

## Bijlage 3. Tabellen met studiekarakteristieken

### 1. Studiekarakteristieken bij het wetenschappelijke bewijs over motivatietechnieken, PICO 1 Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 1: Hoe kan een mondzorgverlener kinderen, adolescenten en ouders/verzorgers motiveren om het gebit gaaf te houden?**

Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Batliner, 2018	<p>Type of study: RCT</p> <p>Setting: Society: Pine ridge IHS hospitals, powwows, health fairs, and local community events.</p> <p>Country: United States of America, Colorado</p> <p>Source of funding: National Institute of Dental and Craniofacial Research of the National Institute of Health (U54DE019259)</p>	<p><u>Inclusion criteria:</u> Mother or primary care giver of a new born. All child (up to 3 mo of age) between 15 and 65 u of age, able to understand and sign a consent form and willing and able to follow study procedures and instructions.</p> <p><u>Exclusion criteria:</u> Not reported</p> <p><u>N total at baseline:</u> Intervention: 290 Control: 289</p> <p><u>Important prognostic factors:</u> Age of child in months <math>\pm</math> SD: I: <math>0.62 \pm 0.89</math> C: <math>0.73 \pm 0.91</math></p>	<p>Motivational interviewing consisted of 4 visits: the first shortly after childbirth and again when the child was 6, 12, and 18 months old. Visits usually required 45 to 60 min for completion.</p> <p>A culturally specific MI script was developed; a training manual was compiled; and interventionists received training before the MI intervention was used in the field. Each interventionist completed 2 d of training.</p> <p>AND</p> <p>Enhanced Community Services included public service announcements broadcast on the tribal radio station, billboards, and broad distribution of brochures focused on behavioural risk factors for ECC and oral</p>	<p>Enhanced Community Services included public service announcements broadcast on the tribal radio station, billboards, and broad distribution of brochures focused on behavioural risk factors for ECC and oral health topics covered in the MI sessions.</p>	<p><u>Length of follow-up:</u> 3 years</p> <p><u>Loss-to-follow-up:</u> Intervention: N=58 (20%) Reasons not reported</p> <p>Control: N=51 (17.6%) Reasons not reported</p>	<p><b>Mean difference (95% BI)</b></p> <p><b>Dmfs:</b> -0.40 [-3.31, 2.51]</p> <p><b>Ds:</b> -0.90 [-2.16, 0.36]</p> <p><b>Oral health knowledge:</b> 2.00 [-0.37, 4.37]</p> <p><b>Oral health behaviour:</b> 1.70 [-1.84, 5.24]</p>	

		<p>Age of caregiver in years <math>\pm</math> SD: I: 28.2 <math>\pm</math> 15.2 C: 27.5 <math>\pm</math> 13.7</p> <p>Groups comparable at baseline? Yes</p>	<p>health topics covered in the MI sessions.</p>				
<p><b>Freudenthal, 2010</b></p>	<p>Type of study: RCT</p> <p>Setting: Woman enrolled in the Supplemental Nutritional Program for Women, Infants and Children.</p> <p>Country: United States of America, Idaho</p> <p>Source of funding: Nor reported</p>	<p><u>Inclusion criteria:</u> Speak English, had 1 or more children in the ages of 6 to 24 months who were not primarily breast-fed.</p> <p><u>Exclusion criteria:</u> Not reported</p> <p><u>N total at baseline:</u> Intervention: 40 Control:32</p> <p><u>Important prognostic factors</u><sup>1</sup>: age of child in months <math>\pm</math> SD: I: 17 <math>\pm</math> 6.53 C: 15 <math>\pm</math> 5.53</p> <p>age of mother <math>\pm</math> SD: I: 27.6 <math>\pm</math> 4.80 C: 27.68 <math>\pm</math> 5.41</p> <p>Groups comparable at baseline? Yes</p>	<p>Motivational interviewing. The researchers providing the MI received training from a renowned dental expert through an interactive continuing education workshop and workbook.</p> <p>Each mother would receive a 20 to 30-minute individualized MI intervention following the pre-test (RAPIDD and PCCT). Following this IM session, the researcher made follow-up telephone calls at 1 and 2 weeks.</p>	<p>No formal education. Pamphlets were available and questions were answered if posted.</p>	<p><u>Length of follow-up:</u> 4 weeks</p> <p><u>Loss-to-follow-up:</u> Intervention n= 1 (3%) Reasons: Not reported</p> <p>Control n= 3 (9%) Reasons: Not reported</p> <p><u>Incomplete outcome data:</u> 4 children from each group did not have teeth during the study. Therefore they did not use utensils.</p>	<p><b>RAPIDD:</b> <b>Valuing dental health: significant</b> difference between pre- and post-test (p&lt;0.05)</p> <p><b>Permissiveness</b> No significant difference</p> <p><b>Convenience and change</b> No significant difference</p> <p><b>Openness</b> No significant difference</p> <p><b>PCCT</b> <b>Frequency of sweets used</b> No significant difference</p> <p><b>Shared utensils</b> Intervention: Pre test=40% Post test= 18% p-value=0.035 Control:</p>	<p>Area without fluoridated water.</p> <p>The district health department provides a fluoride varnish program in the public-school system twice a year.</p>

						Pre test=25% Post test=24%	
						<b>Cleaned or brushed teeth</b> Intervention: Pre test=2.8 Post test= 3.7 p-value=0.001 Control: Pre test=3.2 Post test=3.3	
<b>Harrison, 2007</b>	Type of study: RCT  Setting: Society: community centre; temples; community events; radio  Country: Canada, Surrey  Source of funding: Not reported	<u>Inclusion criteria:</u> 6- to 18- months-old South Asian children and their mothers.  <u>Exclusion criteria:</u> Not reported  <u>N total at baseline:</u> Intervention: 122 Control: 118  <u>Important prognostic factors:</u> <i>age in months ± SD:</i> I: 10.8 ±5.3 C: 12.1 ±5.3  Groups comparable at baseline? Yes	1. The pamphlet and video; 2. One 45-minutes counselling session (MI); 3. Two brief follow-up telephone call at 2 weeks and 1 month after initial contact; 4. Four follow-up telephone calls up to 6 months after the initial contact; 5. Two postcard reminders.  The people how gave the counselling session were trained in MI, which was frequently checked by the supervisor to see that the MI protocol was being delivered consistently.	Each mother would receive a pamphlet on infant oral health designed by the local health unit dental staff. Mothers also watched an 11-minutes educational video for infants and toddlers. Both pamphlet and video recommended that parents take their child to Progressive Intercultural Services Society for fluoride varnish.	<u>Length of follow-up:</u> 4 years  <u>Loss-to-follow-up:</u> Intervention: n= 17 (14%) Reasons: not reported  Control: n= 18 (15%) Reasons: not reported  <u>Incomplete outcome data:</u> Intervention: n = 26 (21%) Reasons: Did not have fully erupted dentition at time of enrolment Control: n = 16 (14%) Reasons: Did not have fully erupted dentition at time of enrolment	Pre test=25% Post test=24%	Area without fluoridated water.

<p><b>Harrison, 2012</b></p>	<p>Type of study: RCT</p> <p>Setting: Society: community clinics</p> <p>Country: Canada</p> <p>Source of funding: Canadian Institute of Health Research (grant #FRN 67817)</p>	<p><u>Inclusion criteria:</u> Cree women who recently had given birth or were between the 12<sup>th</sup> and 34<sup>th</sup> weeks of pregnancy were recruited.</p> <p><u>Exclusion criteria:</u> Not reported.</p> <p><u>N total at baseline:</u> Intervention: 131 Control: 141</p> <p><u>Important prognostic factors<sup>1</sup>:</u> <i>For example</i> <i>age ± SD:</i> I: C:  <i>Sex:</i> I: % M C: % M</p> <p>Groups comparable at baseline?</p>	<p>Test group mothers were to attend one counselling session during pregnancy and up to 6 more sessions post-natally until their child's second birthday. Each test mother received appropriate supplies at each visit to facilitate adoption of selected behaviours. The two MI-style "scripts" were based on scripts from a previous trial (Weinstein et al., 2004, 2006): one script for pregnant and new mothers and another for those whose child had experienced the first tooth eruption. Mothers from test communities also received a "Privilege Card" to expedite dental care.</p> <p>It was the request of the CBHSSJB that existing health workers, called "community health representatives" (CHRs), be enlisted as recruiters and interveners. However, some communities had no CHR; therefore, local women were hired. All staff received necessary training and support.</p>	<p>Pamphlets only.</p>	<p><u>Length of follow-up:</u> Pregnancy to 30 months (30 tot 39 months)</p> <p><u>Loss-to-follow-up:</u> Intervention: N=21 (16%) Reasons 3 lost to follow up; 7 moved; 3 withdrew; 3 away*</p> <p>Control: N=10 (%) Reasons 6 lost; 3 moved</p>	<p><b>RR (95% CI):</b>  <b>Caries prevalence:</b> 0.86 (0.66 - 1.07)</p> <p>No adverse events were reported.</p>	<p>*participants were reported to be away. An explanation why participants were away, is missing.</p>
<p><b>Henshaw, 2018</b></p>	<p>Type of study: RCT</p> <p>Setting:</p>	<p><u>Inclusion criteria:</u> residents of the included PHDs, had no plans to</p>	<p>The intervention group received everything that the control received, plus quarterly MI counselling.</p>	<p>The control group received 1) on-site child clinical examinations to collect data on decayed, missing,</p>	<p><u>Length of follow-up:</u> Two years</p> <p><u>Loss-to-follow-up:</u></p>	<p><b>Mean difference (95% BI)</b></p> <p><b>Dmfs:</b></p>	<p>SSB= Sugar Sweetened beverage</p>

	<p>Society: public housing</p> <p>Country: United States of America</p> <p>Source of funding: National Institute of Dental and Craniofacial Research</p>	<p>move in the ensuing 24 mo, and were women in their third trimester of pregnancy or primary caregivers of a child &lt;6 y old. If a caregiver had &gt;1 child, the youngest child was enrolled in the study as the index child.</p> <p><u>Exclusion criteria:</u> residents of the included PHDs, had no plans to move in the ensuing 24 mo, and were women in their third trimester of pregnancy or primary caregivers of a child &lt;6 y old. If a caregiver had &gt;1 child, the youngest child was enrolled in the study as the index child.</p> <p><u>N (care givers) total at baseline:</u> Intervention: 379 Control:686</p> <p><u>Important prognostic factors:</u> <i>age ± SD:</i></p>	<p>Oral health advocates (OHAs), the interventionists, delivered a maximum of 9 MI counselling sessions (30 min each) to participants in their homes over the 24-mo study period. OHAs were public housing residents themselves with a high school education who were trained in ECC prevention and MI delivery,</p>	<p>or filled surfaces (dmfs), with a report on current oral health status and a dental referral list; 2) fluoride varnish (0.40-mL dose of 3M ESPE CavityShield 5% sodium fluoride varnish); 3) a toothbrush and toothpaste;and 4) written handouts about 1 of the 9 topics described below</p>	<p>Intervention: N=69 (18%) Reasons (describe)</p> <p>Control: N=90 (13%) Reasons (describe)</p> <p>The number of people for each follow-up moment varied widely.</p>	<p>0.00 [-1.10, 1.10]</p> <p><b>Self efficacy:</b> 0.0 [-0.06, 0.06]</p> <p><b>Importance:</b> 0.00 [-0.34, 0.34]</p> <p><b>Motivation:</b> 0.10 [0.06, 0.14]</p> <p><b>Knowledge:</b> 1.80 [0.64, 2.96]</p> <p><b>SSB Intake:</b> -0.20 [-0.42, 0.02]</p>	
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Ismail, 2011	<p>Type of study: RCT</p> <p>Setting: Society: housing units</p> <p>Country: United States of America</p> <p>Source of funding: National Institute of Dental and Craniofacial Research</p>	<p><u>Inclusion criteria:</u> Housing units with families making &lt;250th percentile of the poverty line and having at least one African-American child aged &lt;5 years old were recruited for the study</p> <p><u>N total at baseline:</u> Intervention: 506 Control:515</p> <p><u>Important prognostic factors:</u> <i>Age group: number (%):</i> I: 14-14: 63 (21.07) 25-34: 145 (48.49) 35-44: 64 (21.40) 45+: 27 (9.03)</p> <p>C: 14-14: 71 (23.67) 25-34: 150 (50)</p>	<p>Motivational interviewing and DVD with instructions. Following the video, the MI interviewer engaged the caregiver in a discussion of their thoughts and concerns (if any) regarding their child's oral health, and in particular regarding what changes (if any) they wished to make with respect to their monitoring of their child's oral health.</p>	<p>In the presence of the research assistant or interviewer, caregivers in both conditions viewed a high-quality, 15-minute educational video specifically designed for the project emphasizing the importance of good oral health in children and demonstrating how the caregiver can keep children free from tooth decay</p>	<p><u>Length of follow-up:</u> One year</p> <p><u>Loss-to-follow-up:</u> Intervention: N= 207 (40.1%) Reasons not reported</p> <p>Control: N=215 (41.7%) Reasons not reported</p>	<p><b>OR (p-value) MI+DVD vs. DVD (ref):</b></p> <p><b>Brushes 2 times per day:</b> 1.58 (0.20)</p> <p><b>Brushes 7 days per week:</b> 1.21 (0.59)</p> <p><b>Brushes 7 days at bedtime:</b> 0.71 (0.47)</p> <p><b>Provides child with non sugared snacks:</b> 0.40 (0.1)</p> <p><b>Always gives child healthy meals:</b> 0.29 (0.15)</p> <p><b>Makes sure child brushes at bedtime:</b> 1.71 (0.22)</p> <p><b>Makes sure child brushes 2x per day:</b></p>	<p>The study does report about the number of cavities, but in a non transparent manner.</p>

