

INPLASY202590026  
doi: 10.37766/inplasy2025.9.0026  
Received: 8 September 2025  
Published: 8 September 2025

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ADMINISTRATIVE INFORMATION

**Support** - None.

**Review Stage at time of this submission** - Completed but not published.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202590026

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 8 September 2025 and was last updated on 8 September 2025.

INTRODUCTION

**Review question / Objective** This study aims to assess the effectiveness of fluoride mouth rinses in preventing dental caries in children and adolescents through a systematic review and meta-analysis. It primarily focuses on the impact of different intervention frequencies, durations and types of fluoride on the incidence of dental caries and on changes in decayed, missing and filled surfaces (DMFS) and the surface area of initial caries (SIC) indices.

**Condition being studied** Dental Caries is a globally prevalent oral disease, particularly with a high incidence in children and adolescents. Fluoride mouth rinse effectively reduces the incidence of dental caries, especially in children and adolescents at high risk for caries. While existing studies generally support the use of fluoride mouth rinse in caries prevention, the variations in sample size, study design, fluoride concentration, and usage frequency contribute to some controversy in the results.

METHODS

**Participant or population** Children aged 3–10 years.

**Intervention** The interventions primarily involved fluoride mouth rinse or fluoride foam, with the duration of treatment in the experimental group typically ranging from 1 to 3 years, whereas the control group was usually treated for 1 year or less.

**Comparator** Participants were aged 3–15 years, and the gender distribution was generally balanced. The interventions primarily involved fluoride mouth rinse or fluoride foam, with the duration of treatment in the experimental group typically ranging from 1 to 3 years, whereas the control group was usually treated for 1 year or less.

**Study designs to be included** Randomised controlled trials (RCTs) meeting the inclusion criteria were identified through searches of PubMed, Embase, Web of Science, Cochrane Library, SinoMed, CNKI and Wanfang databases.

The literature search was conducted on 2 June 2025 and covered publications from 1 January 2000 to 31 May 2025. Reference lists of included studies and relevant reviews were also manually screened to identify additional eligible records. Two independent reviewers performed the literature screening, data extraction and risk-of-bias assessment. The included studies examined the effects of fluoride mouth rinse.

**Eligibility criteria** Inclusion Criteria: The inclusion criteria were established according to evidence-based medicine methods as follows. (1) P (population): study participants were children aged 3–15 years identified as being at high risk for dental caries. High caries risk was defined as a baseline DMFS score of  $\geq 3$ , indicating a considerable prevalence of dental caries. (2) I (intervention): the experimental group used local fluoride treatment (e.g. fluoride mouth rinse) to prevent dental caries. (3) C (comparison): the control group received either a placebo or a blank control. (4) O (outcome): new caries incidence, caries rates, reduction in caries and changes in DMFS were reported. (5) S (study design): clinical randomised controlled trials (RCTs) were employed. Publications from 1 January 2000 to 31 May 2025 were included.

Exclusion Criteria: The exclusion criteria were as follows: (1) studies with a dropout rate greater than 20%; (2) studies with a sample size smaller than 150 participants (this threshold was chosen based on a power analysis to ensure sufficient statistical power to detect significant differences in caries incidence between the intervention and control groups), as smaller studies may lack the power to provide reliable estimates of treatment effects; (3) studies in which the experimental group received two or more types of fluoride treatment concurrently; (4) studies with inappropriate outcome measures that could not be included in the meta-analysis.

**Information sources** PubMed, Embase, Web of Science, Cochrane Library, ScienceDirect, SinoMed, CNKI and Wanfang databases.

### **Main outcome(s)** Dental Caries Incidence

A meta-analysis of the overall effectiveness was performed on the 10 included RCTs [10–19]. The heterogeneity test showed no statistical significance ( $P = 0.08$ ,  $I^2 = 41\%$ ,  $<50\%$ ), and a fixed-effect model was used. The results indicated that fluoride mouth rinse was more effective in preventing dental caries in children and adolescents than the method used (such as mechanical oral hygiene, dietary control, antimicrobial intervention, pit and fissure sealants)

in the conventional pharmaceutical group ( $OR = 3.68$ , 95% CI: 2.79–4.86,  $P < 0.00001$ ), as shown in Figure 3.

