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## Interventions for quitting vaping (Protocol)

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[Intervention Protocol]

# Interventions for quitting vaping

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## ABSTRACT

### Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To conduct a living systematic review to assess the benefits and harms of interventions to help people quit vaping compared to each other or to placebo or no intervention.

We will also assess how these interventions affect the use of combustible tobacco, and whether effects vary based on participant characteristics.

## BACKGROUND

### Description of the condition

Vapes or electronic cigarettes are handheld electronic vaping devices that produce an aerosol by heating an e-liquid. The e-liquid, usually comprising propylene glycol (a synthetic liquid substance that absorbs water) and/or glycerol (a naturally occurring alcohol), with or without nicotine and flavours, is stored in disposable or refillable cartridges or a reservoir or 'pod'. Nicotine-containing vapes or electronic cigarettes are considered less harmful to health than tobacco cigarettes, and in some countries are endorsed as smoking cessation aids. ([1][2][3][4]) However, there are concerns about their potential harm to health if used long-term by former smokers or by people who have never smoked, with particular concerns relating to young people, as most tobacco use is initiated at a young age. ([5][6][7][8]) Young people who take up vaping nicotine who have never smoked may develop a dependence on nicotine, which some are concerned could mean they are more likely to try other more harmful nicotine containing products, such as combustible cigarettes. ([9][10][11]) We do not yet have any evidence on the long-term harms of nicotine vaping in the absence of a tobacco smoking history, therefore potential health harms of vaping itself are an additional, as yet unquantified, concern. Even if modest in comparison to smoking tobacco, it is unlikely that vaping nicotine will be completely risk or harm free. Consequently, there are clear reasons to support people to stop nicotine vaping. There are also various reasons that people who have used vapes for smoking cessation (people of any age) may ultimately want to stop using them. Commonly cited reasons include cost, concerns around health, perceptions of friends and family, concerns about dependence on nicotine, and stigma. ([12]) However, as nicotine is an addictive substance, and advancements in vaping technology make them increasingly effective at delivering nicotine to the brain, it may not be easy for people to discontinue their use. In addition, people who have used vapes to quit smoking need to ensure that they are no longer at risk of relapsing to smoking if they stop using vapes. Where nicotine vaping is supported as a smoking cessation aid, there is a growing awareness that support to stop using vapes may be needed once people have fully quit combustible cigarettes.

There is currently a paucity of evidence about the best methods to stop using vapes. However, as the uptake of vaping rises, more research is emerging on how to help people quit vaping, with a number of ongoing studies currently registered. More relevant evidence is thus likely to emerge in the near future, making a living systematic review approach appropriate at present. Our living review approach is well suited to collate and assess the evidence from new and ongoing studies as this information emerges.

### Description of the intervention and how it might work

Treatments to support people to quit vaping may include both pharmacological and behavioural interventions. Potential pharmacological treatments include nicotine replacement therapy (gums, patches, lozenges, etc.), varenicline, bupropion, and cytisine, as are used in approaches to support people to stop smoking. 'Traditional' stop-smoking behavioural interventions may also be adopted or adapted for use to support people to quit vaping, such as in-person or telephone-based counselling (one-to-one or group-based) or alternative therapies such as hypnotherapy or acupuncture. Additionally, intervention delivery approaches, such as text message support, smartphone apps, or

online support tools, could be used. National Institute for Health and Care Excellence (NICE) guidance recommends that the National Health Service (NHS) provide support to help vape or e-cigarette users stop when they are ready to do so, but does not set out how best to achieve this. [13]

Vaping cessation interventions may target different mechanisms of change that should be made explicit or classified. Nicotine replacement strategies offer an approach based on harm reduction principles, substituting the nicotine consumed by vaping with nicotine delivered in other forms (e.g. transdermally or across oral mucous membranes as opposed to inhaling nicotine into the lung through vaping). Cytisine and varenicline (nicotine receptor partial agonists) work by blocking some of the receptors in the brain associated with nicotine addiction, thereby reducing the rewarding effects of smoking. [14] Bupropion increases dopamine release in the brain mesolimbic pathways that are stimulated by other addictive substances. [15] These interventions have been well tested in smoking cessation trials, with evidence of effectiveness for smoking cessation. [16] However, their use for vaping cessation is in its infancy, and no clear conclusions have been drawn on their effectiveness for this purpose as yet.