		35-4451 (17.00) 45+:28 (9.33)				1.72 (0.06)	
		Groups comparable at baseline? Yes					
<b>Naidu, 2015</b>	<p>Type of study: RCT (and a focus group)</p> <p>Setting: Ambulatory care. Preschools form the contact list for community dental outreach activity.</p> <p>Country: Trinidad and Tobago</p> <p>Source of funding: Not reported</p>	<p><u>Inclusion criteria:</u> Families of children attending preschools within the catchment area of the health facility.</p> <p><u>Exclusion criteria:</u> Maximum of 6 preschool would be manageable.</p> <p><u>N total at baseline:</u> Intervention: 25 Control:54</p> <p><u>Important prognostic factors</u><sup>1</sup>: Majority of caregivers were between 25 and 24 years.</p> <p><i>Age of child is not reported.</i></p> <p>Groups comparable at baseline? Yes</p>	<p>Participants in the intervention group received a 30- min talk (as a group) based on a Motivational Interviewing approach, delivered by an MI counsellor /educator (RN) (a dentist trained in MI), assisted by a Dental Nurse. Training of the MI counsellor /educator involved a one-day course (8 h) on Motivational Interviewing and coaching skills for health professionals that included both applied (hands-on) and theoretical elements, with the theoretical materials also made available for self-study. The group-talk was based on an MI protocol designed to aid delivery of oral health information to families with young children: Motivate your Dental Patient: A workbook -Public Health / Paediatric Edition [18]. All participants in the test group received the same DHE information leaflet as the control group along with toothpaste samples as tokens of appreciation. All</p>	<p>All participants (parents and caregivers) in the control group were given a 30 -min talk (as a group) on dental care of preschool children’s teeth by a Dental Nurse. This talk included advice on diet, oral hygiene, fluoride use and dental attendance. At the end of the talk, participants were given a DHE leaflet reinforcing the information to take home. All participants in the control-group were given dental health products (toothpaste samples and floss) as a token of appreciation for taking part in the study. The three control group-talks included 6, 13 and 35 participants, respectively.</p>	<p><u>Length of follow-up:</u> 4 months</p> <p><u>Loss-to-follow-up:</u> Intervention: N=5 (20%) Reasons not reported</p> <p>Control: N=33 (61%) Reasons not reported</p>	<p><b>Mean difference (95% BI)</b></p> <p><b>Child weekly tooth brushing:</b> 2.54 [0.65, 4.43]</p> <p><b>Self-efficacy:</b> 2.19 [-1.55, 5.93]</p> <p><b>Oral health fatalism:</b> -1.86 [-3.02, -0.70]</p> <p><b>Openness to health information:</b> 0.51 [-1.32, 2.34]</p> <p><b>Valuing dental health:</b> -0.38 [-4.21, 3.45]</p> <p><b>Convenience and change difficulty:</b> -1.91 [-3.64, -0.18]</p> <p><b>Child permissiveness:</b> -0.97 [-3.27, 1.33]</p> <p><b>RAPIDD pros:</b> 0.14 [-4.30, 4.58]</p> <p><b>RAPIDD cons:</b> -2.37 [-5.51, 0.77]</p>	

			the talks took place at the preschools after a normal school day. The three test group-talks included 4, 9 and 12 participants respectively.				
<b>Weinstein, 2004; 2006</b>	<p>Type of study: RCT</p> <p>Setting: Society; South Asian Punjabi-speaking community i</p> <p>Country: United States of America and Canada</p> <p>Source of funding: National Institute of Health, National Institute of Dental and Craniofacial Research</p>	<p><u>Inclusion criteria:</u> Healthy infants aged six to 18 months from South Asian Punjabi-speaking community in Surrey.</p> <p><u>Exclusion criteria:</u> A serious acute or chronic disease that would interfere with our ability to examine the child or would prevent the child and parent from participating fully.</p> <p><u>N total at baseline:</u> 240</p> <p><u>Important prognostic factors</u><sup>1</sup>: I: 11 months C: 12 months</p> <p>Groups comparable at baseline? Children in the control group were slightly older. No other baseline</p>	<p>MI counselling. They received the same pamphlet and video, as well as one 45-minute counselling session and two brief follow-up telephone calls during the period of preparation for change and while change was occurring (at two weeks and one month after initial contact). To promote maintaining the behaviour change, we called parents in the experimental group four times during the maintenance stage (up to six months after the initial contact). We also sent two postcard reminders. South Asian woman were trained to perform MI and followed a strict protocol.</p>	<p>Health education. Each subject in the control group received a pamphlet designed by the staff of the local health unit and also viewed a video called "Preventing Tooth Decay for Infants and Toddlers."</p>	<p><u>Length of follow-up:</u> Two years</p> <p><u>Loss-to-follow-up:</u> N=35 (15%) Reasons were not described.</p>	<p><u>One year follow up</u> <b>OR ±SD</b></p> <p>New carious lesions: I: 0.71 ±2.8 C: 1.91 ±2.37 p-value &lt;0.01</p> <p>Percentage with new dfs: I: 15.2% C: 26.0%</p> <p><u>Two years follow up</u></p> <p>New carious lesions (OR and 95% CI): I: 0.35 (0.15-0.83) C: 1.91 ±2.37 p-value &lt;0.01</p> <p>Percentage with new dfs (%): I: 35.2% C: 52.0% p-value &lt; 0.02</p> <p>Number of fluoride varnish applications ± SD: I: 4.1 ± 1.0 C: 0.3 ± 0.6</p>	<p>Weinstein et al. published two separate reports from this study. They are combined in this table of study characteristics.</p> <p>Fluoride varnishes were not part of this study or an outcome. It was reported as a difference between two groups after two years.</p>



		characteristics are reported, and the randomization process is unclear.					
<b>Wu, 2017</b>	<p>Type of study: RCT</p> <p>Setting: Society</p> <p>Country: Hong Kong</p> <p>Source of funding: Health and Medical Research Fund of the Hong Kong government</p>	<p><u>Inclusion criteria:</u> one must (1) be a full-time student enrolled in a participating school; (2) be 12 or 13 years old; (3) not have any major systemic disease; (4) have unfavourable oral health behaviour, defined as “toothbrushing less often than twice a day” AND/OR “snacking three times or more a day”; and (5) be able to communicate in Cantonese or Mandarin.</p> <p><u>N total at baseline:</u> Group 1: 161 Group 2: 163 Group 3: 188</p> <p><u>Important prognostic factors<sup>1</sup>:</u> <i>For example</i> Plaque index ± SD: Group 1: 1.46 (.41) Group 2: 1.36 (.31)</p>	<p>- group II joined a one-on-one face-to-face MI session, which lasted 15e30 minutes. The MI approaches were followed, including the four (evocation, compassion, acceptance, and collaboration), four processes (engaging, focusing, eliciting, and planning), and four skills (open questions, affirmation, reflection, and summary)</p> <p>- group III, the interactive risk assessment (RA) program Cariogram was incorporated at different stages of MI as appropriate to facilitate the counselling process. The RA program was not used at the beginning of the counselling to avoid falling into direct information and advice giving.</p> <p>All interventions were delivered by two dental hygienists.</p>	<p>- group I received a 30-minute oral health talk delivered to the whole school by an experienced dental hygienist. Each participant received three pamphlets, namely “Cleaning teeth properly -You can do it,” “How to use dental floss,” and “Healthy diet, healthy teeth”</p>	<p><u>Length of follow-up:</u> One year</p> <p><u>Loss-to-follow-up:</u> Group I: N= 6 (3.7%) Reasons Dropped out of school n=4; withdraw n=1; Absence n=1</p> <p>Group II N= 14 (8.6%) Reasons Transferred to other school n=2; Dropped out of school n=4; withdraw n=1; absence n=7</p> <p>Group III N= 10 (5.3%) Reasons Transferred to other school n=2; Dropped out of school n=3; absence n=5</p>	<p><b>Group I vs. II Mean difference (95% BI or SD)</b></p> <p><b>Plaque score:</b> -0.11 (-0.55 to 0.32)</p> <p><b>ICDAS 1-6 MFS:</b> 0.45 (0.85) p-value 0.013</p> <p><b>ICDAS 1-6 MFT:</b> 0.36 (0.73) p-value 0.015</p> <p><b>ICDAS 3-6 MFS:</b> 0.04 (0.22) p-value 0.311</p> <p><b>ICDAS 3-6 MFT:</b> 0.02 (0.16) p-value 0.450</p>	<p><b>Group I vs. III Mean difference (95% BI or SD)</b></p> <p><b>Plaque score:</b> -0.21 (-0.65 to 0.23)</p> <p><b>ICDAS 1-6 MFS:</b> 0.34 (0.83) p-value 0.013</p> <p><b>ICDAS 1-6 MFT:</b> 0.26 (0.69) p-value 0.015</p> <p><b>ICDAS 3-6 MFS:</b> 0.02 (0.13) p-value 0.311</p> <p><b>ICDAS 3-6 MFT:</b> 0.02 (0.13) p-value 0.450</p>

		<p>Group 3: 1.40 (.38)</p> <p>Gender male (%):                  Group 1: 55 (34.2)                  Group 2: 82 (50.3)                  Group 3: 125 (66.5)</p> <p>Groups comparable at baseline?                  Yes</p>					
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## 2. Risico op biasbeoordeling bij wetenschappelijke bewijs over motivatietechnieken, PICO 1

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 1:** Hoe kan een mondzorgverlener kinderen, adolescenten en ouders/verzorgers motiveren om het gebit gaaf te houden?

Risico op bias van RCT('s)

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of patient and personell (performance bias)	Blinding of outcome assessor (detection bias)	Follow-up and ITT or per protocol analysis (attrition bias)	Selective reporting	Other bias
Batliner, 2018	Low risk <i>Random number generator.</i>	Low risk <i>Participants were enrolled prior to obtaining group assignment.</i>	High risk <i>No, that is not possible.</i>	Low risk <i>Outcome assessor was blinded.</i>	Low risk <i>Analyzes followed an ITT principle.</i>	Low risk <i>Registered outcomes were reported in publication.</i>	Low risk <i>No other sourcesrisico op bias was found.</i>
Freudenthal, 2010	Low risk <i>The investigators flipped a coin.</i>	High risk <i>The investigators flipped a coin before inviting a mother to participate.</i>	High risk <i>No, that is not possible.</i>	Unclear <i>Not reported</i>	Low risk <i>Low number of drop-outs.</i>	Unclear <i>This study was not registered.</i>	Low risk <i>No other sourcesrisico op bias was found.</i>
Harrison, 2007	Low risk <i>Block randomization table was used.</i>	Low risk <i>The staff was blinded to the allocation.</i>	High risk <i>No, that is not possible.</i>	Unclear <i>Not reported</i>	Low risk <i>Low number of dropouts. An ITT analyses was used although the results were not reported.</i>	Unclear <i>This study was not registered.</i>	Low risk <i>No other sourcesrisico op bias was found.</i>
Harrison, 2012	Low risk <i>Envelops were drawn.</i>	Low risk <i>Communities were randomized after participation.</i>	High risk <i>No, that is not possible.</i>	Low risk <i>The examiners were blinded to allocation and were unfamiliar with the intervention.</i>	Low risk <i>&lt;15% dropouts without reasons related to the intervention.</i>	Unclear <i>This study was not registered.</i>	Low risk <i>No other sourcesrisico op bias was found.</i>
Henshaw, 2018	Low risk <i>Random number generator.</i>	Unclear <i>Not reported</i>	High risk <i>No, that is not possible.</i>	Low risk <i>Outcome assessor was blinded.</i>	Low risk	Unclear <i>This study was not registered.</i>	Low risk

					<i>Low number of dropouts. An ITT analyses was used.</i>		<i>No other sourcesrisico op bias was found.</i>
<b>Ismail, 2011</b>	Low risk  <i>Random number generator.</i>	Unclear  “The assignment of the children was masked to participants, project staff with the exception of coordination desk and interviewing staff, examining dentists, and analysts.”	High risk  <i>No, that is not possible.</i>	High risk  <i>The analysts were not blinded.</i>	High risk  <i>A high number of dropouts (&gt;40%). An ITT was used which can not completely control for the high drop out number.</i>	Unclear  <i>This study was not registered.</i>	Low risk  <i>No other sourcesrisico op bias was found.</i>
<b>Naidu, 2015</b>	Unclear  <i>Randomization was done on an institution level. Only 6 six schools participated so equal distribution cannot be guaranteed.</i>	Unclear  <i>Not reported</i>	High risk  <i>No, that is not possible.</i>	Unclear  <i>Not reported.</i>	High risk  <i>Considerable number of drop-outs (61% in control group)</i>	Unclear  <i>This study was not registered.</i>	Low risk  <i>No other sourcesrisico op bias was found.</i>
<b>Weinstein, 2004; 2006</b>	Low risk  <i>A table of random numbers was used.</i>	Unclear  <i>There is no information who had access to the table with random numbers.</i>	High risk  <i>Not reported but would not have been possible.</i>	Unclear  <i>Not reported.</i>	Unclear  <i>Not reported.</i>	Unclear  <i>This study was not registered.</i>	Low risk  <i>No other sourcesrisico op bias was found.</i>
<b>Wu, 2017</b>	Low risk  <i>“randomization through drawing lots was completed by a research assistant”</i>	Low risk  <i>“Allocation concealment was ensured by sealed and opaque envelops.”</i>	High risk  <i>No, that is not possible.</i>	Low risk  <i>Outcome assessor was blinded.</i>	Low risk  <i>Low number of dropouts. An ITT analyses was used.</i>	Unclear  <i>This study was not registered.</i>	Low risk  <i>No other sourcesrisico op bias was found.</i>

### 3. Studiekarakteristieken bij het wetenschappelijke bewijs over motivatietechnieken, PICO 2

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 1:** Hoe kan een mondzorgverlener kinderen, adolescenten en ouders/verzorgers motiveren om het gebit gaaf te houden?

#### Studiekarakteristieken van systematische review(s)

Study	Study design	Patients	Intervention	Control	Follow-up	Outcomes	Comments
Borelli, 2015	<p><u>Type of study:</u> Systematic review of RCT's</p> <p><u>Search date:</u> August 2014</p> <p><u>Number of included studies:</u> N=25</p> <p><u>Country</u> Not reported</p> <p><u>Source of funding:</u> Not reported</p> <p><u>Inclusion criteria:</u> (1) sample parents of children and/or adolescents 18 years old or younger (participants); (2) implement an intervention that used MI or motivational enhancement that targeted either a parent or a parent-</p>	<p><u>N total at baseline:</u></p> <p>A. 31 B. 72 C. 235 D. 133 E. 191 F. 162 G. 372 H. 350 I. 323 J. 72 K. 121 L.530 M. 272 N. 250 O.1021 P. 89 Q. 49 R. 433 S. 147 T. 67 U. 104 V. 475 W.637 X. 50 Y.240</p> <p><u>Age (years):</u></p> <p>A. 15 B. 9</p>	<p>A. Overweight and obesity B. Overweight and obesity C. Overweight and obesity D. Smoking and tobacco E. Smoking and tobacco F. Smoking and tobacco G. Overweight and obesity H. Smoking and tobacco I. Smoking and tobacco J. Oral health K. Overweight and obesity L. Smoking and tobacco M. Oral health N. Smoking and tobacco O. Oral health P. Alcohol Q. Overweight and obesity R. Overweight and obesity S. Overweight and obesity T. Overweight and obesity U. Smoking and tobacco V. Overweight and obesity W. Overweight and obesity X. Overweight and obesity Y. Oral health</p>	Not reported	<p><u>Length of follow-up:</u> Not reported</p> <p><u>Loss-to-follow-up:</u> Not reported</p>	<p><u>Increasing the oral health hygiene and management of their children</u> RR=0.38, [95% CI 0.08, 0.68]</p> <p><u>Increases in children's level of physical activity</u> RR=0.15, [95% CI 0.03, 0.28]</p> <p><u>Reductions in children's screen viewing time</u> (RR=0.16, [95% CI 0.03, 0.29]</p> <p><u>Less screen access for their children</u> RR=0.19, [95% CI 0.02, 0.3]</p> <p><u>Improvement in their children's diet</u> RR=0.24, [95% CI 0.09, 0.39]</p>	A variety of pediatric health behaviors and outcomes (e.g., oral health, diet, physical activity, reduced screen time, smoking cessation, reduced secondhand smoke, body mass index).

