Prevention of caries in high risk patients

Systematic Reviews

Author **Bader J, Shugars D and Bonito A**

Title ***A systematic review of selected caries prevention and management methods.*** **Community Dent Oral Epidemiol 2001; 29: 399–411.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of incl. studies	Intervention	Comparison	Outcome measure	Results
High caries risk									
Systematic review	1+	35 studies reporting 49 evaluations of preventive interventions	Caries active or high risk individuals classified according to any DMFT/S dmft/s score Age range not given, but almost all studies involved children as subjects	No formal meta-analysis performed	24-60 mths	Professional methods of caries prevention Any fluoride modality (gel, varnish, rinse) (9 evaluations, 1 on primary teeth) **Chlorhexidine** (CHX varnish, gel or rinse) (7 evaluations, all on permanent teeth) **Combinations** of fluoride, chlorhexidine or sealants (7 evaluations, 6 of which involved fluoride) **Other agents** (i.e. sugar free gum, Xylitol gum, 0.9% alum rinse, Fissure sealant, 5% kanamycin gel, high risk	Placebo or no treatment in all but 2 of the included trials	% caries reduction Significance	**Fluorides** % caries reduction: 7 to 30%. 3/9 evaluations had statistically significant results (2 varnish, 1 gel) Evidence for efficacy judged to be fair for fluoride varnish and insufficient for the other fluoride based modalities, due to the small number of studies **Chlorhexidine** % caries reduction: -9% to 52% 2/7 evaluations had statistically significant results Evidence for efficacy judged to be insufficient but suggestive of efficacy for chlorhexidine **Combinations** % caries reduction: 8% to 89% 3/7 evaluations had significant results (2 involved CHX + fluoride and 1 involved CHX + sealant) Evidence for efficacy of combinations of agents was judged to be insufficient but generally suggestive of efficacy for combined treatment approaches **Other agents** % caries reduction: 11 to 88% 2/6 evaluations reported significant results (both involved chewing gum, one sugar free and one containing xylitol) Evidence of efficacy judged to be insufficient for any of the agents involved, none of which was

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of incl. studies	Intervention	Comparison	Outcome measure	Results
						protocol) (6 evaluations)			represented by more than one study, although the evidence for gum-based interventions was found to be suggestive of efficacy. **Head and neck Radiotherapy patients** These studies generally involved fluoride or CHX interventions. The evidence for the efficacy of both fluoride and CHX was judged to be fair for individuals receiving head and neck radiotherapy **Orthodontically banded teeth** All but one of the 9 interventions involved fluoride gel, rinse or varnish. The evidence was judged to be insufficient for the efficacy of any of the interventions included, due to the small sample sizes, generally low quality scores and small number of studies per method. However, the authors state that overall, the studies suggested that a variety of preventive interventions may well reduce demineralisation and hence carious lesions among individuals with orthodontically banded teeth
Management of non-cavitated lesions									
Systematic review	1+	7 studies, 9 interventions	Children Not restricted to high risk individuals Age range not given	final n= 3,627	22-60mths (most 24 mths)	7/9 interventions were fluoride others were occlusal sealant and ammoniacal silver nitrate (ASN) solution	placebo or fluoride rinse or fluoride solution	% progression in test and control group	4 interventions (APF solution, SnF solution, ASN (all from the one study) and occlusal sealant) produced statically significant difference between test and control group for progression of non-cavitated lesions (controls for these 4 interventions were placebo & no treatment)

Author conclusions: One of the main findings of this review was the limited evidence to answer the two key questions posed. Of all the interventions included, only fluoride varnish was judged to have fair evidence of efficacy in high risk or caries active individuals. Fluoride and chlorhexidine were both judged to have fair evidence of efficacy in patients receiving head and neck radiotherapy. The authors point out that the small number of studies for any given intervention, the variation of experimental protocols among any set of studies, the lack of studies on adult subjects and root surfaces, the meagre number of studies examining the effects on primary teeth, the variation in the identification of caries-active and at risk subjects and several study design issues, limited the conclusions that could be drawn about any specific preventive method. The authors called for better quality research, in accordance with the CONSORT criteria, in the two areas covered by this review.

Reviewer comments: The authors' conclusions are valid and were limited by the quality of the included studies.

(Fair = data are sufficient for evaluating efficacy. Sample size is adequate but the data show some inconsistencies in outcomes between intervention and placebo/usual care groups such that efficacy is not clearly established. Insufficient = data are insufficient for assessing the efficacy of the intervention, due to limited number of studies, limited sample sizes and/or poor quality).

Prevention of Early Childhood Caries

Systematic Reviews

Author **Ammari J, Baquin Z, Ashley P**

Title **Effects of programs for the prevention of Early childhood caries: a systematic review. *Med Princ Pract* 2007; 16: 437–442.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review of RCTs	1+	7	Children under the age of 6 at the start of the intervention	No formal meta-analysis performed	2-5.5 years	Preventive interventions other than water fluoridation	Control	Difference in caries levels between the test and control groups. (dmfs, dmft, deft, dfs or dft)	**Dental Health Education:** 1 study: Holt et al , 1985 Better dental health seen among children whose mothers had been given DHE at home compared to DHE by leaflet though post or no intervention **Prenatal fluoride**: 1 study: Leverett et al, 1997 No significant difference in dfs between test and control group at age 5. **Topical fluoride application**: 1 study: Ličir and Rosin-Grget, 1993 Children receiving topical amine fluoride solution (either 10,000ppm every 2mths or 5,000ppm monthly) had significantly lower dmft than the control group after 2 years ($p \leq 0.05$) **Preventive dental programme**: 1 study: Gomez et al, 2001 97% of children in the test group were caries free compared to 77% in the control group after 4 years ($p<0.05$) **Fluoridated toothpaste:** 3 studies: Winter et al, 1989, Davies et al, 2002, You et al, 2002 The study by Winter compared 550ppm toothpaste with 1055ppm toothpaste and found no significant differences in dmft between the two groups after 3 years. The two other studies found a significant benefit with the supervised (You et al, 2002) or unsupervised (Davies et al, 2002) use of toothpaste containing >1000ppm fluoride

Author conclusions: Since this systematic review was unable to provide conclusive evidence regarding the relative effects of the (included) interventions for the prevention of caries in young children, an important conclusion is that more research is needed in this area. However, fluoride-based interventions appear to be effective in young children.

Reviewer comments: The inclusion of only RCTs in this review limited the number of studies that qualified. The overall conclusion concurs with that of the later systematic review by Twetman, 2008: the quality of the evidence in this area is poor and that fluorides seem to be effective.

Author **Twetman S**

Title **Prevention of early childhood caries (ECC) – Review of the literature published 1998–2000. *European Archives of Paediatric Dentistry* 2008; 9(1): 12–18.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review of RCTs and CCTs	1+	22	Children under the age of 3 years at the start of the intervention	No formal meta-analysis performed	Not reported for all stuides	Preventive or non-invasive primary or primary-primary (i.e. mother to child) interventions	Varied in different studies but were mostly no-treatment control groups.	Cavitated or non-cavitated clinical caries expressed as incidence or prevalence.	**Dental Health Education**: 5 studies 3 Medium quality: all had significant results Kowash 2000, Feldens 2007 – *DHE home visits* Weinstein 2004, 2006 – *motivational interviewing* 2 Low quality: both had non-significant results for ECC reduction. Davis 2005 – *staged DHE + feeding cup + toothpaste distribution*, Vichiraroijpisan 2005 – *group DHE with facilitator* Studies were not homogeneous with different focus and displayed conflicting results. There was a clear tendency for DHE efforts based on early start, outreach activities and novel motivational interactive techniques to be more effective than those using more traditional counselling. **Community intervention/Fluoride**: 6 studies 2 medium quality – both had significant results Davis 2002 *-1450 & 440 ppm fluoride toothpaste distribution - 1450 ppm F effective* Weintraub 2006 – *fluoride varnish + chairside DHE* 4 low quality: 3 had significant^ results Aaltonen 2000^ - *pacifier with NaF tablet* Lin 2000^ – *fluoride tablet/liquid* Livney and Sgan-Cohen 2007 - *fluoride toothpaste distribution* Wennhall 2005^ – *fluoride toothpaste & tablets* There is fair evidence to support the daily use of fluoride toothpaste with more than 1000ppm fluoride and professional fluoride varnish applications at least twice yearly for high risk children.

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
									Antibacterial agents: 4 studies 2 medium quality: both had non-significant results Plozitza 2005 – *chlorhexidine varnish* Nase 2001-*probiotics in milk* 2 low quality: one significant^ and the other non-significant Lopez 2002^- *povidone iodine* Zhan 2006- *povidone iodine + APF gel* It seems possible to reduce the incidence of ECC with a 10% povidone iodine solution (Lopez 2002) but the study should be repeated in other settings before it could be a recommended approach. There is also some concern about the use of iodine in infancy. **Primary-Primary prevention**: 6 studies 2 medium quality: both had less caries in the test group Isokangas 2000 – *xylitol gum* Thorild 2006- *xylitol gum* The findings of the two medium quality trials provide limited scientific evidence for xylitol-mediated primary-primary prevention but more large scale trials with a health-economic approach are needed 4 Low quality – all involved comprehensive dental programmes for mothers 3* had significant caries reductions Gomez 2001*, Ercan 2007*, Gunay 1998*, Zanata 2003

Author conclusion: The body of scientific evidence has improved during the last decade. CCTs provide fair evidence for daily use of fluoridated toothpaste and professional fluoride applications at least twice yearly for high-risk children. The evidence for DHE, antimicrobials and mother-child intervention are still inconclusive or contradictory and further well designed and conducted clinical trials are required to establish the best way to maintain oral health in infants.

Reviewer comment: The aim of this review was to examine the literature on ECC prevention published since 1998 and to determine if the new evidence supported a re-grading (up or down) of recommendations suggested in 1998 at an international conference on ECC (Ismail, 1998). Only the recommendation on the use of fluoride toothpaste and varnish could be upgraded from a C recommendation (poor evidence to support the intervention, but it is still recommended on other grounds) to a grade B (fair evidence to support the intervention). Although this review presents the best of the evidence on the prevention of ECC, many of the studies are low quality and have serious methodological flaws, such as historical controls or very high dropout rates.

Prevention of Early Childhood Caries

Primary Studies

Author **Blair Y, Macpherson L, McCall D & McMahon A.**

Title ***Dental health of 5-year-olds following community based oral health promotion in Glasgow, UK. Int J Paediatr Dent 16, 388-398***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Ecological	3	Not applicable	Preschool children in the most deprived (DepCat 7) areas of Glasgow. Approximately 32% of the 5-year-old population in Glasgow live in DepCat 7 areas.	Comparison of data over a 3 - 4 year period	Community-based oral health programme based on the principles of the Ottawa Charter and involving multi-disciplinary oral health action team (OHAT)*. Numerous joint interventions devised in partnership parents, families, teachers etc. working with the community. The three key objectives of the programme were: 1. Sustained distribution of toothpaste and toothbrushes to encourage home toothbrushing; 2. Advocating healthy food and drink policy in preschools 3. Promoting early asymptomatic dental attendance. The intervention commenced in 2 pilot areas in 1996 and by 2001, all severely deprived areas had active OHAT programmes. ** OHAT included:*	All comparisons were temporal, and involved comparing caries experience, taken from a random sample of 5-year-olds participating in routine epidemiological surveys in 1997/1998 (T1) with caries experience in the same age group in 2003/4 (T2). Trends in caries experience were examined for pilot DepCat 7 areas (where intervention commenced in 1996), and for all DepCat 7 areas (all had intervention by 2001). Comparisons were made with data from non-intervention areas (DepCat 1-6) and for Glasgow as a whole.	Changes between 1997/8 and 2003/4 in: Mean $d_3$mft % with $d_3$mft =0 % with missing teeth Odds ratio for $d_3$mft >0 for 2003/4 relative to 1997/8	In pilot areas, in DepCat 7 areas, and in all Glasgow (DepCats 1-6 combined) there was a significant reduction in the percentage of children with $d_3$mft >0, in the % of children with missing teeth, and in the % with dt>0 between 1997/8 and 2003/4 The age adjusted Odds Ratio for $d_3$mft >0 was significantly lower in DepCat 7 and in all Glasgow in 2003/4 compared to 1997/8. (OR = 0.35 (95% CI 0.26-0.47, p<0.001 in DepCat 7 and OR= 0.66 (95% CI 0.57-0.77, p<0.0001 in All Glasgow (DepCats 1-7) Among DepCats 1-6, (which acted as quasi-control areas) DepCat 3 was the only area to show a significant reduction in the odds for $d_3$mft>0 between 2003/4 and 1997/8.

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
					oral health promoter, lead General Dental Practitioner, Community Dental Officer, community pharmacist, liaison health visitor, Public Health Practitioner, education sector staff, community workers/volunteers).			

Author conclusions: Dental health improvements were observed in pilot areas and across all DepCat 7 communities following the rollout of the programme. The change was of sufficient magnitude to impact upon area-wide statistics for Glasgow.

Reviewer comments: This study uses secondary analysis of routinely-collected data to show temporal changes in caries levels. Although it is possible that other factors could have caused the changes found in this study, the fact that there had been no dental health improvement in this age group from the mid 1980s to 1998, and that the other DepCat areas (apart from DepCat 3) showed no significant change in oral health during the time period covered, supports the authors' conclusions.

Author **Blinkhorn A, Gratrix D, Holloway P et al.**

Title **A cluster randomised controlled trial of the value of dental health educators in general dental practice. *BDJ* 2003; 195: 395–400.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Cluster RCT	1+	**Baseline:** 30 practices Test=15 Control=15 Children: Test=172 Control=162 Mothers: Test=138 Control=131 **End:** Children: Test=137 Control=134 Mothers: Test=132 Control=116 **Losses to follow up:** Children: Test=20% Control=17% Mothers: Test=4% Control=14%	Mean age: Test=4.2 yrs Control=4.1 yrs No significant difference in caries levels at baseline. Children had to have some caries experience and be assessed by the dentist as being at risk of developing new caries in the next 2 years. No significant differences at baseline in maternal knowledge or attitudes	2 years	Oral health education programme involving 2 sessions covering diet and toothbrushing instruction, and recall visits at 4mthly intervals for counselling. Toothbrushes and toothpaste were provided at the start and as appropriate. **Setting** Private practice **Personnel** Oral health educator seconded from the Primary Care Trust.	The children in the control group were seen once at the start of the study and were given toothbrushing instruction and toothpaste	Mean dmft (caries prevalence not caries increment)	Test: 2.65 SD 2.56 Control: 3.22 SD 2.85 Difference of 18% between the 2 groups not statistically significant
							% of children with plaque	Test: 39% Control: 47% Difference of 8% not statistically significant
							Maternal knowledge and attitudes	Overall, significantly better knowledge and attitudes towards treatment of primary teeth in test group compared to control p<0.001
							Parental toothbrushing skill	Significantly better brushing technique in mothers in the test group
							Costs	£39.37 for a 2 hour session seeing 10 patients

Author conclusions: The model tested of seconding a qualified dental health educator to general dental practices to counsel mothers of regularly attending, at risk young children failed to reveal a substantial improvement in dental health over a 2-year period. However, there were clear benefits in relation to dental health knowledge, attitudes and toothbrushing skills among these mothers. The authors suggest that regular attenders might have been the wrong target group as they may not benefit greatly from the extra dental health initiative. The authors go on to advise Primary Care Trusts to carefully consider value for money before adopting such a strategy to improve the dental health of young children within their localities.

Reviewer comments: This study was conducted in a high caries risk area and involved children who were assessed as being at high caries risk. It would have been useful if the baseline level of caries was recorded in such a way that allowed the caries increment to be calculated. This would have given a better insight into the caries experience of the participants in the trial over the 2 years. The measurement of toothbrushing skills at the end of the study was done by the oral health educator who had taught the parents, and therefore is open to bias.

Author **Davies, G, Duxbury, J, Boothman N, et al.**

Title **A staged intervention dental health promotion programme to reduce early childhood caries. *Community Dent Health* 2007; 24: 117–121.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Controlled community trial	2-	Total = 842 Test area: 477 Control area: 365 Losses to follow up: Test area: 47% Control area: 21%	Children aged 5 from 2 high caries, non-fluoridated, disadvantaged areas in Manchester Mixed ethnicity Followed up approximately 2.5 years after the cessation of the DHP programme commencing at age 8 months	~ 2 years	DHE at age 8 & 15 months 1450ppm F toothpaste and brush at 15, 20, 26, 32 months. Children who attended their 8mth or 15 month visit were considered participants **Setting** Community **Personnel** Age 8 & 15 months: health visitors	No intervention Children who attended their 8mth or 15 month visit in the control area were considered "potential participants" for analysis	Mean dmft % with dmft>0 % with nursing caries* and % with extraction experience Outcomes were measured in the test and control areas for participants (or "potential participants" in the control area), for non-participants and for both groups combined ** nursing caries defined as: caries on one or more upper incisor*	All caries outcomes were significantly better in participants in the test area compared to "potential participants" in the control area % with caries: 54% v 64%, p=0.03 Mean dmft: 2.23 v 3.72, p=0.0001. PF=40% % with nursing caries 20% v 32%, p=0.002 % with extraction experience 3% v 12%, p= 0.0001 For non-participants, the prevalence and severity of caries was higher in the test area compared to the control area, but the differences were not significant. The only significant difference in any of the caries outcomes when the full sample (participants + non-participants combined) in the test and control areas were compared, was for the percentage of children with extraction experience, which was lower in test area (6% v 12%, p=0.002). The prevalence, mean dmft and ECC were: 63%, 3.12 and 30% in the test area and 64%, 3.60 and 32% in the control area

Author conclusions: The impact of non-participation in a deprived urban conurbation with high levels of population mobility is sufficient to dilute the impact of a health intervention such that few benefits are discernable at a population level.

Reviewer comments: The intervention was effective in those who participated, but the participants may not be representative of the population as they represent settled families in each area. There was a high degree of mobility in the test area, with just over half of the children meeting the eligibility criteria at age 5 even though uptake of the 15 month visit had been 83%. However, the fact that the participants in the test area had better oral health than the "potential participants" in the control area suggests that the intervention could be worthwhile in situations where population mobility is less than in this study. The barrier of entry to the programme by attending the 8th month developmental check or 15 month MMR vaccination would remain however.