Behavioural interventions, whether delivered via counselling or using digital delivery techniques, are usually based on a psychological theory of change. [17] For example, text messages may be developed to address different theorised aspects of addictive behaviour, and thus to attempt to intervene with specific 'behaviour change techniques'. It is generally accepted that nicotine addiction is a complex behaviour, and behavioural interventions will thus seek to address different aspects of the behaviour (e.g. motivation, self-efficacy, beliefs) in order to attempt to influence behaviour change.

The evidence base for how alternative therapies may work is somewhat unclear, with different theories suggesting how these therapies may work for some people. Personal beliefs can be powerful drivers of behaviour, thus 'belief' in a therapy, the placebo effect, or being persuaded to change (e.g. through hypnotherapy), could be potential mechanisms of change for some people.

### Why it is important to do this review

There is currently no guidance based on direct vaping evidence on how to stop vaping or the most effective ways to ensure long-term quitting, and minimise the risk of smoking relapse and other unwanted effects of treatment. In addition, a review of the evidence, including literature published to September 2021, concluded that very little interventional research had been conducted, precluding any conclusions on the benefits and harms of vaping cessation interventions. [18] As smoking is considerably more harmful than vaping, it is critical that vaping cessation efforts do not lead to uptake or re-uptake of smoking.

## OBJECTIVES

To conduct a living systematic review to assess the benefits and harms of interventions to help people quit vaping compared to each other or to placebo or no intervention.

We will also assess how these interventions affect the use of combustible tobacco, and whether effects vary based on participant characteristics.

## METHODS

The living review format means that the review will be continually updated, and new evidence incorporated as it becomes available. We will conduct database searches monthly, contact authors of ongoing studies, and make our monthly search updates publicly available at [www.cebm.ox.ac.uk/research/electronic-cigarettes-for-smoking-cessation-cochrane-living-systematic-review-1](http://www.cebm.ox.ac.uk/research/electronic-cigarettes-for-smoking-cessation-cochrane-living-systematic-review-1). An update to the review will be triggered when the accumulating evidence leads to changes in any one of: the direction of effect or clinical significance of the findings for one or more outcomes; the certainty (e.g. GRADE rating) of one or more outcomes; or the availability of studies investigating new settings, populations, interventions, comparisons, or outcomes. When an update is triggered, we will incorporate new data into meta-analyses and tables in RevMan software.[19]

For full methods relating to the living status of this review, see [Supplementary material 2](#).

We will follow the Methodological Expectations for Cochrane Intervention Reviews (MECIR) when conducting the review and PRISMA 2020 for the reporting.

### Criteria for considering studies for this review

#### Types of studies

Randomised controlled trials (RCTs) (including cross-over trials). We will not exclude studies based on year or language of publication.

#### Types of participants

People of any age, regardless of tobacco use status, currently vaping any kind of nicotine vape. 'Current vaping' will be defined as per study authors, at entrance into the study, and can include people concurrently smoking tobacco and vaping. We will include studies that enrol people regardless of vaping behaviour, but which provide a group of vape users with vaping cessation intervention(s), only where relevant outcomes are available for the subset of the population considered to be current vape users.

We will not include studies exclusively in people who do not vape nicotine (e.g. in people vaping tetrahydrocannabinol, or non-nicotine e-cigarettes). Where studies do not define type of vaping, or include people who vape both nicotine and other types of e-liquid, we will include these studies, separating out and only extracting information on the nicotine vaping subgroup, where available. If separate data for this group are not available, we will test exclusion of the study in a sensitivity analysis.

#### Types of interventions

Any intervention designed to support people who vape to stop vaping. This could include:

- behavioural interventions of any intensity, modality, or frequency and from any provider;
- pharmacological interventions, such as cytisine, nicotine replacement therapy, varenicline, and bupropion, of any dosage or frequency;
- changes in characteristics of vapes, such as reductions in nicotine content;
- any combination of the above interventions.

## Outcome measures

### Critical outcomes

- Vaping cessation at the longest follow-up point, at least six months from the start of the intervention, measured on an intention-to-treat (ITT) basis using the strictest definition of abstinence, preferring biochemically validated results where reported.
- Change in combustible tobacco use between baseline and the longest follow-up point, at least six months from the start of the intervention. Combustible tobacco use includes tobacco cigarettes, loose roll-your-own, cigars, cigarillos, and pipe tobacco. Dependent on smoking status at baseline, this could be continued smoking, uptake of smoking, or smoking cessation. We will measure these as defined by the study authors; however, where there are multiple measures of cessation, we will use the strictest definition, i.e. measured on an ITT basis preferring continuous to point prevalence abstinence, and biochemically validated over self-reported results.
- Number of participants reporting serious adverse events (SAEs) at one week or longer (as defined by the study authors). If SAEs are measured at more than one time point, we will use the measure at longest follow-up.