	<p>child dyad (interventions); (3) compare the intervention group to a control condition (e.g., assessment only, active comparison; comparisons); (4) examine modifiable health behaviors related to one of the leading health indicators specified in Healthy People 202027; (5) use a randomized controlled trial (RCT) design (study design); (6) be written in English; and (7) provide sufficient statistical information to calculate effect sizes.</p> <p><u>Exclusion criteria:</u> Not reported.</p>	<p>C. 13 D. 7 E. 15 F. 16 G. 4 H. 4 I. not reported J. 1 K. 4 L. 7 M. not reported N. 4 O. 5 P. 13 Q. 15 R. 16 S. 14 T. 6 U. not reported V. 5 W. 6 X. 10 Y. 11</p> <p><u>Baseline weight (SD):</u> Not reported</p>				<p><u>Quitting smoking</u> RR=0.33, [95% CI 0.03, 0.68]</p> <p><u>Employing greater smoking restrictions</u> RR=0.17, [95% CI 0.01, 0.34]</p> <p><u>Alcohol use</u> RR=0.91; [95% CI 0.45, 1.37]</p>	
Foster, 2015	<p><u>Type of study:</u> Systematic review of RCT's</p> <p><u>Search date:</u> July 2014</p> <p><u>Number of included studies:</u></p>	<p><u>N total at baseline:</u> A. 253; 192 B. 277; 230</p> <p><u>Age (years):</u> A. 2-6.9 B: 5</p> <p><u>Baseline weight (SD):</u></p>	<p>A. Motivational interviewing and education focused on: TV, sugar sweetened beverages and fast food (PNP, 4); also enhanced EMR 4 clinic visits (25 min each), 4 phone calls (15 min each) over 1 year</p> <p>B. Motivational interviewing on 1) playing outdoors 2)</p>	<p>A. Standard of care in the practice (pediatrician)</p> <p>B. General information on a healthy lifestyle during the well-child visit (physician-nurse team)</p>	<p><u>Length of follow-up:</u> A. 1 year B. 2 years</p>	<p><u>BMI:</u> A: MD = -0.21kg/m<sup>2</sup> [95% CI: -0.50, 0.07] B: MD=-0.16kg/m<sup>2</sup> [95% CI: -0.6, 0.27]</p>	Overweight and obesity

	<p>N=6 but only 2 relevant for our question</p> <p><u>Country</u> A. United States of America B. Netherlands</p> <p><u>Source of funding:</u> Not reported</p> <p><u>Inclusion criteria:</u> studies that enrolled children age 0-6, included a measure of adiposity as an outcome, and had a specific strategy for addressing children age 0-6 if other ages were included.</p> <p><u>Exclusion criteria:</u> Not reported.</p>	Not reported	<p>eating breakfast 3) reducing sweet drinks 4) watching TV, computer gaming (physician-nurse team, 4)</p> <p>4 visits in clinic over 1 year (unclear time per visit)</p>				
Li, 2015	<p><u>Type of study:</u> Systematic review of RCT's</p> <p><u>Search date:</u> April 2015</p> <p><u>Number of included studies:</u> N=10</p> <p><u>Country</u> A. United States of America B. Netherlands</p>	<p><u>N total at baseline:</u> A. 25; 14 B. 66; 51 C. 22; 20 D. 11; 7 E. 46; 48 F. 166; 176 G. 97; 82 H. 164; 162 I. 59; 45 J. 103; 102</p> <p><u>Age (years):</u> A. 16.93</p>	<p>A. 30-60 minutes personalized MI feedback B. BMI in 4 shorter sessions C. 15-20-minute MI + booster telephone call D. 25 minutes E. 3-session MET + personalized feedback F. Single session G. 1-hour single-session face-to-face interview H. Single-session MI I. 2 sessions MI J. Single MET +CBT</p>	<p>A. No personalized MI feedback B. Treatment as usual C. Care as usual D. Care as usual E. Educational materials F. Health-risk information only G. Education as usual H. Drug information and advice I. Relaxation training J. Educational feedback/ delayed feedback</p>	<p><u>Length of follow-up:</u> A. 3 months B. 3 months C. 3 months D. 3 months E. NA F. 6 months G. 3 months H. 6 months I. 3 months J. 12 months</p>	<p><u>Postintervention effect</u> RR=0.13 [95% CI 0.01, 0.24]</p> <p><u>Attitude change</u> RR=0.44 [95% CI 0.20, 0.67]</p> <p><u>Behaviour change (extent of drug use)</u> RR=0.05[95% CI-0.06, 0.17]</p>	Drugs

	<p><u>Source of funding:</u> Not reported</p> <p><u>Inclusion criteria:</u> (a) they tested an intervention or therapy based on MI or claimed to use the principles and techniques of MI or MET; (b) at least one type of illicit drug was included in the study; (c) the primary outcomes included the extent of drug use, intention to use drugs and readiness for change; (d) the intervention was delivered on an individual or face-to-face basis; (e) the study design met the criteria for a RCT with at least one comparison/control group, such as treatment as usual (TAU), assessment only, educational materials only, relaxation training (RT) or no intervention; (f) there was adequate measurement targeting pertinent</p>	<p>B. 17.9 C. 12-18 D. 16.1 E. 16.8 F. 18.4 G. 18.8 H. 18 I. 14-19 J. 16</p> <p>Population A. Youth with out-patient substance abuse treatment B. Homeless youth C. High-risk teens D. At-risk students E. Adolescents who had used MDMA or MAMP F. Young ecstasy and cocaine users G. Young people currently using illegal drugs H. Students who had smoked cannabis I. Incarcerated adolescents on DUI J. High school and middle-school students</p>					
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<p>problem areas; and (g) the study reported adolescents as the target group.</p> <p><u>Exclusion criteria:</u>                  (a) the paper was based on data that had already been included in another study; (b) the study included alcohol or other drugs of abuse, but not illicit drugs; (c) the paper was based on a sample with mean age &gt; 21 years; (d) the study did not assign participants to groups at random; (e) the study used a group MI design; and (f) the study reported insufficient data on the control group, intervention group or an associated statistic.</p>						
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**4. Risico op biasbeoordeling bij wetenschappelijke bewijs over motivatietechnieken, PICO 2**  
 Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 1:** Hoe kan een mondzorgverlener kinderen, adolescenten en ouders/verzorgers motiveren om het gebit gaaf te houden?

Risico op bias in systematische review(s)

Item	Borelli, 2015	Foster, 2015	Li, 2015
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1. Did the research questions and inclusion criteria for the review include the components of PICO?	Partial <i>All PICO items were reported</i>	Partial <i>All PICO items were reported.</i>	Partial <i>All PICO items were reported.</i>
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No <i>There was no information off a previous published protocol</i>	Yes <i>A detailed protocol was developed and is available by request from the corresponding author.</i>	No <i>There was no information off a previous published protocol</i>
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes <i>RCTs</i>	Yes <i>RCTs</i>	Yes <i>RCTs</i>
4. Did the review authors use a comprehensive literature search strategy?	Partial <i>They searched in different database but did not use other methods to identify literature</i>	Partial <i>They searched in different database but did not use other methods to identify literature</i>	Partial <i>They searched with simple terms in different database and reference lists</i>
5. Did the review authors perform study selection in duplicate?	No <i>Not reported</i>	Yes <i>Using the inclusion and exclusion criteria by two authors independently</i>	No <i>Not reported</i>
6. Did the review authors perform data extraction in duplicate?	No <i>Not reported</i>	Yes <i>The data were extracted independently by two authors</i>	No <i>Not reported</i>
7. Did the review authors provide a list of excluded studies and justify the exclusions?	No <i>The patients and intervention were well described</i>	Partial <i>Reasons for exclusion were given per group</i>	Partial <i>Reasons for exclusion were given per group</i>
8. Did the review authors describe the included studies in adequate detail?	Yes	Yes <i>The patients and intervention were well described</i>	Yes <i>The patients and intervention were well described</i>
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	No <i>Jaded and a sum score without information of the individual results</i>	Yes <i>Cochrane riskrisico op bias</i>	No <i>No RoB assessed</i>
10. Did the review authors report on the sources of funding for the studies included in the review?	No	No	No
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes <i>Random effects model with low heterogeneity</i>	Not applicable	Yes <i>Random effects model with low heterogeneity</i>

12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No	Not applicable	No
13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	No	Yes	No
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Not applicable <i>There was little heterogeneity</i>	Yes <i>They explained the heterogeneity and did not combine results.</i>	Not applicable <i>There was little heterogeneity</i>
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Yes <i>Was not possible because of too little data in a meta-analysis.</i>	Not applicable <i>Was not possible because of too heterogenous data.</i>	Yes Funnel plot
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No <i>Not reported</i>	No <i>Not reported</i>	No <i>No conflicts of interest</i>

## 5. Studiekarakteristieken bij het wetenschappelijke bewijs over fluoridevernis bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 2.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met melkelementen?

**Uitgangsvraag 2.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

### Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Marinho, 2012*  A. Holm, 1979 B. Clark, 1985 C. Frostell, 1991 D. Chu, 2002 E. Weintraub, 2006 E2. Borutta, 2006 F. Hardman, 2007 G. Lawrence, 2008 H. Yang, 2008 I. Salazar, 2008 J. Gugwad, 2011 K*. Agouropoulos, 2014 L. Anderson, 2017 M. Patil, 2017	Type of study: Systematic review of RCT's  Search date: 13 May 2013  Number of included studies: N=10 from review and N=3 from the update  Country A. Sweden B. Canada C. Sweden D. Hong Kong E. USA E2: Germany F. UK G. Canada H. China I. Brazil J. India K. Greece L. Sweden	N total at baseline (n analysed): A. 250 (125, 125) B. 787 (232, 280, 275) C. 206 analysed (113, 93) D. 146 (73, 73) E. 376 (unclear) E2: 288 (84, 113, 91) F. 2091 (1025, 1066) G. 1275 (915, 360) H. 150 I. 200 (unclear) J. 250 (106, 105) K. 424 (216, 193) L. 801 (426, 375) M. 200 (100, 100)  Age: A. Mean and median 3 years	A. NaF varnish group (Duraphat® 22,600 ppm F), applied twice a year, with thin brush, left to dry (duration NR)  B. Group I: FV group: Fluor Protector® Difluorsilane (7000 ppm F), applied twice a year, about 0.5 ml applied per child Group II: FV group: Duraphat® NaF (22,600 ppm F), applied twice a year, about 0.5 ml applied per child  C. NaF group (Duraphat®) = 22,600 ppm F. All tooth surfaces were polished with pumice and rubber cap, and approximal surfaces were flossed, followed by a "thorough	A. No treatment  B. Water, applied in the same manner as test groups  C. No treatment  D. Water painted onto carious teeth  E. NaF varnish applied to gauze, which was then folded and the dry area used to wipe the child's teeth ensuring that no NaF varnish was applied  E2: No treatment  F. No treatment  G. No treatment  H. Placebo (water) applied with cotton swab	Length of follow-up: A. 2 years B. 1,5; 2,5***; 4,5 years C. 2 years D. 18; 30 months E. 1; 2 years E2: 2 years F. 2 years G. 2 years H. 2 years I. 1 year J. 1 year K. 2 years L. 2 years M. 1 year  Loss-to-follow-up: A. 25 (13, 12) B. 111 (unclear) at 2,5 years C. unclear D. 23 (12, 11) E. 5 (unclear)	d(e/m)fs increment (prevented fraction - nearest to 3 years (10 trials))  Studies =12 Partic. = 4324  Prevented fraction: 0.35 (95% CI 0.24 to 0.46) I <sup>2</sup> = 67% P=0.0005	*only studies from review on primary dentition were abstracted. This review has been updated with studies published since the last search date  **Starting from study K, studies from the update where added  *** Results closest to 3 years chosen  FV = Fluoride varnish NT = No treatment PT = Placebo treatment

	<p>M. India</p> <p>Source of funding:  <ul style="list-style-type: none"> <li>• CAPES - Ministry of Education, Brazil.</li> <li>• Cochrane Oral Health Group Global Alliance, UK.</li> </ul>                     All reviews in the Cochrane Oral Health Group are supported by Global Alliance member organisations (British Orthodontic Society, UK; British Society of Paediatric Dentistry, UK; Canadian Dental Hygienists Association, Canada; National Center for Dental Hygiene Research &amp; Practice, USA and New York University College of Dentistry, USA) providing funding for the editorial process (<a href="http://ohg.cochrane.org/">http://ohg.cochrane.org/</a>)  <ul style="list-style-type: none"> <li>• National Institute for Health Research (NIHR), UK.</li> </ul>                     CRG funding acknowledgement:                      The NIHR is the largest single funder of the Cochrane Oral Health Group</p> <p>Inclusion criteria:                      Randomised and quasi randomised controlled trials using or indicating blind outcome assessment, in which fluoride varnish is compared concurrently to</p>	<p>B. 6-7 years                      C. 4 years                      D. mean = 4 (3-5 years)                      E. mean 1,8 years (6 - 44 months)                      E2: 2-4 years                      F. mean 7 (6-8 years)                      G. mean 2,5 (5 months- 5 years)                      H. 3 years                      I. 12-48 months                      J. 6-7 years                      K. 2-5 years                      L. 1 year                      M. 6-7 years</p> <p>Baseline caries (SD):                      A. defs: 1,05 in FV and 0,71 in NT                      B. not reported                      C. not reported                      D. caries in upper primary anteriors                      E. no initial caries                      E: FV mean dmfs = 3.75, NT = 1.94                      F. not reported                      G. not reported                      H. not reported                      I. High caries prevalence population.                      Approximately 1/2 children had caries in the primary teeth and approximately 1/4 had dental caries</p>	<p>mouthrinse with water". Varnish was applied twice a year, with small brush, left to dry for 2 minutes, teeth were rinsed, and any surfaces not coated were re-coated.</p> <p>D. 5% NaF varnish group (Duraphat® 22,600 ppm F), applied 4 times a year, at schools (kindergartens), to carious surfaces, with small brush, left to dry (duration NR)</p> <p>E. Group I: NaF varnish (Duraphat® 22,600 ppm F), twice a year                      Group II: NaF varnish (Duraphat® 22,600 ppm F), once a year                      Application in health centres, to all teeth surfaces, teeth dried with gauze, varnish applied with brush, 0.1 mL (1 drop) applied per arch, left to dry (duration NR)</p> <p>E2: Group I: 5% Na varnish (Fluoridin N5 = 22,600 ppm F) applied twice a year, total of 4 applications                      Group II: 5% NaF varnish (Duraphat® = 22,600 ppm F) applied twice a year, total of 4 applications</p>	<p>twice after teeth were dried. Children told not to eat or drink for 30 minutes. Treatment was applied every 6 months</p> <p>I. Placebo applied every 6 months (2 applications)</p> <p>J. No treatment</p> <p>K. Biannual applications of a placebo varnish without fluoride. Both varnishes (test and placebo) had the same smell, texture and packed in identical boxes.</p> <p>L. No treatment</p> <p>M. No treatment</p>	<p>E2: 88 (24, 37, 27)                      F. unclear                      G. 115 (83, 32)                      H. 2                      I. 52 (unclear)                      J. 39 (unclear)                      K. 81 (42, 39)                      L. 137 (112, 25)                      M. 7 (4, 3)</p>		
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	<p>a placebo or no treatment group during at least one year.</p>	<p>J. not reported K. dmfs 2.5 FV; 3.1 PT L. Dental caries (ICDAS 3-6) was 3% at baseline, when the children were 1 year old. Prevalence was 16% at age 2 and 42% at age 3. M. dmft: 0.35 FV; 0.26 NT</p>	<p>F. NaF varnish group (Duraphat® 22,600 ppm F), applied 6 monthly, at schools, to all surfaces of the primary and first permanent molars, with small brush, and left to dry (duration NR)</p> <p>G. 5% NaF varnish group (Duraflor® 22,600 ppm F), applied 2 to 3 times/year, to all surfaces of the primary dentition, with small brush, and left to dry (duration NR)</p> <p>H. Group I: 0.5% FV (Fluor Protector = 5000 ppm) applied with cotton swab twice after teeth were dried. Children told not to eat or drink for 30 minutes. Treatment was applied every 6 months Group II: 0.1% FV (Fluor Protector = 1000 ppm) applied with cotton swab twice after teeth were dried. Children told not to eat or drink for 30 minutes. Treatment was applied every 6 months</p> <p>I. 5% NaF varnish group (Duraphat® 22,600 ppm F), applied every 6 months (2 applications)</p>				
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			<p>J. 5% NaF (Cavity Shield = 22,600 ppm F), unclear which dose used (0.25, 0.40 ml). Unclear where applied, 3 times in 1 week with small brush, left to dry for few seconds</p> <p>K. FV (0.9% difluorosilane®, 5000 ppm F) applications twice a year (Fluor Protector). The applications were performed at 6 months intervals in the schools by one single dentist. The teeth were cleaned and dried with gauze and approximately 0.2 ml of the varnish was applied with a micro-brush on all maxillary and mandibular teeth.</p> <p>L. FV (Duraphat®, 22,600 ppm F) biannual between 1 and 3 years of age</p> <p>M. FV (5% sodium fluoride, 3M ESPE 22,600 ppm F) three times in 1 week.</p>				
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## 6. Risico op biasbeoordeling bij wetenschappelijke bewijs over fluoridevernis bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 2.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met melkelementen?

