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# Community-based interventions for the prevention or management of dental caries in children (Protocol)

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[Intervention Protocol]

# Community-based interventions for the prevention or management of dental caries in children

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## ABSTRACT

### Objectives

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

To undertake network meta-analysis (NMA) and component network meta-analysis (CNMA) to explore the comparative effectiveness of different community-based interventions, and the components within the interventions used singly or in combination, for the prevention or management of dental caries in children.

# BACKGROUND

## Description of the condition

The global burden of oral disease is increasing, with dental caries being the most widespread non-communicable disease; it is a major public health concern [1]. The prevalence of untreated caries in primary teeth ranges from 18.7% to 53.2% globally, with those living in lower-income countries most impacted [1].

Caries is a debilitating condition which may cause children substantial pain [2, 3], difficulty eating [4], and is associated with poorer levels of nutrition [5]; it may also have wider impacts on quality of life [6]. Caries occurs when teeth demineralise; this happens following exposure to acids which are released by oral bacteria during the metabolisation of sugars [7]. It is known that children who develop caries in their primary teeth are at greater risk of developing future caries in permanent teeth and being impacted across their life-course [8].

Caries is, in most cases, a completely preventable disease; optimal oral health behaviours are key to prevention. Where caries develops, it can be treated and managed by professional intervention. Access to dental health services is a challenge around the world for a variety of reasons, including insufficient workforce and low levels of accessible provision. Where provision exists, barriers to access include cost to the individual as well as low perception of need. Such barriers may be felt far more by people living in low-income communities.

## Description of the intervention and how it might work

In otherwise healthy children, caries is largely preventable through the adoption and maintenance of optimal oral health behaviours, including regular toothbrushing with a fluoride toothpaste and restriction of dietary sugars [9, 10]. Regular dental attendance is generally recommended for prevention; screening and early detection and diagnosis of carious lesions means caries can be treated before symptoms are felt. These behaviours can keep children free from caries. Although it is clear what actions prevent and manage caries, less clear is how best to support children and families to put these actions in place. There are a variety of interventions that work at the community level; for example, education or behavioural change initiatives. Professional care may help prevent or manage caries through the provision of topical fluoride or physical barriers, including fissure sealants and pre-formed metal crowns. Screening programmes may identify individual need and lead to appropriate referrals for required treatment. Policy interventions may work to change the environment, thereby encouraging better oral health behaviours.

## Why it is important to do this review

Caries is a widespread and major public health problem globally; it is the single leading cause of admission to hospital for younger children in the UK [11]. While the incidence of caries has declined following the widespread introduction of fluoride toothpaste in the 1970s [12], levels of caries have stagnated in recent years, with some communities experiencing persistent and high levels of disease. Epidemiological research demonstrates that caries experience is consistently correlated with social deprivation [13, 14], meaning that the prevention and management of childhood caries is a matter of social justice. It is critical to provide accessible prevention and management of childhood caries to families in the community.

The James Lind Alliance Priority Setting Partnership has ranked the question addressed by this review as the number one priority for oral health [15]. This demonstrates significant interest from the public and clinical community in this area. This review aims to assess the effectiveness of community-based interventions. Data allowing, it will be possible to determine the optimal components of community-based interventions for the prevention or management of childhood caries.

Components of community-based interventions may have similar or independent mechanisms of action for preventing or managing caries. There is limited evidence to date about the components that, when delivered in combination, can produce the most beneficial effects. This review aims to help identify the benefits and harms of community-based caries prevention and management interventions and their constitutive components. A better understanding of these complex interventions and how they work (or not) could provide evidence to support the implementation of more parsimonious, efficient, and effective community-based interventions.

# OBJECTIVES

To undertake network meta-analysis (NMA) and component network meta-analysis (CNMA) to explore the comparative effectiveness of different community-based interventions, and the components within the interventions used singly or in combination, for the prevention or management of dental caries in children.

# METHODS

We will follow the guidance in the Methodological Expectations of Cochrane Intervention Reviews (MECIR) standards when conducting the review [16], and the PRISMA extension statement for reporting of systematic reviews that incorporate network meta-analyses of healthcare interventions for reporting the review [17].

## Criteria for considering studies for this review

### Types of studies

We will include randomised controlled trials (RCTs) and cluster-randomised controlled trials (cRCTs) in which participants or clusters of participants are randomly allocated to receive interventions that are delivered at community level. We will not limit the size of a community in a study (which may include a centre, or a local, regional, or larger geographic area).

We will exclude cross-over study designs because of the potential for carry-over or learned effects from the interventions, and because these study designs are problematic for the long-term nature of caries incidence.

We will not restrict studies based on language or publication dates. As well as reports of published studies, we will also include unpublished studies. We will include abstracts and contact authors to locate full study reports where necessary. If we are unable to obtain sufficient information, we will list these studies as 'awaiting classification'.