### Important outcomes

- Vaping cessation at three or more but less than six months from the start of the intervention, measured as per primary vaping cessation outcome.
- Change in combustible tobacco product use between baseline and the longest follow-up point, three or more but less than six months from the start of the intervention, measured as per primary change in tobacco use outcome.
- Number of participants reporting adverse events at one week or longer (as defined by the study authors). If adverse events are measured at more than one time point, we will take the measure at longest follow-up.
- Number of people vaping a substance other than nicotine at longest follow-up, at three months follow-up or longer.
- Changes in weight between baseline and longest follow-up point.
- Changes in alcohol use status between baseline and longest follow-up point.
- Changes in the following measures at longest follow-up (one week or longer):
  - carbon monoxide (CO), as measured through breath or blood;
  - blood pressure;
  - heart rate;
  - blood oxygen saturation;
  - lung function measures;
  - cotinine;
  - known toxins/carcinogens, as measured through blood or urine (toxicant names and abbreviations are listed in Appendix 2 of our review on e-cigarettes for smoking cessation). [16]

Studies must report one of the critical or important outcomes above to be eligible for inclusion.

### Interventions for quitting vaping (Protocol)

## Search methods for identification of studies

### Electronic searches

We will conduct searches on the first working day of each month. We will search the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL via CRS-Web, from 1 January 2004);
- MEDLINE (via Ovid SP, from 1 January 2004);
- Embase (via Ovid SP, from 1 January 2004);
- PsycINFO (via Ovid SP, from 1 January 2004);
- ClinicalTrials.gov (via our search of CENTRAL, from 1 January 2004);
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (via our search of CENTRAL, from 1 January 2004).

We will conduct an initial search employing a targeted search strategy using terms focused on vape use cessation (listed in [Supplementary material 1](#)). This search will be limited to 2004 to present because vapes were not available before 2004. Subsequent monthly searches will be conducted combined with the monthly searches for the Cochrane review of electronic cigarettes for smoking cessation. [16] The search terms for these searches are broad enough to retrieve studies eligible for either review, using free text and subject headings relating to vape use, alongside study design filters matching our inclusion criteria. All ongoing search strategies are listed in [Supplementary material 1](#).

### Searching other resources

We will search the reference lists of eligible studies found in the literature searches. We will contact authors of known and eligible studies for further information when needed. We will also search abstracts from the Society for Research on Nicotine and Tobacco (SRNT) Annual Meetings.

## Data collection and analysis

### Selection of studies

We will immediately screen any new citations retrieved by the monthly searches using Covidence.[20] Two review authors will independently check the titles and abstracts of studies generated by the search strategy for relevance against the eligibility criteria. Any disagreements will be resolved through discussion with a third review author. We will obtain the full-text versions of papers considered to be potentially relevant. Two review authors will independently assess the full-text reports for inclusion in the review. Any disagreements will be resolved through discussion with a third review author. Where necessary, we will contact study investigators for further information to aid our decision-making. We will record and report reasons for exclusion of studies excluded at the full-text stage.

We will screen and include studies reported in any language, and arrange for the translation of non-English language papers. In the first instance, we will attempt translation through Google Translate. Where this is not sufficient, we will ask a native speaker to translate relevant parts of the paper to allow for screening. Where we find multiple citations of the same study, we will group them into one study record with a single study ID.

## Data extraction and management

For each included study, two review authors will independently extract data to be used in analyses (including covariates) and for risk of bias assessment. Study characteristics will be extracted by a single review author. We will cross-check dual extraction, with any disagreements between review authors resolved through discussion or by involving a third review author when necessary. Data extraction processes will be carried out using Covidence and piloted before use. We will import extracted and checked data into RevMan software.[19][20] See [Supplementary material 3](#) for the information we plan to extract from the included studies.

### Risk of bias assessment in included studies

Two review authors will independently assess risk of bias for each included study, using the methods set out by the Cochrane Tobacco Addiction Review Group [21], which is based on the domains from the Cochrane RoB 1 tool [22]. This approach uses a domain-based evaluation that addresses seven different areas: random sequence generation; allocation concealment; blinding of participants and providers; blinding of outcome assessment; incomplete outcome data; selective outcome reporting; and other potential sources of bias. We will assign a grade (low, high, or unclear) for each domain. Any disagreements will be resolved by discussion or by consulting a third review author when required.