**Uitgangsvraag 2.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

Risico op bias in systematische review(s)

Study: <b>Marinho, 2013</b>	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	All PICO elements were described.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	The protocol was prior the review. The review gave an explanation why it deviated on some points.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	Yes, a list of in- and excluded studies was provided.
4. Did the review authors use a comprehensive literature search strategy?	Yes	Yes, different databases and trial registers with an extensive search. In addition, they checked references and did handsearching.
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Yes	-
8. Did the review authors describe the included studies in adequate detail?	Yes	Information about the patients, intervention and control were reported. There was no information about follow up or sponsoring.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Riskrisico op bias
10. Did the review authors report on the sources of funding for the studies included in the review?	No	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	Random effects model
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Yes	Meta-regression was used.
13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	Yes	-
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Not applicable	-
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Yes	-
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.



Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of patient and personell (performance bias)	Blinding of outcome assessor (detection bias)	Follow-up and ITT or per protocol analysis (attrition bias)	Selective reporting	Other bias
Agouropoulos, 2014	Low risk <i>Random permuted blocks of size 8 were used and the randomization lists were produced with computer software.</i>	Low risk <i>The random lists were generated by the principal investigator and a secretary allocated the names of the children for every school.</i>	Low risk <i>The allocation of the subjects was unknown to the examiner, parents and their children.</i>	Low risk <i>The allocation of the subjects was unknown to the examiner, parents and their children.</i>	Unclear <i>Not reported.</i>	Unclear <i>The study was not registered in a trial register.</i>	Low risk <i>No other sourcesrisico op bias were found.</i>
Anderson, 2017	Unclear <i>Not reported.</i>	Unclear <i>Not reported.</i>	Unclear <i>Not reported.</i>	Unclear <i>Not reported.</i>	Unclear <i>Not reported.</i>	Unclear <i>A large to which this study is a sub question is registered. The outcomes of his sub question are not specified.</i>	Low risk <i>No other sourcesrisico op bias were found.</i>
Patil, 2017	Unclear <i>Not reported.</i>	Unclear <i>Not reported.</i>	Unclear <i>Not reported.</i>	High risk <i>Not blinded.</i>	Unclear <i>Not reported.</i>	Unclear <i>The study was not registered in a trial register.</i>	Low risk <i>No other sourcesrisico op bias were found.</i>

## 7. Studiekarakteristieken bij het wetenschappelijke bewijs over fluoridegel bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 2.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met melkelementen?

**Uitgangsvraag 2.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

### Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Marinho, 2015  A. Englander, 1978 B. Treide, 1988 C. Van Rijkom, 2004	<p><u>Type of study:</u> Systematic review of RCT's</p> <p><u>Search date:</u> 5 November 2014</p> <p><u>Number of included studies:</u> N=27 (42 articles) only 3 studies studied primary dentition</p> <p><u>Country</u> A USA B. Germany C. Netherlands</p> <p><u>Source of funding:</u></p> <ul style="list-style-type: none"> <li>• Queen Mary University of London, UK.</li> <li>• Department of Epidemiology and Public Health (UCL), UK.</li> <li>• Systematic Reviews Training</li> </ul>	<p><u>N total at baseline (n analysed):</u> A. 231 (145) B. 643 (433) C. 773 (732)</p> <p><u>Age:</u> A. 2-6 years B. 3.5 years C. 4.5-6.5 years</p> <p><u>Baseline caries (SD):</u> A. 3.7 defs - 43% caries-free B. NR (but dmft data reported from original sample only = 0.8) C. d3mfs = 0</p>	<p>A. FG (APF 5,000 ppm) s.a. 76 times a year B1. FG + ptc (NaF + hexaf 12,500 ppm) s.a. 130 times a year B2. FG + ptc (NaF 12,500 ppm) s.a. 130 times a year B3. FG + ptc (AmF concentration NR) s.a. 130 times a year C. FG (Neutral 1% NaF gel, 4500 ppm) p.a. with flexible tray, for 4 min, 2 times a year twice a year</p>	<p>A. Placebo B. Placebo + ptc C. Placebo</p>	<p><u>Length of follow-up:</u> A. 2.3 years B. 3 years C. 4 years</p>	<p><u>Primary elements:</u>  D(M)FT increment nearest to 3 years (Prevented fraction [95% CI]) (3 studies)  Compared to placebo control: 0.20 [ 0.01, 0.38 ] I<sup>2</sup> = 0%</p>	<p>FG= fluoridegel Ptc = prior tooth cleaning performed with or without a non-fluoride paste AmF= amine fluoride APF =acidulated phosphate fluoride NaF=Natrium Fluoride p.a. professional applied s.a. = self applied NR = Not reported</p>

	<p>Unit, Institute of Child Health (UCL), UK.</p> <ul style="list-style-type: none"> <li>• Medical Research Council, UK.</li> <li>• School of Dentistry, The University of Manchester, UK.</li> </ul> <ul style="list-style-type: none"> <li>• National Institute for Health Research (NIHR), UK.</li> <li>• Cochrane Oral Health Group Global Alliance, Other.</li> <li>• CAPES - Ministry of Education, Brazil.</li> </ul> <p><u>Inclusion criteria:</u></p> <p><u>Exclusion criteria:</u></p>						
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## 8. Risico op biasbeoordeling bij wetenschappelijke bewijs over fluoridegel bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 2.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met melkelementen?

**Uitgangsvraag 2.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

### Risico op bias in systematische review(s)

Study: Marinho, 2015	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	An extensive description of all PICO items and time frame for follow up was reported.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	The detailed protocol was published in advance.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	RCT's.
4. Did the review authors use a comprehensive literature search strategy?	Yes	Different databases, no language restrictions, trial registers, reference lists, hand searching and person contact.
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Yes	-
8. Did the review authors describe the included studies in adequate detail?	Yes	All PICO elements, follow up and sponsoring were reported.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Riskrisico op bias
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	-
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Yes	-
13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	Also reported in the summary of findings table.

14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	-
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Yes	Funnel plot assessment
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.

## 9. Studiekarakteristieken bij het wetenschappelijke bewijs over SDF bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

### Uitgangsvraag 2.4: Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics <sup>1</sup>	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Gao, 2016 A. Duangthip, 2016 B. dos Santos, 2012 C. Zhi, 2012 D. Yee, 2009 E. Braga, 2009 F. Huang, 2006 G. Llodra, 2005 H. Mauro, 2004 I. Chu, 2002 J. Yang, 2002 K. Fukumoto, 1997 L. Miasato, 1996 M. Ye, 1995 N. Marciel, 1988	<u>Type of study:</u> Systematic review of RCT's  <u>Search date:</u> March 2016  <u>Number of included studies:</u> N=19 (16 on primary elements)  <u>Country</u> A. Hong Kong B. Brazil C. China D. Nepal <b>E. Brazil</b> F. China G. Cuba <b>H. Argentina</b> I. Hong Kong J. China	<u>N total at baseline:</u> A. 1407 B. 345 C. 719 D. 6638 E. 58 (permanent teeth) F. 738 G. 1333 H. 141 (permanent teeth) I. 1490 J. 158 K. 130 L. 88 M. 300 N. 184 O. 54 (permanent teeth) P. 214 Q. 66 R. 52	A. Gp1: 30% SDF, annually (n = 458) Gp2: 30% SDF, one-off (n = 426)  B. Gp1: 30% SDF, one-off (n = 183)  C. Gp1: 38% SDF, annually (n = 218) Gp2: 38% SDF, semi-annually (n = 239)  D. Gp1: 38% SDF, one-off (n = 3,396) Gp2: 12% SDF, one-off (n = 1,652)  E. Gp1: CTT, one-off (n = 18) Gp2: 10% SDF, one-off (n = 20)  F. Gp1: 38% SDF biannually, anterior teeth (n = 226)	A. Gp3: 5% sodium fluoride, one-off (n = 523)  B. Gp2: glass ionomer, one-off (n = 162)  C. GP3: glass ionomer, annually (n = 262)  D. Gp3: no treatment (n = 1,590)  <b>E. Gp3: glass ionomer, one-off (n = 20)</b>  F. Gp4: no treatment, posterior teeth (n = 145)  G. Gp2: no treatment (n = 658)  <b>H. Gp3: 5% sodium fluoride, one-off (n = 44)</b>	<u>Length of follow-up:</u> A. 18 months B. 12 months C. 24 months D. 24 months E. 30 months F. 18 months G. 36 months H. 12 months I. 30 months J. 6 months K. 48 months L. 6 months M. 12 months N. 6 months O. 12 months P. 18 months Q. 18 months R. 12 months S. 6 months	A. Caries-arresting rate: Gp1 (40%) > Gp2 (35%) > Gp3 (27%)  B. Caries-arresting rate: Gp1 (67%) > Gp2 (39%)  C. Caries-arresting rate: Gp2 (91%) > Gp1 (79%), Gp3 (82%)  D. Caries-arresting rate: Gp1 (31%) > Gp2 (22%), Gp3 (15%)  E. Carious scores: no difference among groups	

<p>O. Oliveira, 1985 P. Wang, 1984 Q. Tsutsumi, 1981 R. Yoshida S. Nishino, 1969</p>	<p>K. Japan L. Brazil M. China N. Brazil <b>O. Brazil</b> P. China Q. Japan R. Japan S. Japan</p> <p><u>Source of funding:</u> A grant (17107 315) from the General Research Fund of the Research Grants Council of Hong Kong. The authors declare no potential conflicts of interest with respect to the authorship.</p> <p><u>Inclusion criteria:</u> Prospective clinical studies investigating the caries-arresting effect of SDF treatment in children with or without control groups were selected</p> <p><u>Exclusion criteria:</u> Literature reviews, case</p>	<p>S. 188</p> <p><u>Age:</u> A. primary B. primary C. primary D. primary E. permanent F. primary G. primary H. permanent I. primary J. primary K. primary L. primary M. primary N. primary O. permanent P. primary Q. primary R. primary S. primary</p> <p><u>Baseline caries (SD):</u> dentine caries</p>	<p>Gp2: no treatment, anterior teeth (n = 223) Gp3: 38% SDF biannually, posterior teeth (n = 144)</p> <p>G. Gp1: 38% SDF, semi-annually (n = 675)</p> <p>H. Gp1: ammonium fluoride, one-off (n = 48) Gp2: 38% SDF, one-off (n = 49)</p> <p>I. Gp1: 38% SDF, annually (n = 641)</p> <p>J. 38% SDF, one-off (n = 158)</p> <p>K. 38% SDF, one-off (n = 130)</p> <p>L. 30% SDF, every 3 mo (n = 88)</p> <p>M. 38% SDF, one-off (n = 300)</p> <p>N. Gp1: 10% SDF, one-off (n = 104)</p> <p>O. Gp1: 38% SDF, one-off (n = 7) Gp2: 38% SDF, twice in 1 wk (n = 9) Gp3: 38% SDF, biannually (n = 21) Gp4: 38% SDF, twice in 1 wk, then biannually (n = 17)</p> <p>P. Gp1: 38% SDF, every 3 to 4 mo (n = 110)</p> <p>Q. Gp1: 38% SDF, every 3 mo (n = 33)</p>	<p>I. Gp2: 5% sodium fluoride, every 3 mo (n = 576) Gp3: no treatment (n = 273)</p> <p>J. no comparison</p> <p>K. no comparison</p> <p>L. no comparison</p> <p>M. no comparison</p> <p>N. Gp2: no treatment (n = 80)</p> <p><b>O. no comparison</b></p> <p>P. Gp2: no treatment (n = 104)</p> <p>Q. Gp2: no treatment (n = 33)</p> <p>R. Gp2: no treatment (n = 26)</p> <p>S. Gp2: no treatment (n = 82)</p>		<p>F. Caries-arresting effect: Gp1 &gt; Gp2 (no data provided) Gp3 &gt; Gp4 (no data provided)</p> <p>G. Caries-arresting rate: Gp1 (85%) &gt; Gp2 (62%)</p> <p>H. Caries-arresting rate: Gp1 (56%), Gp2 (57%), Gp3 (47%) No difference among groups</p> <p>I. Caries-arresting rate: Gp1 (65%) &gt; Gp2 (41%), Gp3 (34%)</p> <p>J. Caries-arresting rate: 94.4%</p> <p>K. Caries-arresting rate: 54%</p> <p>L. Caries-arresting rate: 83%</p> <p>M. Caries-arresting rate: 92%</p> <p>N. Caries-arresting rate: Gp1 (90%) &gt; Gp2 (74%)</p> <p>O. Caries-arresting effect: Caries arrested in all groups</p>	
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	<p>reports, laboratory studies, clinical trials in other clinical treatment guidelines, and other irrelevant studies.</p>		<p>R. Gp1: 38% SDF, every 3 mo (n = 26)</p> <p>S. Gp1: 38% SDF, one-off (n = 106)</p>		<p>No difference among groups</p> <p>P. Caries-arresting rate: Gp1 (86%) &gt; Gp2 (31%)</p> <p>Q. Caries-arresting effect: Gp1 &gt; Gp2 (no data provided)</p> <p>R. Caries-arresting effect: SDF was effective (no data provided)</p> <p>S. Caries without progression: Laterally: Gp1 (69%) &gt; Gp2 (52%) Pulpally: Gp1 (76%) &gt; Gp2 (65%)</p>	
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## 10. Risico op biasbeoordeling bij wetenschappelijke bewijs over SDF bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

### Uitgangsvraag 2.4: Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

#### Risico op bias van systematische review(s)

Study: Gao, 2016	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Partial	Only de patients and intervention were predefined.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No	The protocol was not separately published. Also the methods section already some of the results.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	All studies
4. Did the review authors use a comprehensive literature search strategy?	Partial	Different databases, many languages, no mesh terms of other methods.
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Partial	A flow chart shows information about reasons for exclusion but no explicit reason per reference.
8. Did the review authors describe the included studies in adequate detail?	Yes	Information about the patients, intervention and control were reported. There was no information about follow up or sponsoring.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Riskrisico op bias
10. Did the review authors report on the sources of funding for the studies included in the review?	No	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	No	There was significant heterogeneity even though they performed a meta-analysis.
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No	-
13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	No	-
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	No	-



15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	No	-
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.