We will include references to protocols (or trial registration reports) of ongoing studies in the review, and will report details of these ongoing studies to illustrate the emerging research landscape. We will also include references of studies that have insufficient detail for inclusion in our review but may be eligible for inclusion in future review updates. For example, we may identify a recently completed study that has yet to publish results; we will include such studies in the list of studies 'awaiting classification'.

As there are many published RCTs globally, we will exclude from this review non-randomised and quasi-randomised studies of interventions (in which participants or clusters are allocated to interventions using a non-random method, such as participants' date of birth). However, we will note in supplementary materials any such studies identified from the electronic searches that would otherwise meet the eligibility criteria.

### Types of participants

We will include studies in which interventions are focused on the prevention or management of dental caries in children (from birth to 18 years of age). We will include participants irrespective of caries risk status. Interventions may be directed at children themselves (for example, in a school setting), or at the family or caregivers of children (in the home or community space, such as a family hub); we will include both, provided the intervention aims to impact the oral health of the child (or children). We will analyse outcomes recorded for the primary and permanent dentition of younger and older children separately.

Where an intervention targets a mixed population (adults and children), we will use only the data reported for the children. If the data are not reported separately for children and adults, we will contact the study authors to request separate data for the children. If we are unable to obtain the data, we will report the data for these mixed studies separately and will not include these data in statistical analysis.

### Types of interventions

We will include any intervention that aims to prevent or manage dental caries in children and is delivered in a community setting (i.e. not in a traditional dental clinic). We will not restrict eligibility by delivery, dose, duration, or intensity of the intervention. Interventions included in this review are likely to be diverse; Table 1 categorises the intervention types and details their components by mechanism of action. Studies will be eligible if they compare at least one of the intervention components with the comparator 'no intervention/placebo', or with another intervention component. For multi-component interventions, we will assume that each child received all components given to the group to which they were randomised.

For the purposes of this review, we define community-based interventions as those that aim to improve or maintain the oral health of children living within the specified community. Communities may be defined by any shared characteristics that tie them together, including but not limited to area of residence, membership of a community asset (e.g. school), socioeconomic status, ethnicity, or religious status. We will include interventions delivered in a community setting; for example, schools, nurseries, residential facilities, or in people's homes. Community settings can be broadly defined as any non-traditional medical or dental setting, and may include mobile clinics. The interventions may be delivered to an individual participant or to a group of participants, in a single session or multiple sessions. The intervention may be delivered by a dental health professional, a general health professional, an education professional, or any other person that has been charged to deliver the intervention. We will include complex interventions (i.e. including more than one component) as well as single component interventions. We consider complex interventions to comprise multiple components or target more than one behaviour, or both [18]. These components may aim to address the prevention or management of caries in different but complementary ways.

We are aware that some oral health studies of intervention efficacy/effectiveness are carried out in school settings for convenience: these settings provide access to stable populations to assess outcomes such as caries, which require longer follow-up periods. Where studies were conducted in a community setting (e.g. a school) for convenience purposes only and this can be determined by the reported aim being to test the efficacy of a medicinal product or device, we will exclude these studies as they did not set out to test a community-based intervention.

We will include comparisons in which comparator group children receive no intervention or an alternative intervention. However, we will not use studies with a 'no intervention' comparator to assess the uptake and compliance outcomes (see Outcome measures), as it is not possible to assess these outcomes in people who have received no intervention.

We have devised a typology of the included interventions and their constituent components specifically for this review (see Table 1), and piloted it on 33 potentially eligible studies identified in a scoping search. We will use this typology, which is based on published literature and expert content knowledge, to determine the principal mechanisms of action from the trial reports and trial registrations. In the unlikely event that we identify a potentially eligible study with an intervention consisting of one or more components not included in our prespecified typology, we will exclude the study from the meta-analysis but report it narratively.

## Outcome measures

### Critical outcomes

For primary dentition, we will collect data for the following outcomes.

- Caries prevention. We will collect caries data measured at the cavitation level, at a minimum of 12 months after exposure to the intervention. If a study reports data at more than one time point, we will prioritise follow-up data closest to three years. We will use the following measures for this outcome:
  - decayed, missing, or filled surfaces in the primary dentition (d(m)fs);
  - decayed, missing, or filled teeth in the primary dentition (d(m)ft);
  - proportion of children who develop caries.
- Caries management, measured as caries arrest. Arrest is indicated by a change in lesion activity from active to arrested (inactive) through visual and tactile assessment. We will include caries arrest data in the primary dentition measured at least six months after exposure to the intervention.
- Adverse effects.

For permanent dentition, we will collect data for the following outcomes.