Author **Feldens, C, Vitolo, M & Drachler M.**

Title **A randomised controlled trial of the effectiveness of home visits in preventing early childhood caries. *Community Dent Oral Epidemiol* 2007; 35: 215–223.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1+	500 at baseline 200 test, 300 control 376 at end (for dental exam) 157 test, 219 control Losses to follow-up: 21% test 27% control	Fullterm, healthy, Brazilian infants, with birthweight ≥ 2,500g, not a twin, born to low-income mothers. Fluoridated area (0.7ppm)	1 year	Dietary advice to mothers on healthy breast feeding and weaning. First visit 10 days after birth, with Monthly home visits up to age 6mths and then visits every 2 months up to age 12 months (10 visits in first year of life). **Setting** Participants' homes **Personnel** 12 trained fieldworkers delivered the dietary advice Intervention based on "Ten Steps for Healthy Feeding Children younger than 2 years" which is a public health priority in Brazil.	No intervention other than routine care provided by health service and research assessment at 6 and 12 months	% of children with caries (caries defined as any white spot lesion or cavitation)	Full sample: 15% (56/376) Test: 10.2% (16/157) Control: 18.3% (40/219)
							Odds ratio for ECC (adjusted for number of teeth)	(OR 0.52. 95% CI 0.27-0.97) Odds of caries 48% lower in the intervention group compared to the control group
							Mean number of decayed surfaces	Test: 0.37 Control: 0.63 p=0.03
							Self-reported dietary practices	Self-reported dietary practices such as duration of exclusive breastfeeding, later introduction of sugar, eating biscuits, chocolate, honey, soft drinks or fromage frais were more favourable in the test group (all differences in proportions statistically significant).

Author conclusions: Home visits for dietary advice appear to help reducing dental caries in infants.

Reviewer comments: The trial was well conducted and the caries outcome is just part of a wider evaluation of the effectiveness of the intervention on general health. The prevalence of caries at age 1, even in the intervention group, is alarmingly high, highlighting the difficulty in changing ingrained cultural feeding practices that predispose to caries, even with a very intensive intervention such as this.

Author **Gomez S & Weber A**

Title **Effectiveness of a caries preventive program in pregnant women and new mothers on their offspring. *Int J Paediatr Dent* 2001; 11: 117–122.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
CCT	2-	930 pregnant women recruited to the study from 4th month of pregnancy. Losses to follow up = 74% Of the 241 available mother/child pairs, 180 were randomly selected for evaluation.	The age range of the children was 1 to 3.5 years. Mother and child pairs in Chile who had been involved in a preventive dental programme operated by the Chilean Navy dental service. Middle socio-economic status. Exposure to 1ppm fluoridated water	4 years. But children in the evaluation group had participated for varying lengths of time	Preventive dental programme involving: 1. Examination of pregnant women, and subsequently their children 2. Education (DHE, OHI) reinforced every 6 months 3. Treatment of mother with restorative and preventive treatments. **Setting** Dental Clinic **Personnel** Dental (Not specified)	Mother-child pairs not involved in any specific preventive programme.	% of children caries free Mean dft ± SD	Significantly higher proportion of caries free children in the whole test group, and in the 3-3.5 age group compared to control Test: Age 1-2: 98%; Age 2-3: 99%; Age3-3.5: 94%; All: 97% Control: Age 1-2: 96%; Age 2-3: 76%; Age3-3.5: 58%*; All: 77%* Mean dft was significantly lower in the whole test group and in the 2-3 and 3-3.5 age groups Test: Age 1-2: 0.16± 1.13; Age 2-3: 0.01± 0.11; Age3-3.5: 0.20± 0.95; All: 0.11± 0.78 Control: Age 1-2: 0.14 ±0.7; Age 2-3: 0.51± 1.24*; Age3-3.5: 1.40± 2.22*; All: 0.66± 1.55* *Difference statistically significant p<0.05

Author conclusions: The preventive dental programme was effective at inhibiting caries in preschool children even in a population already receiving the benefits of community water fluoridation

Reviewer comments: The study was well conducted, and the researchers deal with the huge losses to follow-up by randomly selecting those who remained. However, it is possible that those who remained might have differed systematically from those who were lost to follow up.

Author **Gomez, S, Emilson C, Weber A & Uribe, S.**

Title ***Prolonged effect of a mother-child caries preventive program on dental caries in the permanent 1st molars of 9-10 year old children. Acta Odontol Scand 65, 271-4***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Cohort study	2-	Test: 37 mother/child pairs Controls: 42 The 37 children in the test group represent 15% of all children assessed 4 years into the programme	Mean age of children 9.6. Mother and child pairs who participated in a 6 year preventive program in Chile, followed up 4 years after cessation of the programme.	Programme ran for 6 years. This study is a follow-up 4 years after programme cessation	1. Examination of pregnant women, and subsequently their children 2. Education, reinforced every 6 mths 3. Treatment of mother with restorative and preventive treatments.	A random selection of 42 mother/child pairs attending the same dental clinic as the test group who were not involved in a preventive programme	% caries free in FPMs (DFS=0)	Test: 26/37 70% Control: 14/42 33% p<0.001
							Mean DFS (SD) (Unclear if this is for the FPMs only or for the permanent dentition in total)	Test: 0.51 (SD 0.93) Control: 1.57 (SD 1.38) p=0.002

Author conclusions: The results support and emphasise the importance of preventive interventions in mothers from the time of pregnancy in protecting their children from long-lasting caries

Reviewer comments: The sample size is so small and the drop out is so huge (85% drop out from number assessed at ages 1-3) that it is difficult to draw any conclusion from this follow-up.

Author **Harrison R, Benton T, Everson-Stewart S, Weinstein P.**

Title **Effect of motivating interviewing on rates of early childhood caries: a randomized trial. *Pediatric Dent* 2007; 29 (1): 16-22.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1+	Baseline: 240 children End: 205 Drop out: 15%	Children aged 6-18 months of South Asian Punjabi mothers living British Columbia, Canada Mean age of control group at recruitment slightly higher than test group 12.1 v 10.8 mths p=0.06 and mean time in Canada lower in control group (95.7 v 138 mths, p=0.06) All other baseline characteristics similar in both groups	2 years	1. DHE involving pamphlet and video 2. One 45 minute Motivational interviewing (MI) session followed by 2 follow-up telephone calls within 1 month of initial contact, and 4 further calls up to 6 months to encourage maintenance of behaviour change, and attendance for fluoride varnish application. 2 postal reminders also sent. **Setting** Unclear if intervention was conducted in a clinic or in the participant's home **Personnel** 3 trained South Asian women	DHE involving pamphlet and video	Mean dmfs No. fluoride applications Intention to treat analysis (Poisson regression analysis controlling for differences in age)	Test: 3.35 ± 7.8 Control: 7.59 ± 14.2, p = 0.001 Test: 3.81 ± 1.2 Control: 0.25 ± 0.5 p=0.01 Hazard ratio 0.54 (95% CI 0.35-0.84) i.e. the children in the MI group had a 46% lower dmfs rate than the control group
							Maternal risk factors for caries in the child	Mother pre-chewing child's food (p< 0.008) Mother raised in rural environment (p<0.004) Annual family income > $30,000 (p<0.007)

Author conclusions: A Motivational Interviewing-style intervention shows promise to promote preventive behaviours in mothers of young children at high risk for caries.

Reviewer comments: Participants were volunteers and may not be representative of the target population. The authors also note that design elements of the study, such as small incentives for participants and "appreciation" parties for project volunteers coupled with support from the targeted community in "tracking down" families who had lost contact with project staff were important elements in ensuring the low losses to follow up.

Author **Isokangas P, Soderling E, Pienihakkinen K, Alanen P.**

Title **Occurrence of dental decay in children after maternal consumption of xylitol chewing gum, a follow-up from 0-5 years of age. *J Dent Res* 2000; 79(11):1885–1889.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1-	N=195 total 3 groups: Xylitol=120 CHX varnish=32 F varnish=36 Drop-outs 26.7% total	Pregnant women with high levels of MS in their saliva (CFU≥10^5/mL)	5 years (2 years active intervention & 3 years post intervention follow up)	Daily Xylitol (65%) chewing gum used by mothers three months after the birth of the baby until child was age 2 years. Average consumption 4 times a day Average daily dose xylitol - 6-7g	CHX varnish (EC40) treatments 6, 12 and 18 months after delivery of the baby. F varnish (Duraphat) treatments 6, 12 and 18 months after delivery of the baby.	Mean dmf	Mean dmf Age 2 Age 5 Xylitol 0.02 0.83* n=90 CHX 0.21 3.22 n=23 Fluoride 0.21 2.87 n=30 *Xyitol group differs significantly from CHX and fluoride groups, p<0.001 Regardless of treatment group, children who were not colonised by MS at age 2 showed less caries at all annual examinations than children colonised with MS. The results of this study at two years (Soderling et al., 2000) showed that habitual consumption of xylitol by mothers was associated with a statistically significant reduction in the probability of mother-child transmission of MS

Author conclusions: Maternal use of xylitol chewing gum can prevent dental caries in their children by prohibiting the transmission of MS from mother to child.

Reviewer comments: The difference in size between the Xylitol and the control groups means that there is a greater chance of missing an effect in the smaller groups, thus biasing the results in favour of Xylitol. The Xylitol intervention continued from the time the children were aged 3mths until they were aged 24mths whereas for the two other groups, the interventions stopped when the children were aged 18mths. The examiners weren't blind to the group allocation of the mothers for the first two years and may have remembered the allocation in the later years (2-5years), although they were blind to the MS status of the children. Inter- and intra-examiner variability was not measured.

Author **Kowash M, Pinfield A, Smith J. & Curzon M.**

Title **Effectiveness on oral health of a long-term health education programme for mothers with young children. BDJ 2000; 188 (4): 201–205.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1-	Baseline: Test=228 End Test=179 Comparison group N=55 Losses to follow up (all intervention groups): 21% Group A: 25% Group B: 20% Group C: 15% Group D: 26%	Aged 8 months at start of intervention Sample of birth cohort resident in low-income/high caries areas of Leeds. Mean age at baseline 11.4 months. Mean age of mothers: 29 years. 96% of children were white Caucasian. No significant difference in mothers' level of education between intervention groups.	3 years	4 models of DHE were tested: A: focusing on diet and briefly on oral hygiene (OH) B: focusing on OH and briefly on diet C: Equal focus on diet and OH D: diet and OH Models A-C were delivered every 3 months for the first 2 years and 2/yr in year 3. Model D was delivered 1/year for all 3 years. **Setting** Participants' homes **Personnel** 1 dental hygienist and 1 paediatric outreach nurse	No treatment	% children with caries	2 children (1%) in the intervention group developed caries. Both children were in group A. In the comparison group, 18 children (33%) had caries.
							Mean dmfs	Significantly higher dmfs in control group Group A: 0.29 SD 1.64 Groups B, C & D: 0 Control: 1.75 SD 5.09 p<0.001
							% with gingivitis	Test: 3/179 (2%) Control: 9/55 (16%)
							% with plaque	Test: 9/179 (5%) Control: 22/55 (40%)
							Risk factors for caries	Significant difference between intervention group and control for all caries related risk factors (p<0.01) for frequency of dental attendance and p<0.001 for diet and brushing factors)

Author conclusions: Regular home visits to mothers with infants commencing at or soon after the time of eruption of the first deciduous teeth, was shown to be effective at preventing the occurrence of caries, improving oral hygiene and dental attendance. There was no difference in effect between visits every 3 months or every 12 months between the ages of 1 and 3 years. An added benefit was that mothers of the children in the test group significantly improved their oral hygiene in terms of debris, gingivitis and calculus compared to baseline. There were no differences in caries levels between the test groups for the 2 educators, indicating that midwives and health visitors may be as effective as dental personnel.

Reviewer comments: For ethical reasons, no control group was selected at baseline as there was concern that participants randomised to the control group would withdraw and thus bias the study. The compromise was to examine children at age 3 who had originally been eligible to enter the study but had not been selected. These children were examined in a nursery school setting while the intervention children were examined in their own homes. Thus the examiner could not have been blind to the test/control status of the children, although she would not have known which intervention group a child was in. This could have introduced bias into the results. The comparison of the results of the self-reported questionnaires must also be treated with caution, as only 21 questionnaires in the control group (38%) were returned.

Author **Pienihakkinen K, Jokela J.**

Title **Clinical outcomes of risk-based caries prevention in preschool aged children. *Community Dent Oral Epidemiol* 2002; 30 (2): 143–50.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr>
<td>CCT</td>
<td>2-</td>
<td>End:
Test: 299
Control: 226
Drop outs:
Test: 13%
Control: 16%</td>
<td>Cohort of Finnish children aged 2 and born in 1987 or 1988, drawn from 2 communities with similar population and economic structure.
Low level of fluoride in soil.
Children in Vanha Korpilahti were the intervention group while children from Saarijarvi acted as controls</td>
<td>3 years</td>
<td>Risk-based* prevention:
Low risk (LR): annual exam, OHE
Intermediate risk (IR): exam, OHE, fluoride varnish twice/yr., Xylitol products recommended.
High risk (HR): exam and intensive prevention twice a year. Fluoride varnish 4/yr plus CHX 4/yr if MS positive. GIC sealant if discoloured fissures in molars.
Setting
Dental Clinic
Personnel
Specially trained dental assistants did screening and prevention
* Risk assessed at age 2, based on MS colonisation and caries experience
LR: no MS, no caries
IR: MS, no caries
HR: MS, caries</td>
<td>Routine prevention consisting of exam and preventive and restorative treatment when examining dentist considered it necessary, based on clinical findings only.
MS and caries were examined at baseline, but children were not assigned to risk categories until the end of the study.</td>
<td>% with dmfs>0 (at enamel + dentine level, (d1-3mfs), dentine level without cavitation (d23mfs) and cavitation level d3mfs)

% with $d_3$mfs>0 by risk status</td>
<td>
<table>
<tr><th></th><th>Test (n=299)</th><th>Control (n=226)</th><th>RR (95% CI)</th></tr>
<tr><td>D1-3mfs>0</td><td>43%</td><td>37%</td><td></td></tr>
<tr><td>D23mfs>0</td><td>30%</td><td>18%</td><td>1.7 1.2-2.4</td></tr>
<tr><td>D3mfs>0</td><td>23%</td><td>11%</td><td>2.1 1.3-3.2</td></tr>
</table>

<table>
<tr><th></th><th>Test</th><th>Control</th><th>Group diff
OR (95% CI)</th></tr>
<tr><td>Low risk</td><td>6.2% n=209</td><td>10.1% n=148</td><td>1.7 (0.8 - 3.7) NS</td></tr>
<tr><td>Intermed risk</td><td>16.9% n=59</td><td>37.5% n=58</td><td>2.8 (1.2-6.6)</td></tr>
<tr><td>High risk</td><td>35.5% n=31</td><td>85% n=20</td><td>10.3 (2.5-43.1)</td></tr>
</table>
</td>
</tr>
<tr>
<td colspan="9">Author conclusions: The results indicate that in young children, risk-based management of caries seems practical, and prevention of caries can be targeted efficiently to individuals at risk

Reviewer comments: Most children in this study were low risk (70% in the test group and 65% in the control). There is a significant effect for the intermediate risk group, which constituted 20% of the risk-based group and 26% of the routine prevention group. The percentage of high risk children (assessed at age 2) was similar in both groups (10% in risk-based group and 9% in control group). The significant difference between the high risk test and control groups in the odds of having caries (OR=10.3) must be interpreted with caution, due to the small numbers involved and the wide confidence interval (2.5 to 43.1) which indicates a high degree of imprecision.</td>
</tr>
</table>

Author **Plutzer K, Spencer A.**

Title **Efficacy of an oral health promotion intervention in the prevention of early childhood caries. *Community Dent Oral Epidemiol* 2008; 36 (4): 335–346.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT (Zelen randomisation)	2+	Baseline Test: 321 Control: 318 End Test: 232 Control: 209 Losses to follow-up: Test: 28% Control: 34%	Women expecting their first child Recruited during 5th-7th month of pregnancy Attending hospital for prenatal care Similar sociodemographic characteristics. Only significant baseline differences were in the percentage of mothers who used dental floss and who took alcoholic drinks during pregnancy (both variables more prevalent in the test group).	20 months	Printed oral health information (anticipatory guidance) provided during 5th–7th month of pregnancy and when the child was 6 months and 12 months old (post partum info sent by post) A randomly selected subset (50%) of the test group also received a telephone consultation when the infants were 6–12 months old.	No anticipatory guidance	Prevalence of Severe Early childhood caries, defined as ≥ 1 upper incisor with caries (cavitated or non-cavitated)	Test: 1.7% Control: 9.6%, p<0.001

Author conclusions: An oral health promotion programme based on repeated rounds of anticipatory guidance initiated during the mother's pregnancy was successful in reducing the incidence of S-ECC in these very young children.

Author **Rong W, Bian J, Wang W, Wang J.**

Title **Effectiveness of an oral health education and caries prevention programme in kindergartens in China. *Community Dent Oral Epidemiol* 2003; 31 (6): 412–6.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT Double blind	1+	731 at baseline Test =361 control = 370 514 at end Test=258 control =256 Drop out 30%	Children attending kindergarten in Miyun county, Beijing Mean age= 3 at baseline baseline mean dmfs: Test: 5.24 ± 7.08 Control: 5.96 ± 7.74 NS Water fluoride= 0.2 ppm Most toothpaste on market non fluoridated Socio economic status included in stratification of kindergartens prior to randomisation	2 years	OHE training for teachers 3 mthly OHE to children mthly Supervised toothbrushing with 0.5g 1100ppm NaF toothpaste for 1 minute 2/day Supervisor: teacher TP & TB given 3 mthly for home use.	Non-fluoridated toothpaste for home use. No oral health education was provided	Difference in caries increment (dmft/dmfs) reported at cavitation level	Mean dmfs increment after 2 years: Test: 2.47 ± 4.09 Control: 3.56 ± 5.30 Difference: 1.09, p = 0.009 Prevented fraction: 30.6%, p=0.009
							Changes in parental reported behaviour, attitiudes and knowledge	Parents in test group had better self-reported oral health knowledge and attitude than the parents of children in the control group

Author conclusions: This oral health education program was effective in establishing good oral health habits among preschool children and in increasing oral health knowledge of their parents, in conjunction with supervised daily tooth brushing with fluoridated toothpaste, which could reduce the development of new dental caries in preschool children in China.