## 11. Studiekarakteristieken bij het wetenschappelijke bewijs over partiële of stapsgewijze excavatie bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

### Uitgangsvraag 2.4: Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

#### Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics <sup>1</sup>	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Rickets, 2013* A. Lula, 2009 B. Magnusson, 1977 C. Orhan, 2010 D. Ribeiro, 1999	<p><u>Type of study:</u> Systematic review of RCT's</p> <p><u>Search date:</u> 12 December 2012</p> <p><u>Number of included studies:</u> N=8 (3 studies relevant for question about primary teeth and 2 studies relevant for question about permanent teeth)</p> <p><u>Country</u> A. Brazil B. Sweden C. Turkey D. Brazil</p> <p><u>Source of funding:</u> Cochrane Oral Health Group</p>	<p><u>N total at baseline:</u></p> <p>A. 30 (36 teeth) B. 62 (110 teeth) C. 123 (94 primary and 60 permanent teeth) D. 38 (48 teeth)</p> <p><u>Age:</u> A. 5-8 years B. 5-10 years C. 4-15 years D. 7-11 years</p> <p><u>Baseline caries (SD):</u> A. Healthy child with at least one active primary carious lesion, on a primary tooth, which extends into the inner half of dentine. B. Carious molars, with no signs/symptoms of irreversible pulpitis or</p>	<p>A. Partial caries removal</p> <p>B. Stepwise removal. Re-entry was carried out at 4 to 6 weeks. Teeth were temporised with calcium hydroxide (Calxyl or Calasept), and intermediate layer of 'Dropsin' and sealed with ZOE cement.</p> <p>C. Stepwise (n = 49 teeth) two-visit 'indirect pulp treatment' (IPT). Caries was removed until the operator thought pulp exposure would occur with further excavation. Two-visit IPT after the initial excavation, calcium hydroxide base was placed and provisionally restored with ZOE cement- re-entry was at 3 months. In all groups, following the final excavation, glass ionomer (Ionofil) was placed as a cavity base</p>	<p>A. Complete caries removal</p> <p>B. Complete removal. Restoration material for the control group was not clearly Stated.</p> <p>C1. Partial (n = 50 teeth) one-visit 'indirect pulp treatment'. Caries was removed until the operator thought pulp exposure would occur with further excavation. C2. Complete (n = 55 teeth) direct complete excavation. All carious dentine was removed till hard dentine was reached or pulp exposure occurred</p> <p>D. A caries detecting solution was used. "All identified irreversibly infected dentin was removed with a No 2 low-speed round bur". Preparation removed all stained dentine.</p>	<p><u>Length of follow-up:</u> A. 3 tot 6 months B. not reported C. not reported D. not reported</p>	<p><b>Results for Stepwise RR [95% CI]**</b></p> <p><u>Pulp exposure during caries removal:</u> 0.31 [0.17, 0.57]</p> <p><u>Signs or symptoms of pulpal disease (1 year):</u> 0.48 [0.04, 5.08]</p> <p><b>Results for Partial RR [95% CI]</b></p> <p><u>Pulp exposure during caries removal:</u> 0.13 [0.04, 0.37]</p> <p><u>Signs or symptoms of pulpal disease (1 year):</u> 0.27 [0.05, 1.60]</p> <p><u>Failure of restorations:</u> 1.35 [0.36, 5.11]</p>	<p>ICDAS 4-6</p> <p>*Not described: Bjørndal, 2010 and Mertz-Fairhurst 1987 (excluded because of adult patients) Innes, 2007 (no relevant intervention)</p> <p>**These results come from the relevant RCT's for this question combined with the extra RCT, Franzon, 2014.</p>

	<p>Global Alliance, UK. National Institute for Health Research (NIHR), UK.</p> <p><u>Inclusion criteria:</u> Participants with caries, affecting any tooth surface(s), in unrestored primary and permanent teeth. Stepwise, partial, or no dentinal caries removal prior to restoration.</p> <p><u>Exclusion criteria:</u> Not reported.</p>	<p>periradicular involvement</p> <p>C. No symptoms of irreversible pulpitis or signs of pulpal or periradicular pathology. Pulp vitality was confirmed by a cold stimulation tester (Chloroethyl) and/or electric pulp tester</p> <p>D. 48 carious primary molars. Equal numbers of Class I and Class II lesions (n = 12) in both treatment groups. Primary molars with carious lesions involving dentine.</p>	<p>D. Thorough removal of carious dentine from the dentino-enamel junction, while the carious dentine from the pulpal and axial walls was left. Visibly moist and soft carious dentine was intentionally left in the cavity and definitive restoration placed. No re-entry was carried out. All teeth definitively restored with composite (Z100).</p>				
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### Studiekenmerken van RCT('s)

Study	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Franzon, 2014	<p>Type of study: RCT</p> <p>Setting: General dental practice</p>	<p><u>Inclusion criteria:</u> Children aged 3-8, in good health, with at least one molar with acute, deep carious lesion in the</p>	<p>After the administration of anesthesia and rubber dam isolation, dentinal carious lesions were accessed when necessary with a round diamond bur (#1011/1012) operated at high speed under</p>	<p>In teeth treated with TCR, the absence of caries was confirmed after removal of all softened dentin using a blunt-tipped probe. PCR was performed using visual and tactile clinical criteria.</p>	<p><u>Length of follow-up:</u> 24 months</p> <p><u>Loss-to-follow-up:</u> Intervention: N=1 (1%)</p>	<p>Outcome measures and effect size</p> <p><u>Mean operative Time:</u> PCR: 17.9 min; [95%</p>	

	<p>Country: Brazil</p> <p>Source of funding: Not reported. The authors had no conflict of interest.</p>	<p>dentin of one molar. Lesions had to be radiographically located in the inner quarter of dentin and could involve one (occlusal) or two surfaces (occlusal and proximal). Absence of sensitivity and/or spontaneous pain, swelling, fistula and mobility incompatible with the root resorption stage; absence of periapical or interradicular radiolucency or other radiographic signs indicative of pulp necrosis</p> <p><u>Exclusion criteria:</u> If there was impossibility to perform the restorative procedures to be tested.</p> <p><u>N total at baseline:</u> 51 children (124 teeth) I: 67 teeth C: 57 teeth</p>	<p>water cooling. Decayed dentin was removed completely from the lateral walls of cavities in both groups using round burs operated at low speed. TCR or PCR was then performed in the pulpal wall of each tooth.</p>	<p>Excavation was stopped when hardened, dried dentin with a leathery consistency was achieved. Following caries removal, each cavity was cleaned, washed, and dried. Calcium hydroxide cement (Dycal; Dentsply, Milford, Del., USA) was applied to the pulpal wall, followed by 37% phosphoric acid etching of enamel for 15 s and dentin for 7 s. The cavity was then flushed with air/water spray and dried with sterilized cotton pellets while retaining tissue moisture. All cavities were restored with composite resin (Filtek TM Z 350 ® , color B2; 3M) after hybridization with an adhesive system (Single Bond; 3M ESPE) according to the manufacturer's specifications.</p>	<p>Reasons: did not show up.</p> <p>Control: N=3 (5%) Reasons: did not show up.</p>	<p>CI: 16.3-19.5 min]. TCR: 28.1 min; [95% CI: 23.6-32.6 min] p &lt; 0.001</p> <p><u>Pulp exposure:</u> PCR: 1/66 TCR: 15/54</p> <p><u>Overall clinical and radiographic success rate:</u> PCR: 92%; [95% CI: 81-96%] TCR: 96%; [95% CI: 85-99%]</p>	
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		<p><u>Dental characteristics:</u>  <i>41 (34.2%) and 79 (65.8%) teeth presented with class I and II cavities, respectively.</i></p> <p><u>Groups comparable at baseline?</u>                  Yes</p>					
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## 12. Risico op biasbeoordeling bij wetenschappelijke bewijs over partiële of stapsgewijze excavatie bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

### Uitgangsvraag 2.4: Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

Risico op bias van systematische review(s)

Study: Ricketts, 2013	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	An extensive description of all PICO items and time frame for follow up was reported.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	The detailed protocol was published in advance.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	RCTs.
4. Did the review authors use a comprehensive literature search strategy?	Yes	Different databases, no language restrictions, reference checking and contacting authors.
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Yes	-
8. Did the review authors describe the included studies in adequate detail?	Yes	All PICO elements, follow up and sponsoring were reported when available.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Riskrisico op bias
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	-
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Not applicable	Was not possible because of too little data in a meta-analysis.
13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	Yes	Also reported in the summary of findings table.
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Not applicable	Was not possible because of too little data in a meta-analysis.

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Not applicable	Was not possible because of too little data in a meta-analysis.
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.

Risk or bias van RCT('s)

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of patient and personell (performance bias)	Blinding of outcome assessor (detection bias)	Follow-up and ITT or per protocol analysis (attrition bias)	Selective reporting	Other bias
Franzon, 2014	Low risk <i>Coin toss.</i>	Unclear <i>Not reported</i>	High risk <i>The patients were blinded but the dentist was not.</i>	Low risk <i>The examiner who assessed outcomes was blinded to the treatment.</i>	Low risk <i>ITT and PP was used.</i>	Unclear <i>The study was not registered.</i>	Low risk <i>No other sources risk of bias was found.</i>

### 13. Studiekarakteristieken bij het wetenschappelijke bewijs over Hallkroon bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

#### Uitgangsvraag 2.4: Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Innes, 2015 E. Atieh, 2008 F. Hutcheson, 2012 G. Innes, 2011 H. Ram, 2003 I. Santamaria, 2014*	<p><u>Type of study:</u> Systematic review of RCT's</p> <p><u>Search date:</u> 21 January 2015</p> <p><u>Number of included studies:</u> N=5 (8 articles)</p> <p><u>Country</u> A. Saudi Arabia B. United States of America C. Scotland E. Israel F. Germany</p> <p><u>Unit of randomisation:</u> A. teeth B. split-mouth trial C. split-mouth trial D. split-mouth trial E. Unit of randomisation: patient</p>	<p><u>N total at baseline:</u> A. 87 (160 teeth) B. 40 (80 teeth) C. 132 (264 teeth) D. 22 (teeth) E. 169 (split mouth design)</p> <p><u>Age:</u> A. 4-7 years (mean 5.5 (SD 1.1)) B. mean 5.1 years (2.6 to 8) C. 3-10 years, mean 6.8 years; SD 1.58 D. not reported E. 3-8 years</p> <p><u>Baseline caries (SD):</u> A. restorable primary molar with cariously exposed pulp B. large carious lesions of similar</p>	<p>A. PMCs</p> <p>B. SSC; All participants had MTA pulpotomy All teeth had pulpotomies carried out before the crowns or restorations were placed</p> <p>C. PMC (SSC) placed by the Hall Technique with no caries removal. 4 teeth were not successfully fitted with crown but were managed under intention-to-treat protocol</p> <p>D. SSC; The conventional technique was used for both groups. Glass ionomer cement was used. However, the occlusal surface reduction was more extensive for the aesthetic crown (approximately 1.5 mm), as the crowns were thicker</p> <p>E. SSC using the Hall Technique</p>	<p>A. modified open-sandwich technique using resin-modified glass ionomer cement or composite resin restorations</p> <p>B. resin composite multi-surface fitted using open sandwich technique. A layer of glass ionomer was used to cover the MTA before resin was applied</p> <p>C. restorations of the operator's choice: glass ionomer (69%), amalgam (8%), compomer (5%), composite (11%), SSC (1% - with tooth preparation), fissure sealant (2%), and no restoration provided (3%)</p> <p>D. aesthetic crown - a composite veneer had been added to cover the facial, occlusal, mesial and distal aspects.</p> <p>E1. fillings using resin composite</p>	<p><u>Length of follow-up:</u> A. 6, 12, 18 and 24 months ± 2 weeks B. 6, 12 months C. 5 years D. 6 months and 4 years E. 1 year</p>	<p><u>Crown versus filling:</u> <u>Major failure (12 to 48 months):</u> RR: 0.18 [0.06, 0.56]</p> <p><u>Pain (12 to 24 months):</u> RR: 0.15 [0.04, 0.67]</p> <p><u>Discomfort:</u> RR: 0.56 [0.36, 0.87]</p> <p><u>Bleeding short term:</u> RR: 1.69 [0.61, 4.66]</p> <p><u>Bleeding long term (&gt;12 mo)</u> RR: 1.74 [0.99, 3.06]</p> <p><u>Crown versus NRCT:</u> <u>Major failure (12 to 48 months):</u></p>	<p>ICDAS 3-5</p> <p>Data from the 2018 publication was added.</p>



	<p><u>Source of funding:</u> NIHR, via Cochrane Infrastructure funding to the Cochrane Oral Health Group</p> <p><u>Inclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• RCT's</li> <li>• Children with at least one primary molar affected by decay or developmental defects.</li> <li>• Preformed crowns of any material placed using any method.</li> </ul> <p>Interventions with incomplete or no carious tissue removal, or any pulp therapy prior to placement of the crown. The comparison was with another crown, or any type of restoration, or another method for managing carious tissue.</p> <ul style="list-style-type: none"> <li>• at least 6 months follow-up</li> </ul>	<p>size approaching the pulp</p> <p>C. Carious primary molars; 68% approximal lesions and 42% &gt; half way into dentine radiographically (where radiographs were available). 73 study teeth pairs (55%) were first primary molars and 59 (45%) were second primary molars</p> <p>D. not reported</p> <p>E. primary molars; maxillary first = 62; maxillary second = 29; mandibular first = 54; mandibular second = 24.</p> <p>ICDAS; code 3 = 6 teeth, 4 = 25 teeth, 5 = 138 teeth</p>		<p>E2. non-restorative caries treatment</p>		<p>RR: 0.12 [0.01, 2.18]</p> <p><u>Discomfort:</u> RR: 1.67 [0.65, 4.25]</p> <p><u>Bleeding long term (&gt;12 mo)</u> RR: 1.09 [0.42, 2.86]</p>	
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	<u>Exclusion criteria:</u> Not reported.						
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Study	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Lakshmi, 2018	<p>Type of study: RCT</p> <p>Setting: Primary school</p> <p>Country: India</p> <p>Source of funding: Not reported</p>	<p><u>Inclusion criteria:</u> children in the age group of five to eight years with at least one occlusoproximal carious primary molar were randomly selected.</p> <p><u>Exclusion criteria:</u></p> <p><u>N total at baseline:</u> 30</p> <p><u>Age ± SD:</u> 5 to 8 years</p> <p><u>Groups comparable at baseline?</u> yes</p>	<p>ART</p> <p>The tooth to be treated was isolated using cotton wool rolls alongside and plaque removal was done using wet cotton pellets. Then the tooth surface was dried with dry cotton pellets and a dental hatchet was used to make the cavity entrance wider. Residual carious dentine was removed using excavator and the unsupported thin enamel was fractured off with the hatchet. Any soft caries near the pulp was removed carefully and cavity cleaned with wet cotton pellets. Then the cavity was dried using dry cotton pellets and a precurved matrix strip was placed between the teeth. A wedge was inserted to support the strip under the contact point. The cavity and adjacent fissures were then conditioned using a moist cotton pellet dipped in GC cavity conditioner liquid for 10-15 seconds. Finally, the cavity was washed with three</p>	<p>Hall Technique</p> <p>The treatment of selected teeth for HT (Group B) was carried out according to the HT protocol of Innes NP et al., [Table/Fig-2]. No local anaesthesia was used as it was not required (no dentine was removed) and as per standard HT.</p>	<p><u>Length of follow-up:</u> After treatment</p> <p><u>Loss-to-follow-up:</u> Not applicable</p>	<p><u>Discomfort (Wong-Baker Faces pain scale):</u> -1,34 [-2,00, to -0,68]</p> <p><u>Pain:</u> No pain in both groups after 15 months</p> <p><u>Duration of the intervention:</u> ART takes 428 seconds longer [287,60 to 568,40].</p>	

			sequences of wet cotton pellets and dried with three sequences of dry cotton pellets. After ensuring the tooth to be dry, cavity was restored with Fuji IX, GC glass ionomer restorative material.				
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Studiekaracteristieken van RCT('s)

#### 14. Risico op biasbeoordeling bij wetenschappelijke bewijs over Hallkroon bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 2.4:** Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

Risico op bias in systematische review(s)

Study: Innes, 2015	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	An extensive description of all PICO items and time frame for follow up was reported.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	The detailed protocol was published in advance.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	RCTs.
4. Did the review authors use a comprehensive literature search strategy?	Yes	Different databases, no language restrictions, trial registers, grey literature.
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Yes	-
8. Did the review authors describe the included studies in adequate detail?	Yes	All PICO elements, follow up and sponsoring were reported.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Risk of bias
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	-
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Not applicable	Was not possible because of too little data in a meta-analysis.
13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	Also reported in the summary of findings table.
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Not applicable	Was not possible because of too little data in a meta-analysis.

