and the economic analyses showed they were cost effective.
63	The Depart ment of Health and Social Care, Office	Guideli ne	Gen eral	Gen eral	We are concerned that the recommendation to make Alan Carr's Easyway in-person group seminars available reinforces misperceptions about the harmfulness of nicotine and could result in more smokers becoming resistant to using stop smoking medications and nicotine-containing e-cigarettes	Thank you. Allen Carr's Easyway is an additional choice that people can have as an intervention to stop smoking. It does not prevent people choosing an intervention which includes a medicinal product containing nicotine. Allen Carr's Easyway also conveys the expectation that people will smoke as they normally would until the ritual final cigarette.



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	for Health Improve ment and Dispariti es				There is robust evidence that smokers overestimate the harms of nicotine, and many do not use enough, long enough for effective cessation. Inclusion of a treatment that undermines this, risks reducing confidence and quits achieved through other smoking cessation routes.	
64	The Depart ment of Health and Social Care, Office for Health Improve ment and Disparities	Guideli ne	Gen eral	Gen eral	The Allan Carr methods are inconsistent with core recommendations in this NICE guidance, that all smokers should be offered multiple sessions of behavioural support and stop smoking medications or nicotine-containing ecigarettes. Its inclusion in this guidance risks causing confusion and undermining existing service models.	Thank you. Recommendation 1.12.2 begins "Ensure the following are available to people who smoke". The list remains unchanged other than having Allen Carr's Easyway added to it. This list broadens people's choices to find the right intervention for them. Therefore, Allen Carr's Easyway is an addition rather than an inconsistency.



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- xvi APPG on Smoking and Health. 2021. Delivering a Smokefree 2030: The All Party Parliamentary Group on Smoking and Health recommendations for the Tobacco Control Plan 2021. Accessed April 2022.
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