Reviewer comments: The study involves the supervised use of fluoride toothpaste as part of an oral health promotion programme. It is unclear what effect, if any, the education programme had on caries levels. Different questions were asked in the pre- and post-study questionnaires, which makes comparison difficult. For questions that were similar pre and post study, i.e. the importance of primary teeth and starting brushing before age 3, both test and control groups showed a substantial increase in the percentage of parents who considered these important, although the percentage in the test group was significantly higher than that of the control group.

Author **Schwartz E, Lo E, Wong M.**

Title **Prevention of early childhood caries – results of a fluoride toothpaste demonstration trial on Chinese preschool children after 3 years. *J Public Health Dent* 1998; 58 (1): 12–18.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
CCT Outcome assessment not blind	2-	289 at baseline Test=168 Control=121 251 at end Test=152 Control=99 Drop out Test=10% in Control=19%	Preschool children in Guangdong, China 94% were age= 3 at baseline baseline mean dmfs: Test=4.9 Control= 6.8 Significance of difference not reported Water fluoride= 0.1ppm Mostly rural. Middle level income for China F TP not available on market No organized preventive or tx services	3 years	OHE training for teachers Supervised toothbrushing with 0.2 -0.4g 1000ppm MPF toothpaste for 2-3 minute 1/day **Setting** Kindergarten Personnel **Teacher** Toothpaste dispensed by teacher or class prefect	No intervention	Difference in caries increment (dmft/dmfs) reported at cavitation level and including category *arrested caries*	Mean dmfs increment after 3 years: Without arrested caries Test: 6.2 Control: 8.4 Difference: 2.2 p=0.016 PF = 26.2% Excluding arrested caries and examiner reversals Test: 3.6 Control: 6.3 Difference: 2.7 p=0.002 PF = 42.9%
							Plaque score and gingival bleeding	Control group had significantly more plaque at end (28% v 22%) No significant difference in gingival bleeding

Author conclusions: Daily toothbrushing with limited involvement of professional staff was feasible in Chinese kindergarten and that caries development was significantly slowed in the test children.

Reviewer comments: This study was a feasibility study, and was not randomised. The examiners were not blind to the allocation of the children and this could have introduced bias into the outcome assessment.

Author **Thorild I, Lindau B, Twetman S.**

Title **Caries in 4-year-old children after maternal chewing of gums containing combinations of xylitol, sorbitol, chlorhexidine and fluoride. *European Archives of Paediatric Dentistry* 2006; 7(4): 241–245.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1	N=173 A Xyitol=61 B CHX=55 C Fluoride=57 Drop-outs A Xylitol=15% B CHX=20% C Fluoride=16%	Mothers (of newborn infants) with high counts of salivary MS Intervention started when infants 6 months old	Intervention 1 year Follow-up children to age 4	A) Chewing gum containing 650mg Xylitol Chewed for 5 min, 3 times/day Daily dose Xylitol~2g B) Chewing gum containing 5mg CHX, 533mg Xylitol, 141.9mg sorbitol Chewed for 5 min, 3 times/day Daily dose Xylitol ~1.6g	C) Chewing gum containing 0.55mg sodium fluoride, 289mg Xylitol, 188.8mg sorbitol Chewed for 5 min, 3 times/day Daily dose Xylitol ~0.9g	defs Non cavitated lesions in enamel scored separately	defs(mean±SD): A 0.38±0.97* B 0.66±1.64 C 1.38±3.02* *Statistically significant difference between groups A-C, p<0.05 Mean caries increments between age 3 and 4 A 0.3± 0.7* B 0.5± 1.6 C 1.0 ±2.0* *Statistically significant difference between groups A-C, p<0.05 OR for cavitated dentine lesions (A compared to C)= 2.8 (95%CI 1.1-7.2; p<0.05) NNT 5.5 (At least 5 mothers with initially high counts of salivary MS had to complete the program in order to gain one cavity-free child.)

Author conclusions: Less caries was observed in children of mothers who chewed gums with Xylitol as the single sweetener during the time of eruption of the first primary teeth compared with those who used gums containing fluoride, sorbitol and lower amounts of xylitol.

Reviewer comments: The method of randomisation is not stated, and although the dental examiners were calibrated the intra- and inter- examiner reliability was not measured. The authors note that because potential differences in diet, use of toothpaste and supervised toothbrushing between the groups can't be ruled out, that the findings should be regarded with some caution.

Author **Vachirarojpisan T, Shinada K. & Kawaguchi Y.**

Title **The process and outcome of a programme for preventing early childhood caries in Thailand. *Community Dental Health* 2005; 22: 253–259.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr><td rowspan="3">Cluster RCT</td><td rowspan="3">1+</td><td rowspan="3">Baseline:
Test=270
Control=250

End
Test=213
Control=191

Dropouts:
Test: 21%
Control: 24%</td><td rowspan="3">Mothers/caregivers of children aged 6-19 months (mean age 12.1-12.2 mths) in rural district of Suphanburi Province, Thailand.
Mean baseline dmfs of children
Test=0.36
Control=0.51 NS
No significant differences in baseline characteristics of mothers/caregiver
All participants were volunteers attending health centres which were randomly assigned to intervention and control groups.</td><td rowspan="3">1 year</td><td rowspan="3">Participatory DHE, 3 times during the year, at 3 month intervals based on small group discussions (6-8 mothers/caregivers). Toothbrushes and fluoride toothpaste (500ppm) were distributed after each session.
Setting
Health centre
Personnel
Trained health centre staff, who seem to be non-dental, but this is not explicitly stated.</td><td rowspan="3">National DHE programme, which involved didactic teaching about ECC prevention and provision of free toothbrushes. The DHE programme was given at the same time as the vaccination programme at age 9 and 18 months.</td><td>1 year caries increment measured at cavitated and non-cavitated level</td><td>
<table>
<tr><td></td><td>Test</td><td>Control</td></tr>
<tr><td>Cavitated (C)</td><td>3.82 (3.65)</td><td>3.74 (3.93)</td></tr>
<tr><td>C+NonCavitated</td><td>7.80 (4.99)</td><td>7.78 (5.22)</td></tr>
</table>
No significant difference in 1 year caries increment</td></tr>
<tr><td>Proportion of children with cavitated caries increment</td><td>Test: 74.2%
Control: 68.1% (no p value reported)</td></tr>
<tr><td>Reported oral health knowledge and behaviour</td><td>A significantly higher proportion of mothers in the test group reported brushing their child’s teeth, brushing twice daily, using fluoride toothpaste and using the proper amount of toothpaste, compared to the control group (p<0.001). No significant differences were found between the groups for dietary habits such as falling asleep with bottle, night time feeding or sweet food between meals.</td></tr>
<tr><td colspan="2"></td><td colspan="2"></td><td></td><td></td><td></td><td>Health staff evaluation</td><td>65% of staff in test health centres strongly agreed with participating in the ECC programme and 16/17 wanted to extend the format to other areas of general health</td></tr>
<tr><td colspan="9">Author conclusions: The overall results of this programme revealed the effectiveness of a participatory DHE approach to increase self-reported toothbrushing and fluoride toothpaste behaviour as preferred individual /collective choices for preventing ECC, but was not sufficient to prevent ECC. The authors acknowledge that ECC is a severe problem in Thailand and therefore a single intervention in the short term is not sufficient to prevent the development of ECC.

Reviewer comments: The lack of change in dietary habits between the two groups is notable and highlights the difficulty in changing this risk factor for caries. The authors accept the reported toothbrushing habits of the test group although it could be that mothers in the test group had better knowledge of what should be done and therefore gave what they thought was the “expected” answer. The lack of effect in the test group who received fluoride toothpaste as part of the intervention could be due to the low fluoride concentration (500ppm) or could indicate that the dietary habits were so influential that fluoride toothpaste could not reverse the damage. The cultural differences in child-rearing practices between rural Thailand and Western economies limit the generalisability of the results of this study.</td></tr>
</table>

Author **Weintraub J, Ramos-Gomez F, Jue B *et al.***

Title **Fluoride varnish efficacy in preventing Early Childhood Caries. *J Dent Res*; 85(2): 172–176.**

Aim ***To determine the efficacy of different fluoride application frequencies with parental/caregiver oral health counseling vs counseling alone in preventing ECC incidence in young, initially caries free children***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1+	N = 376 at base N = 261 children at 12 months Dropout = 30% N= 202 at 24 months Dropout = 33%	Mean age 1.8 yrs Resident in fluoridated area of San Francisco, recruited from public health centres serving primarily low income families Caries free dentition at start. 53% were girls, 47% Hispanic, 46% Asian and 7% other race/ethnicity. Children with medical conditions or medications that could affect their oral health were excluded.	2 years	Parental counselling + NaF varnish (Duraphat) twice a year Parental Counselling + F varnish once a year	Parental counselling only	Caries incidence measured at the d_{2+} (cavitated) and d_{1+} (precavitated level) according to intended frequency of application and actual frequency of application. The presence of fillings was also recorded. Prevented fraction	See tables below

	No F	F x 2 (intended)	F x 4 (intended)
Baseline (n)	126	124	126
No. with no caries at 2 years	48 (38.1%)	59 (47.6%)	67 (53.2%)

No. actual active treatments				
	0 (n=118)	1 (n=79)	2 (n=57)	3-4 (n=26)
Mean d_{2+}fs*	1.6	0.8	0.7	0.1
Mean d_{1+}fs^	2.8	1.2	1.2	0.6
PF		53%	58%	93%

**cavitated lesions*

^ *includes precavitated lesions*

The odds ratio by actual number of treatments for caries incidence in

Control v 3-4 applications = 18.3 (95% CI 2.4-138.5)

Control v 2 applications = 3.4 (95% CI 1.6-7.5)

Control v 1 application = 2.5 (95% CI 1.3 -4.7)

Author conclusions: Fluoride varnish added to caregiver counselling is efficacious in reducing early childhood caries incidence.

Reviewer comments: This study is complicated by the fact that placebo varnish was inadvertently used for children in the intervention group during part of the trial. Results are therefore presented for the actual number of active applications and the intended number of applications.

Author **Wennhall I, Martensson E, Sjunnesson, I.*et al.***

Title **Caries preventive effect of an oral health program for preschool children in a low socio-economic, multi-cultural area in Sweden: Results after one year. *Acta Odontol Scand* 2005; 63: 136–167.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr><td rowspan="4">Cohort study with historic reference group</td><td rowspan="4">2-</td><td rowspan="4">Baseline
Test: 804

End
Test: 738

Drop out: 8.2%

Reference group: 217</td><td rowspan="4">Immigrant children aged 2 years at start of study and resident in Rosengard suburb, Malmo, Sweden

No baseline caries levels are provided</td><td rowspan="4">1 year</td><td rowspan="4">4 OHP sessions between age 2 and 3 involving :

1) Toothbrushing instruction

2) 1,000-1100ppmF toothpaste offered at discounted price

3) Fluoride tablets provided (0.25mg/day)

4) Diet recommendations

Setting

outreach facility

Personnel

2 trained dental assistants.</td><td rowspan="4">Historic reference group, 6mth- 1 year older than the test group, from same area, who received an invitation to local Child health centre for dental health information at age 18 months</td><td>Proportion of children with caries at age 3</td><td><table><tr><td></td><td>Test</td><td>Control</td></tr><tr><td>Cavitated</td><td>29%</td><td>55%*</td></tr><tr><td>Initial lesions</td><td>52%</td><td>45%</td></tr><tr><td>Caries free</td><td>37%</td><td>15%*</td></tr></table>*p<0.001</td></tr>
<tr><td>Oral health behaviours</td><td>Significantly better dietary habits, brushing habits, use of fluoride toothpaste or tablets compared to baseline. There was no significant difference in the proportion of children taking sweet drinks at night compared to baseline.

Significant differences between the test and reference group at age 3 were found for all oral health behaviours except the use of fluoride toothpaste.</td></tr>
<tr><td>Relative risk of caries</td><td>2.5 (95% CI 1.8-3.4)</td></tr>
<tr><td>NNT</td><td>4.6</td></tr>
<tr><td colspan="9">Author conclusions: This study clearly indicates that a comprehensive oral health program, based on repeated parent education, which included dietary guidance, toothbrushing instruction and guidelines for the regular use of fluoride toothpaste and tablets is an effective approach to preventing caries in young children living in a multi-cultural, low socio-economic urban area.

Reviewer comments: The before/after evaluation of parental knowledge in the test group is valid. However, the measurement of caries was not recorded blind to the child’s group, which could introduce bias. The lack of baseline caries measures in both the test and reference group means that it impossible to tell if there were differences in caries experience between these two groups at the start of the study, which would bias the results. The authors themselves state that the lack of baseline data at age 2 “implies that conclusions from this field project must be drawn with caution.”. The fact that the reported oral health behaviours of the reference group at age 3 are substantially worse than the intervention group at age 2 (e.g. % eating > 5 times/ day was 46.2% in the reference group at age 3 and 28.1% in the test group at age 2) could suggest that the two groups were not similar at the outset.</td></tr>
</table>

Author **Whittle J, Whitehead H & Bishop C**

Title **A randomised control trial of oral health education provided by a health visitor to parents of pre-school children. *Community Dent Health* 2008; 25: 28–32.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1+	Baseline: n=501 Test=250 Control=251 End: n=352 Test=181 Control=171 Losses to follow up: Test: 28% Control: 32%	Children attending hearing test developmental check at age 8 months East Lancashire, known areas of poor oral health. Characteristics of test and control groups not described in this paper, although demographic data was collected to ensure test and control groups had similar characteristics	28 months	DHE when child aged 8 months and 20 months (coinciding with developmental checks). DHE based on Health Education Authority recommendations. Printed information plus toothbrush and 440ppm F toothpaste also provided at both visits **Setting**: Participants' home **Personnel**: Specially trained health visitor	Dental advice currently provided by health visitors in the area	Mean dmfs and its individual components at age 3	No significant difference in mean dmfs or its components at age 3: Mean dmfs: Test: 2.03 (95% CI.41-2.97) Control: 2.19 (95% CI.39-2.67)
							Comparison made at age 5, as part of BASCD epidemiological survey	Age 5: Test*: 3.99 (95%CI 2.94-5.04) Control: 4.84 (95%CI 3.39-6.29) Census: 5.94 (95%CI 5.55-6.33) * *significantly lower than census group*

Author conclusions: No statistically significant differences between the test and control groups, but gap widened as they got older. Asking the control parents to take part in the study and examining their children at age 3 years may have had an effect on their dental health status and may have made it more difficult to detect any differences achieved by the programme. The authors suggest that it may be best to randomise localities so that the control group is not alerted to the intervention.

Reviewer comments: The lack of difference between the two groups could have been due to the similarity between the intervention and the "standard" advice given to the comparison group. The comparison at age 5 seems to be opportunistic rather than a planned part of the intervention.

Author **You BJ, Jian WW, Sheng RW, *et al.***

Title **Caries prevention in Chinese children with sodium fluoride dentifrice delivered through a kindergarten-based oral health program in China. *J Clin Dent* 2002; 13: 179–184.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT Double blind	1-	Baseline n=1334 Test=682 control=652 End n=916 Test=386 Control=445 (includes 85 children who were involved in another oral care study) Drop out: 31.3% overall 43.4% test 31.7% control	Mean age= 3 at baseline Baseline dmfs = 6.24 in test & control groups Water fluoride= 0.2-0.35ppm 24 kindergartens in 2 districts (Miyun and Huairou) Most toothpaste on market non fluoridated Socio economic status included in stratification of kindergartens prior to randomisation	2 years	Toothbrushing with ~0.48g 1100ppm NaF toothpaste for 1 minute 2/day **Setting** Kindergarten **Personnel** Teacher TP & TB given for home use. OHE to teachers and children. Audio visual materials shown to children at least every 2 weeks	Non-fluoridated toothpaste for home use. No oral health education was provided	1. Difference in caries increment (dmfs) reported using criteria of Radike. 2. Urinary fluoride excretion	Mean dmfs increment after 2 years : (excludes children involved in another oral care study) Examiner 1 Test: 3.81 (0.24) Control: 4.81 (SE 0.26) Difference: 1.0, p = 0.004 PF 20.7% Examiner 2 Test: 3.67 (SE 0.31) Control: 4.71 (SE 0.29) Difference: 1.04 , p = 0.014 PF 22.1% A county by treatment interaction was found for examiner 2 (the percent reduction in one county was a non-significant 6.8% compared to 39.9% in the other There was no measure of inter examiner reliability Urinary fluoride levels at 24 hours 0.442mg F Test and 0.313mgF control

Author conclusions: These results demonstrate that fluoride in conjunction with increased dental awareness can deliver important reductions in caries in preschool children.

Reviewer comments: Although this study is double blind, calibration of examiners is not mentioned in the report, which could account for the examiner variability found at county level. This casts doubt over the reliability of the results. The study is useful, however in that it provides information on urinary fluoride excretion at baseline and during the programme. The authors report that urinary fluoride levels at 24 hours were well within the accepted normal ranges for optimal fluoride ingestion in children 3 years of age. This modest difference in fluoride intake was no longer evident at one and two years in this study.

School-based oral health education

Primary Studies

Author **Petersen, P, Peng B, Tai, B *et al.***

Title **Effect of a school-based oral health education programme in Wuhan City. *Peoples Republic of China International Dental Journal* 2004; 54: 33–41.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Community trial	2+	**Baseline:** Study group: 404 (86% of original sample) Control group: 399 (89% of original sample) **End of study:** Study group 335 Control group 331 **Losses to follow-up:** 17% in both groups	Children in grade 1 (age 6) attending randomly selected primary schools in the District of Wuhan City. Drinking water 0.2ppm F	3 years	School-based OHE programme based on the concept of the WHO Health Promoting Schools Project. Teachers trained to conduct OHE (conducted monthly, mothers encouraged to be present). Daily oral hygiene instructions supervised by the teacher and were instructed in brushing method. Toothbrushing twice a day with fluoride toothpaste was recommended.	No intervention	Caries increments: DMFT/DMFS	There were no significant differences in DMFS and DMFT increments between the two groups after 3 years (the caries increment was very low in both groups 0.2 of a permanent tooth surface over 3 years) Gingival bleeding scores were lower for the study group, $p<0.01$. F-S (Filled surfaces) were higher in the study group, $p<0.05$. From questionnaire: More children in study schools reported adopting regular oral health behaviour such as toothbrushing, recent dental visits, use of F toothpaste and less frequent consumption of cakes/biscuits. Study mothers reported significant improvements in knowledge attitudes and habits. Knowledge and attitudes of teachers in study schools also improved compared to control schools.