- Caries prevention. We will collect data measured at the cavitation level, at a minimum of 12 months after exposure to the intervention. If a study reports data at more than one time point, we will prioritise follow-up data closest to three years. We will use the following measures for this outcome:
  - decayed, missing, or filled surfaces in the permanent dentition (D(M)FS) measured at the cavitation level;
  - decayed, missing, or filled teeth in the permanent dentition (D(M)FT) measured at the cavitation level;
  - proportion of children who develop caries.
- Caries management, measured as caries arrest, as indicated above. We will include caries arrest data in the permanent dentition measured at least 12 months after exposure to the intervention.
- Adverse effects.

We acknowledge that caries data (d(m)fs, d(m)ft, D(M)FS, and D(M)FT) may be reported differently across studies and may be recorded using different visual classification systems, such as the World Health Organization (WHO) classification or the International Caries Detection and Assessment System (ICDAS) [19, 20]. We will use a set of a priori rules in line with other Cochrane Oral Health reviews (see, for example, Marinho 2013 [21]) to choose the form of the caries outcome data extracted for analysis from each study (see Measures of treatment effect for details).

#### Important outcomes

- Uptake of the intervention, measured as the proportion of eligible children (or their parents/guardians) who consented to be randomised to the intervention or control group, and received at least one dose or session.
- Compliance with the intervention, measured as the proportion of children who continued to engage with the intervention throughout the duration of the study.

### Search methods for identification of studies

#### Electronic searches

Using tailored search strategies, we will search the following electronic databases for relevant trials.

- Cochrane Central Register of Controlled Trials (CENTRAL) (from inception to present).
- MEDLINE PubMed (from 1946 to present).
- Embase Ovid (from 1980 to present).
- CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature) (from 1937 to present).
- APA PsycExtra (from 1989 to present).
- APA PsycInfo (from 1806 to present).
- SSCI (Social Sciences Citation Index) (from 1985 to present).

We will impose no limitations based on language or publication type. In MEDLINE, we will combine subject-specific terms with the sensitivity-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying randomised trials [22]. We will adapt the search strategy for MEDLINE for use in the other listed electronic databases (Supplementary material 1).

We will search the following trials registries.

- World Health Organization International Clinical Trials Registry Platform (https://trialsearch.who.int/).
- US National Institutes of Health Ongoing Trials Register, ClinicalTrials.gov (https://clinicaltrials.gov/).

#### Searching other resources

We will search for further studies in the reference lists of included studies and relevant systematic reviews identified in the results of electronic database searches. In addition, we will check that none of the included studies have been retracted due to error or fraud using Retraction Watch (retractionwatch.com/). Should serious concerns be raised about the trustworthiness of any included study, we will apply the Cochrane policy for managing potentially problematic studies [23]; we will use the associated implementation guidance to apply this policy.

### Data collection and analysis

#### Selection of studies

We will import references identified from electronic sources to Covidence; we will use this software to manage the selection of eligible studies for this review [24]. Two review authors, independently and in duplicate, will screen the titles and abstracts of all references retrieved from electronic searches for possible inclusion in the review. We will obtain the full-text copies of potentially eligible articles, which we will evaluate for inclusion using the criteria specified above (Criteria for considering studies for this review); again, two review authors independently and in duplicate will evaluate these reports for inclusion. If translation is required to confirm eligibility, we will first use Google Translate; for any outstanding consensus requirements, we will seek advice from a native speaker. If additional information is required to confirm a study's eligibility, we will contact the study authors by email. We will resolve any disagreements through discussion, consulting a third review author to achieve consensus when necessary.

#### Data extraction and management

Two review authors, independently and in duplicate, will extract study characteristics and quantitative data from each included study using a data extraction form in Covidence [24], which we will initially pilot on a small sample of studies (10% of the included studies). We will contact study authors by email for clarification or to request missing data where necessary and feasible. If translation is required, we will first use Google Translate, or otherwise seek advice from a native speaker. We will resolve any disagreements through discussion, consulting a third review author to achieve consensus when necessary.

We will record the following information for each included study.

- Study characteristics: study design, study dates, comparison group.
- Participants: inclusion/exclusion criteria, recruitment centre and country, number randomised to groups, number of losses and number analysed at follow-up, baseline characteristics of clusters and participants in each group (to include PROGRESS-Plus characteristics [25], and caries using decayed, missing, or filled teeth (d(m)ft or D(M)FT for primary or permanent dentition, respectively)). For cluster-RCTs, we will also extract

the number of clusters allocated to each trial arm, the mean cluster size, and intra-cluster correlation coefficient (ICC).
- Interventions: details of intervention (to include intervention components, location of delivery, personnel involved in delivery, and person(s) to whom intervention is delivered, mode of delivery, number of sessions/doses or duration of delivery); details of comparator intervention (as applicable).
- Outcomes: review outcomes (to include measurement tool and time point of measurement), quantitative outcome data for outcomes listed in Outcome measures (e.g. mean d(m)ft/D(M)FT per trial arm, and total number analysed per trial arm); other outcomes reported by study authors.
- Other: funding sources and study author declarations of interest; study registration details; and other relevant study information.