Specific considerations about judgements for individual domains in this review are outlined below and are in line with our existing review 'Electronic cigarettes for smoking cessation' [16].

- Blinding of participants and providers: we will not assess this domain for studies solely investigating behavioural interventions, as specific risk of bias guidance developed by the Cochrane Tobacco Addiction Group advises this due to it being impossible to blind these types of interventions.[21] For studies of pharmacological interventions that do not use blinding, we will consider studies at low risk of bias for this domain if the intervention was compared to a placebo or an active control of similar intensity, as we judge performance bias to be unlikely in this circumstance. However, if a study was unblinded, and the comparator group was a minimal-intervention control or of lower intensity than the intervention group, we will consider the study to be at high risk of bias for this domain.
- Blinding of outcome assessment: following the standard methods of the Cochrane Tobacco Addiction Review Group, we will consider studies to be at low risk of detection bias if they assess our primary outcome(s) objectively, or if the intensity of the intervention was similar between groups, or both.[21]
- Incomplete outcome data: again, following the standard methods of the Cochrane Tobacco Addiction Group, we will rate studies at high risk of attrition bias if loss to follow-up was greater than 50% overall, or if there was a difference in follow-up rates of more than 20% between study arms at the longest follow-up used in our analysis.[21]

We will judge studies to be at high risk of bias overall if they are rated at high risk in at least one domain, and at low risk of bias overall if they are judged to be at low risk across all domains evaluated. We will judge the remaining studies to be at unclear risk of bias overall.

Where a study reports on more than one of our outcomes of interest, we will assess risk of bias for our critical outcomes only.

## Measures of treatment effect

We will calculate risk ratios (RR) and their 95% confidence intervals (CI) for dichotomous outcomes for each study. For continuous outcomes, we will compare the difference between the relevant intervention and control groups using mean differences (MD) and 95% CI. We will use data reported at the longest follow-up point for all outcomes.

## Unit of analysis issues

In the case of trials with multiple intervention or comparator arms, we will not combine data between arms, unless this is how the information was presented by study authors, or there is no evidence of difference between similar trial arms for the outcome of interest. We will note in our analyses where this was the case.

If cluster-randomised trials are eligible for inclusion, we will assess whether study authors have adjusted for clustering, and whether this had an impact on the overall result. Where clustering appears to have had little impact on the results, we will use unadjusted quit-rate data; however, if clustering does appear to have impacted the results, we will adjust for this using the intraclass correlation (ICC) reported by the paper (or where this is not provided, one used in a similar study).

In the case of eligible cross-over trials (ensuring that the first assignment period is sufficiently long to meet our inclusion criteria), we will extract and report on results at the end of the first assignment period, where available.

## Dealing with missing data

When assessing change in tobacco use, we will use the standard Cochrane Tobacco Addiction Group approach, treating participants with missing data as still smoking. We will make the same assumption for vaping when assessing whether vaping cessation has taken place, that is assuming those lost to follow-up are continuing to vape.

We will base the proportion of people affected by SAEs/adverse events on the number of people available for follow-up, and not the number randomised, where reported.

For other continuous outcomes, we will use complete-case data and will not attempt to impute missing values.

## Reporting bias assessment

As noted above, we will take selective reporting into consideration as part of the risk of bias assessment for each study. When interpreting the results, we will account for this, as well as the potential findings of studies that we know have taken place, but for which we do not have the results.

Reporting bias can also be assessed using funnel plots, where 10 or more studies contribute to a given outcome. [23] We will therefore generate funnel plots for any analyses that include sufficient studies to support this approach.

## Synthesis methods

We will take the clinical variance of studies into account when grouping them for analyses. Studies will be split into comparisons based on intervention and comparator type (e.g. studies investigating behavioural interventions will not be grouped

with those investigating pharmacological interventions, and different types of pharmacological interventions will also be grouped separately).

Where appropriate, we will carry out pairwise meta-analyses for comparisons for which there is more than one eligible RCT. We will use random-effects Mantel-Haenszel models to calculate pooled RR with 95% CI for dichotomous outcomes. For continuous outcomes, we will calculate pooled MDs (or standardised MDs for studies using different measures for the same construct), using the inverse variance approach (also with 95% CI).

