NICE National Institute for Health and Care Excellence

2020 exceptional surveillance of stop smoking interventions and services NICE guideline NG92

Surveillance report
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Surveillance decision

We will update the NICE guideline on stop smoking interventions and services.

The update will focus on evidence-based stop smoking interventions.

Reason for the exceptional review

NICE was notified of the publication of 2 randomised controlled trials (Keogan et al. 2019 and Frings et al. 2020) assessing the effectiveness of Allen Carr's Easyway (ACE) programme on stopping smoking. This programme is not currently considered as a stop smoking intervention in NICE guidelines. This exceptional review examined the impact of this evidence on the NICE guideline on stop smoking interventions and services.

Methods

The exceptional surveillance process consisted of:

- Considering the new evidence that triggered the exceptional review.
- Considering the evidence used to develop recommendation 1.3.1 in the guideline in 2018.
- Assessing the new evidence against current recommendations to determine whether or not to update the guideline.

Focused literature searches were run to identify further evidence on ACE for stopping smoking but no new relevant studies were identified.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Information considered in this exceptional surveillance review

Two randomised controlled trials evaluating the effectiveness of ACE for stopping smoking were assessed in this exceptional surveillance review. The first study compared ACE with Quit.ie, the online Health Service Executive National Smoking Cessation Service in Ireland (Keogan et al. 2019) and the second study compared ACE with a specialist behavioural and pharmacological smoking cessation support service in the UK (Frings et al. 2020).

ACE compared with Quit.ie

This study was conducted in the Tobacco Free Research Institute in Ireland. People aged 18 years and above who were English speakers, smoking 5 or more cigarettes per day, and willing to attend the follow-up visits (4 to 5 in total) were included. People with a history of acute cardiac or respiratory disease, psychiatric disease or receiving treatment for alcohol or drug misuse were excluded. Participants were recruited through public advertisement. Participants were randomised using a randomised block design, and incentives were used to improve retention.

The ACE intervention consisted of a group seminar (5 hours, maximum of 20 participants) delivered by an experienced therapist. During the group session participants could smoke during breaks, having their final cigarette at the end of the session following a ritual and finishing with a relaxation exercise. Participants were instructed not to use pharmacological treatment. Up to 2 additional sessions were available for participants if needed.

Quit.ie is an online service that provides information and behavioural support to smokers by phone, text messages or online using a website or social media. As part of the Quit.ie plan, participants agree on a quit date and receive daily support texts messages or emails (or both) during the first month, a minimum of 2 follow-up communications, and a call from a quit team specialist. Participants could use pharmacological treatment (nicotine replacement therapy [NRT] or other medication) and they were responsible for obtaining it (to purchase or get a prescription if needed).

Participants were followed at 1, 3, 6 and 12 months after their quit date. The outcomes assessed during the follow-up visits were smoking cessation (both self-reported and biochemically verified using expired carbon monoxide), weight gain, relapse rates, smoking

cessation medication use, and motivational contacts received (by phone, text, email or at presential meetings).

A total of 3,065 participants were eligible to participate in the study. A total of 300 participants were randomised (149 in the ACE group and 151 in the Quit.ie group). No differences were identified in the baseline characteristic of the participants between the groups compared.

Following an intention-to-treat analysis (Russell Standard), quit rates were significantly higher at 1, 3, 6 and 12 months in the ACE group compared with the Quit.ie group. Multivariate analysis showed that being in the ACE group and having a higher educational level were significantly associated with having higher quitting rates at all follow-up points. The ACE intervention was associated with a higher increase in body weight at 1, 3 and 6 months but not at 12 months compared with Quit.ie.

A total of 28 participants in the Quit.ie group took pharmacological treatment (42 NRT and 14 varenicline). Varenicline was associated with higher quit rates at 3 months compared with NRT or no pharmacological treatment. Results of this outcome at 12 months were not reported. A total of 12 participants in the ACE group and 15 in the Quit.ie group reported the use of electronic cigarettes. The use of electronic cigarettes did not have an impact on the quit rates in the ACE group. Participants using electronic cigarettes in the Quit.ie group before the 3-month visit had lower quit rates than those who did not use them at 3 months (results at 6 and 12 months were not reported).

The retention rates were higher in the ACE group compared with the Quit.ie group at all follow-up points. No attendees were contacted, and self-reported quit rates were obtained. Complete case analysis was conducted to assess the impact of the differences in the retention rates on the results. The analysis showed similar results to the intention-to-treat analysis. No serious side effects were reported. One participant in the ACE group needed pharmacological treatment to manage withdrawal symptoms.

The study has some limitations. There is a risk of selection bias that could affect the representativeness of the target population in the study. People with a history of cardiovascular or respiratory disease were excluded, so only healthy people were recruited. Only around 10% of those eligible were randomised in the study. Young and older people and those with a lower educational level were not well represented in the sample. Only English speakers were included, so effectiveness for non-English speaking minority groups was not assessed. There is also a risk of performance bias due to

knowledge of the allocated interventions by participants and personnel, and detection bias due to no blinding of outcome assessment. Authors highlighted that it was not possible to determine the mechanisms incorporated in the ACE intervention that help to promote successful smoking cessation. They also noted that it was not possible to customise Quit.ie content. These factors limit the understanding of how and why the interventions assessed were successful or unsuccessful. Finally, incentives to improve retention rates were used, but the retention rates in the study were low (101/300, 33.6% at 12 months).