### Risk of bias assessment in included studies

Two review authors, independently and in duplicate, will assess the risk of bias using RoB 2 [26]; we will also be guided by Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* [27]. We will resolve any disagreements through discussion, consulting a third review author to achieve consensus when necessary.

RoB 2 covers the following five domains:

- bias arising from the randomisation process;
- bias due to deviations from intended interventions;
- bias due to missing outcome data;
- bias in measurement of the outcome;
- bias in selection of the reported result.

For cluster-RCTs, we will use the most up-to-date modified RoB 2 tools for this type of study design (https://www.riskofbias.info/welcome/rob-2-0-tool).

We will prioritise the assessment of risk of bias for the study results of the critical outcomes (at time points described in Outcome measures).

We are interested in quantifying the effect of assignment to the intervention at baseline, regardless of whether the interventions were received as intended (the intention-to-treat (ITT) effect). To implement RoB 2, we will use the RoB 2 Excel tool (available at www.riskofbias.info/welcome/rob-2-0-tool/current-version-of-rob-2). For each domain, we will use the signalling questions provided by the RoB 2 tool, answering 'yes', 'probably yes', 'probably no', 'no', or 'no information'.

We will use this process to reach a risk of bias judgement for each result of low risk of bias, some concerns, or high risk of bias. Generally, the overall risk of bias score for a result is based on the least favourable assessment made for any of the domains. However, if 'some concerns' arise in multiple domains, we will assign an overall high risk of bias judgement for that result. The RoB 2 tool automatically generates a judgement regarding bias for each domain and overall bias. However, we will check these automatically-generated judgements and amend them if necessary [27].

We will use the overall risk of bias assessment in each study to inform the certainty of the evidence for the critical outcomes.

### Measures of treatment effect

#### *Relative treatment effects*

We will report the pooled effect estimates as difference in means (MD) where studies report continuous outcomes measured on the same scale, and as standardised mean difference (SMD) where studies report outcomes measured on different scales (e.g. d(m)/(e)fs, dfs, ds; 'e' stands for 'extracted'). For the purpose of interpretation, we will consider an SMD of 0.2 to indicate a small effect, an SMD of 0.5 to indicate a moderate effect, and an SMD of 0.8 to indicate a large effect [28].

We acknowledge that caries outcomes are reported differently across studies, and we will adopt the set of a priori rules developed by Cochrane Oral Health to select the outcome data for analysis from each study [21]. We will choose:

- DFS data over DMFS data, and DMFS data over DS or FS;
- 'all surface types combined' data over data for 'specific surface types' only;
- data for 'all erupted and erupting teeth combined' over data for 'erupted' only, and 'erupted' only data over 'erupting' only data;
- data from 'clinical and radiological examinations combined' over data from 'clinical' only, and 'clinical' only data over 'radiological' only data;
- net caries increment data over crude (observed) increment data;
- change-from-baseline (caries increment) scores over final scores;
- follow-up nearest to three years for caries prevention over all other lengths of follow-up, unless otherwise stated.

For dichotomous data, we will report the pooled effect estimates as odds ratios (ORs).

We will report all pooled effect estimates together with their associated 95% confidence intervals (CIs).

For the active intervention versus no intervention comparison, we will be unable to estimate the relative effect on the uptake and compliance outcomes, as it is not possible to assess these outcomes in children who have not received an intervention. For this comparison, we will report the proportion of eligible children in the active intervention arm who consented to the study and received at least one dose/session of the intervention (uptake outcome). For the compliance outcome, we will report the proportion of children in the active intervention arm who remained engaged with the intervention for the duration of the study.

#### *Relative intervention ranking*

For the network meta-analyses (NMAs), we will seek to obtain a comprehensive ranking of all interventions and components for the d(m)fs/D(M)FS and d(m)ft/D(M)FT outcomes, provided there is a well-connected network with a sufficient number of studies to inform the comparisons. Should there be a sparse number of studies informing the network, then we will not undertake this analysis as the resulting rankings could be misleading. We plan to use the surface under the cumulative ranking curve (SUCRA) and mean ranks to rank the interventions from best to worst and to estimate the probability that each intervention is the first, second, third (and so on) most effective in the network [29, 30].

### Unit of analysis issues

Where studies measure outcomes for caries prevention or management at multiple time points, we will prioritise the time points identified in Outcome measures.

We anticipate that trials in this area may randomise participants at the level of the individual or cluster (e.g. school or school class). For cluster-RCTs where the analysis has taken into account the clustering of the data, we will use the effect size as reported. Where clustering has not been accounted for, we will use Cochrane methods described in Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* to account for clustering [31]. We will inflate the variance of the reported intervention effect estimates by a design effect [31], using an estimate of the intra-cluster correlation coefficient (ICC) from the trial authors or using an ICC estimate from other published trials with comparable study characteristics.