Where meta-analysis is not appropriate, we will synthesise comparisons and outcomes using effect direction plots.[23]

## Investigation of heterogeneity and subgroup analysis

We will assess the clinical and methodological diversity between studies to guide decisions as to whether data should be pooled. Where we pool studies using meta-analysis, we will calculate the  $I^2$  statistic.[22][23] We will consider a value greater than 50% as evidence of substantial heterogeneity. Where an  $I^2$  exceeds 75%, we will consider whether it is appropriate to present a pooled result based upon the directions of the contributing effects (e.g. where all studies show a benefit of an intervention, it may still be deemed appropriate to present a pooled estimate despite differing magnitudes of effect across studies).

Where possible, we will use subgroup analyses to investigate the following variables as potential moderators of effects.

- Vaping/smoking history. We expect some studies may be carried out in people who have never smoked and some to be carried out in people who have used vapes to reduce or quit smoking.
- Frequency of vaping. We expect interventions may operate differently based on the levels of vaping at baseline.
- Age. Some interventions may specifically be aimed at young people, as there are specific concerns around vaping in young people who have never smoked. It may be that interventions in young people target different elements of behaviour than those in adults, and we will test whether the effects of interventions differ in younger people compared to adults.
- Relevant intervention characteristics, such as the intensity, provider, or modality of behavioural interventions, or the dose, duration, or timing of pharmacological interventions.
- Interventions conducted in specific groups, e.g. based on level of nicotine addiction.

We will assess the significance of subgroup differences based on whether the effects of subgroups would lead to differing clinical interpretations and the  $I^2$  statistic (interpreted according to the thresholds discussed earlier in this section).

We may also be able to use meta-regression to investigate the following variables as moderators of our aggregate outcomes.

- Average age of participants in the study
- Length of vaping at baseline (as reported by study authors)

We will also extract any reports of analyses of associations between outcomes and our moderators of interest. We will synthesise these narratively using effect direction plots.[23]

### Equity-related assessment

We do not plan to investigate health inequity in this review, beyond the investigations specified above.

### Sensitivity analysis

We will carry out sensitivity analyses for all meta-analyses by removing studies:

- judged to be at overall high risk of bias;
- funded by the manufacturer/provider of the intervention;
- where not all participants vaped nicotine, and we are unable to separate out those people who only vaped nicotine.

We will judge effects sensitive to these exclusions if the resulting effect would lead to a different clinical interpretation than the original effect.

### Certainty of the evidence assessment

We will carry out grade assessments and create summary of findings tables for our critical outcomes (i.e. vaping cessation at six months follow-up or longer; change in combustible tobacco use between baseline and six months follow-up or longer; number of people reporting SAEs at one week follow-up or longer) using GRADEpro GDT software.<sup>[24]</sup>

We will include the following in our summary of findings table:

- pharmacotherapies used for smoking cessation compared to no pharmacotherapy/placebo, i.e. nicotine replacement therapy, bupropion, cytisine, varenicline;
- behavioural support compared to usual care by modality, e.g. counselling, text message support;
- change to the characteristics of vapes compared to no change.

Following standard Cochrane methodology, we will use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of the body of evidence for each outcome, and to draw conclusions about the certainty of the evidence within the text of the review.

### Consumer involvement

We held a consumer planning consultation in June 2023, and will hold two further consumer consultations over the next 18 months. At these meetings we will consult on protocol, dissemination, and future planning. Our first meeting was an online workshop with five consumer representatives and two review authors (ARB and NL). At this workshop, participants concluded that it would be clearer to use the term 'vape' rather than 'e-cigarette' in the review title. We amended the title in response to this feedback. When the results of analyses are available for the first version of this review, we plan to hold a second workshop with the panel to present findings and co-develop dissemination plans. We will ask for further dissemination ideas online. Eighteen months into the project, we will run a third consumer workshop to determine next steps. This will incorporate an evaluation of the living systematic review approach, dissemination used so far, and suggestions for improvements and new ways of working. This will allow us to assess whether it is appropriate and useful to continue the review. Our consumer panel have diverse vaping and smoking experiences

and are from differing social backgrounds. All consumers are reimbursed for their time.

We have a consumer co-applicant (CJ) who has experience of smoking combustible cigarettes and using vapes. Through phone, email, online, and in-person project meetings, CJ will contribute to the proposed work, meeting with the chair to discuss the agenda beforehand, and debrief afterwards.

We will run a survey disseminated on public-facing forums, such as Gumtree and Nextdoor, and Twitter to gain the input of people who may not volunteer to be part of a more formal panel or attend a workshop in person (consumer input has indicated different groups may be comfortable with different levels of involvement, and we want to be as inclusive as possible).