### **Decayed, Missing and Filled Surfaces Changes**

A total of 6 RCTs were included for the meta-analysis of DMFS changes ( $P = 0.01$ ,  $I^2 = 96\%$ ), with heterogeneity in the remaining studies showing  $I^2 > 50\%$ , and a random-effects model was applied. The weighted mean difference (WMD) for DMFS change was 0.35 (95% CI: 0.07–0.63,  $P < 0.00001$ ). The results showed that fluoride mouth rinse was more effective in reducing DMFS changes following treatment than the method used in the control group, as shown in Figure 4.

### **Surface Area of Initial Caries Changes**

Five RCTs were included for the meta-analysis of SIC changes ( $P = 0.01$ ,  $I^2 = 68\%$ ), with heterogeneity in the remaining studies showing  $I^2 > 50\%$ , and a random-effects model was used. The WMD for SIC changes was  $-0.85$  (95% CI:  $-1.66$  to  $-0.05$ ,  $P < 0.00001$ ). The results demonstrated that fluoride mouth rinse was superior in reducing SIC changes following treatment to the method used in the control group, as shown in Figure 5.

**Quality assessment / Risk of bias analysis** The publication bias in studies evaluating the effect of fluoride mouth rinse in preventing dental caries in children and adolescents was assessed, as shown in Figure 6. The studies included in the analysis were symmetrically distributed in the funnel plot, indicating a low degree of publication bias. Most scatter points were concentrated in the upper part of the funnel plot, suggesting that the sample representation of the included studies was good and the results were highly reliable.

**Strategy of data synthesis** Two independent researchers extracted data from the selected studies, including basic information (authors, publication year, study type), participant characteristics (age, gender, health status), intervention details (type of fluoride, frequency of use, duration) and primary outcome data (caries incidence, DMFS, SIC). Outcome assessors were independent of both participants and staff, and blinding was applied to prevent bias. Any disputes were resolved by a third expert. The quality of each study was assessed using the Cochrane risk of bias tool, evaluating random sequence generation, allocation concealment, blinding of participants and personnel, incomplete outcome data, selective reporting and other aspects of study design and analysis.

**Subgroup analysis** Subgroup analysis was conducted to evaluate the impact of fluoride mouth rinse on the incidence of dental caries. The

results indicated that high-frequency interventions ( $\geq 2$  times/year) had considerable advantages in reducing caries incidence. Additionally, long-term interventions ( $\geq 6$  months) were more effective than short-term interventions ( $< 6$  months). The effect of fluoride mouth rinse on caries prevention was particularly pronounced in children aged 3–10 years, which may be related to the fact that their oral hygiene habits are still developing. Regarding different types of fluoride, sodium fluoride mouth rinse was slightly more effective than monofluorophosphate mouth rinse in reducing caries incidence, though both types demonstrated good clinical outcomes. These results suggest that fluoride mouth rinse has a major impact on improving oral health, with the frequency and duration of intervention being key factors in enhancing therapeutic efficacy (Table 2).

We compared the effects of 0.05% and 0.2% fluoride mouth rinse on caries incidence and changes in DMFS and SIC. The meta-analysis revealed that both concentrations significantly reduced caries incidence, with the 0.2% concentration showing a slightly greater effect (OR = 4.20, 95% CI: 3.10–5.60,  $P < 0.00001$ ) than the 0.05% concentration (OR = 3.50, 95% CI: 2.60–4.70,  $P < 0.00001$ ). Similarly, the 0.2% concentration resulted in a greater reduction in DMFS (WMD = 0.40, 95% CI: 0.10–0.70,  $P < 0.00001$ ) than the 0.05% concentration (WMD = 0.30, 95% CI: 0.05–0.55,  $P < 0.00001$ ). For SIC, both concentrations showed significant reductions, with the 0.2% concentration having a slightly greater effect (WMD = –1.00, 95% CI: –1.80 to –0.20,  $P < 0.00001$ ) than the 0.05% concentration (WMD = –0.80, 95% CI: –1.60 to 0.00,  $P < 0.00001$ ).

**Sensitivity analysis** Two independent researchers extracted data from the selected studies, including basic information (authors, publication year, study type), participant characteristics (age, gender, health status), intervention details (type of fluoride, frequency of use, duration) and primary outcome data (caries incidence, DMFS, SIC). Outcome assessors were independent of both participants and staff, and blinding was applied to prevent bias. Any disputes were resolved by a third expert. The quality of each study was assessed using the Cochrane risk of bias tool, evaluating random sequence generation, allocation concealment, blinding of participants and personnel, incomplete outcome data, selective reporting and other aspects of study design and analysis.

**Country(ies) involved** China.

**Keywords** fluoride mouth rinse; caries prevention; meta-analysis; clinical trials.

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