Where appropriate, we will include multi-armed trials and account for the correlation between the effect sizes in the NMAs.

### Dealing with missing data

We will contact study authors of the selected studies where methodology or other information is unclear or missing; we will distinguish between published data and data sourced by personal communication in the review. If we are unable to source additional outcome data for missing participants, we will include only the available data in meta-analysis. If data are missing for continuous outcomes (e.g. missing standard deviations (SDs)), we will try to obtain them using methods described in Section 6.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* [32].

### Reporting bias assessment

For all included studies, we will seek prospective clinical trials registration or a prespecified analysis plan or protocol. We will use information from these reports to assess the risk of bias in the selection of the reported result. We will also assess whether studies have selectively reported findings of a particular outcome measurement or analysis. We will assess this information during the risk of bias assessment (Risk of bias assessment in included studies). In addition, we will assess the risk of bias due to missing evidence using the ROB-ME tool (https://methods.cochrane.org/bias/resources/rob-me). Two review authors will conduct these bias assessments independently and in duplicate, reaching consensus through discussion and involving a third review author to resolve any disagreements.

Where there are sufficient numbers of studies, we will use funnel plots or comparison-adjusted funnel plots for the NMAs that account for the different treatment comparisons included in the networks [29, 33].

As there is currently no established way of assessing reporting bias within CNMAs, we will limit our assessment of reporting bias to the methods described above.

### Synthesis methods

#### *Methods for direct comparisons*

We will analyse the Important outcomes using pairwise random-effects meta-analysis with studies that have sufficiently similar participants, interventions, comparisons, and measurement of outcome measures. We will pool studies regardless of the overall risk of bias judgement. For all analyses, we will report pooled results as MD, SMD, or ORs with 95% CIs. We will determine the method used to calculate the confidence interval for the summary effects based on the observed between-study variance and number of studies in the meta-analysis, according to Cochrane guidance [34]. Specifically, when the between-study variance estimate is greater than zero and the number of study results is greater than two, we will use the Hartung, Knapp, Sidik, Jonkman (HKSJ) confidence interval method for the summary effect rather than the Wald-type method, as outlined in section 10.10.4 of the *Cochrane Handbook* [34]. This reduces the risk of producing overly narrow confidence intervals (when the estimated between-study variance is zero), or overly wide confidence intervals (when the number of studies is two). We will present the findings in forest plots.

We will use the restricted maximum likelihood (REML) method to estimate the between-study variance. We will assess statistical heterogeneity in the results of the pairwise meta-analyses by visually inspecting the point estimates and CIs in the forest plots. Lack of overlap of CIs may indicate heterogeneity. We will also assess statistical heterogeneity using Cochran's test for heterogeneity and the $I^2$ statistic. We will use the thresholds outlined in the *Cochrane Handbook* to interpret the presence and extent of statistical heterogeneity [34].

#### *NMA and CNMA methods for indirect and mixed comparisons*

The use of NMA methods will enable us to simultaneously compare the effects of multiple interventions using direct and indirect sources of evidence [35]. Additional benefits arising from this approach include the ability to estimate the comparative effects of interventions that have not been previously (directly) compared, the ability to rank the relative effectiveness/safety of interventions, and increased precision of effect estimates [36, 37].

Community-based interventions for the prevention or management of caries may consist of multiple components; for example, professionally applied fluoride varnish with distributed toothbrush and toothpaste packs. The use of CNMA will allow us to disentangle the effects of the components within the interventions in order not only to determine which are effective, but also to determine the effects of reconstructed interventions [38, 39, 40]. We will use CNMA random-effects models to evaluate the effectiveness of the different components identified within the included interventions compared with no intervention/placebo or standard practice, and compared with one another. As CNMA uses evidence from all studies that have the same component within an intervention, this approach can be considered to provide more precise and more moderate effects than those obtained from a standard NMA [41].

We will conduct meta-analyses for each caries prevention and management outcome using random-effects models (Critical outcomes); we will conduct separate analyses for studies reporting caries outcomes in the primary and permanent dentition. For all analyses, we will report pooled results as MDs, SMDs, or ORs with 95% CIs and present the findings as forest plots, league tables of pairwise comparisons, and tables of rankings.

Where there is no or limited clinical and methodological heterogeneity, and where we consider the distribution of potential

effect modifiers to be sufficiently similar, then we will take the following approach to data synthesis:

- a full-interaction model (standard NMA model), whereby each possible combination of components is considered a different intervention that has its own effect, regardless of the number of components;
- an additive CNMA model that assumes that the effect of an intervention comprising two or more components is the sum of the effects of those individual components. This allows a separate effect for each of the different components but constrains the total effect of an intervention to be the sum of the relevant component effects; that is, it assumes no interaction between the different components [39, 40]; and
- a two-way interaction CNMA model that allows pairs of components to have either a larger (synergistic) or smaller (antagonistic) effect than would be expected from the sum of their effects alone [39, 40].