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Not applicable	Was not possible because of too little data in a meta-analysis.
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.

Risico op bias van RCT('s)

Name of study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of patient and personell (performance bias)	Blinding of outcome assessor (detection bias)	Follow-up and ITT or per protocol analysis (attrition bias)	Selective reporting	Other bias
Lakshmi, 2018	Low risk  <i>Randomization was carried out using a chit-pull method.</i>	Unclear  <i>Not reported</i>	High risk  <i>No, that is not possible.</i>	High risk  <i>No, that is not possible.</i>	Low risk  <i>Not applicable</i>	Unclear  <i>The study was not registered.</i>	Low risk  <i>No other sources for risk of bias were found.</i>

For risk of

### 15. Studiekarakteristieken bij het wetenschappelijke bewijs over restauratie, afsluiting of preventieve methode bij melkelementen

Dit wetenschappelijke bewijs onderbouwt:

#### **Uitgangsvraag 2.4:** Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

Studiekarakteristieken van RCT('s)

Study	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Maguire, 2020	<p>Type of study: RCT</p> <p>Setting: Primary dental care</p> <p>Country: Scotland, England, and Wales</p> <p>Source of funding: National Institute for Health Research (NIHR) Health Technology Assessment programme</p>	<p><u>Inclusion criteria:</u> Children (aged 3-7 years) who had at least one primary molar tooth with decay into dentine (i.e. carious lesion) on clinical examination</p> <p><u>Exclusion criteria:</u> At the recruitment appointment presented with either dental pain and/or dental sepsis due to caries</p>	<p><u>NRCT, Best-practice prevention alone (PA)</u> No drilling, filling, or sealing of primary teeth occurred. Treatment plans for participants were based on best-practice preventative care for teeth and oral health.</p> <ul style="list-style-type: none"> <li>- dietary investigation, analysis, and intervention to reduce fermentable carbohydrates in the diet</li> <li>- tooth-brushing twice daily with a fluoridated toothpaste, plus fluoride mouth-rinsing in children &gt; 7 years of age</li> <li>- topical fluoride varnish applied to primary and permanent teeth by a dental professional</li> <li>- fissure sealants for permanent teeth.</li> </ul>	<p>1. Conventional management of carious lesions, with best-practice prevention (CP)</p> <p>Conventional management is commonly known as the 'drill-and-fill' method and is the traditional approach to managing dental caries</p> <p>2. Biological management of carious lesions, with best-practice prevention/ Hall crown (BP)</p> <p>This minimally invasive approach to managing carious lesions involves sealing decay into the tooth and separating it from the oral cavity; this is achieved by application of an adhesive filling material over the caries or by covering with a metal</p>	<p><u>Length of follow-up:</u> Planned follow-up= 6 years Realized follow up: median 561 days (IQR 482-822 days)</p> <p><u>Loss-to-follow-up:</u> I: 124 Withdrawn, n = 43 Practice withdrawal, n = 16 Moving away, n = 11 Trial fatigue, n = 3 Dental reason, n = 3 Personal reason, n = 3 Other, n=6 No reason given, n=1</p>	<p><u>Adjusted risk difference was (include 97,5%CI)</u></p> <p><u>Dental pain and/or dental sepsis</u></p> <p><u>Hall crown compared with the restauration</u> -0.02 (97.5% CI -0.10 to 0.06)</p> <p><u>NRCT compared with the restauration</u> 0.04 (97.5% CI -0.04 to 0.12)</p> <p><u>Incidence of carious lesions in primary and permanent teeth</u></p>	<p>which indicates, on average, a 2% reduced risk of dental pain and/or dental sepsis in the B+P arm compared with the C+P arm.</p> <p>a 3% increased risk of caries development/progression in the B+P arm compared with the C+P arm.</p>

		<p><u>N total at baseline:</u> I: 377 C1: 386 C2: 382</p> <p><u>Age ± SD:</u> I: 5.91 (1.2) C1: 5.97 (1.3) C2: 6.01 (1.3)</p> <p><u>d<sub>3</sub>mft ± SD:</u> I: 2.6 (2.6) C1: 2.8 (2.7) C2: 2.8 (2.7)</p> <p><u>Groups comparable at baseline?</u> Yes</p>		<p>crown. It may be clinically necessary, on occasion, to partially remove superficial carious tissue prior to the tooth being sealed.</p>	<p>Lost to follow-up, n = 81</p> <p>C1: 108 Withdrawn, n = 40 Practice withdrawal, n = 10 Moving away, n = 12 Trial fatigue, n = 1 Dental reason, n = 3 Personal reason, n = 2 Other, n=6 No reason given, n=6 Lost to follow-up, n = 68</p> <p>C2: 115 Withdrawn, n = 35 Practice withdrawal, n = 12 Moving away, n = 11 Trial fatigue, n = 0 Dental reason, n = 2 Personal reason, n = 1 Other, n=6 No reason given, n=3 Lost to follow-up, n = 80</p>	<p><u>Hall crown compared with the restoration</u> 0.03 (97.5% CI - 0.06 to 0.11)</p> <p><u>NRCT compared with the restoration</u> 0.05 (97.5% CI - 0.03 to 0.14)</p>	
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**16. Risico op biasbeoordeling bij wetenschappelijke bewijs over restauratie, afsluiting of preventieve methode bij melkelementen**

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 2.4:** Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met melkelementen?

Risico op bias van RCT('s)

Name of study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of patient and personell (performance bias)	Blinding of outcome assessor (detection bias)	Follow-up and ITT or per protocol analysis (attrition bias)	Selective reporting	Other bias
Maguire, 2020	Low risk  <i>Allocation sequence was generated by a statistician not otherwise involved in the trial.</i>	Unclear  <i>Allocation sequence was generated by a statistician not otherwise involved in the trial.</i>	High risk  <i>No, that is not possible.</i>	High risk  <i>No, that is not possible.</i>	High risk  <i>30.3% loss to follow-up, however an ITT was used</i>	Low risk  <i>Registered outcomes were reported.</i>	Low risk  <i>No other sources of bias were found.</i>

### 17. Studiekarakteristieken bij het wetenschappelijke bewijs over fluoridegel bij kinderen met blijvende elementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 3.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met blijvende elementen?

**Uitgangsvraag 3.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Marinho, 2015  A. Abadia, 1978 B. Bijella, 1981 C. Bryan, 1970 D. Cobb, 1980 E. Cons, 1970 F. DePaola, 1980 G. Englander, 1967 H. Englander, 1971 I. Englander, 1978 J. Gisselsson, 1999 K. Hagan, 1985 L. Heifetz, 1970 M. Horowitz, 1971	<u>Type of study:</u> Systematic review of RCT's  <u>Search date:</u> 5 November 2014  <u>Number of included studies:</u> N=27 (42 articles)  <u>Country</u> A. Brazil B. Brazil C. USA D. USA E. USA F. USA G. USA	<u>N total at baseline (n analysed):</u> A. 291 (254) B. 401 (320) C. 287 (208) D. 237 (193) E. 795 (589) F. NR (270) G. 574 (500) H. 896 (557) I. 231 (145) J. 317 (280) K. 428 (316) L. 525 (309) M. 552 (352) N. 512 (233) O. 155 (119) P. 456 (421) Q. NR (631) R. NR (120) S. NR (41) T. 218 (174)	A. FG + ptc (APF 12,300 ppm), o.a. once a year B. FG + ptc (APF 12,300 ppm) o.a. once a year C. FG + ptc (APF = not report) o.a. once a year D. FG + ptc (APF 12,300 ppm) o.a. twice a year E. FG (APF 12,300 ppm) o.a. once a year F. FG (APF 12,300 ppm) s.a. 10 consecutive applications G1. FG (APF 5,000 ppm) s.a. 140 times a year G2. FG (NaF = 5,000 ppm) s.a. 140 times a year H. FG (APF 5,000 ppm) s.a. 85 times a year I. FG (APF 5,000 ppm) s.a. 76 times a year J1. FG (NaF = 4500 ppm) o.a. 4 times a year	A. No treatment B. No treatment C. No treatment D. No treatment E. Placebo F. No treatment G. Placebo + ptc H. No treatment I. Placebo J. Placebo K. Placebo + ptc L. Placebo + ptc M. No treatment + ptc N. Placebo + ptc O. No treatment P. No treatment Q. Placebo + ptc R. Placebo S. Placebo T. No treatment U. Placebo V. Placebo W. Placebo + ptc	<u>Length of follow-up:</u> A. 1 year B. 1.5 years C. 2 years D. 2 years E. 3 years F. 2 years G. 1.8 years H. 2.5 years I. 2.3 years J. 3 years K. 2 years L. 2 years M. 3 years N. 3 years O. 2 years P. 2 years Q. 3 years R. 3 years S. 4 years T. 1 year U. 2 years	<b>D(M)FT increment nearest to 3 years (Prevented fraction [95% CI]) (10 studies)</b> 0.32 [ 0.19, 0.46 ] I <sup>2</sup> = 90%  <b>Compared to placebo control:</b> 0.18 [ 0.09, 0.27 ] I <sup>2</sup> = 6%  <b>Compared to no treatment:</b> 0.43 [ 0.29, 0.57 ] I <sup>2</sup> = 90%  <b>Signs of acute toxicity (mean difference [95% CI])</b> 0.01 [-0.01, 0.02]	FG= fluoridegel Ptc = prior tooth cleaning performed with or without a non-fluoride paste AmF= amine fluoride APF =acidulated phosphate fluoride NaF=Natrium Fluoride s.a. = self applied NR = Not reported

<p>N. Horowitz, 1974 O. Ingraham, 1970 P. Jiang, 2005 Q. Mainwaring, 1978 R. Marthaler, 1970 S. Marthaler, 1970a T. Mestrinho, 1983 U. Olivier 1992 V. Ran, 1991 W. Shern, 1976 X. Szejda, 1972 Y. Treide, 1988 Z. Trubman, 1973 AA. Truin, 2005 BB. Van Rijkom, 2004</p>	<p>H. USA I. USA J. Sweden K. USA L. USA M. USA N. Hawaii O. USA P. China Q. UK R. Switzerland S. Switzerland T. Brazil U. Canada V. Israel W. Venezuela X. USA Y. Germany Z. USA AA. Netherlands BB. Netherlands</p> <p><u>Source of funding:</u></p> <ul style="list-style-type: none"> <li>• Queen Mary University of London, UK.</li> <li>• Department of Epidemiology and Public Health (UCL), UK.</li> <li>• Systematic Reviews Training Unit, Institute of Child Health (UCL), UK.</li> </ul>	<p>U. 488 (431) V. 140 (83) W. 614 (562) X. NR (316) Y. 643 (433) Z. 575 (311) AA. 594 (530) BB. 773 (732)</p> <p><u>Age:</u></p> <p>A. 11-12 years B. 7-10 years C. 8-12 years D. 11-14 years E. 6-11 years F. 12-14 years G. 11-15 years H. 11-15 years I. 2-6 years J. 13 years K. 11-15 years L. 12-13 years M. 10-2 years N. 11-14 years O. 6-11 years P. 6-7 years Q. 11-12 years R. 6-7 years S. 7-9 years T. 7-10 years U. 6-7 years V. 13 years W. 6-13 years X. 7-9 years Y. 3.5 years Z. 8.1 years AA. 9.5-11.5 years BB. 4.5-6.5 years</p> <p><u>Baseline caries (SD):</u></p>	<p>J2. FG (SnF<sub>2</sub> = 2425 ppm) o.a. 4 times a year K1. FG + ptc (APF 12,300 ppm) twice a year K2. FG + ptc (APF 6,000 ppm) o.a. twice a year L. FG + ptc (APF 12,300 ppm) s.a. 5 times a year M. FG + ptc (APF 12,300 ppm) o.a. once a year N. FG + ptc (APF 12,300 ppm) s.a. 5 times a year O. FG + ptc o.a. once a year P. FG (APF 12,300 ppm) o.a. twice a year Q. FG (APF 12,300 ppm) o.a. twice a year R. FG (AmF/NaF 12,300 ppm) S. FG (AmF/NaF 12,500 ppm) s.a. 22 times a year T. FG + ptc (APF 9150 ppm) o.a. twice a year U. FG (APF 12,300 ppm) o.a. twice a year V1. FG (AmF 4000 ppm) s.a. 25 times a year V2. FG (AmF 12,500 ppm) s.a. 25 times a year W1. FG + ptc (APF 12,300 ppm) o.a. 5 consecutive times W2. FG + ptc (AmF 12,500 ppm) o.a. 5 consecutive times W3. FG + ptc (AmF 12,500 ppm) o.a. 5 consecutive times X. FG + ptc (APF concentration NR) o.a. once a year</p>	<p>X. Placebo + ptc Y. Placebo + ptc Z. Placebo + ptc AA. Placebo gel BB. Placebo</p>	<p>V. 1.5 years W. 1 year X. 3 years Y. 3 years Z. 3 years AA. 4 years BB. 4 years</p>	<p>I<sup>2</sup> = 0%</p> <p><u>Primary elements:</u></p> <p>D(M)FT increment nearest to 3 years (Prevented fraction [95% CI]) (3 studies)</p> <p>Compared to placebo control: 0.20 [ 0.01, 0.38 ] I<sup>2</sup> = 0%</p>	
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	<ul style="list-style-type: none"> <li>• Medical Research Council, UK.</li> <li>• School of Dentistry, The University of Manchester, UK.</li> <li>• National Institute for Health Research (NIHR), UK.</li> <li>• Cochrane Oral Health Group Global Alliance, Other.</li> <li>• CAPES - Ministry of Education, Brazil.</li> </ul> <p><u>Inclusion criteria:</u></p> <p><u>Exclusion criteria:</u></p>	<p>A. 12.2 DMFS                  B. 6.6 DMFS                  C. 8.3 DMFS                  D. 5.7 DMFS                  E. 3 DMFS                  F. NR                  G. 10.1 DMFS                  H. 3.7 DMFS                  I. 3.7 defs - 43% caries-free                  J. 0.24 DFS* - 39% caries-free                  K. 4.6 DMFS                  L. 8.2 DMFS                  M. 8.9 DMFS                  N. 11.4 DMFS                  O. 2.4 DMFS                  P. 1stm DMFS = 0.11 (SD 0.41)                  Q. 7.9 DFS                  R. 0.81 DFS                  S. 2.5 DFS                  T. NR                  U. 0.68 DMFS                  V. 6.5 DMFS                  W. 2.7 DMFS                  X. 0.86 DMFS                  Y. NR (but dmft data reported from original sample only = 0.8)                  Z. 2.1 DMFS                  AA. D2S                  BB. D3MFS = 0, d3mfs = 0</p>	<p>Y1. FG + ptc (NaF + hexaf 12,500 ppm) s.a. 130 times a year                  Y2. GF + ptc (NaF 12,500 ppm) s.a. 130 times a year                  Y3. FG + ptc (AmF concentration NR) s.a. 130 times a year                  Z. FG + ptc (APF 12,300 ppm) s.a. 4 times a year                  AA. FG (Neutral 1% NaF gel, 4500 ppm) o.a. twice a year                  BB. FG (Neutral 1% NaF gel, 4500 ppm) o.a. twice a year</p>				
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### 18. Risico op biasbeoordeling bij wetenschappelijke bewijs over fluoridegel bij blijvende elementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 3.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met blijvende elementen?