Author conclusions: In the present OHE programme, positive effects were found on oral health behaviour and gingival status of the children, on oral health attitudes and behaviour of the mothers and on oral health knowledge and attitudes of the teachers. No effect as regards prevention of dental caries was observed. Meanwhile, involvement of teachers in this school-based OHE programme proved to be feasible and effective, and it is recommended to establish such programmes in other areas of China.

Reviewer comments: Although the 6 schools were randomly selected, it is unclear whether the schools were then randomly allocated to study and control groups. The method of randomization for the selection of schools is not described. The investigators were not 'blind' and may have been aware of the allocation of schools to study and control groups, which may have introduced bias. The authors do not actually state the age of the participants at baseline- this remains unclear (age 6 was deduced from the discussion). There may have been co-intervention in this study as improvements in oral health behaviour were also found in the control group-the authors refer to another health education activity called the LTD campaign.

Author **Vanobbergen J, Declerck D, Mwalili, S. & Martens, L**

Title **The effectiveness of a 6-year oral health education programme for primary school children. *Community Dent Oral Epidemiol* 2004; 32: 172–82.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Cohort study	2+	**Baseline** Test=4,351 Control=800 **End** Test=3,291 Control=676 **Losses to follow up** Test=24% Control=15%	Mean age 7.1 at start and 11.6 at end. Cohort of children born in Flanders in 1989 followed up from age 7 as part of the Signal-Tandmobiel® longitudinal study	6 years	School-based 1 hour OHE session to pupils and teachers once a year for 6 years	Children who had not received the OHE programme	Changes in DMF levels, plaque indices, sulcus bleeding index, restorative index and changes in oral health behaviours in children reported in questionnaire completed by parents	No significant difference in mean DMFT/S or prevalence of caries between test and control groups Mean DMFT 0.92 v 1.0, p=0.49 in test and control group respectively Prevalence 40.7% v 41.3%, p=0.76 The restorative index * was significantly higher in the test group 80% v 73%, p<0.01 Significantly fewer children in test group snacked more than twice between meals (29.9% v 36.9%, p<0.001). Significantly more children in test group reported never having toothache 78.1% v 51%, p<0.001 Difference between test and control group for use of fluoridated toothpaste borderline significant 88% v 86%, p=0.05

Author conclusions: The implemented yearly, minimal school-based oral health education programme did not result in a significant reduction in caries prevalence. The effectiveness on plaque level and gingival health was inconclusive. However, the favourable reported behavioural changes and the increased restoration level together with the educational responsibility of the profession justify the efforts and costs of the programme.

Reviewer comments: This is a well conducted, large scale study that confirms earlier findings that DHE programmes do not result in measurable improvements in oral health. The authors highlight that the schools in Flanders supported and organised a lot of continuing initiatives at achieving healthy lifestyles. Therefore, the OHE programme may not have been the only intervention to which children were exposed.

** restorative index: proportion of the D(M)F index attributable to the F component (F/DF). Represents the amount of treated decay*

Clinical Interventions: Pit and fissure sealants

Systematic Reviews

Author **Ahovuo-Saloranta A, Hiiri A, Norblad A, *et al.***

Title **Pit and fissure sealants for preventing dental decay in the permanent teeth of children and adolescents. *Cochrane Database of Systematic Reviews* 2008; Issue 4: Art No. CD001830.DOI:10.1002/14651858.CDO001830.pub3.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of included studies</th><th>Patient characteristics</th><th>No. of patients included in meta analysis</th><th>Duration of included studies</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr><td rowspan="3">Systematic review of RCTs or quasi-randomised trials</td><td rowspan="3">1++</td><td rowspan="3">16 studies
13 split-mouth
3 parallel</td><td rowspan="3">Children and adolescents age 5-16 years
Participants Exposed to fluoridated water in 5 studies</td><td rowspan="3">Not reported</td><td rowspan="3">1-9 years</td><td>Resin sealant</td><td>No sealant</td><td>Caries Yes/No on occlusal surfaces of permanent molar teeth
Caries defined as caries into dentine</td><td>Resin FS vs No sealant (7 studies)
<table>
<tr><th>Time mths</th><th>RR</th><th>(95% CI)</th><th>% caries reduction</th><th>No. studies</th></tr>
<tr><td>12</td><td>0.13</td><td>0.09-0.20</td><td>87%</td><td>3</td></tr>
<tr><td>24</td><td>0.22</td><td>0.15-0.34</td><td>78%</td><td>3</td></tr>
<tr><td>36</td><td>0.30</td><td>0.22-0.40</td><td>70%</td><td>3</td></tr>
<tr><td>48-54</td><td>0.40</td><td>0.31-0.51</td><td>60%</td><td>3</td></tr>
<tr><td>108</td><td>0.35</td><td>0.22-0.55</td><td>65%</td><td>1</td></tr>
</table></td></tr>
<tr><td>Glass ionomer</td><td>No sealant</td><td></td><td>1 study – non significant result</td></tr>
<tr><td>Resin sealant</td><td>Glass ionomer</td><td></td><td>Resin sealant v Glass ionomer sealant (8 studies)
3 studies: resin better caries reductions than GI
2 studies: GI better caries reductions than resin
3 studies: no difference in caries reductions between materials</td></tr>
</table>

Author **Ahovuo-Saloranta A, Hiiri A, Norblad A, *et al.***

Title **Pit and fissure sealants for preventing dental decay in the permanent teeth of children and adolescents. *Cochrane Database of Systematic Reviews* 2008; Issue 4: Art No. CD001830.DOI:10.1002/14651858.CDO001830.pub3.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
						Resin sealant	Compomer		**Resin sealant** v **Compomer** at 24 months (2 studies) No difference in caries reductions between the materials Too few studies provided information on baseline levels of caries to evaluate the effectiveness of FS in children and adolescents with different background levels of caries.
								Secondary outcome: sealant retention	**Sealant vs No treatment** Complete Retention ranged from: 79% to 92% at 12 months 71% to 85% at 24 months 61% to 80% at 36 months 52% at 48 months72% at 54 months 39% at 9 years (with reapplication up to 36 months) **Resin sealant** v **Glass ionomer sealant** 4 studies: retention with resin better than GI 3 studies: low retention reported for both types of sealant **Resin sealant** v **Compomer** 1 study: Complete retention of over 70% for both materials 1 study: Complete retention 16% for compomer and 66% for resin
Author conclusions: Sealing is a recommended procedure to prevent caries of the occlusal surfaces of permanent molars. The effectiveness of sealants is obvious at high caries risk but information on the benefit									

Author **Ahovuo-Saloranta A, Hiiri A, Norblad A, *et al.***

Title **Pit and fissure sealants for preventing dental decay in the permanent teeth of children and adolescents. *Cochrane Database of Systematic Reviews* 2008; Issue 4: Art No. CD001830.DOI:10.1002/14651858.CDO001830.pub3.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
of sealing related to different caries risks is lacking. More research is needed on the effectiveness of sealants at different caries risk levels and to clarify the relative effectiveness of different sealant materials. **Reviewer comments:** The review update added 8 new studies to the review. Overall, the clinical conclusions were unchanged from the previous version of the review.									

Author **Ahovuo-Saloranta A, Hiiri A, Norblad A *et al.***

Title **Pit and Fissure sealants for preventing dental decay in the permanent teeth of children and adolescents, 2004. *The Cochrane Database of Systematic Reviews* Issue 4, Art. No.: CD001830. DOI: 001810.001002/14651858.CD14001830.pub14651853.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of included studies</th><th>Patient characteristics</th><th>No. of patients included in meta analysis</th><th>Duration of included studies</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr><td rowspan="4">Systematic review of RCTs or quasi-randomised trials</td><td rowspan="4">1++</td><td rowspan="4">8 studies
7 split-mouth
1 parallel</td><td rowspan="4">The age range of children in the included studies was from 5-13 years, recruited from selected schools or dental clinics.</td><td rowspan="4">Not reported</td><td rowspan="4"></td><td>Resin sealant</td><td>No treatment</td><td>Caries Yes/No at various time points</td><td>
<table>
<tr><th>Time mths</th><th>RR</th><th>(95% CI)</th><th>% caries reduction</th><th>No. studies</th></tr>
<tr><td>12</td><td>0.14</td><td>0.09- 0.19</td><td>86%</td><td>3</td></tr>
<tr><td>24</td><td>0.24</td><td>0.23-0.30</td><td>76%</td><td>3</td></tr>
<tr><td>36</td><td>0.30</td><td>0.26-0.35</td><td>70%</td><td>3</td></tr>
<tr><td>48-54</td><td>0.43</td><td>0.37-0.50</td><td>57%</td><td>2</td></tr>
</table>
The caries-preventive effect of the resin-based sealants declined over time.
</td></tr>
<tr><td>Glass ionomer</td><td>No treatment</td><td>mean difference</td><td>1 study – non significant result</td></tr>
<tr><td>Glass ionomer</td><td>Resin sealant</td><td>Caries Yes/No at various time points</td><td>3 studies were involved in this comparison, and the findings were conflicting. One study favoured glass ionomer sealant and the two others favoured resin sealant. As the results of the studies were so extreme, no meta analysis was attempted.</td></tr>
<tr><td>Any sealant</td><td></td><td>Sealant retention</td><td>Complete retention of resin-based sealant ranged from 79 – 92% at 12 months to 71% -85% at 24 months and 61% -80% at 36 months.
Retention of glass ionomer sealant ranged from <1% to 9% at 24 months and 3% at 36 months</td></tr>
<tr><td colspan="10">Author conclusions: Sealing is a recommended procedure to prevent caries of the occlusal surfaces of permanent molars. However, we recommend that the caries prevalence level of both individuals and the population should be taken into account. Only 2 studies in the review reported baseline levels of caries, so it was not possible to analyse if this has an effect on sealant retention. Future: The methodological quality of published studies concerning pit and fissure sealants was poorer than expected. Further research in the area of fissure sealants should comply with current criteria for RCTs (CONSORT statement) and include baseline level of caries, exposure to fluoride and other preventive measures. More research is needed to clarify the effectiveness of glass ionomer sealants.</td></tr>
</table>

Author **Beiruti, N., Frencken J E, van 't Hof M A & van Palenstein Helderman W H.**

Title **Caries preventive effect of resin-based and glass ionomer sealants over time: a systematic review. *Community Dent Oral Epidemiol* 2006; 34: 403–9.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review of RCTs	1-	12 All split mouth trials (2 included in Cochrane review)	Not reported	Not reported	from 1-7 years	Glass ionomer sealant (categorised separately as low and medium viscosity) Or Low viscosity resin-modified GI sealant	Resin-based sealant (RBS) (auto-cured (AC) or light cured (LC)	Attributable risk (percent difference in caries incidence between RBS and GI sealants)	Meta analysis not possible due to heterogeneity between studies. **AC RBS v low viscosity GI**: (4 studies) Significantly more caries for teeth sealed with GI in 2 trials (at 2 and 3 years) Difference NS in remaining 2 trials **LC RBS v low viscosity GI** (4 studies) Significantly more caries in RBS teeth in 2 trials (at 2 and 3.8 years). Difference NS in other 2 trials. **AC RBS v medium viscosity GI** (2 studies) Significantly more caries in RBS teeth in 1 trial at 3.6 years. Difference NS in other trial **LC RBS v low viscosity RMGIC** (2 studies) Significantly more caries in GI teeth in both trials at 2 and 3 years.

Author conclusions: There is no evidence that either resin-based or glass ionomer sealant material is superior in preventing caries development in pits and fissures over time.

Reviewer comments: The authors of this review make the point that the effectiveness of sealant should be based on caries prevention rather than retention. This review included 2 of the 3 studies that met the inclusion criteria for the original Cochrane FS review (2004). Of the remaining 10 trials, 9 had been excluded from the Cochrane review because pair-wise data was not presented. Statistical methods were used to calculate pair-wise comparisons for the included studies in this review. The conclusion of the authors, based on this analysis, is consistent with the results of the review. The lower level of evidence given to this review is based on the fact that the authors did not conduct a quality assessment of the included studies.

Author **Llodra J C, Bravo M, Delgado-Rodriguez, M *et al.***

Title **Factors influencing the effectiveness of sealants: a meta-analysis. *Community Dent Oral Epidemiol* 1993; 21: 261–8.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	24 studies reported in 36 articles	Age range of children at start of trials 5-15 yrs	Not reported	3-120 mths	UV light-cured sealant or autopolymerised sealant applied to permanent teeth (mostly first permanent molar)	No treatment.		Autopolymerised sealant significantly more effective than UV light-cured sealant PF 71.4% (95% CI 73.3 – 81.4) v 45.9% (95% CI 43.5 – 48.2 Effectiveness decreases over time for both types of sealant Effectiveness increased when water was fluoridated (PF 82.7% v 71.3%) There was significant heterogeneity between studies and evidence of publication bias.

Author conclusions: Fissure sealants are effective in preventing caries. Their effectiveness decreases with time and periodic reapplication is advisable. There appears to be a positive interaction between fluoride in the drinking water and fissure sealants in preventing caries.

Reviewer comment: All but one of the included studies was carried out in the 1970s

Author **Mejare I, Lingstrom P, Petersson L *et al.***

Title **Caries preventive effect of fissure sealant: a systematic review. *Acta Odontol Scand* 2003; 61: 321–330.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	13	Age range 5-14. Studies where children were selected on the basis of special general health conditions were excluded Children had to have at least one pair of caries free molars in order to qualify for a split-mouth study	No. children not reported No. teeth = 4,024	2-5 years	UV-cured, autopolymerised sealant, glass ionomer sealant or resin-modified glass ionomer sealant	Studies involving other preventive measures were not specifically excluded from the review.		The pooled estimate of relative risk reduction of resin-based sealants on first permanent molars compared to unsealed was 33% (RR 0.67 95% CI 0.55 -0.83) . The level of evidence was graded as “limited” 4 studies showed a close relationship between sealant retention and caries risk reduction. (Relative risk reduction >80% where sealants retained and < 20% where sealants lost) 2 studies that replaced defective sealants had risk reductions of 69% and 93% The evidence of effectiveness of sealants was incomplete for permanent 2nd molars, premolars and primary molars, and for glass ionomer cements.
Author conclusions: There remains a need for well designed randomised, controlled trials, particularly in child populations with low and high caries risk, which take into account the benefit, cost effectiveness and long term effects of sealants.									

Author **Muller-Bolla M, Courson F, Droz D *et al.***

Title ***Retention of resin-based pit and fissure sealants: a systematic review*, 2006.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of included studies</th><th>Patient characteristics</th><th>No. of patients included in meta analysis</th><th>Duration of included studies</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr><td rowspan="3">Systematic review</td><td rowspan="3">1+</td><td rowspan="3">31 studies

16 studies compared one resin-based sealant with another.

15 studies focused on sealant applicatio n technique</td><td rowspan="3">Minimum age 5 yrs</td><td rowspan="3">Not reported</td><td rowspan="3">At least 6 months</td><td>Visible Light cured resin sealant (LRBS)</td><td>Autopolymerised resin sealant (ARBS)</td><td>Complete retention of sealant according to duration of follow up.</td><td><table><tr><th>Time mths</th><th>RR</th><th>(95% CI)</th><th>No. studies (total =7)</th></tr><tr><td>6</td><td>0.98</td><td>0.87-1.11</td><td>2</td></tr><tr><td>12</td><td>0.95</td><td>0.91-1.00</td><td>6</td></tr><tr><td>24</td><td>0.99</td><td>0.93-1.06</td><td>4</td></tr><tr><td>36</td><td>0.99</td><td>0.93-1.07</td><td>2</td></tr><tr><td>60</td><td>0.99</td><td>0.92-1.07</td><td>1</td></tr></table>(no significant difference in retention between the 2 types of sealant)</td></tr>
<tr><td>Visible Light cured resin sealant (LRBS)</td><td>Fluoride-containing resin-based sealant (FRBS)</td><td>Complete retention of sealant according to duration of follow up.</td><td><table><tr><th>Time mths</th><th>RR</th><th>(95% CI)</th><th>No. studies (total=9)</th></tr><tr><td>12</td><td>1.01</td><td>0.96-1.06</td><td>5</td></tr><tr><td>24</td><td>0.95</td><td>0.79-1.15</td><td>1</td></tr><tr><td>48</td><td>0.80</td><td>0.72-0.89*</td><td>2</td></tr><tr><td>54</td><td>0.80</td><td>0.68-0.93*</td><td>2</td></tr></table>* significant difference in complete retention, in favour of light cured sealant without F</td></tr>
<tr><td>Rubber dam (RD)</td><td>Cotton wool roll (CW) isolation

Using autopolymerised and fluoride containing resin-based sealants</td><td>Complete retention of sealant</td><td>No difference in retention for autopolymerised sealant using rubber dam or cotton wool rolls RR=1 (3 studies)

Sealant retention significantly higher for fluoride containing light cured sealants when rubber dam was used RR = 2.03 95% CI 1.5-2.7 – 1 study

There were too few studies to determine the best clinical procedure for sealants.</td></tr>
</table>

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Author conclusions: The authors noted the small number of studies meeting the inclusion criteria, and their low to moderate quality. They also noted that further RCTs of FRBS retention should consider RBS filler It was not possible to determine the best clinical procedure for sealant application because of the insufficient number of studies. They concluded that “It is still necessary to carry out well-designed, randomised clinical trials focused on sealant retention considering different procedures, particularly new enamel preparation techniques such as air-abrasion or sono-abrasion.”									