#### *NMA methods for indirect and mixed comparisons (full-interaction model)*

Where included studies form a connected network, we plan to conduct random-effects NMAs using frequentist methods with the netmeta package in R [42], considering each single or multi-component intervention as separate nodes in the network. We will assume a common estimate for heterogeneity variance across the different comparisons of the connected network. A graphical representation (network plot) of the different interventions will be produced to illustrate the features of the network in terms of the number and nature of interventions and the number of participants analysed per intervention. Where feasible, we will report direct, indirect, and combined estimates and their associated 95% CIs for all pairwise comparisons from each NMA. Should the number of pairwise comparisons be excessively large, we will confine this to reporting the relative effects of each intervention compared to a reference intervention for analyses of caries prevention and caries management outcomes in the main text, and list the results for the remaining comparisons in the supplementary material.

#### *Transitivity across treatment comparisons*

Transitivity requires that all competing interventions of a systematic review be jointly randomisable [35]. We will assess the clinical and methodological characteristics of the studies that form the networks for each outcome to determine whether any observed differences are likely to violate this assumption. We will compare the distribution of potential effect modifiers pertaining to characteristics of the participants and the interventions of the included studies (e.g. participant age, community water fluoridation in place, universal or targeted delivery), producing a descriptive table to facilitate assessment.

In order to conclude that the transitivity assumption has not been violated, the potential effect modifiers should be similarly distributed across the network. If the assumption of transitivity could be considered to be markedly violated – for example, in terms of substantially imbalanced distributions of effect modifiers – then we will consider whether removing an intervention from the network would provide resolution. Alternatively, we may revert to performing a series of pairwise comparisons. We will document any changes from the published protocol in this regard in the completed review.

#### *Assessment of coherence (consistency)*

We will evaluate the coherence (consistency) between the various sources of evidence for a particular relative effect in each of the NMA networks. Since different approaches to evaluation may lead to different conclusions about the magnitude of any incoherence, we will use both local and global approaches.

We will use the 'Separating Indirect from Direct Evidence' (SIDE) local approach for investigating incoherence [43]. We will calculate the magnitude of the difference between direct and indirect estimates and the 95% CI to evaluate the presence of incoherence in each loop of the network; and plot the results in a forest plot using the netsplit function in R [42]. As tests of incoherence typically have low power, we will additionally inspect the 95% CIs for the incoherence factors to determine whether they include clinically important differences [35].

We will use the netmeta package in R to calculate the between-designs Q statistic based on the full design-by-treatment interaction random-effects model to evaluate global incoherence [42, 44].

We will report all measures of global and local incoherence for all NMAs.

#### *Presentation of results*

We will follow the PRISMA extension statement for reporting of systematic reviews incorporating NMAs of healthcare interventions when reporting the results from each NMA [17].

#### *Component network meta-analysis (CNMA)*

If there are a sufficient number of studies with multi-component interventions in each network, we plan to use random-effects CNMA models to estimate the individual effects of each component within an intervention, and where possible, to identify an optimal combination of components [42]. We will use the netcomb function of the R package netmeta to evaluate additive and two-way interaction CNMA models in a frequentist framework based on the full-interaction (standard) NMA model [42]. Our approach to analysis will follow that specified by Rücker and colleagues [39], and Balduzzi and colleagues [42]. We will report the component effects with accompanying forest plots for the results from the full-interaction NMA and additive CNMA models. We will compare the effect estimates from the full-interaction NMA and the additive CNMA models to assess whether the additivity assumption is compatible with the data (i.e. no evidence of interactions). We will formally compare nested models using Q tests [39]. We will use the R function netcomparison to estimate the effects of clinically important multi-component interventions. Finally, we will rank the components based on estimates from the CNMA.

Should the additivity test suggest that the assumption of additivity may not hold, and if there are sufficient studies, then we will extend the additive model to explore the use of a two-way interaction model. This will allow different combinations of components to have synergistic or antagonistic effects. For this interaction model, we will prespecify the pairs of components we anticipate may interact prior to fitting the model.

For all analyses, we will report pooled results as MDs, SMDs, or ORs with 95% CIs and present the findings in forest plots.

Where it is not possible to synthesise data using meta-analysis, we will utilise the Synthesis Without Meta-analysis (SWiM) guidelines to synthesise the findings [45].

### Investigation of heterogeneity and subgroup analysis

Provided that there are sufficient studies, we will perform network regression analyses to explore the impact of the following participant and intervention characteristics separately on the critical outcomes: participant age, community water fluoridation, setting, and universal or targeted delivery.

