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Electronic cigarettes for smoking cessation.  
*Cochrane Database of Systematic Reviews* 2016, Issue 9. Art. No.: CD010216.  
DOI: [10.1002/14651858.CD010216.pub3](https://doi.org/10.1002/14651858.CD010216.pub3).

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[Intervention Review]

# Electronic cigarettes for smoking cessation

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**Editorial group:** Cochrane Tobacco Addiction Group.

**Publication status and date:** Edited (no change to conclusions), published in Issue 12, 2016.

**Citation:** Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P. Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews* 2016, Issue 9. Art. No.: CD010216. DOI: [10.1002/14651858.CD010216.pub3](https://doi.org/10.1002/14651858.CD010216.pub3).

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## ABSTRACT

### Background

Electronic cigarettes (ECs) are electronic devices that heat a liquid into an aerosol for inhalation. The liquid usually comprises propylene glycol and glycerol, with or without nicotine and flavours, and stored in disposable or refillable cartridges or a reservoir. Since ECs appeared on the market in 2006 there has been a steady growth in sales. Smokers report using ECs to reduce risks of smoking, but some healthcare organizations, tobacco control advocacy groups and policy makers have been reluctant to encourage smokers to switch to ECs, citing lack of evidence of efficacy and safety. Smokers, healthcare providers and regulators are interested to know if these devices can help smokers quit and if they are safe to use for this purpose. This review is an update of a review first published in 2014.

### Objectives

To evaluate the safety and effect of using ECs to help people who smoke achieve long-term smoking abstinence.

### Search methods

We searched the Cochrane Tobacco Addiction Group's Specialized Register, the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, Embase, and PsycINFO for relevant records from 2004 to January 2016, together with reference checking and contact with study authors.

### Selection criteria

We included randomized controlled trials (RCTs) in which current smokers (motivated or unmotivated to quit) were randomized to EC or a control condition, and which measured abstinence rates at six months or longer. As the field of EC research is new, we also included cohort follow-up studies with at least six months follow-up. We included randomized cross-over trials, RCTs and cohort follow-up studies that included at least one week of EC use for assessment of adverse events (AEs).

### Data collection and analysis

We followed standard Cochrane methods for screening and data extraction. Our main outcome measure was abstinence from smoking after at least six months follow-up, and we used the most rigorous definition available (continuous, biochemically validated, longest follow-up). We used a fixed-effect Mantel-Haenszel model to calculate the risk ratio (RR) with a 95% confidence interval (CI) for each study, and where appropriate we pooled data from these studies in meta-analyses.

### Main results

Our searches identified over 1700 records, from which we include 24 completed studies (three RCTs, two of which were eligible for our cessation meta-analysis, and 21 cohort studies). Eleven of these studies are new for this version of the review. We identified 27 ongoing

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studies. Two RCTs compared EC with placebo (non-nicotine) EC, with a combined sample size of 662 participants. One trial included minimal telephone support and one recruited smokers not intending to quit, and both used early EC models with low nicotine content and poor battery life. We judged the RCTs to be at low risk of bias, but under the GRADE system we rated the overall quality of the evidence for our outcomes as 'low' or 'very low', because of imprecision due to the small number of trials. A 'low' grade means that 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. A 'very low' grade means we are very uncertain about the estimate. Participants using an EC were more likely to have abstained from smoking for at least six months compared with participants using placebo EC (RR 2.29, 95% CI 1.05 to 4.96; placebo 4% versus EC 9%; 2 studies; 662 participants. GRADE: low). The one study that compared EC to nicotine patch found no significant difference in six-month abstinence rates, but the confidence intervals do not rule out a clinically important difference (RR 1.26, 95% CI 0.68 to 2.34; 584 participants. GRADE: very low).

Of the included studies, none reported serious adverse events considered related to EC use. The most frequently reported AEs were mouth and throat irritation, most commonly dissipating over time. One RCT provided data on the proportion of participants experiencing any adverse events. The proportion of participants in the study arms experiencing adverse events was similar (ECs vs placebo EC: RR 0.97, 95% CI 0.71 to 1.34 (298 participants); ECs vs patch: RR 0.99, 95% CI 0.81 to 1.22 (456 participants)). The second RCT reported no statistically significant difference in the frequency of AEs at three- or 12-month follow-up between the EC and placebo EC groups, and showed that in all groups the frequency of AEs (with the exception of throat irritation) decreased significantly over time.

### Authors' conclusions

There is evidence from two trials that ECs help smokers to stop smoking in the long term compared with placebo ECs. However, the small number of trials, low event rates and wide confidence intervals around the estimates mean that our confidence in the result is rated 'low' by GRADE standards. The lack of difference between the effect of ECs compared with nicotine patches found in one trial is uncertain for similar reasons. None of the included studies (short- to mid-term, up to two years) detected serious adverse events considered possibly related to EC use. The most commonly reported adverse effects were irritation of the mouth and throat. The long-term safety of ECs is unknown. In this update, we found a further 15 ongoing RCTs which appear eligible for this review.

## PLAIN LANGUAGE SUMMARY

### Can electronic cigarettes help people stop smoking, and are they safe to use for this purpose?

#### Background

Electronic cigarettes (ECs) are electronic devices that produce an aerosol (commonly referred to as vapour) that the user inhales. This vapour typically contains nicotine without most of the toxins smokers inhale with cigarette smoke. ECs have become popular with smokers who want to reduce the risks of smoking. This review aimed to find out whether ECs help smokers stop smoking, and whether it is safe to use ECs to do this.

#### Study characteristics

This is an update of a previous review. The first review was published in 2014 and included 13 studies. For this update, we searched for studies published up to January 2016 and found 11 new studies. Only two of the included studies are randomized controlled trials and followed participants for at least six months. These provide the best evidence. The remaining 22 studies either did not follow participants for very long or did not put people into treatment groups so could not directly compare ECs with something else. These studies can tell us less about how ECs might help with quitting smoking but can tell us about short-term safety. The two randomized trials, conducted in New Zealand and Italy, compared ECs with and without nicotine. We judged these studies to be at low risk of bias. In one study, people wanted to quit smoking, while in the other study they did not. The trial in people who wanted to quit smoking also compared ECs to nicotine patches.

#### Key results

Combined results from two studies, involving 662 people, showed that using an EC containing nicotine increased the chances of stopping smoking in the long term compared to using an EC without nicotine. We could not determine if EC was better than a nicotine patch in helping people stop smoking, because the number of participants in the study was low. More studies are needed to evaluate this effect. The other studies were of lower quality, but they supported these findings. None of the studies found that smokers who used EC short- to mid-term (for two years or less) had an increased health risk compared to smokers who did not use ECs.

#### Quality of the evidence

The quality of the evidence overall is low because it is based on only a small number of studies, although these studies were well conducted. More studies of ECs are needed. Some are already underway.