Clinical Interventions: *Remineralising Products*

Systematic Reviews

Author **Azarpazhooh A, Limeback H.**

Title **Clinical Efficacy of casein derivatives. *J Am Dent Assoc* 2008; 139: (7) 915–24.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1++	12 10 on caries prevention (8 in situ, 2 clinical trials) 1 on mouth lubrication 1 on dentine hypersensitivity	Mostly adults (Adolescents in 1 study) In 2 studies participants had dry mouth (severe xerostomia in one trial and salivary gland dysfunction in the other) Only 2 studies (both trials involving patients with dry mouth) had more than 30 participants	No meta-analysis	7 to 21 days for all but 1 of the in situ trials 1 trial had outcome measured at 1 year	CPP-ACP* as paste (1 study) Chewing gum (5 studies) Milk (1 Study) Gum & rinse (1 study) Lozenge (1 study) Tooth Moose (1 study) CD-CP^ (2 studies) * *casein phosphopeptide -amorphous calcium phosphate* ^*casein derivatives coupled with calcium*	Other remineralising agents or placebo	Caries prevention /remineralisation	7 in situ studies found that CPP-ACP had caries-preventive potential and resulted in subsurface remineralisation in a dose-response fashion. 6 of these studies came from the same research team in Australia. (Cai 2003, Cai 2007, Iijima 2004, Shen 2001, Reynolds 2003, Walker 2006) 1 in situ trial found no difference in effect between CPP-ACP and the control chewing gums (Schirrmeister, 2007) 1 clinical trial in head and neck radiotherapy patients did not find any additional caries-preventive effect of casein derivatives compared to the fluoride mouthrinse control group (Hay and Thomson, 2002). 1 clinical trial in adolescent orthodontic patients had conflicting results: On visual examination of white spot lesions, there was significant regression of white spot lesions in the CPP-ACP group compared to the fluoride mouthrinse comparison group. However, no significant difference between the groups was found when the lesions were examined with laser fluorescence. (Andersson et al, 2007)
								Relief from dry mouth	1 study reported potential benefit from a spray containing CPP-ACP for relief of dry mouth - however reviewers state that study design was flawed

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
						phosphate		Hypersensitivity	1 study found the effect of CPP-ACP insufficient to relieve hypersensitivity - however reviewers state that study design was flawed
Author conclusions: The authors of the review concluded that there was insufficient clinical evidence to make a recommendation on the long term efficacy of CPP-ACP at preventing caries and recommended further clinical trials in which outcomes are measured in vivo.									

Clinical Interventions: *Remineralising Products*

Primary Studies

Author **Cai F, Manton DJ, Shen P *et al.***

Title **Effect of addition of citric acid and casein phosphopeptide-amorphous calcium phosphate to a sugar-free gum on enamel remineralisation. *Caries Res* 2007; 41(5): 377–83.**

Aim ***To determine if the inclusion of citric acid in a sugar-free gum would decrease the gum's ability to promote enamel remineralisation and to determine if inclusion of CPP-ACP with citric acid would restore the gum's ability to promote enamel remineralisation with acid-resistant material*.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr>
<td>RCT Double blind crossover in situ trial</td>
<td></td>
<td>10</td>
<td>Staff and post graduate students of the School of Dental Science, Melbourne.
Age range: 23-46
At least 22 teeth
No active caries</td>
<td>14 days</td>
<td>Sugar-free gum containing: Citric acid (20mg) and CPP-ACP (18.8mg)
Chewed for 20 min
4 times /day while wearing removable palatal appliance containing 4 demineralised human enamel half-slabs. Appliance worn for 40 min afterwards and then stored in a sealed, humidified container at 37^0 until reinserted.</td>
<td>1. Sugar-free gum containing: Citric acid (20mg)
2. Neutral sugar-free gum</td>
<td>Level of remineralisation
Salivary flow rate
Mean salivary pH</td>
<td>
<table>
<tr><th></th><th>Neutral gum</th><th>Citric gum</th><th>Citric plus CPP-ACP gum</th></tr>
<tr><td>% remin before acid challenge</td><td>9.4 ± 1.2</td><td>2.6 ± 1.3</td><td>13.0 ±2.2</td></tr>
<tr><td>% mineral loss after acid challenge</td><td>-12.2±1.5</td><td>-14.3±2.0</td><td>-10.1±1.2</td></tr>
</table>
Remineralisation before acid challenge was significantly higher with gum containing CPP-ACP than either of the 2 other gums and change in mineral content was less after acid challenge with gum containing CPP-ACP
There was no difference in salivary flow rate between the 3 gums. Salivary pH was significantly lower in the 2 gums containing citric acid in the first 2 minutes (6.5 v 7.1) but not at any other time point.
</td>
</tr>
<tr><td colspan="9">Author conclusions: The researchers concluded that inclusion of citric acid did not increase salivary flow rate as expected, but did significantly lower the remineralising ability of the sugar-free gum. Adding CPP-ACP to gum containing citric acid negated the effect of citric acid and produced a remineralising effect greater than that of neutral gum.</td></tr>
</table>

Author **Cai F, Shen P, Morgan MV *et al.***

Title **Remineralisation of enamel subsurface lesions in situ by sugar free lozenges containing casein phospopeptide-amorphous calcium phosphate. *Aus Dent J* 2003; 48 (4): 240–243.**

Aim ***To test the ability of a CPP-ACP containing lozenge to remineralise enamel subsurface lesions in an in-situ model.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Double blind crossover In situ trial		10	Staff and post graduate students of the school of dental science, Melbourne No current caries activity		Sugar-free lozenges containing: 18.8mg CPP-ACP 56.4mg CPP-ACP Consumed without chewing (dissolving time~8min), 4 times/day while wearing palatal appliance. Appliances stored between exposures as described in Shen 2001	1. Sugar-free Lozenge without CCP-ACP 2. No lozenge, nil treatment control	% remineralisation	No treatment control: 1.97 Control lozenge: 7.03 CPP-ACP 18.8mg lozenge 12.5 CPP-ACP 56.4mg lozenge 19.39 18.8mg CCP-ACP = 78% increase in remineralisation 56.4mg CPP-ACP = 176% increase in remineralisation compared to control
Author conclusions: Lozenges are a suitable vehicle for the delivery of CCP-ACP to promote enamel remineralisation.								

•

Author **Hay D, Thomson M.**

Title **A clinical trial of the anti-caries efficacy of casein derivatives complexed with calcium phosphate in patients with salivary gland dysfunction. *Oral Surg Med Oral Path Oral Radiol Endod* 2002; 93: 271–5.**

Aim ***To compare the caries preventive efficacy of a fluoride solution containing CD-CP with that of a 0.05% NaF mouthrinse in patients with dry mouth.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1+	138 baseline 124 end Drop out 10.1%	82 had received head and neck radiotherapy. 56 had Sjogren's syndrome No significant differences at baseline between the test and control groups for sex, age, disorder, time since last dental visit, or in any of the dental measures (DMFT etc)	12 months	CD-CP* mouthrinse (Gencal) 3 times/day **casein derivatives complexed with calcium phosphate*	0.05% NaF mouthrinse 3 times/day	% developing caries 12 month caries increment Tooth loss Acceptability of flavour Using rinse as directed	See table below

	Test N=61	Control N=63	P
No. (%) developing coronal* caries	17 (27%)	21 (34.4%)	NS
Mean DFS increment (SD)	0.32 (0.59)	0.39 (0.61)	NS
% experiencing tooth loss since baseline	10 (15.9)	3 (4.9)	p<0.05
Mean no. teeth lost	0.38 (1.35)	0.07 (0.31)	p<0.05
% finding rinse flavour acceptable	89.8%	96.8%	NS
% of time rinse used as directed	85.1%	83.9%	NS

**results for root caries not presented as only 2 subjects (both in the CD-CP group) developed root caries*

Author conclusions: The researchers concluded that CD-CP preparations "hold promise as caries preventive agents for individuals with dry mouth" but called for further research before a definitive conclusion can be reached.

Reviewer comments: The study failed to recruit the required number of patients (90 required to show a 30% difference in caries incidence between the 2 groups) and therefore there is the possibility that a significant effect may have been missed (Type II error). Overall, tooth loss was highest amongst Sjorgren's syndrome cases, and this group had higher baseline caries compared to the radiotherapy group. However, the baseline caries levels of the Sjogren's syndrome patients were not significantly different between the test and control groups. The researchers were unable to account for the difference in tooth loss between the 2 groups, but concluded that it was not due to lower efficacy of the CD-CP rinse, otherwise a difference in the caries increment would have been observed.

Author **Iijima I, Cai F, Shen P *et al.***

Title **Acid resistance of enamel subsurface lesions remineralized by a sugar free chewing gum containing casein phosphopeptide-amorphous calcium phosphate. *Caries Res* 2004; 38: 551–556.**

Aim ***To investigate the acid resistance of enamel lesions remineralised in situ by a sugar free chewing gum containing CCP-ACP.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Double-blind Crossover in situ trial		10	Staff and post graduate students form School of Dental Science, Melbourne Age range: 21-45 years Mean age: 32.3 ± 7.9 1ppm fluoride in water fluoride toothpaste twice a day	14 days followed by a 1 week wash out	Xylitol gum containing 18.8mg CCP-ACP Exposure: 20min 4 times/day + 20 min after Palatal appliance containing 4 demineralised human enamel slabs. Storage as for Shen *et al*, 2001. After each 14 day treatment period, each test block was cut in two and half of the exposed enamel was covered with nail varnish, leaving 2 "remineralised" windows exposed for in vitro acid challenge at pH 4.8 for 8 or 16 hours.	Xylitol gum without CCP-ACP Same procedure as for intervention.	% remineralisation	%R / Control / CCP-ACP No acid challenge: 9.02 ± 0.74 / 17.88 ± 0.97* 8 hour acid challenge: 3.12 ± 0.88 / 12.43 ± 0.90 16 hour acid challenge: 1.08 ±1.02 / 10.40 ± 1.19 ** sig diff between test and control: p<0.05* Percent remineralisation was greater using CCP-ACP chewing gum compared to regular sugar free gum. The reduction in enamel remineralisation following acid challenge was greater in the control group compared to the intervention group. In both groups, the bulk of the secondary demineralisation occurred below the remineralised zone, indicating that the remineralised enamel was more resistant to acid challenge than the original enamel.

Author conclusions: Sugar free gum containing CCP-ACP is superior to an equivalent gum not containing CCP-ACP in remineralisation of enamel subsurface lesions in situ, with mineral that is more resistant to subsequent acid challenge.

Author **Itthagarun A, King NM, Yiu C *et al.***

Title **The effect of chewing gums containing calcium phosphates on the remineralisation of artificial caries-like lesions. *Caries Res* 2005; 39: 251–254.**

Aim ***To test the remineralisation effect of chewing gums containing urea alone against chewing gums containing urea plus dicalcium phosphate or CPP-ACP.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Double blind, non-randomised, crossover, in situ trial		12 (3 drop outs)	Volunteers age 20-47 Good OH, no active caries Hong Kong	21 days 5 day washout	Group B: 25mg dicalcium phosphate dehydrate Group C: 47mg CCP-ACP All gums also contained 30mg urea Mandibular appliances Artificially demineralised human enamel slabs lingual to 2nd molars *Worn all the time*, only removed for toothbrushing Subjects supplied with cariogenic snacks to consume 2 sets of snacks between meals, midmorning and mid afternoon. Attempt to standardise diet of participants during experimental period	Group A: Gum containing urea only	% change in lesion depth (before/after) % change in max mineral content	Group A Control 0.4 Group B 25mg Ca -6.9 Group C 47mg CPP-ACP -10.0 Group A Control 10.0 Group B 25mg Ca 52.3 Group C 47mg CPP-ACP 65.7 Both test groups were significantly different from the control for lesion depth and mineral content, but no significant difference between each other. Tested using paired t-tests

Author conclusions: The addition of dicalcium phosphate or CPP-ACP to urea-containing chewing gum may have a caries preventive effect.

Reviewer comments: The lack of a clear difference between the two test gums is in contrast to other studies where CPP-ACP is significantly more effective than other calcium containing products. The difference could be due to the different study design (lower appliance, worn all the time and exposed to cariogenic challenge) which replicates “normal” oral conditions, or to different statistical analysis.

•

Author **Morgan MV, Adams GG, Bailey DL *et al.***

Title **The anti cariogenic effect of sugar-free gum containing CPP-ACP nanocomplexes on approximal caries determined using digital bitewing radiography. *Caries Res* 2008; 42: 171–184.**

Aim ***To compare the effect of sugar-free chewing gum containing CPP-ACP with that of sugar-free gum containing sorbitol on approximal caries progression in adolescents.***

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr>
<td>Double blind RCT</td>
<td>1+</td>
<td>Baseline: 2,720
Test: 1,369
Control: 1,351

End: 1,820
Test: 926
Control: 894

Drop out: 33%</td>
<td>School children from 29 schools in Melbourne
Aged between 11.5 and 13.5 years
Low caries population.
Fluoridated (1ppmF)
No significant differences in Baseline demographic characteristics and oral health behaviours between test and control groups.</td>
<td>24 months</td>
<td>Sorbitol gum containing 54 mg CPP-ACP per serving
3 times/day,
10 min
One supervised session in school
Fluoride toothpaste + toothbrush supplied every 3 months</td>
<td>Sorbitol gum
Same frequency as test group
Fluoride toothpaste + toothbrush supplied every 3 months</td>
<td>24-month approximal caries progression using standardised digital bitewing radiography
(measured by 1 examiner, blind to status of subject)

Adverse events</td>
<td>
<table>
<tr><th></th><th>CPP-ACP</th><th>Control</th><th>Absolute difference</th><th>Prevented Fraction</th></tr>
<tr><td>% approximal surfaces with caries progression</td><td>5.4%</td><td>6.5%</td><td>1.1%</td><td>17%</td></tr>
<tr><td>OR for caries progression</td><td colspan="4">0.82 (95% CI 0.68-0.93, p=0.03)
The odds of a surface experiencing caries progression for subjects in the CPP-ACP group was 18% less than the odds of a surface experiencing caries progression in the control group</td></tr>
</table>
<table>
<tr><th></th><th>CPP-ACP</th><th>Control</th></tr>
<tr><td>Non-serious adverse events related to gum e.g. nausea, headaches, diarrhoea</td><td>93 (6.9%)</td><td>90 (6.6%)</td></tr>
</table>
</td>
</tr>
<tr>
<td colspan="9">Author conclusions: CPP-ACP gum significantly slowed progression and enhanced regression of approximal caries relative to a control sugar-free gum in a 24 month clinical trial.

Reviewer comments: This trial was conducted in a generally low caries population with exposure to water fluoridation and with fluoride toothpaste supplied. In these conditions the study showed less approximal caries progression in the CPP-ACP group. Although the result was statistically significant, the absolute difference between the test and control groups in the percentage of approximal surfaces showing caries progression was only 1.1%, which translates into an NNT of 100. A no-treatment control group would have made the interpretation of the results more meaningful.</td>
</tr>
</table>

Author **Papas A, Russell D, Singh M *et al.***

Title **Caries clinical trial of a remineralising toothpaste in radiation patients. *Gerodontology* 2008; 25: 76–88.**

Aim ***To test the efficacy and safety of a remineralising toothpaste in controlling caries in head and neck radiation patients.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Double Blind RCT	1+	Baseline: 57 Test: 28 Control: 29 End: 42 Test: 23 Control: 19 Drop out: Test: 18% Control: 34.5%	Head and neck radiation patients (current and past: 0-15 years) Salivary flow <0.2ml/min Age ≥ 18 years Groups comparable for age, salivary flow, radiation dose and S mutans and Lactobacilli. No socio-economic comparison Test group had significantly more gingival recession than control group	12 months	2–phase remineralising toothpaste (Enamelon) containing calcium and phosphate and 1100 ppmF In addition, Duraphat varnish at enrolment, daily 0.05% F mouthrinse and Pilocarpine to stimulate saliva	1100 ppmF toothpaste Same additional interventions as test group	Net caries increment on coronal and root surfaces at 12 months	See table below The researchers controlled for dropouts by analysing the data using the value of the last observation obtained for the subjects carried forward to the end of the trial. This did not change the findings: there was still a significant difference between the 2 groups for root caries but not for coronal caries.

	Test N=23	Control N=19	P
Mean coronal caries increment ± SD	1.17 ± 0.61	0.58 ± 0.42	0.30
Mean root caries increment ± SD	0.04 ± 0.54	1.74 ± 0.53	0.037

Author conclusions: The results indicate that the remineralising toothpaste provides a significant benefit in preventing and remineralising root caries in high risk patients

Reviewer comments: Current and past radiation therapy patients were included. It is impossible to say if this had any effect on the results.