#### *Equity-related assessment*

People living in more socioeconomically deprived circumstances have a greater risk of developing dental caries. We will extract data related to participant characteristics using PROGRESS-Plus as a framework [25]. These characteristics relate to place of residence, race/ethnicity/culture/language, occupation, gender/sex, religion, education, socioeconomic status (SES), social capital, personal characteristics associated with disability, features of relationships, and time-dependent relationships. We will report these in tables of study characteristics. We will also extract data indicative of socioeconomic status (e.g. household income level or Index of Multiple Deprivation), if studies provide these data. We will note the country that the intervention has been conducted in and use the World Bank classifications to determine the income level of the country.

### Sensitivity analysis

We will investigate whether our findings are robust to the removal of studies from the NMA on the basis of the following factors:

- studies judged to be at overall high risk of bias;
- studies with incomplete reporting of results and where imputation has been undertaken (e.g. missing standard deviations, re-analysis using an assumed ICC value).

### Certainty of the evidence assessment

For standard NMAs comprising five or more studies, we will use the Confidence in Network Meta-Analysis online tool (CINeMA) to assess the certainty of the body of evidence associated with the following critical outcomes [46, 47].

- Caries prevention:
  - decayed, missing, or filled surfaces in the primary and permanent dentition (d(m)fs/D(M)FS, respectively);
  - decayed, missing, or filled teeth in the primary and permanent dentition (d(m)ft/D(M)FT, respectively);
  - proportion of children who develop caries;
  - adverse effects.
- Caries management:
  - caries arrest;
  - adverse effects.

CINeMA uses a methodological framework based on the GRADE approach to assess the certainty of a body of evidence [48]. Assessment considers the following domains: within-study risk of bias (study limitations), directness of the evidence (indirectness), heterogeneity of the data (inconsistency), precision of the effect estimates (imprecision), risk of publication bias, and incoherence. We will base our assessment of within-study risk of bias on the overall risk of bias from our RoB 2 assessments. The certainty of the evidence can be summarised using the levels of certainty – high, moderate, low, or very low – according to the GRADE approach, with downgrades of one or two levels depending on the presence and extent of concerns in each of the domains. Two review authors will assess the certainty of the evidence, independently and in duplicate, reaching consensus through discussion and consulting a third author in the event of any disagreement. We will explain our reasons for downgrading the certainty of the evidence for each outcome, and we will use these judgements when drawing conclusions in the review.

We will construct summary of findings tables for the included interventions compared to the reference intervention for caries prevention and caries management for the outcomes listed above.

Should CNMA evaluation prove feasible in this review, we will present a summary of findings for the included intervention components compared to the reference intervention for caries prevention and caries management for the outcomes listed above. We acknowledge that at present there is very little guidance and no consensus on the preferred method for evaluating the certainty of CNMA evidence. We will follow the methodology of previously published Cochrane reviews regarding adaptations to some GRADE domains to better suit CNMA (see, for example, work by Lindson and colleagues [49]).

## Consumer involvement

The question for this review is the number one priority research question for oral and dental health put forward by the James Lind Alliance Priority Setting Partnership. The prioritisation process involves input from members of the public and clinicians [15]. We anticipate that the interventions included in this review will be diverse in terms of components and settings. We will convene a group of consumers who have experience with either the interventions included in the review or in the settings where similar interventions may be conducted (e.g. school staff). We will meet with this group throughout the review process to update them on our findings and seek their input throughout. This will help to ensure that we deliver a review that is useful to our consumer audience. We will discuss our findings with this group and, in particular, ask for insight into the acceptability of these interventions. We will use this information to inform the discussion of our findings. We will work with this group to produce our plain language summary.

## SUPPLEMENTARY MATERIALS

Supplementary materials are available with the online version of this article: 10.1002/14651858.CD016145.

**Supplementary material 1** Search strategies

## ADDITIONAL INFORMATION

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### Editorial and peer-reviewer contributions

The following people conducted the editorial process for this article:

- Sign-off Editor (final editorial decision): Toby Lasserson, Acting Editor-in-Chief, Cochrane Library;
- Managing Editor (selected peer reviewers, provided editorial guidance to authors, edited the article): Liz Bickerdike, Cochrane Central Editorial Service;
- Editorial Assistant (conducted editorial policy checks, collated peer-reviewer comments, and supported editorial team): Leticia Rodrigues, Cochrane Central Editorial Service;
- Copy Editor (copy editing and production): Faith Armitage, Cochrane Central Production Service;
- Peer-reviewers (provided comments and recommended an editorial decision): Nuala Livingstone, Cochrane Evidence Production and Methods Directorate (methods); Jo Platt, Central Editorial Information Specialist (search); Amirul Faiz Luai, Dental Public Health Unit, Department of Family Oral Health, Faculty of Dentistry, Universiti Kebangsaan Malaysia (UKM), Kuala Lumpur, Malaysia Centre of Population Oral Health and Clinical Prevention Studies, Faculty of Dentistry, Universiti Teknologi MARA (UiTM), Sungai Buloh, Selangor, Malaysia Alliance for Cavity Free Future - Malaysia Chapter ACFF-MC (clinical); and Jessica M. Langenhoff, MSc (consumer).