ACE compared with a specialist behavioural and pharmacological smoking cessation support service

Frings et al. (2020) compared the effectiveness of ACE with a specialist behavioural and pharmacological smoking cessation support service in the UK (standard care). People 18 years and above who were current smokers wanting to quit were included. Pregnant women, people with a history of respiratory or psychiatric disease, those participating in a similar study or not wanting to take part in an intervention that was not NHS or NICE approved were excluded. Participants were recruited through public advertisement. They were then randomised using a randomised block design in an independent centre, and incentives were used to improve retention in both arms.

The ACE intervention consisted of a group seminar (4.5 to 6 hours, number of participants between 1 to 19) delivered by an experienced therapist that included elements of cognitive behavioural therapy (CBT) and a relaxation exercise. During the group session participants were allowed to smoke during breaks, having their final cigarette at the end of the session following a ritual and finishing with a relaxation exercise. Participants received regular text messages from the clinical team. Up to 2 additional sessions (3.5 hours, face-to-face or online) were available for participants if needed.

The specialist stop smoking service (SSS) consisted of a single half-hour session combining motivational interviewing and CBT, delivered by a therapist. Advice on pharmacological treatment was also discussed during the meeting (vouchers or letter to GP were provided depending on the treatment chosen), and a quit date was decided. Follow-up sessions were available at 1, 2, and 3 weeks post quit date.

Participants were followed up at 1, 3, and 6 months after their quit date. The outcomes assessed were smoking cessation at 6 months (self-reported, less than 5 cigarettes in total verified using expired carbon monoxide), and the use of pharmacological treatment.

From the initial 2,115 participants assessed for eligibility, 620 were randomised (half of them assigned to each group). No differences were identified in the baseline characteristic of the participants between the groups when comparing them.

No differences were identified in the quit rates at any of the follow-up points between the groups compared. Significant differences were identified in the pharmacotherapy usage between the groups (SSS group 159 participants, 95.7%; ACE group 64 participants, 47.8%). The most common pharmacological treatments received were NRT, electronic cigarettes, and varenicline.

A post-hoc non-inferiority analysis was conducted using a non-inferiority limit for the risk difference of 5%. Based on the results obtained in the primary outcome assessed (absolute risk difference 4.5; 95% confidence interval -1.4 to 10.4), ACE is not inferior to SSS for achieving continuous abstinence for 26 weeks.

Limitations of the study include risk of selection bias that could affect the representativeness of the target population in the study. People with a history of respiratory or psychiatric disease were excluded, so only healthy people were recruited. Younger and older people were not well represented in the sample as well as those with a lower educational level. The sample was mostly white (448, 72.2%), with small representation of other ethnic groups. There is also a risk of performance bias due to knowledge of the allocated interventions by participants and personnel, and detection bias due to no blinding of outcome assessment. The non-inferiority analysis was not planned and a post-hoc analysis was conducted. This introduces a risk of bias because the selection of the non-inferiority margin was done once the results of the study were available.

Information considered when developing the NICE guideline

The NICE guideline includes a review question assessing behavioural support alone (delivered to a person or a group). Evidence from 9 Cochrane systematic reviews (SR) and 1 non-Cochrane SR assessing individual support, group support and mixed individual and group support strategies was identified. The studies evaluating mixed individual and group support strategies focused on young people, motivational interviewing, or included any behavioural approach or advice and focused on the deliverer or setting.

One Cochrane SR focused on the effectiveness of group smoking cessation interventions. It found that group-based behavioural programmes were more effective than no intervention, self-help or brief advice. No differences were identified between group style interventions and intensive individual counselling. It was considered that behavioural support interventions, across a range of intervention types and settings, group or individually delivered are effective in helping people to stop smoking. Most of the evidence included in the SRs identified came from the USA. In the SR assessing group-based interventions, only those group behaviour therapy programmes delivering information, advice, and encouragement or CBT over at least 2 sessions were included. This Cochrane SR has not been updated since its publication in 2017. The glossary of the guideline includes a description of group behavioural support interventions. They involve meetings in which information, advice and some form of behavioural intervention is provided to participants. At least 4 sessions are offered on a weekly basis after the quit date, and it is normally combined with pharmacological treatment. ACE includes 1 group session but, in the studies, participants were offered up to 2 further sessions if needed.

Equalities

Young and older people as well as those with a lower educational level were not well represented in the studies. Only English speakers were included, so effectiveness for non-English speaking minority groups was not assessed. Although these issues are not specific to ACE (and could occur in other similar studies) and in fact, the book has been translated into different languages, these are important equality considerations if the guideline is to be updated.

Overall decision

The evidence identified from 2 randomised controlled trials showed that ACE has significantly higher quit rates compared with Quit.ie and is not inferior to SSS provided in the UK for achieving continuous abstinence. No serious adverse events were associated with ACE in the 2 trials assessed. The studies report results at different time points (including 6 months and 12 months of follow up) and use validated tools for evaluating relevant outcomes. The studies have some limitations, including risk of selection, performance, and detection bias. Also, the resource use and cost implications were not assessed in the studies evaluated. The current guideline recommends that commissioners and provides 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. Evidence identified in this surveillance review suggests that ACE is a non-pharmacological option that could be considered for adults who want to stop smoking.

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