**Uitgangsvraag 3.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

Risico op bias in systematische review(s)

Study: Marinho, 2015	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO	Yes	An extensive description of all PICO items and time frame for follow up was reported.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	The detailed protocol was published in advance.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	RCTs.
4. Did the review authors use a comprehensive literature search strategy?	Yes	Different databases, no language restrictions, trial registers, reference lists, hand searching and person contact.
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Yes	-
8. Did the review authors describe the included studies in adequate detail?	Yes	All PICO elements, follow up and sponsoring were reported.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Risk of bias
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	-
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Yes	-
13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	Yes	Also reported in the summary of findings table.
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Yes	-

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Yes	Funnel plot assessment
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.

## 19. Studiekarakteristieken bij het wetenschappelijke bewijs over sealants en fluoridevernis bij kinderen met blijvende elementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 3.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met blijvende elementen?

**Uitgangsvraag 3.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics <sup>1</sup>	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Ahovuo-Salorant, 2016  <u>Included studies</u> A. Bravo, 2005 B. Florio, 2001 C. Ji, 2007 D. Liu, 2012 E. Raadal, 1984 F. Salem, 2014* G. Splieth, 2001 H. Tagliaferro, 2011	<u>Type of study:</u> Systematic review of RCT's  <u>Search date:</u> 18 December 2015 (updated in this guideline up until April 2019)  <u>Number of included studies:</u> N=8  <u>Country</u> A. Spain B. Brazil C. China D. China E. Raadal, 1984 F. Iran, G. Germany H. Brazil	<u>N total at baseline:</u> A. 112; 115; 135 B. 34; 12; 11 C. 205; 207; 210 D. 124; 125; 128 E. 121 (split mouth design) F. 200; 200 G. 98 (split mouth design) H. 55; 57; 53; 52  <u>Important prognostic factors:</u> age: A. 6 to 8 years B. 6 years C. 6 to 8 years D. 9.1 years (range 8 - 10) E. 6 to 9 years F. 6 to 7 years	A. resin-based sealants applied after 6, 12, 18, 24, 36;  B. sealants group (resin-modified glass ionomer fissure sealants;  C. glass ionomer fissure sealant (Fuji II)  D. light-cured, fluoride-releasing resin-based sealant Clinpro Sealant (3M ESPE)  E. occlusal surface of 1 tooth sealed with autopolymerised resin-based Concise  F. resin-based sealant (Eco Seal)  G. occlusal surface of 1 tooth sealed with visible-light activated Fissurit Trans-	A. fluoride varnish (NaF) applied after 6, 12, 18, 24, 36 and 42 months; control  B. fluoride varnish (NaF) applied every 6 months; control group  C. silane fluoride varnish group (fluor protector 0.1% fluoride)  D. NaF - semi annual application of 5% sodium fluoride (NaF) varnish (Duraphat)  E. on occlusal surface of the other tooth of the tooth pair, fluoride varnish (Duraphat, sodium fluoride (NaF)) was applied	<u>Length of follow-up:</u> A. 9 years (4 years programme, 5 years follow-up) B. 12 months C. 36 months D. 24 months E. 23 months F. 24 months G. 2 years H. 24 months	[95% CI]  <u>Resin fissure sealant versus fluoride varnish</u>  <u>Caries after 23 or 24 months:</u> OR: 0.69 [0.50, 0.94]  <u>Caries after 4 years:</u> RR: 0.42 [0.21, 0.84]  <u>Caries after 9 years</u> RR: 0.48 [0.29, 0.79]  <u>Resin-modified glass ionomer fissure sealant versus fluoride varnish</u>  <u>Caries after 12 months:</u> OR: 0.18 [0.01, 4.27]	ICDAS 1-3  * The study of Salem, 2014, was not considered in analyses of this review because results and data - complex multi-level model with teeth nested in a school class nested in a school - were not in useable form for this review (unit of analysis was chosen to be a tooth surface, but clustering of data was not considered in the analyses.



	<p><u>Source of funding:</u> NIHR, UK. This project was supported by the NIHR, via Cochrane Infrastructure funding to the Cochrane Oral Health Group.</p> <p><u>Inclusion criteria:</u></p> <ul style="list-style-type: none"> <li>• RCT's with min. 12 months follow-up.</li> <li>• Children and adolescents from the general population, aged up to 20 years at the start of the study.</li> <li>• Pit and fissure sealants of all materials (except first-generation resin-based sealants) versus fluoride varnish.</li> <li>• Pit and fissure sealants together with fluoride varnish versus fluoride varnish.</li> <li>• Applications were placed on occlusal surfaces of permanent</li> </ul>	<p>G. 5 to 8 years H. 7 years (mean)</p> <p><u>Baseline caries (SD):</u> A. dft 2.24 (2.59); 2.42 (3.26) B. dmfs 3.8 (2.5); 4.5 (2.7) C. 21% caries of control teeth were decayed after 3 years D. dmft 3.19 (2.68); 3.58 (2.25) E. dmft 4.7 (SD 3.3) F. dmft 4.41 (0.92); 2.76 (2.75) G. DMFS 0.2 H. dmft 4.51 (2.81); 4.28 (2.54)</p>	<p>parent (VOCO GmbH, Cuxhaven, Germany)</p> <p>H. Group 3 (high caries risk): OHE and single sealant application (resin-modified glass ionomer cement) Group 6 (low caries risk): OHE and single sealant application (resin-modified glass ionomer cement)</p>	<p>F. sodium fluoride varnish (Durafluor, NaF 5%)</p> <p>G. occlusal surface of the other tooth of the tooth pair applied with fluoride varnish (Duraphat, sodium fluoride (NaF))</p> <p>H. Group 2 (high caries risk): OHE and fluoride varnish application biannually</p> <p>Group 5 (low caries risk): OHE and fluoride varnish application biannually</p>		<p><u>Resin fissure sealant plus fluoride varnish versus fluoride varnish</u></p> <p>Caries after 2 years OR: 0.30 [0.17, 0.55]</p>	
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	<p>premolar or molar teeth for the purpose of preventing caries, regardless of who did the application. • Materials could be applied on sound surfaces or on enamel lesions (if scored using the ICDAS II scale, codes 0, 1, 2 and 3 were accepted).</p> <p><u>Exclusion criteria:</u> Not reported.</p>						
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### Studiekaracteristieken van RCT('s)

Study	Study characteristics	Patient characteristics <sup>1</sup>	Intervention (I)	Comparison / control (C) <sup>2</sup>	Follow-up	Outcome measures and effect size <sup>3</sup>	Comments
Muller-Bolla, 2018  NCT00674869	<p><u>Type of study:</u> RCT</p> <p><u>Setting:</u> General dental practice</p> <p><u>Country:</u> Switzerland</p> <p><u>Source of funding:</u></p>	<p><u>Inclusion criteria:</u> age between 5 and 15 years with at least one pair of contralateral permanent molars and high ICR due to the detection of at least one ICDAS 3-6 lesion at baseline. Occlusal surfaces had to be</p>	<p>Following the prophylactic cleaning with a rotating brush (allowing the data collection at baseline to be completed), the tooth to seal was isolated with cotton rolls or a rubber dam according to the stage of eruption. Cotton rolls were chosen only if the tooth was insufficiently erupted to retain a clamp. The occlusal surface was dried and etched with 37% phosphoric acid gel</p>	No treatment	<p><u>Length of follow-up:</u> 12 months</p> <p><u>Loss-to-follow-up:</u> <u>At 6 months:</u> N=100 tooth pairs Reasons: 26 children dropped out and 39 children were absent)</p> <p><u>At 12 months</u> N=153 tooth pairs</p>	<p><u>Risk of ICDAS 3-6 lesions (hazard ratio-univariate regression):</u> 0.16 p-value&lt;0.0001</p> <p><u>Risk of ICDAS 3-6 lesions (hazard ratio-multivariate regression):</u> 0.17 p-value&lt;0.0001</p>	Only ICDAS 3-6 carious lesions were considered for calculating D3MFT and d3ft

	<p>Regional PHRC (France) funded this study. The promotor was the CHU in the city of Nice (CHUN). Dentsply kindly provided the sealant materials and light-curing lamp.</p>	<p>accessible for dental sealant placement, but the corresponding permanent molars did not need to be fully erupted. If more than one tooth pair was eligible per child, we included a maximum of two pairs, choosing those for which eruption was the most recent.</p> <p><u>Exclusion criteria:</u> Children were not included if they did not cooperate during the first clinical examination. The tooth pairs in the recruited children consisted of at least one pair of caries-free (ICDAS 0) or noncavitated carious lesions (ICDAS 1–2)-affected contralateral permanent molars. Tooth pairs were excluded when a dental sealant, a restoration, or a dentinal carious</p>	<p>for 20 s, followed by thorough rinsing for 20 s using an oil-free air-water syringe. Afterwards, resin-based sealant (Delton plus® or Delton®; Dentsply, Montigny-le-Bretonneux, France) was applied on the occlusal surface of the randomized tooth by a single operator (L.L.-P., F.C., or C.T.) according to the manufacturer’s instructions in each of the 3 centers.</p>		<p>Reasons: 6 children dropped out and 39 children were absent</p> <p><u>At 18 months</u> N=219 tooth pairs Reasons: 83 children dropped out and 52 children absent)</p> <p><u>24 months</u> N=180 tooth pairs Reasons: 110 children dropped out</p> <p>The major reason for dropout was related to leaving the district.</p>	<p>All our results showed that the preventive effect of sealants in the development and progression of caries remained regardless of caries risk factors.</p> <p><u>Risks:</u> No adverse events were reported in the participating centers.</p>	
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		<p>(ICDAS 3–6) lesion was present on one of the teeth.</p> <p><u>N total at baseline:</u> Intervention: 400 (663) Control: 400 (663)</p> <p><u>Mean age (±SD):</u> I: 8.60 (2.23) C: 8.61 (2.24)</p> <p><u>Mean D<sub>3</sub>MFT (±SD)*:</u> I: 1.30 (1.92) C: 1.30 (1.92)</p> <p><u>Mean d<sub>3</sub>mft (±SD)*:</u> I: 3.47 (2.40) C: 3.46 (2.40)</p> <p><u>Visible plaque w/o agents disclosing Yes/No):</u> I: 465/198 C: 464/199</p> <p>Groups comparable at baseline? Yes</p>					
<p>Chestnutt, 2017</p> <p>ISRCTN: 17029222</p>	<p><u>Type of study:</u> RCT</p> <p><u>Setting:</u> General dental practice</p>	<p><u>Inclusion criteria:</u> - aged 6 or 7 years and attended the schools participating in the current</p>	<p>Resin based fissure sealants. The FS used was Delton® Light Curing Opaque Pit and Fissure Sealant (Dentsply Ltd, Stonehouse, UK; CE0086). This is one of the most used</p>	<p>The FV used for evaluation in the study was Duraphat 50 mg/ml dental suspension (PL 00049/0042), equivalent to 22,600 ppm. fluoride. This is the most used</p>	<p><u>Length of follow-up:</u> 42 months</p> <p><u>Loss-to-follow-up:</u> Intervention: 96 (19%)</p>	<p><u>The proportion of children developing new caries in dentine on any one of up to four treated FPMs at 36 months:</u></p>	<p>The proportion of children who received FV who were likely to develop caries into dentine was lower</p>

	<p><u>Country:</u> United Kingdom</p> <p>Source of funding: Health Technology Assessment programme of the National Institute for Health Research.</p>	<p>Designed to Smile programme - had at least one fully erupted FPM free of caries into dentine.</p> <p><u>Exclusion criteria:</u> their medical history precluded inclusion.</p> <p><u>N total at baseline:</u> Intervention: 514 Control: 501</p> <p><u>Important prognostic factors:</u></p> <p><i>D<sub>(4-6)mft</sub>:</i> I: 342 (66.5%) C: 339 (66.7%)</p> <p>Groups comparable at baseline? Yes</p>	<p>FS brands in the UK. FS was supplied as 2.7-ml bottles for multiple applications and applied topically as a thin layer to the occlusal surface of eligible FPMs. The standard clinical protocol, as described by the product manufacturers, was used to apply the FS (Box 1).</p> <p>The initial application of FS took place within 2 weeks of the baseline dental examination and was performed by a suitably qualified and trained dental hygienist. In the case of partially erupted molars, sealant was applied if sufficient tooth surface was available. This situation was most common in the case of upper molars. The same two dental hygienists provided treatments throughout the trial using two MDCs.</p>	<p>FV brand in the UK. FV was supplied in 10-ml tubes for multiple applications and applied topically as a thin layer to the pits, fissures and smooth surfaces of eligible FPMs.</p> <p>The initial application of FV occurred within 2 weeks of the baseline dental examination and was performed by a qualified and trained dental hygienist in accordance with the conventional clinical protocol established by the CDS (see Box 2). FV was reapplied at 6, 12, 18, 24 and 30 months, that is, on six occasions at 6-monthly intervals during the trial.</p>	<p>Reasons: loss to follow up or withdrew</p> <p>Control: 85 (17%) Reasons: loss to follow up or withdrew</p>	<p>I: 82 (19.6%) C: 73 (17.5%)</p> <p><u>Number of treated FPM teeth that were free of caries into dentine at 36 months</u> I: 336 (80.4%) C: 344 (82.5%)</p> <p><u>Primary analysis of the proportion of children with dentine caries, a restoration or extraction (D4-6MFT) on any FPM in the trial by trial arm at 36 months</u> <u>Adjusted OR (95% CI):</u> 0.84 (0.59 tot 1.21) p-value=0.351</p> <p>Subgroup analysis of the proportion of children with ICDAS caries (levels 4-6) on any FPM in the trial: 0.35 (0.13 to 0.92) p-value=0.032</p> <p><u>Quality-adjusted life-years at 12 months</u> I: 0.928 C: 0.931</p> <p><u>Quality-adjusted life-years at 36 months</u></p>	<p>than the proportion of those developing dentine caries in the FS arm, but this difference was not statistically significant.</p>
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						<p>I: 0.933 C: 0.933</p> <p>Quality-adjusted tooth-years 36 months: I: 0.932 C: 0.925</p> <p>FV had a cost saving of £68.13 (95% CI £5.63 to £130.63; p = 0.033) compared with FS.</p>	
Kalnina, 2016	<p><u>Type of study:</u> RCT</p> <p><u>Setting:</u> General dental practice</p> <p><u>Country:</u> Riga</p> <p><u>Source of funding:</u> Not reported</p>	<p><u>Inclusion criteria:</u> Children, 10 years, with at least one health and fully erupted premolar.</p> <p><u>Exclusion criteria:</u> Not reported</p> <p><u>N total at baseline:</u> Intervention: 22 (110) Control: 22 (110)</p> <p><i>DMFT index average:</i> 1.97</p> <p>Groups comparable at baseline? Yes</p>	<p>After prophylaxis and polishing of the selected 78 premolars in group (3), acid etchant (37% orthophosphoric acid) was applied to the pits and fissures and rinsed after 15 seconds. After drying, sealant (Clinpro 3M ESPE Dental products, St Paul, USA) was applied. Articulating paper was used to check for high points and was removed with a micro motor using a polishing bur.</p>	<p>Fluocal solute, Septodont, France) was applied on to 103 premolars occlusal surface with an applicator brush left in place for 1 minute. After the application subject was made to expectorate and advised not to rinse the mouth for 4 hours and not to brush until the following day.</p>	<p><u>Length of follow-up:</u> 12 months</p> <p><u>Loss-to-follow-up:</u> Intervention: 5 (23%) Reasons: declined to participate</p> <p>Control: 1 (5%) Reasons: declined to participate</p>	<p><u>Mean (IQR):</u></p> <p><u>Decayed:</u> I: 0.94 (0-8.0) C: 0.48 (0-2.0)</p> <p><u>Missing:</u> I: 0 C: 0.05 (0-1.0)</p> <p><u>Filled:</u> I: 1.65 (0-6.0) C: 0.67 (0-4)</p> <p><u>DMFT:</u> I: 2.59 (0-13.0) C: 1.19 (0-5.0)</p>	<p>This study also included a control group and an intervention group (ozon)</p>



## 20. Risico op biasbeoordeling bij wetenschappelijke bewijs over sealants en fluoridevernis bij blijvende elementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 3.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met blijvende elementen?