•

Author **Reynolds EC, Cai F, Cochrane NJ *et al.***

Title **Fluoride and Casein Phosphopeptide-amorphous calcium phosphate. *J Dent Res* 2008; 87 (4): 344–348.**

Aim ***To determine the ability of CPP-ACP in the presence of fluoride ions, to increase the incorporation of fluoride into supragingival plaque and subsurface enamel and to promote enamel remineralisation in situ with acid-resistant material.***

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr><td rowspan="4">Randomised double-blind crossover in situ trial</td><td rowspan="4"></td><td rowspan="4">14</td><td rowspan="4">Age: 21-45
Staff and students of the School of Dental Science, Melbourne.
Fluoridated (1ppmF)</td><td rowspan="4">5 days per product for the plaque trial
14 days per product for remineralisation trial</td><td colspan="4">PLAQUE TRIAL</td></tr>
<tr><td>1. 2% w/v CPP-ACP (Recaldent) mouthrinse plus 450 ppm F (as NaF) in deionised water
2. 450ppmF (as NaF) in deionised water</td><td>Deionised water</td><td>Plaque fluoride</td><td>
<table>
<tr><th></th><th>Placebo mouthrinse</th><th>Fluoride (450ppm) Rinse</th><th>2% CPP-ACP + 450ppmF</th></tr>
<tr><td>Mean fluoride level (nmol/mg dry weight) ± SD</td><td>7.4 ± 4.7</td><td>14.4 ± 6.7</td><td>33.0 ± 17.6</td></tr>
<tr><td colspan="4">The fluoride rinse produced higher fluoride plaque levels compared to placebo while the CPP-ACP + fluoride rinse produced more than twice the level of fluoride in plaque compared to the fluoride rinse. All values were significantly different from the others in the row (p<0.001)</td></tr>
</table>
</td></tr>
<tr><td colspan="4">REMINERALISATION TRIAL</td></tr>
<tr><td>1. 2% CPP-ACP
2. 2% CPP-ACP plus 1100ppmF
Both products were dentifrices used as slurries.
Subjects rinsed for 60sec 4/day while wearing removable appliance containing demineralised enamel</td><td>1. Placebo
2. 1100ppm F
3. 2800ppm F</td><td>Remineralisation</td><td>
<table>
<tr><th></th><th>Placebo</th><th>1100 ppm F</th><th>2800 ppm F</th><th>2% CPP - ACP</th><th>2% CPP-ACP+ 1100 ppmF</th></tr>
<tr><td>% remin</td><td>3.1 ±1.6</td><td>8.2 ±2.0</td><td>15.5 ±2.4</td><td>13.5 ±1.5</td><td>21.0 ±5.9*</td></tr>
<tr><td>% remin after acid challenge</td><td>-4.1 ±1.6</td><td>7.1 ±1.3</td><td>13.2 ±1.1</td><td>8.7 ±1.5</td><td>17.4 ±1.2</td></tr>
</table>
</td></tr>
</table>

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
					slabs			All dentifrice formulations replaced mineral in the enamel subsurface in this in situ study. Fluoride produced dose-related remineralisation, with the 2800ppmF formulation replacing significantly more mineral than the 1100ppmF which in turn replaced more mineral than the placebo. The dentifrice containing 2% CPP-ACP+ 1100 ppmF produced superior remineralisation, even after acid challenge. Microradiography of the lesions showed that fluoride ion alone tended to promote remineralisation of the surface layer whereas CPP-ACP promoted remineralisation thoughout the body of the lesion.
Author conclusions: The results suggest that CPP-ACP plus fluoride products may be superior in reducing caries risk compared to products containing fluoride alone.								

-

Author **Reynolds EC, Cai F, Shen P *et al.***

Title **Retention in plaque and remineralisation of enamel lesions by various forms of calcium in a mouthrinse or sugar-free chewing gum. *J Dent Res* 2003; 82 (3): 206–211.**

Aim ***To compare the ability of CPP-ACP with that of other forms of calcium, to be retained in the supragingival plaque and remineralise enamel subsurface lesions in situ when delivered in a mouthrinse or sugar free gum.***

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr><td rowspan="4">Double blind
Cross over, in situ trial</td><td rowspan="4"></td><td rowspan="4">30</td><td rowspan="4">Staff and students of the school of dental science, Melbourne
Age range: 22-44
No current caries activity</td><td rowspan="4">Mouthrinse study:
5 days
Gum study 1
14 days
Gum study 2
7 days</td><td colspan="4">MOUTHRINSE STUDY</td></tr>
<tr><td>2% Recaldent™ mouthrinse
6% Recaldent™ mouthrinse
Calcium phosphate mouthrinse</td><td>Deionised water</td><td>Calcium and inorganic phosphate levels in plaque</td><td>CCP-ACP significantly increased plaque calcium and phosphate levels in a dose dependent fashion. The calcium phosphate and control rinses did not result in a significant change in calcium or phosphate.</td></tr>
<tr><td colspan="4">GUM STUDY</td></tr>
<tr><td>Gum study 1:
3 pellet gums containing different forms of calcium:
CaCO3
CaHPO4 /CaCO3
CCP-ACP
20 min 4/times day for 14 days

Gum study 2:
3 slab gums containing different forms of calcium:</td><td>Gum study 1 & 2:
CaCO3 gum
CaHPO4/CaCO3 gum. Different concentration in study 1 and study 2</td><td>% remineralisation</td><td>% remineralisation significantly higher for CCP-ACP in each study than comparison gums.
<table>
<tr><th></th><th colspan="3">% remineralisation</th></tr>
<tr><td></td><td>CaCO3</td><td>CaHPO4 /CaCO3</td><td>CCP-ACP</td></tr>
<tr><td>Gum study 1</td><td>8.9 ± 1.4</td><td>12.0 ± 1.6</td><td>19.0 ± 2.5</td></tr>
<tr><td>Gum study 2</td><td>6.3 ± 1.2</td><td>8.6 ±1.0</td><td>19.4 ± 1.6</td></tr>
</table></td></tr>
</table>

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
					CaCO3 CaHPO4 /CaCO3 CCP-ACP 5min, 7 times/day for 7 days			
Author conclusions: In the mouthrinse study, only mouthrinse containing CCP-ACP significantly increased plaque calcium and inorganic phosphate ions. Gums containing CCP-ACP were superior to other forms of calcium in remineralising enamel subsurface lesions.								

•

Author **Schirrmeister JF, Seger RK, Altenburger MJ *et al.***

Title **Effects of various forms of calcium added to chewing gum on initial enamel carious lesions in situ. *Caries Res* 2007; 41: 108–114.**

Aim ***To determine the effects of 4 chewing gums on artificial caries-like subsurface lesions.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Randomised, observer blind, crossover, in situ trial		15	Volunteers from staff and students of school and dental hospital of Freiberg Mean age=27.5 ± 2.5 years 7 male, 8 female Mean salivary flow rate= 1.7 ± 0.5ml/min. salivary buffer capacity high for all volunteers	14 days followed by at least 1 week between treatments. All subjects crossed over to each treatment	Sugar free chewing gums all containing the same sugar substitutes, with 3 different test compounds: **Group 1** Dicalcium phosphate 3.9%, Calcium gluconate 1.8%, Calcium lactate 0.45% **Group2** Same as group 1 + zinc citrate **Group 3** CPP-ACP 0.7% Calcium carbonate Chewed for 20 min 4 times a day while wearing removable mandibular appliance with a buccal resin wing on each side, each containing 2 demineralised *bovine* enamel slabs. Appliance worn for	2 comparison groups: **Group 4** Same Sugar free gum without any calcium added And **Group 5** No gum	Average % remineralisation	Group 1 = 8.9 ± 12.7% Group 2 = -1.2 ± 8.0 Group 3= 4.4 ± 10.6 Group 4 = 2.2 ± 12.8 (gum control) Group 5 = 5.4 ± 15.9 (no treatment control) There were no statistical differences among the 5 groups concerning mineral change (p=0.36) or lesion depth (p=0.31)

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
					20 min afterwards and then stored in a moist tissue in a plastic container at room temperature			

Author conclusions: Under the conditions of the present study, it may be concluded that chewing gums with and without calcium have no significant effect on the remineralisation of buccal initial caries lesions in the mandibular posterior teeth. It may be argued that they do not enhance remineralisation of initial lesions that are not in direct contact with the chewing gum. Further work is required for the investigation of the effects of chewing gums containing various forms of calcium.

Reviewer comments: This study uses bovine rather than human enamel, which might have influenced the result. There is no reference to funding.

•

Author **Shen P, Cai F, Nowicki A *et al.***

Title **Remineralization of enamel subsurface lesions by sugar-free chewing gum containing casein phosphopeptide-amorphous calcium phosphate. *J Dent Res* 2001; 80 (12): 2066–-2070.**

Aim ***To determine the ability of CCP-ACP in sugar free chewing gum to remineralise enamel subsurface lesions in a human in situ model.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT Double blind, crossover, in situ trial		30 in total 10 in each study group	Staff and post graduate students of School of Dental Science, Melbourne Age range: 30-34	14 days with at least one week between treatments	**Sorbitol-based gum** 0.19mg CCP-ACP (Recaldent) 18.8mg CCP-ACP 56.4mg CCP-ACP **Xylitol-based gum** 10.0mg CCP-ACP 18.8mg CCP-ACP Chewed for 20 min 4 times a day while wearing removable palatal appliance containing 6 demineralised human enamel half-slabs Appliance worn for 20 min afterwards and then stored in a sealed, moist plastic bag at room temperature until next exposure.	**Control 1:** appliance worn as for intervention group but no gum **Control 2:** Appliance worn as per intervention group + Xylitol or sorbitol gum without CCP-ACP	Average %remineralisation Increment in % remineralisation compared to control gum	**Average** / **% remin v control** No gum = 3.6 ± 0.9 No CCP-ACP = 9.0 ± 0.4 CCP-ACP doses 0.19mg = 9.8 ± 1.8 / 0.8% 10.0mg = 14.7 ± 0.9 / 63% 18.8mg = 18.2 ± 1.7 / 102% 56.4mg = 22.7 ± 3.4 / 152%

Author conclusions: The addition of CCP-ACP to either sorbitol or Xylitol based gum resulted in a dose-related increase in enamel remineralisation, with 0.19, 10.0, 18.8, and 56.4mg CCP-ACP producing remineralisation of 9, 63, 102 and 152% respectively, relative to the control gum, independent of weight or type.

Reviewer comments: The study tested the efficacy of the product at producing remineralisation, in a situation that did not replicate the normal oral environment. Funded by Pfizer and the Australian National Health and Medical Research Council.

-

Author **Suda R, Suzuki T, Takiguchi R *et al.***

Title **The effect of adding calcium lactate to Xylitol chewing gum on remineralisation of enamel lesions. *Caries Res* 206; 40: 43–46.**

Aim ***To measure the effect on enamel mineralization of adding calcium lactate to xylitol chewing gum.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
In situ crossover trial. Blind outcome assessment		10	Dental hospital hygienists or students (Japan). No untreated caries	2 weeks 1 week washout before changing to other gum	2.5g Xylitol + 94mg calcium lactate 2.5g Xylitol 4times/day for 20 min Subjects wore a palatal appliance containing artificially demineralised human enamel slabs while chewing and for 20 min after	Appliance worn but no gum chewed	Mean degree of remineralisation	No gum control: 0.16 Xylitol: 0.33 Xylitol + Ca: 0.46* *Degree of remineralisation significantly higher with the Xyltol+Ca gum than with the Xylitol gum. Both test products produced significantly higher remineralisation values than the no gum control.
Author conclusions: Chewing gum containing calcium lactate as well as Xylitol enhanced remineralisation of sub surface enamel lesions more than gum containing Xylitol only.								

-

Author **Walker G, Cai F, Shen P *et al.***

Title **Increased remineralisation of tooth enamel by milk containing added CPP-ACP. *Journal of Dairy Research* 2006; 73 (1): 74–78.**

Aim ***To investigate the capacity of CPP-ACP added to milk to remineralise enamel subsurface lesions in situ.***

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Double-blind Crossover In situ trial		10	Staff and students of the school of dental science, Melbourne Caries status not recorded	5 days per product, followed by 1 week washout	200ml milk containing 2.0mg CPP-ACP 5.0mg CPP-ACP (Recaldent) Consumed once/day by sipping for 60sec Midpalatal appliance with demineralised enamel slabs worn while drinking and for 40min after	Milk without any CPP-ACP	% remineralisation	<table><tr><td></td><td>Milk</td><td>CPP-ACP 2mg</td><td>CPP-ACP 5mg</td></tr><tr><td>Mean remin (%R)</td><td>4.6</td><td>7.8</td><td>11.4</td></tr></table>All 3 milks remineralised enamel subsurface lesions, but the milks containing CPP-ACP produced significantly higher remineralisation than the control milk ($p<0.001$) - 70% increase in remineralisation with 2mg CPP-ACP and 148% increase in remineralisation with 5mg CCP-ACP compared to control. The 5mg CPP-ACP milk had a significantly higher % remineralisation value than the 2mg CPP-ACP milk.

Author conclusions: The addition of 2.0-5.0mg CCP-ACP to milk substantially increases its ability to remineralise enamel subsurface lesions.

Clinical Interventions: *Chlorhexidine*

Systematic reviews

Author **Twetman S.**

Title **Antimicrobials in future caries control? *Caries Res* 2004; 38: 223–229.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	22	Children, adults, the elderly	The results were not combined but were described under a number of headings.	Not restricted. 0.75-3 years Mother-child transmission: Until child age 4/5	Chlorhexidine rinse, gel or varnish, but all included studies on children & adolescents involved chlorhexidine varnish	Not restricted. Other treatment, no treatment, placebo.	Incidence or progression/regression of manifest and incipient caries lesions on crowns and roots as diagnosed by visual inspection, probing and/or radiographs	**Young permanent dentition/ all tooth surfaces-** The three studies described failed to show a statistically significant reduction in caries increment. **Proximal sites**- 2 of 4 studies failed to show an additional caries-preventive effect for CHX varnish over fluoride varnish alone and other 2 studies concluded that CHX varnish did not affect the overall proximal progression rate of caries. **Fissures**- 3 of 5 studies reported findings in favour of the 1% CHX/Thymol varnish (regular use of fluoride toothpaste or exposure to fluoride supplements was low or uncertain). One study (40% CHX varnish) found no significant difference between the CHX and a placebo varnish and one study reported a small but statistically significant reduction in caries increment. **White spot lesions-** Conflicting results. 3 of 4 studies were unable to disclose any benefit from CHX application. One study found a statistically significant reduction of white spot lesions following CHX varnish treatments among children with a higher caries increment. (All studies involved patients undergoing FA treatment.) **Root caries & Maternal antibacterial intervention-** conflicting results.
Author conclusions: The evidence for an anticaries effect of CHX-containing varnishes was rated as inconclusive for caries-active schoolchildren and adolescents with daily exposure to fluoride as well as for root caries arrest in elderly subjects.									

Author **van Rijkom HM, Truin GJ, van't Hof MA.**

Title **A Meta-analysis of Clinical Studies on the Caries-inhibiting Effect of Chlorhexidine Treatment. *J Dent Res* 1996; 75 (2): 790–795.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1-	8	11-15 year old children	Not stated	At least one year. 1.8-3 years.	Chlorhexidine treatment in the form of gel, toothpaste and rinse for caries prevention (applied to permanent teeth).	Not stated	Caries incidence at surface level (DFS)	The overall caries-inhibiting effect of the chlorhexidine treatment studies was 46%, (95% CI 35% - 57%). Multiple-regression analysis showed no significant influence on the prevented fractions for the variables "application method", "application frequency", "caries risk", "fluoride regime", "caries diagnosis", and "tooth surface", indicating homogeneity of the studies.

Author conclusions: It could be concluded that the average caries-inhibiting effect from the chlorhexidine treatment studies was 46% (95% CI = 35% - 57%).

Reviewer comments: After an initial screening of the selected papers inclusion criteria were modified to (subjectively) include with consistent methodological features. This approach, although an advantage in the meta-analytical approach, resulted in the exclusion of a large number of studies from the analysis, and potentially introduced bias into the review. No included study evaluated the effectiveness of CHX without the concomitant use of fluoride. In all but one of the included studies, the fluoride regime of the treatment and control groups included fluoride rinsing or application additional to the use of fluoride toothpaste.

•

Author **Zhang Q, van Palenstein-Helderman WH, van't Hof MA, Truin GJ.**

Title **Chlorhexidine varnish for preventing dental caries in children, adolescents and young adults: a systematic review. *Eur J Oral Sci* 2006; 114: 449–455.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic Review	1+	10 (Excluding trials on root caries, on primary teeth and on older adults (>25 yr); and control sites or groups receiving a preventive measure.)	Children adolescents and young adults aged 6 to 23	No meta analysis conducted	0.75 to 3 years	CHX varnish 1%, 10% or 40%	Placebo controls or with controls not receiving any type of anticaries application	Outcome measures differed between the studies, DMFT and DMFS. Prevented fraction and 95% confidence intervals were calculated to obtain comparability of the results.	An overall PF could not be calculated because of the large variation without overlap of the outcome results (statistical heterogeneity). An association between a caries-inhibiting effect and duration between last application and evaluation was not evident. The studies with a split-mouth design reported a greater caries-inhibiting effect of CHX varnish than the parallel-group design studies. The authors attribute this to the application frequency, because four out of five split-mouth design studies had a 3–4 month time interval between applications, whereas in the parallel group design studies, only one study out of 6 had this short time interval between applications. Owing to the limited number of studies and the large variation in effects, it was not possible to establish whether publication bias had occurred.

Author conclusions: The frequency of application of CHX varnish seems to be important for its anticaries efficacy. The number of studies was too small to analyze application frequency as a covariable in regression analysis. Considering this limitation, it is tentatively concluded that CHX varnish has a moderate caries-inhibiting effect when applied every 3–4 months, but its caries-inhibiting effect seems to have diminished around 2 yr after the last application.

Reviewer comments: Although the review itself was well conducted, the variation in outcome of the included studies makes it very difficult to draw any useful information from this review.

Clinical Interventions: *Chlorhexidine*

Primary Studies

Author **Baca P, Munoz MJ, Bravo M, Junco P, Baca A.**

Title **Effectiveness of chlorhexidine-thymol varnish in preventing caries lesions in primary molars. *J Dent Child (Chic)* 2004; 71 (1):61–5.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1-	229 children Dropouts 21% overall After 2 years, 181 children 86 test 95 control	Age 6-7 of lower-middle socioeconomic level, Spain	2 years	86 children, treated 3 monthly with chlorhexidine-thymol varnish (Cervitec)	95 children served as controls and received no treatment	Caries increment dftm/dfsm	There was no statistically significant difference between these 2 groups in the increment in decayed and filled primary molars. The children in the varnish group with no decayed or filled primary teeth at baseline (n=34) showed a significantly lower incidence of caries lesions (dftm and dfsm, p = .049 and .041 respectively) in primary molars (at 24 months) compared with the control group (n=49). For those caries free at baseline PF 44% (dftm)

Author conclusions: Chlorhexidine-thymol varnish can be said to reduce caries lesions in the primary molars of schoolchildren ages 6 to 7 with no previous caries lesion experience.

Reviewer comments: There was a greater level of caries and a lower percentage caries free at baseline in the test group although these differences were not statistically significant. The outcome assessment of caries was performed by one dentist who was not blind to the allocation of children to test and control groups. The conclusion is based on a subset of the initial study group; those with dft=0 at baseline, with only 34 in the varnish and 49 in the control group. Although the p values are reported to be less than 0.05, they are only just less than this, 0.049 for dftm and 0.41 for dfsm.