## Contributions of authors

Conception of the review: TW, LO'M, AMG, JC
Design of the protocol: LO'M, TW, AMG, PR, JC, LG, RK, GK, CD, DM, SL
Co-ordination of the protocol: LO'M, SL
Writing the protocol: LO'M, TW, AMG, PR, JC, LG, RK, GK, CD, DM, SL

## Declarations of interest

No commercial or non-commercial conflicts of interest relevant to this review for the following authors: CD, LG, RK, DM.

JC is Joint Co-ordinating Editor for Cochrane Oral Health; she has had no role in the editorial process for this protocol.

AMG is Joint Co-ordinating Editor for Cochrane Oral Health; she has had no role in the editorial process for this protocol.

GK is part-funded through the Colgate-Palmolive Dental Health Unit based at The University of Manchester.

SL is a former Deputy Co-ordinating Editor for the Bone, Joint and Muscle Trauma group; she has had no role in the editorial process for the protocol. No commercial or non-commercial interests relevant to this review.

LO'M is a former editor for the Cochrane Oral Health group; she was not involved in the editorial process for this protocol. No commercial or non-commercial interests relevant to this review.

PR is a former Deputy Co-ordinating Editor for Cochrane Oral Health; he has had no role in the editorial process for this protocol. No commercial or non-commercial interests relevant to this review.

TW is a former statistical editor for Cochrane Oral Health; she has had no role in the editorial process for this protocol. She is a former academic lead for the Colgate-Palmolive Dental Health Unit based at The University of Manchester.

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## Registration and protocol

Cochrane approved the proposal for this review in March 2024.

## Data, code and other materials

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

## Notes

Published notes in RevMan are for editor use only. Authors should leave this section blank.

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## ADDITIONAL TABLES

**Table 1. Intervention types, components, and mechanisms of action**

| Intervention category | Component | Mechanism of action |
|---|---|---|
| Educational Interventions | Knowledge | Knowledge: the premise is that informing individuals of what they should do will result in better health outcomes. |
| Behavioural interventions | Behaviour change techniques (BCTs) | These interventions may work through a number of mechanisms of action which have their basis in psychological theories of health behaviour. We will differentiate between behavioural components of interventions on the basis of the mechanism of action (MoA) on which they work. To do this we will use the Theory and Techniques Tool developed by Michie and colleagues, available here: https://theoryandtechniquetool.humanbehaviourchange.org/tool. This tool describes 26 mechanisms of action and allows linkage between these MoAs and BCTs. We will code the interventions by BCT and link these to the MoAs which will be considered as components. |
| Professional care delivered by an appropriately trained professional (this may include generic health or community workers who are trained in these specific tasks) | Fluoride varnish | Concentrated topical fluoride to promote remineralisation |
| | Fissure sealants | Barrier to protect enamel from acid<br>OR<br>Barrier to arrest decay<br>Some sealants may also release fluoride to differing degrees. |
| | Silver diamine fluoride (SDF) | Topical fluoride application for arrest |
| | Acidulated phosphate fluoride (APF) gel | Concentrated topical fluoride to promote remineralisation. Typically, lower concentration of fluoride than fluoride varnish |
| Outreach treatment (restorative treatment delivered as outreach in communities) | May include restorations including hall crowns and atraumatic restorative treatment (ART) | Management of diseased teeth |
| Supervised tooth brushing | Application of fluoride paste by individual in group setting | Topical fluoride application for remineralisation |
| Provision of supplies (e.g. paste, floss, brushes, etc) | Provision | Opportunity for self-care |
| Screening programmes[a] | Prompt treatment | Access for management of decay. Works on needs perception for the individual and provides a referral pathway for care |
| Commercial determinants interventions | Change in policy of provision that directs choice | Choice restriction or direction. These types of intervention may occur at a variety of levels, including national, regional or community level. For example, |

**Table 1. Intervention types, components, and mechanisms of action** *(Continued)*

| | |
|---|---|
| | school policies may be changed to restrict the availability of sugar-sweetened beverages on site. |

[a]Dental screening conducted in a community setting which is provided together with an appropriate referral pathway that includes the provision of an appointment for care. In this review, we will exclude screening which does not refer individuals directly to care but only signposts services, because there is a weak mechanism of action for screening without prompt treatment in terms of preventing or managing caries.
**APF:** acidulated phosphate fluoride; **ART:** atraumatic restorative treatment; **BCT:** behaviour change techniques; **MoA:** mechanism(s) of action; **SDF:** silver diamine fluoride