**Uitgangsvraag 3.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

### Risico op bias in systematische review(s)

Study: Ahovuo-Saloranta, 2016	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	An extensive description of all PICO items and time frame for follow up was reported.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	The detailed protocol was published in advance.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	RCT's on individual and group level.
4. Did the review authors use a comprehensive literature search strategy?	Yes	Different databases, no language restrictions, trial registers, reference list screening
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Yes	-
8. Did the review authors describe the included studies in adequate detail?	Yes	All PICO elements, follow up and sponsoring were reported.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Risk of bias
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	-
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Not applicable	Was not possible because of too little data in a meta-analysis.
13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	Also reported in the summary of findings table.
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Not applicable	Was not possible because of too little data in a meta-analysis.



15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Not applicable	Was not possible because of too little data in a meta-analysis.
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.

Risico op bias van RCT('s)

Name of study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of patient and personell (performance bias)	Blinding of outcome assessor (detection bias)	Follow-up and ITT or per protocol analysis (attrition bias)	Selective reporting	Other bias
Muller-Bolla, 2018	Low risk <i>The random allocation sequence (per center) was generated blinded using a randomization table.</i>	Low risk <i>The random allocation sequence (per center) was generated blinded using a randomization table.</i>	High risk <i>No, that is not possible.</i>	High risk <i>Not specified but due to the nature of the intervention it is still possible to know.</i>	Low risk <i>27% of the participants dropped-out but there was no relation between drop out and treatment.</i>	Low risk <i>Registered outcomes were reported in publication.</i>	Low risk <i>No other sourcesrisico op bias was found.</i>
Chestnutt, 2017	Low risk <i>Eligible children were randomised using the minimization algorithm.</i>	Low risk <i>All randomisation and allocation lists were produced by SEWTU independently of the recruiting and examining personnel in the CDS.</i>	High risk <i>No, that is not possible.</i>	High risk <i>Outcome assessor was blinded but due to the nature of the intervention it is still possible to know.</i>	Low risk <i>Analyzes followed an ITT principle)</i>	Low risk <i>Registered outcomes were reported in publication.</i>	Low risk <i>No other sources of bias were found.</i>
Kanina, 2016	Unclear <i>Not reported.</i>	Unclear <i>Not reported.</i>	High risk <i>No, that is not possible.</i>	Unclear <i>Not reported.</i>	Unclear <i>Not reported.</i>	Unclear <i>The study was not registered.</i>	Low risk <i>No other sources of bias were found.</i>

## 21. Studiekarakteristieken bij het wetenschappelijke bewijs over SDF bij blijvende elementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 3.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met blijvende elementen?

**Uitgangsvraag 3.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

**Uitgangsvraag 3.4:** Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

### Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics <sup>1</sup>	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Gao, 2016 A. Duangthip, 2016 B. dos Santos, 2012 C. Zhi, 2012 D. Yee, 2009 E. Braga, 2009 F. Huang, 2006 G. Llodra, 2005 H. Mauro, 2004 I. Chu, 2002 J. Yang, 2002 K. Fukumoto, 1997 L. Miasato, 1996 M. Ye, 1995 N. Marciel, 1988	<u>Type of study:</u> Systematic review of RCT's  <u>Search date:</u> March 2016  <u>Number of included studies:</u> N=19 (16 on primary elements)  <u>Country</u> A. Hong Kong B. Brazil C. China D. Nepal E. Brazil F. China G. Cuba H. Argentina I. Hong Kong J. China K. Japan	<u>N total at baseline:</u> A. 1407 B. 345 C. 719 D. 6638 E. 58 (permanent teeth) F. 738 G. 1333 H. 141 (permanent teeth) I. 1490 J. 158 K. 130 L. 88 M. 300 N. 184 O. 54 (permanent teeth) P. 214 Q. 66 R. 52 S. 188	A. Gp1: 30% SDF, annually (n = 458) Gp2: 30% SDF, one-off (n = 426)  B. Gp1: 30% SDF, one-off (n = 183)  C. Gp1: 38% SDF, annually (n = 218) Gp2: 38% SDF, semi-annually (n = 239)  D. Gp1: 38% SDF, one-off (n = 3,396) Gp2: 12% SDF, one-off (n = 1,652)  E. Gp1: CTT, one-off (n = 18) Gp2: 10% SDF, one-off (n = 20)  F. Gp1: 38% SDF biannually, anterior teeth (n = 226)	A. Gp3: 5% sodium fluoride, one-off (n = 523)  B. Gp2: glass ionomer, one-off (n = 162)  C. GP3: glass ionomer, annually (n = 262)  D. Gp3: no treatment (n = 1,590)  E. Gp3: glass ionomer, one-off (n = 20)  F. Gp4: no treatment, posterior teeth (n = 145)  G. Gp2: no treatment (n = 658)  H. Gp3: 5% sodium fluoride, one-off (n = 44)	<u>Length of follow-up:</u> A. 18 months B. 12 months C. 24 months D. 24 months E. 30 months F. 18 months G. 36 months H. 12 months I. 30 months J. 6 months K. 48 months L. 6 months M. 12 months N. 6 months O. 12 months P. 18 months Q. 18 months R. 12 months S. 6 months	A. Caries-arresting rate: Gp1 (40%) > Gp2 (35%) > Gp3 (27%)  B. Caries-arresting rate: Gp1 (67%) > Gp2 (39%)  C. Caries-arresting rate: Gp2 (91%) > Gp1 (79%), Gp3 (82%)  D. Caries-arresting rate: Gp1 (31%) > Gp2 (22%), Gp3 (15%)  E. Carious scores: no difference among groups  F. Caries-arresting effect: Gp1 > Gp2 (no data provided) Gp3 > Gp4 (no data provided)	

<p>O. Oliveira, 1985 P. Wang, 1984 Q. Tsutsumi, 1981 R. Yoshida S. Nishino, 1969</p>	<p>L. Brazil M. China N. Brazil O. Brazil P. China Q. Japan R. Japan S. Japan</p>	<p><u>Age:</u> A. primary B. primary C. primary D. primary E. permanent F. primary G. primary H. permanent I. primary J. primary K. primary L. primary M. primary N. primary O. permanent P. primary Q. primary R. primary S. primary</p> <p><u>Source of funding:</u> A grant (17107 315) from the General Research Fund of the Research Grants Council of Hong Kong. The authors declare no potential conflicts of interest with respect to the authorship.</p> <p><u>Baseline caries (SD):</u> dentine caries</p>	<p>Gp2: no treatment, anterior teeth (n = 223) Gp3: 38% SDF biannually, posterior teeth (n = 144)</p> <p>G. Gp1: 38% SDF, semi-annually (n = 675)</p> <p>H. Gp1: ammonium fluoride, one-off (n = 48) Gp2: 38% SDF, one-off (n = 49)</p> <p>I. Gp1: 38% SDF, annually (n = 641)</p> <p>J. 38% SDF, one-off (n = 158)</p> <p>K. 38% SDF, one-off (n = 130)</p> <p>L. 30% SDF, every 3 mo (n = 88)</p> <p>M. 38% SDF, one-off (n = 300)</p> <p>N. Gp1: 10% SDF, one-off (n = 104)</p> <p>O. Gp1: 38% SDF, one-off (n = 7) Gp2: 38% SDF, twice in 1 wk (n = 9) Gp3: 38% SDF, biannually (n = 21) Gp4: 38% SDF, twice in 1 wk, then biannually (n = 17)</p> <p>P. Gp1: 38% SDF, every 3 to 4 mo (n = 110)</p> <p>Q. Gp1: 38% SDF, every 3 mo (n = 33)</p>	<p>I. Gp2: 5% sodium fluoride, every 3 mo (n = 576) Gp3: no treatment (n = 273)</p> <p>J. no comparison</p> <p>K. no comparison</p> <p>L. no comparison</p> <p>M. no comparison</p> <p>N. Gp2: no treatment (n = 80)</p> <p>O. no comparison</p> <p>P. Gp2: no treatment (n = 104)</p> <p>Q. Gp2: no treatment (n = 33)</p> <p>R. Gp2: no treatment (n = 26)</p> <p>S. Gp2: no treatment (n = 82)</p>	<p>G. Caries-arresting rate: Gp1 (85%) &gt; Gp2 (62%)</p> <p>H. Caries-arresting rate: Gp1 (56%), Gp2 (57%), Gp3 (47%) No difference among groups</p> <p>I. Caries-arresting rate: Gp1 (65%) &gt; Gp2 (41%), Gp3 (34%)</p> <p>J. Caries-arresting rate: 94.4%</p> <p>K. Caries-arresting rate: 54%</p> <p>L. Caries-arresting rate: 83%</p> <p>M. Caries-arresting rate: 92%</p> <p>N. Caries-arresting rate: Gp1 (90%) &gt; Gp2 (74%)</p> <p>O. Caries-arresting effect: Caries arrested in all groups No difference among groups</p> <p>P. Caries-arresting rate: Gp1 (86%) &gt; Gp2 (31%)</p> <p>Q. Caries-arresting effect: Gp1 &gt; Gp2 (no data provided)</p>
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	laboratory studies, clinical trials in other clinical treatment guidelines, and other irrelevant studies.		<p>R. Gp1: 38% SDF, every 3 mo (n = 26)</p> <p>S. Gp1: 38% SDF, one-off (n = 106)</p>			<p>R. Caries-arresting effect: SDF was effective (no data provided)</p> <p>S. Caries without progression:                      Laterally: Gp1 (69%) &gt; Gp2 (52%)                      Pulpally: Gp1 (76%) &gt; Gp2 (65%)</p>	
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## 22. Risico op biasbeoordeling bij wetenschappelijke bewijs over SDF bij blijvende elementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 3.2:** Hoe dienen glazuurlaesies behandeld te worden bij kinderen met blijvende elementen?

**Uitgangsvraag 3.3:** Hoe dienen niet-gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

**Uitgangsvraag 3.4:** Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

Risico op bias in systematische review(s)

Study: Gao, 2016	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Partial	Only de patients and intervention were predefined.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No	The protocol was not separately published. Also the methods section already some of the results.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	All studies
4. Did the review authors use a comprehensive literature search strategy?	Partial	Different databases, many languages, no mesh terms of other methods.
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Partial	A flow chart shows information about reasons for exclusion but no explicit reason per reference.
8. Did the review authors describe the included studies in adequate detail?	Yes	Information about the patients, intervention and control were reported. There was no information about follow up or sponsoring.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Riskrisico op bias
10. Did the review authors report on the sources of funding for the studies included in the review?	No	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	No	There was significant heterogeneity even though they performed a meta-analysis.
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No	-

13. Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?	No	-
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	No	-
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	No	-
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.

### 23. Studiekarakteristieken bij het wetenschappelijke bewijs over partiële of stapsgewijze excavatie bij blijvende elementen

Dit wetenschappelijke bewijs onderbouwt:

#### **Uitgangsvraag 3.4:** Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

Studiekarakteristieken van systematische review(s)

Study	Study characteristics	Patient characteristics <sup>1</sup>	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Rickets, 2013  I. Leksell, 1996 J. Orhan, 2010	<p><u>Type of study:</u> Systematic review of RCT's</p> <p><u>Search date:</u> 12 December 2012</p> <p><u>Number of included studies:</u> N=8 (2 studies relevant for question about primary teeth and 2 studies relevant for question about permanent teeth)</p> <p><u>Country</u> A. Sweden B. Turkey</p> <p><u>Source of funding:</u> Cochrane Oral Health Group Global Alliance, UK. National Institute for Health</p>	<p><u>N total at baseline:</u> A. 116 (134 teeth) B. 123 (94 primary and 60 permanent teeth)</p> <p><u>Age:</u> A. 6-16 years B. 4-15 years</p> <p><u>Baseline caries (SD):</u> A. Permanent posterior teeth were selected if the radiographs revealed carious lesions to such a depth that pulp exposure could be expected if direct complete excavation was chosen.  B. No symptoms of irreversible pulpitis or signs of pulpal or periradicular pathology. Pulp</p>	<p>A. Stepwise (n = 64 teeth). Calcium hydroxide (Calasept) was placed as a base and temporised with zinc oxide eugenol (ZOE) cement. Re-entry at 8 to 24 weeks</p> <p>B. Stepwise (n = 49 teeth) two-visit 'indirect pulp treatment' (IPT). Caries was removed until the operator thought pulp exposure would occur with further excavation. Two-visit IPT after the initial excavation, calcium hydroxide base was placed and provisionally restored with ZOE cement- re-entry was at 3 months. In all groups, following the final excavation, glass ionomer (Ionofil) was placed as a cavity base</p>	<p>A. Complete caries removal</p> <p>B1. Partial (n = 50 teeth) one-visit 'indirect pulp treatment'. Caries was removed until the operator thought pulp exposure would occur with further excavation.</p> <p>B2. Complete (n = 55 teeth) direct complete excavation. All carious dentine was removed till hard dentine was reached or pulp exposure occurred</p>	<p><u>Length of follow-up:</u> A. 1 year B. not reported</p>	<p><b>Results for Stepwise RR [95% CI]*</b></p> <p><u>Pulp exposure during caries removal:</u> 0.41 [0.22, 0.74]</p> <p><b>Results for Partial RR [95% CI]</b></p> <p><u>Pulp exposure during caries removal:</u> 0.21 [0.03, 1.60]</p>	<p>ICDAS 4-6</p> <p>Not described: Bjørndal, 2010 and Mertz-Fairhurst 1987 (excluded because of adult patients) Innes, 2007 (no relevant intervention)</p>

	<p>Research (NIHR), UK.</p> <p><u>Inclusion criteria:</u> Participants with caries, affecting any tooth surface(s), in unrestored primary and permanent teeth. Stepwise, partial, or no dentinal caries removal prior to restoration.</p> <p><u>Exclusion criteria:</u> Not reported.</p>	<p>vitality was confirmed by a cold stimulation tester (Chloroethyl) and/or electric pulp tester.</p>					
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## 24. Risico op biasbeoordeling bij wetenschappelijke bewijs over partiële of stapsgewijze excavatie bij blijvende elementen

Dit wetenschappelijke bewijs onderbouwt:

**Uitgangsvraag 3.4:** Hoe dienen gecaviteerde dentinelaesies behandeld te worden bij kinderen met blijvende elementen?

Risico op bias in systematische review(s)

Study: Ricketts, 2013	Yes, partial yes or no	Explanation
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	An extensive description of all PICO items and time frame for follow up was reported.
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	Yes	The detailed protocol was published in advance.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	RCTs.
4. Did the review authors use a comprehensive literature search strategy?	Yes	Different databases, no language restrictions, reference checking and contacting authors.
5. Did the review authors perform study selection in duplicate?	Yes	-
6. Did the review authors perform data extraction in duplicate?	Yes	-
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Yes	-
8. Did the review authors describe the included studies in adequate detail?	Yes	All PICO elements, follow up and sponsoring were reported when available.
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?	Yes	Cochrane Risk of bias
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes	-
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes	-
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Not applicable	Was not possible because of too little data in a meta-analysis.
13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	Also reported in the summary of findings table.
14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	Not applicable	Was not possible because of too little data in a meta-analysis.

15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Not applicable	Was not possible because of too little data in a meta-analysis.
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	No	The authors had no conflict of interest.