-

Author **Du MQ, Tai BJ, Jiang H, Lo ECM, Fan MW, and Bian Z.**

Title **A Two-year Randomized Clinical Trial of Chlorhexidine Varnish on Dental Caries in Chinese Preschool Children. *J Dent Res* 2006; 85 (6): 557–559.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1+	334	Aged 4-5 attending Kindergartens in the Hongshan district, central China	2 years	6 monthly applications (to all surfaces of the primary molars) of 40% chlorhexidine acetate in a sandarach resin dissolved in water-free alcohol (varnish). Application in the Kindergarten.	6 monthly applications (to all surfaces of the primary molars) of a placebo varnish containing only an alcohol solution of sandarach. Application in the Kindergarten	dmfs-molar	The mean caries increment of the primary molars was 1.0 dmfs-molar in the test-group children and 1.6 dmfs-molar in the placebo group. The difference of 0.6 tooth surface equated to a 37.3% reduction in caries increment, and was statistically significant (p = 0.036; 95% CI = 0.04-1.16). No side-effects (such as soft-tissue lesions and staining of teeth) were found at the 24-month examination.

Author conclusions: It was concluded that six-monthly applications of chlorhexidine varnish were effective in reducing the incidence of dental caries in primary molars.

Reviewer comments: The concentration of fluoride in the drinking water was 0.1-0.3ppm and there was no organized oral health care programmes for preschool children in the study site. The authors do not report on the home use of fluoride toothpaste by the study group. Assuming that the overall exposure to fluoride is low, it is unclear whether the benefit demonstrated here would persist in the Western world in communities with optimal exposure to fluoride.

•

Author **Ersin NK, Eden E, Eronat N, Totu FI, Ates M.**

Title **Effectiveness of 2-year application of school-based chlorhexidine varnish, sodium fluoride gel, and dental health education programs in high-risk adolescents. *Quintessence Int* 2008; 39 (2): e45-51.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr>
<td>RCT</td>
<td>1+</td>
<td>149
126/15.4% drop-outs
CHX 14%
F 14%
Education 20.4%</td>
<td>11-13-year-olds, previous caries experience in the primary dentition, Strep mutans levels higher than 10^5
DMFS=0, from a deprived area.
High-caries risk adolescents with low caries activity.</td>
<td>2 years</td>
<td>At baseline supervised oral hygiene instructions, toothbrush and toothpaste-brushed with f toothpaste before CHX and F applications
Chlorhexidine (1% CHX and 1% thymol-Cervitec) at baseline and every 3 months.
Sodium fluoride gel at baseline and every 6 months</td>
<td>At baseline supervised oral hygiene instructions, toothbrush and toothpaste
3 monthly 10 minute individual dental health education sessions</td>
<td>DMFS
Dental plaque scores
Salivary S Mutans counts</td>
<td>
<table>
<tr><th colspan="4">Caries increments by tooth surface</th></tr>
<tr><th></th><th>Proximal</th><th>Occlusal</th><th>Smooth</th></tr>
<tr><td>CHX</td><td>0.07±0.34</td><td>0.53±1.03</td><td>0.35±0.81</td></tr>
<tr><td>F</td><td>1.10±0.39</td><td>0.45±0.95</td><td>0.33±0.78</td></tr>
<tr><td>Educ</td><td>0.11±0.38</td><td>0.56±1.29</td><td>0.38±0.78</td></tr>
</table>
No statistically significant differences between the three groups in relation to caries increments and number of caries-free children.
No statistically significant differences between the 2 year plaque scores.
After 2 years statistically significant increase in S Mutans counts for the education groups and a non significant decrease in S Mutans counts in the CHX and F groups.
</td>
</tr>
<tr><td colspan="9">Author conclusions: Although all three preventive programs in this high-caries-risk group of children with low caries activity resulted in similar plaque and caries values after 2 years, longer follow-up studies are needed to clarify the effect of reduction in S Mutans growth by chemotherapeutic agents in caries incidence.</td></tr>
</table>

•

Author **Gisselsson H, Birkhed D & Bjorn AL.**

Title **Effect of a 3-year Professional Program with Chlorhexidine Gel on Approximal Caries and Cost of Treatment in Preschool Children. *Caries Res* 1994; 28: 394–399.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1-	**Two experimental groups:** 132 initially selected 117 fulfilled the 3 year study: CHX gel group 59 Placebo gel group 58 dropouts 11% **Control group:** 131 initially selected: 116 fulfilled the 3 year study: dropouts 11% Total 233	The total population of children born in 1983 and living in a small industrial town in Southern Sweden (n=132), Age 4 at start of trial, made up the CHX gel group and the placebo group. Control group was made up of children living in the same city born Aug-Dec 1982 (n=55) and Jan-June 1984 (n=76)	3 years	CHX gel group (n=59): 1% CHX gel 4 times a year Placebo gel (n=58): identical gel without CHX 4 times a year. Application by trained dental nurse was by quadrant after placing cotton wool rolls in vestibule and drying with compressed air. 0.7ml gel syringed into interproximal space and flossed about ten times with flat floss. Participants were advised to use 250ppm toothpaste twice a day and to suck one 0.25mg fluoride tablet daily.	Control group: No flossing or gel treatment	Caries increment deft and defs in dentine and enamel +dentine and caries progression	Mean defs(dentine) in the CHX group (0.97) was significantly lower than increment in both the placebo (1.85) and control (2.12) groups p<0.05. Mean defs(enamel +dentine)) in the CHX group (2.59) was significantly lower than increment in both the placebo (4.53) and control (4.20) groups p<0.01 PF (compared to control) 38% In the CHX gel group more children without approximal caries or fillings at baseline remained caries free during the three year period than the other two groups. More lesions were unchanged in the CHX group than in the placebo group. Combination of CHX gel with regular use of fluoride tablets resulted in the lowest incidence compared to the other 3 combinations (i.e. CHX gel alone, Placebo+F tab, or Placebo gel alone).

Author conclusions: The results indicate that professional application 4 times a year of chlorhexidine gel in combination with dental flossing has a caries-reducing effect on approximal caries in primary teeth.

Reviewer comments: Whereas >95% of the participants reported the recommended daily toothpaste use, the authors reported that the use of fluoride tablets varied considerably. They defined children who had taken one tablet daily from the age of 3 years (or earlier) as ‘users’ and children who had never used any tablets as ‘nonusers’. 40% of the CHX group were ‘users’ compared to only 28% of the placebo group. F tablet use in the control group is not reported nor is the F tablet use of the participants who do fall into the ‘user’ and ‘non-user’ groups. Variable use of fluoride tablets may have influenced the study result.

•

Author **Petti S, Hausen H.**

Title **Caries-preventive effect of chlorhexidine gel applications among high-risk children. *Caries Res* 2006; 40: 514–521.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr>
<td>CCT</td>
<td>2+</td>
<td>High risk
Test (HRT) 70
High risk control (HRC) 71
Low risk control (LRC) 70
Risk classification based on salivary mutans streptococci levels < / ≥ $1.0x10^5$ cfu/ml</td>
<td>3 years old at baseline
$d_3ft=0$
Attending kindergartens in one of five public health care districts of Rome.
Only regular fluoride exposure from toothpaste</td>
<td>18 months</td>
<td>HRT: 1% CHX gel applications twice a day for 3 consecutive days at 3 month intervals.
Hygienists spread gel on teeth and brushed for 3-5 mins with an electric toothbrush.
Oral hygiene and dietary counselling every 4 months.
Advised to use fluoride toothpaste twice a day for 3 minutes</td>
<td>HRC
LRC
Oral hygiene and dietary counselling every 4 months. Advised to use fluoride toothpaste twice a day for 3 minutes</td>
<td>d_3ft increments</td>
<td>
<table>
<tr><th rowspan="2">Group</th><th colspan="2">d_3ft increment≥1</th><th rowspan="2">d_3ft increment (mean ± SD)</th></tr>
<tr><th>%</th><th>n</th></tr>
<tr><td>HRT</td><td>34.3</td><td>24</td><td>0.56±0.86</td></tr>
<tr><td>HRC</td><td>32.4</td><td>23</td><td>0.54±0.88</td></tr>
<tr><td>LRC</td><td>11.4</td><td>8</td><td>0.11±0.32</td></tr>
</table>
HRT v HRC p=0.82
HRT v LRC p=0.0005
HRC v LRC p=0.001
CHX gel applications resulted in significantly decreasing MS levels.
</td>
</tr>
<tr><td colspan="9">Author conclusions: In this study periodical CHX gel applications had a moderate anti-MS effect, but did not reduce caries incidence.
Reviewer comments: High risk children were not randomly assigned to test and control groups. LRC were selected were a convenience sample of low risk children attending the same classrooms as the high risk children. There does not appear to have been blind outcome assessment.</td></tr>
</table>

•

Author **Plotzitza B, Kneist S, Berger J, Hetzer G.**

Title **Efficacy of chlorhexidine varnish applications in the prevention of early childhood caries. *European Journal of Paediatric Dentistry* 2005; 6 (3): 149–54.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
CCT	2-	Baseline :n=200 1 year: n=172 Dropouts 14% High risk group n=47 CHX n=23 No Tx n=24 Low risk group n=125	Patients from five country or city paediatric offices visiting paediatricians between Sept 2001 and March 2002. Aged 11.7 months ±0.7months. F in water ≤ 0.2ppm	12 months	Explained causes of ECC (5 advisory impulses) Cervitec (1% CHX & 1% Thymol) 3/12 after teeth cleaned with a small brush and dried with a swab. N=23	High risk Control Explained causes of ECC (2-3 advisory impulses) N=24 N=125	Salivary MS scores d_{1-4}mft	<table><tr><td></td><td>Low risk</td><td>CHX</td><td>Control</td></tr><tr><td>d_{1-4}mft</td><td>0.5±1.8</td><td>1.2 ±1.7</td><td>1.9±3.9</td></tr></table> <table><tr><td></td><td>Low risk</td><td>CHX</td><td>Control</td></tr><tr><td>d_{14}mfs</td><td>1.0±3.6</td><td>3.2±4.4</td><td>4.5±8.5</td></tr></table> d_{1-4}mft Low risk v CHX p<0.001 CHX v Control p=0.06 d_{1-4}mfs Low risk v CHX p<0.001 CHX v Control p=0.02 After 1 year children in CHX and control groups showed no significant differences for the prevalence of MS in saliva

Author conclusions: Poor feeding habits and deficits in oral hygiene cannot be compensated by the application of Cervitec. The mere application of CHX-containing varnish does not prevent early childhood caries, but may influence progression tendency of carious lesions.

Reviewer comments: No blind outcome assessment. Small sample size.

•

Author **Rodrigues CRMD, Marquezan M, Barroso LP, Grande RHM, Kabakura V, Miyamura A.**

Title **Effect of chlorhexidine-thymol varnish on caries lesion development in first permanent molars. *J Clin Dent* 2008; 19: 18–21.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr>
<td>RCT
Split-mouth</td>
<td>1-</td>
<td>57 6-8-year-old children
99 pairs of first permanent molars</td>
<td>6-8 year-olds from a public school in Sao Paulo, Brazil (low socioeconomic background)
At least two homologous, newly erupted first permanent molars with visually sound occlusal surfaces
Fluoride 0.7ppm in public water supply
Caries prevalence at baseline(at least one surface affected) 68.4%</td>
<td>1 year</td>
<td>Cervitec (1% Chlorhexidine and 1% thymol) after pumice and isolation, every 15 days for 75 days (6 applications)</td>
<td>Placebo varnish after pumice and isolation, every 15 days for 75 days (6 applications)</td>
<td>Caries increment (including white spots)</td>
<td>
<table>
<tr><th></th><th>No. of pairs with same outcomes</th><th>No. of pairs with different outcomes</th><th>Pvalue</th></tr>
<tr><td>Eruption stage</td><td>98</td><td>1</td><td>0.51</td></tr>
<tr><td>Biofilm</td><td>76</td><td>23</td><td>0.27</td></tr>
<tr><td>Caries lesion development</td><td>87</td><td>12</td><td>0.20</td></tr>
</table>
No statistically significant differences in eruption stage and biofilm presence at baseline or 1 year.
No statistically significant differences in caries increment at 1 year.
</td>
</tr>
<tr>
<td colspan="9">Author conclusions: “Six applications of CHX-T varnish had no protective effect against caries development.”
Reviewer comments: The operator randomly determined the tooth to be assigned to the CHX-T varnish or placebo group. No blinding of children or the examiner is reported. No measure of intra examiner reliability is reported</td>
</tr>
</table>

Clinical Interventions: Sugar Substitutes/Xylitol

Systematic Reviews

Author **Lingstrom P, Holm, AK, Mejare, I *et al***

Title **Dietary factors in the prevention of dental caries: a systematic review. *Acta Odontol Scand* 2003, 61: 331–340.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic Review	1+	18 were included in the evaluation of evidence and 7 reached level B and were used as a basis for conclusions RCT or CCT with coronal caries increment in the primary (dmfs/t) or permanent (DMFS/T) dentition as a primary endpoint. Follow up time of at least 2 years.	Participants in most studies aged 3-18 years (one study 27.5 years)	No meta analysis	At least 2 years	Any dietary measure used to prevent dental caries	Not stated	Coronal caries increment in the primary(dmfs/t) or permanent (DMFS/T) dentition	No studies were identified in which the effect of a reduced sugar intake on caries prevalence was studied separately from improvements in OH and frequent use of fluoride. There is no evidence to suggest that information to reduce sugar intake is an effective activity. **Total substitution of sucrose for xylitol/fructose (Turku sugar study):** There were no new carious lesions in the xylitol group and a 47% reduction in caries in the fructose group. The results in the xylitol group were explained by the almost complete substitution of sucrose in the diet but also by the effect of xylitol itself. **Partial substitution of sucrose:** **By sorbitol in chewing gum** (compared to no gum)**:** 2 CCTs Graded B showed contradictory results and no conclusion can be drawn about the use of sorbitol as a substitute for dietary sucrose. In both studies, the use of gum was partly supervised by teachers. **By candies and chewing gum with xylitol, sorbitol or carbamide:** Four studies of the caries preventive effect of chewing gum with xylitol found a high caries preventive effect of 30-70% but were graded as low level of evidence. Two studies graded B showed a statistically significant caries preventive effect after adding xylitol to chewing gum/candies compared to no chewing

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
									gum/candies in the control groups. In a third study graded B the caries reduction in the xylitol group (35%) was almost equivalent to the caries reduction in the control gum group (33%) indicating that a considerable part of the caries preventive effect of chewing sugar free gum could be related to the effect of chewing rather than the xylitol. The use of gum/candies in these three studies was supervised by teachers. **Protective factors:** 2 level B studies on the addition of dicalcium phosphate dehydrate and calcium phosphate to gum were included. No effect and a 10% reduction in caries incidence were reported respectively. However, these agents are no longer available.
Author conclusions: The results of the 5 studies evaluating sorbitol or xylitol with a moderate level of evidence (grade B) are too limited to enable conclusions to be drawn. **Reviewer comments:** The quality of the evidence was very poor and there were no RCTs graded B (moderate level of evidence). The only study that used a placebo gum found the same caries preventive effect the placebo gum as with the xylitol gum indicating that the effect of chewing is interlinked with any possible caries preventive effect for xylitol or other sugar substitutes. Further research is clearly needed in this area.									

Clinical Interventions: Sugar Substitutes/Xylitol

Primary Studies

Author **Honkala E, Honkala S, Shyama M, Al-Mutawa SA.**

Title **Field trial on caries prevention with xylitol candies among disabled school students. *Caries Res* 2006; 40: 508–513.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
CCT	2-	176 Xylitol candy group 126 Control group 50 (Those who didn't consent to be in the involved in the study) Drop-outs : Xylitol 16.7% Control 20%	Physically disabled school students aged 10-27	18 months	Xylitol candy (49% xylitol) three times each school day (not weekends/holidays)	No intervention	18 month DMFS increment	Caries increment: xylitol group -1.2 ± 3.4 Control group 3.5 ± 4.6 P<0.001 212 surfaces scored decayed at baseline and sound at 18 months in xylitol group compared to 1 surface in the control group(caries scored at dentine level according to WHO critera)

Author conclusions: Regular use of xylitol candies over 1.5 years has a significant preventive and clear remineralising effect on caries among individuals with special needs in Kuwait.

Reviewer comments: Participants were not randomly assigned to the groups, and as the control group consisted of those who didn't consent to participate in the study, they may differ systematically from those in the xylitol group. The issue of inter and intra examiner reliability is not adequately addressed. This study has a very high risk of bias and presents very weak evidence for the effectiveness of xylitol for caries prevention.

•

Author **Kovari H, Pienihakkinen K, Alanen P.**

Title **Use of xylitol chewing gum in daycare centers: a follow-up study in Savonlinna, Finland. *Acta Odontol Scand* 2003; 61: 367–370.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Community Trial Cluster randomised	1-	921 392 xylitol 529 Brushing At age 9: 328 Xylitol 458 brushing Drop-outs 16.3% Xylitol 13.4% Brushing	Children born in the period 1987-1990 and attending a daycare centre in Savonlinna between age 3 and 6 years in 1993-1995. External reference group of children not attending daycare centres in the study years.	To age 9 (3-6 years)	One piece of 65% xylitol gum three times a day after meals/snacks Supervised chewing for 5-10 minutes. Daily dose 2.5g Not during holidays	Toothbrushing after lunch with 0.05% NaF toothpaste.	% caries free Difference in dmf and DMF indices between the xylitol and control groups at age 9 NNT	At age 9: 57% caries free Xylitol group 49% caries free brushing group Report statistical significance but no p values. NNT 12.2 95%CI 6.5-108.7 Difference in mean dmf between groups NS (p=0.098) at age 9. Difference in mean DMF between groups NS(p=0.078) at age 9. Children with one xylitol period statistically significantly more often caries free at age 9 than children in the brushing groups. No p value.

Author conclusions: "..oral health status in the xylitol group was a little bit better than in the control group. The use of xylitol can therefore be recommended, especially if the personnel do not have the possibility to supervise the brushing."

Reviewer comments: Registration of caries was not blind during the years that the children attended the daycare centres and no Kappa values were reported. Baseline levels of caries were not reported. P values supporting the main results appear to be missing. The clinical significance of these results must be questioned.