We will use Cancer Research UK's consumer toolkit and Cochrane consumer resources to assist our consumer involvement.

## SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: [10.1002/14651858.CD016058](https://doi.org/10.1002/14651858.CD016058).

**Supplementary material 1** Search strategies

**Supplementary material 2** Justification and methods for 'Living Review' approach

**Supplementary material 3** Data to be extracted from included studies.

## ADDITIONAL INFORMATION

### Acknowledgements

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### Editorial and peer-reviewer contributions

Cochrane Central Editorial Team supported the authors in the development of this protocol.

The following people conducted the editorial process for this article.

- Sign-off Editor (final editorial decision): Peter Tugwell, University of Ottawa, Canada
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Colleen Ovelman, Cochrane Central Editorial Service
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments, and supported the editorial team): Jacob Hester, Cochrane Central Editorial Service
- Copy Editor (copy editing and production): Lisa Winer, Cochrane Central Production Service
- Peer reviewers (provided comments and recommended an editorial decision): K Michael Cummings, PhD, MPH, Department

of Psychiatry & Behavioral Sciences Medical University of South Carolina, Charleston, SC USA (clinical/content review); Professor Natalie Walker, School of Population Health, Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand (clinical/content review); Phil Kading (consumer review); Nuala Livingstone, Cochrane Evidence Production and Methods Directorate (methods review); Jo Platt, Cochrane Central Editorial Information Specialist (search review)

### Contributions of authors

Conception, design and co-ordination of the review. Search and study selection, data extraction, syntheses, risk of bias and GRADE assessment, write-up: NL, JHB, ARB

Critical appraisal, writing of protocol, and reviewing manuscript: NL, ARB, JLB, CN, TT, NAR, TF, LD, JHB

Search strategy and monthly searches, Information Specialist on project: JLB

Statistician for the project: TF

### Declarations of interest

ARB's work on this review has been supported by Cancer Research UK Project Award funding. This is not deemed a conflict of interest.

NL has received payment for lectures on systematic review methodology (Oxford University Hospitals NHS Foundation Trust), and has been an applicant and principal investigator on project funding to carry out research in the area of tobacco control from the NIHR Evidence Synthesis programme, Cancer Research UK (charity), Clarion Futures (charity), Oxfordshire County Council and the NIHR Oxfordshire and Thames Valley ARC, and Greater Manchester NHS Integrated Care. None of this is deemed a conflict of interest.

JLB was employed by the University of Oxford to work as a Managing Editor and Information Specialist for the Cochrane Tobacco Addiction Review Group before becoming an author on this review. During this time, he was involved in the editorial processing of the review. He is now an Editor for Cochrane. Since becoming an author, he has not been involved in the editorial process for this review. Core infrastructure funding for the Cochrane Tobacco Addiction Group was provided by the National Institute for Health and Care Research (NIHR) to the University of Oxford.

CN has received an honorarium from Vox Media for filming a 'nicotine explainer' on the role of nicotine in addiction. This is not deemed a conflict of interest. CN is a member of the advisory council for 'Action on Smoking and Health (ASH)'. CN is co-principal investigator on an ongoing trial (protocol) Cessation of Smoking Trial in the Emergency Department (CoSTED), National Institute for Health Research, Health Technology Assessment. NIHR129438.

TT has no known conflicts of interest. TT is a Cochrane editor, but was not involved in the editorial process for this protocol.

NAR has received royalties from UpToDate, Inc., for chapters on electronic cigarettes and occasional fees from academic hospitals or professional medical societies for lectures on smoking cessation that include discussion of electronic cigarettes. NAR was a member of the committee that produced the 2018 National Academies of Science, Engineering, and Medicine's Consensus Study Report on

the Public Health Benefits of E-cigarettes. She was unpaid for this work. NAR is employed by Massachusetts General Hospital (MGH). Outside the topic of e-cigarettes, NAR is a consultant for Achieve LifeSciences, which is developing an investigational smoking cessation medication for US Food and Drug Administration (FDA) approval (cytisine), and her institution (MGH) receives a grant from the company as a site for a clinical trial testing the safety and efficacy of cytosine. NAR holds grants from the National Institutes of Health (NIH) for research work.

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### **Registration and protocol**

Protocol (2023) DOI

Cochrane approved the proposal for this review in April 2024.

### **Data, code and other materials**

Data sharing not applicable to this article as it is a protocol, so no datasets were generated or analysed.

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