•

Author **Oscarson P, Holgerson, PL, Sjostrom I *et al***

Title **Influence of a low xylitol-dose on mutans streptococci colonisation and caries development in preschool children. *European Archives of Paediatric Dentistry* 2006; 7 (3): 142–147.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT Single blind	1+	132 71 boys 61 girls Test 66 Control 66 Loss to follow-up 10.6% 17% test 5% control	Mean age 2 years and 1 month Children born in 2000 and 1st quarter of 2001 and attending the Public Dental Clinic in Lycksele, Sweden.	2 years	Sucking tablets 0.48g xylitol – one tablet at bedtime after tooth-brushing After 6 months, dose increased to two per day, one morning and one evening. Semi-annual diet counselling and OH instruction with hygienist.	No tablets. Semi-annual diet counselling and OH instruction with hygienist.	MS colonisation at 2½, 3, 3½, &4. Caries prevalence at age 4-dmfs	There was less caries in the xylitol tablet group compared to the control but the difference was not statistically significant. Mean dmfs test n=55 0.8±2.8 Mean dmfs control n=63 1.2±3.5 Only 18% of the test and 25% of the control group developed any caries in the 2 years. There was no statistically significant difference in mutans streptococci colonization between the test and control groups at any of the designated follow-ups.
Author conclusions: "The findings do not support a low dose xylitol tablet program for caries prevention in preschool children."								

•

Author **Stecksen-Blicks C, Holgerson PL, Twetman S.**

Title **Effect of xylitol and xylitol-fluoride lozenges on approximal caries development in high-caries-risk children. *International Journal of Paediatric Dentistry* 2008; 18: 170–177.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT 2 randomised treatment arms and a non–randomised reference group	2+	330 Xylitol:80 Xyl/F: 80 Ref: 70 Xylitol:24% Xyl/F: 26% Ref: 9%	10–12-year-olds with predicted high caries risk or proven caries activity	2 years	Slow-melting lozenges 0.25mg NaF 422mg Xylitol Or 422mg Xylitol Two tablets three times a day	Nonrandomised reference group. High caries risk subjects who didn't consent to participate in the intervention group.	Total approximal DMFS DSe-proximal enamel lesions	No significant differences between the groups at baseline or after 2 years. For those with good compliance: Mean DMFSa value Xyl/F 1.0±2.3 n=20 Xyl 3.3±4.6 p<0.05 n=27

Author conclusions: These results "do not support a self-administered regimen of xylitol- or xylitol/fluoride-containing lozenges for the prevention of approximal caries in young adolescents with high-caries risk".

Reviewer comments: The results of the subanalysis for those with good compliance should be treated with caution as the numbers in these groups are very small and differences may have occurred by chance. It does highlight the difficulties with compliance that can be expected in a self-administered regimen in this age group. The reference group in this study received 6-monthly fluoride varnish applications. Information on fluoride varnish applications is not provided for the test groups. 41% were classified as having good compliance with the regimen.

Clinical Interventions: *Combinations of Caries Preventive Interventions*

Systematic Reviews

Author **Axelsson S, Soder B, Nordenram G *et al***

Title **Effect of combined caries-preventive methods: a systematic review of controlled clinical trials. *Acta Odontol Scand* 2004; 62: 163–169.**

Study Type	Evidence Level	No. of included studies	Patient characteristics	No. of patients included in meta analysis	Duration of included studies	Intervention	Comparison	Outcome measure	Results
Systematic review	1+	24 studies Children and adolescents (14 studies): 1 graded A 8 graded B 5 graded C. Elderly patients (3 studies): 1 graded B 2 graded C. Risk patients (7 studies): 4 graded B 3 graded C.	Included all ages. Results reported for children and adults, elderly patients, and risk patients		At least two years (except studies on primary teeth)	Investigations of the caries-preventive effect of a combination of caries-preventive methods i.e. two or more different interventions in combination each expected to prevent caries to some degree.	Standard care (OHI, F toothpaste for unsupervised use, or F rinsing every second week) No treatment or placebo.	Caries increment in the primary (Δdmfs/t) or permanent dentition (ΔDMFS/T)	Children and adolescents: 5 studies(1A, 4B) found fluoride products +OHI/supervised toothbrushing more effective than control 2 studies(B) Professional tooth cleaning with Fluoride +supervised toothbrushing/OHI superior to same treatment with placebo 1 study (B) showed no additional effect for different combinations of F and placebo products. 1 study (B) showed no additional effect for professional tooth cleaning with F +OHI compared to standard care as described. Risk patients: 2 studies graded B and 1 study graded C showed statistically significant reductions in caries (Professional cleaning with F+ weekly Frinse V weekly F rinse, supervised toothbrushing F toothpaste +F gel 5x/yr v no intervention, CHX gel, fissure sealant V no intervention) I study (B) showed no additional benefit when CHX was combined with other preventive treatments. 2 studies(1 B and 1C) showed non significant results

Author conclusions: Moderate scientific evidence that combinations of treatments involving fluoride have a preventive effect on caries in children and adolescents. The evidence was incomplete for elderly patients. No conclusion can be drawn from the evidence for combinations of treatments being effective for groups at high caries risk, as the results from the identified studies are conflicting.

Reviewer comments: The review includes widely varying interventions and comparisons with other interventions that involve fluoride in addition to no treatment and placebo comparison groups. This variation leads to difficulties in synthesizing results from the very different studies. Nevertheless, this is a well conducted review and the conclusions drawn accurately reflect the evidence provided by the included studies.

•

Clinical Interventions: *Combinations of Caries Preventive Interventions*

Primary Studies

Author **Arrow A.**

Title **Oral Hygiene in the control of occlusal caries. *Community Dent Oral Epidemiol* 1998; 26: 324–30.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
CCT	2+	At baseline: 207 test 197 control At 24 months: 179 test 156 control Drop-out Test 13.5% Control 20.8%	404 West Australian children in the first year of primary school (mean age 6.3 years) with sound newly erupted first permanent molars. 76% of eligible children participated in the study. F water 0.8mg/L	2 years	OHI + professional prophylaxis with 0.15% CaF2 paste on an individual recall interval	Standard school dental service care. One application of 10% stannous fluoride paste to newly erupted molars and FS with GIC if FPM considered at high risk of becoming carious	Caries increment DF teeth & DF sites Plaque level expressed as the mean number of plaque covered sites per erupted first permanent molar.	32 test children and 31 control children developed caries on their first permanent molars. RR 0.90 (95%CI 0.58-1.41) NS Mean first permanent molar caries increment (tooth and sites) and plaque levels for the two groups were not statistically significant.

Mean caries increment	Test	Control	P value
DF teeth	0.30	0.30	0.96
DF sites	0.36	0.41	0.62

Plaque levels	Test	Control	P value
Baseline plaque	6.52	6.61	0.67
24-month plaque	5.67	5.60	0.76

Author conclusions: Professional cleaning and individually tailored oral health education and recall intervals achieved a similar level of occlusal caries prevention to that achieved with the standard preventive procedures used in the Western Australian SDS.

Reviewer comments: It is worth noting that 19 individuals in the test group received fissure sealants in the course of the study compared to 71 individuals in the control group. The authors conclude that the test programme cannot be recommended for widespread use in a public health setting because of its potential to create dependency on the health care professional because frequent contact is required for adequate prevention.

•

Author **Ekstrand KR, Kuzmina IN, Kuzmina E & Christiansen ME**

Title **Two and a half-year outcome of caries preventive programs offered to groups of children in the Solntsevsky District of Moscow. *Caries Res* 2000; 34: 8–19.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
CCT	2+	Group A: 45 3-yr-olds (45 5-year olds from the same Kindergarten chosen as controls) Group B: 50 6-yr olds (50 controls) Group C: 50 11-yr-olds (50 controls) Groups B & C: children screened to find 100 who were in the earliest stage of eruption of first and second permanent molars respectively. Every second child selected to participate in the test group; the remaining 50 children in each group were controls.	The 3 year olds & 6 year olds attended a Kindergarten in the Solntsevsky district of Moscow The 11 year olds were chosen from those attending two schools in the Solntsevsky district of Moscow A previous survey had found that the majority of the children in this area had poor oral hygiene gingivitis and caries	2.5 years	Group A: Two 45 minute lectures for parents & children about oral health and caries prevention and toothbrushing training. F toothpaste given each month Group B & C: two 45 minute lectures to parents and children educating about oral health, training in toothbrushing, Professional tooth cleaning with F paste, local applications of 2% sodium fluoride and sealants all given according to individual requirements. Received fluoride toothpaste when they attended the clinic.	Group A: 45 5-year-olds who had attended the Kindergarten during the study period were selected after 2.5 years. Group B & C: 50 control children in each group received no preventive programme. They were screened by the public dental service at age 6 and 11 for restorative treatment.	def-s/def-t DMF-S Plaque status Gingival status	Group A: mean def-s/def-t significantly higher in the control (8.60/5.67) group than in the study group (4.91/3.62). Baseline caries was not recorded for this group. Group B: No significant difference in mean def-s/def-t between the test and control groups. The DMF-S in the study group was significantly lower after 2.5 years (0.28) than the DMF-S in the control group (2.24) $p<0.001$ Group C: After 2.5 years the DMF-S in the study group (3.12) was significantly lower than the DMF-S in the control group (6.35) $p<0.001$ Plaque status improved significantly in groups B and C from baseline to 1 year to 2.5 years while the plaque status did not change in the control groups. After 2.5 years the children in the control groups had significantly poorer gingival status than children in test groups B & C.

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
Author conclusions: The preventive programs were highly effective with regard to improving the level of oral hygiene, and thereby reducing or even controlling the plaque-induced disease activity. **Reviewer comments:** The results for group A are difficult to interpret due to the lack of any baseline data for the test and control groups. The Kindergarten and school for groups B and C respectively were randomly selected and although the children were randomly assigned to test and control groups the process of randomization could easily have been subverted. The authors do not say if there was blind outcome assessment and there is no information on initial participation rates. It is unclear how many participants dropped-out during the study (in fact there seems to have been only two drop-outs in total). It is notable that the majority of the children in test groups B & C received topical application of 2% NaF in each year of the study and that the mean frequency of application ranged from 4-6 times a year in year1 to 2-5 times in year two. This high compliance with intensive topical fluoride application undoubtedly contributed to the effectiveness of the programme.								

Author **Hausen H, Karkkainen S, Seppa L.**

Title **Application of the high-risk strategy to control dental caries. *Community Dent Oral Epidemiol* 2000; 28: 26–34.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT (with additional randomly selected low risk comparison group)	1+	Vantaa, Finland Caries risk for 1465 children was assessed using data from clinical examinations and salivary tests. 511 12-year-old children regarded as being at high risk of developing caries were randomized into one of two groups; HRI- high risk intensive prevention, and HRB- high risk basic prevention. A random sample of low risk children were also followed up (n=261).	511 12 year old children assessed as being at high caries risk from Vantaa, Finland	3 years	The HRI group were offered intensive prevention (extensive oral hygiene and dietary counselling, F-varnish applications, F-lozenges, sealants, chlorhexidine). A self administered questionnaire on habits related to oral health was completed by all study participants at baseline and at the end of follow up.	The HRB group were provided the same basic prevention given to low-risk children (counseling, one F-varnish application/year, sealants on newly erupted 7s with deep fissures). A random sample (LRB) of low risk children (n=261) receiving basic prevention were also followed up.	3 year caries increments	After 3 years, both high risk groups had higher DMFS then the low-risk group (HRI 4.4, HRB 5.1, LRB 2.0) but there was only a negligible difference between the two high-risk groups in favour of the HRI group. The total increment in the HRI group was 0.6 surfaces (12%) lower than the HRB group but the difference was not statistically significant. The results from the questionnaires showed a slight trend towards healthier behaviour at the end of the follow-up but the pattern of improvement was fairly similar in the three groups.

Author conclusions: The negligible difference between the HRI and HRB groups implies that intensifying prevention produced virtually no additional benefit. By offering all children only basic prevention, nearly the same preventive effect could have been obtained with substantially less effort and lower costs. The authors suggest that caution should be observed before implementing major shifts from the population strategy to the high-risk approach.

Reviewer comments: It is important to recognise that the basic preventive programme described here could be seen as intensive in certain dental healthcare systems including the Irish public dental service . For this study, the level of preventive care could not be lowered from that usually given for ethical reasons.

•

Author **Hausen H, Seppa L, Poutanen R *et al***

Title **Noninvasive control of dental caries in children with active initial lesions. *Caries Res* 2007; 41: 384–391.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT (single-blind)	1+	577 **Test group:** 278 children at baseline and 250 at the end of follow-up. **Control group:** 282 at baseline and 247 at the end of follow-up **Drop-outs** Test 17.6% Control 17.7%	11–12-year-olds with at least one active carious lesion in Pori Finland	Mean 3.4 years	Interactive counselling by hygienists (trained by experts in patient- and empowerment-centered counselling). Intensive OHI, given 1500ppm fluoride toothpaste with 10% xylitol and toothbrushes, F lozenges, Xylitol lozenges, F varnish + CHX varnish.	Control group received measures for caries control normally given in the public dental clinics of Pori; F varnish application and health education on dietary and oral hygiene habits.	DMFS increment including cavitated lesions only Children were examined at baseline, at 2 years and at the end of the study.	At both 2 years and at the end of the study the DMFS increments were significantly lower in the experimental group than in the control group. Test: 2.56 (95% CI 2.07-3.05) Control: 4.60 (95% CI 3.99-5.21) Mean difference 2.04 (95% CI 2.82-1.26) PF 44% (95% CI 30.2-56.4%) Mean percentages for both visible plaque and gingival bleeding were non-significantly lower in the experimental group than the control. Differences in dietary habits were slight and non-significant and there was no significant difference in reported toothbrushing frequency between the two groups at the end of the follow-up.

Author conclusions: A regimen that includes multiple measures for controlling dental caries can significantly reduce caries increment among caries-active children living in an area where the overall level of caries experience is low.

Reviewer comments: This was a well conducted study but the reduction in caries increment in the experimental group was achieved with considerable effort and cost, and unfortunately the study design does not allow the contribution of the individual caries-controlling measures used in the study to be determined. The control group only received a mean of 1.6 F/CHX treatments compared to 11.4 in the test group during the follow-up period, which undoubtedly contributed to the significant reduction in DMFS in the experimental group. The authors note that the level of prevention in the control group was lower than in their previous trial (Hausen 2000), which may partly explain why better results were obtained in this study.

•

Author **Kallestal C.**

Title **The effect of five years' implementation of caries-preventive methods in Swedish high-risk adolescents. *Caries Res* 2005; 39: 20–26.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
RCT	1-	4,355 were invited to participate and 3,373 agreed to participate. Drop-outs 18%	12-year-old children (all children born in 1983) from 26 public dental health clinics throughout Sweden	Children in the four experimental groups were examined every year for 5 years	Children identified as being high risk (n=1,134) were randomly assigned into one of four preventive programmes. Group A: Information on toothbrushing techniques. Group B: Prescription of fluoride lozenges. Group C: Semi-annual applications of fluoride varnish Group D: quarterly appointments with individualized information on oral hygiene and diet and a topical fluoride application	No control group for ethical reasons	Caries increment DMFS and DeMFS (includes enamel caries)	Mean 5 year caries increments Group A: DMFS 4.06, DeMFS 7.00 Group B: DMFS 4.21, DeMFS 7.10 Group C: DMFS 3.93, DeMFS 6.49 Group D: DMFS 3.64, DeMFS 5.95 The difference in caries increments between the groups is not statistically significant. Compliance After 5 years; 31% of the toothbrushing group (A) had good compliance 62% of the fluoride lozenge group (B) had good compliance 76% of the fluoride varnish group (C) had good compliance 65% of the F varnish OHI and dietary counselling had good compliance Risk for caries increment in the study group: Elevated risks for caries development were present for both dentine and enamel + dentine caries for adolescents living in working-class households, those who in all questionnaires reported eating sweets often & those who reported not always brushing their teeth twice a day Less risk for caries development was shown for those having at least one sealant & those who belonged to the fluoride varnish group(C)

Author conclusions: The risk of caries was reduced when fluoride varnish was applied 3 times during 1 week, semi-annually, and when at least one sealant was present. A higher risk was observed for adolescents from working class homes, and for adolescents who reported frequently eating sweets and not always brushing twice daily. It appears that the preventive programmes tested were equal in showing low efficiency in adolescents with high caries risk.

Reviewer comments: Because study data was collected by the dentists in the public dental health clinics, blind outcome assessment was not possible in this study. It is possible that some individuals in this study were exposed to other population-based programmes during the course of the study.

•

Author **Maltz M, Barbachan e Silva B, Carvalho DQ & Volkweis A**

Title **Results after two years of non-operative treatment of occlusal surface in children with high caries prevalence. *Braz Dent J* 2003; 14 (1): 48–54.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr>
<td>CCT</td>
<td>2-</td>
<td>Baseline 201
After 2 years: 145
Test=74
Control= 71
Drop-outs
27.9% total</td>
<td>201 5–6 year-old children from two public schools in Porto Alegre (city centre) in Brazil.
Public oral health care is not provided to this population free of charge.</td>
<td>2 years</td>
<td>Biannual basic programme: 3 weeks in 1st semester and 2 weeks in 2nd semester where children received OHE, supervised OH and supervised toothbrushing with 1.23% fluoride gel for 1 min & recall sessions based on their individual caries activity.</td>
<td>No preventive programme
The diagnosis from the clinical examination was given to parents to seek dental treatment</td>
<td>DMFS</td>
<td>
<table>
<tr><th></th><th>Test</th><th>Control</th><th>P value</th></tr>
<tr><td>Baseline</td><td>1.32</td><td>1.41</td><td>NS</td></tr>
<tr><td>Year1</td><td>0.90</td><td>1.75</td><td><0.05</td></tr>
<tr><td>Year2</td><td>0.93</td><td>2.04</td><td><0.05</td></tr>
</table>
At baseline 42% of children in the test group had no active lesions and 96% had no active lesions after 2 years (cavitated and non-cavitated).
In the first year 53% of children needed no recall visits in addition to the basic programme. This was 82% in the second year.
There was a reduction of 52% in gingival bleeding in the test group after 2 years (p<0.05) and no significant difference in the control group between the two periods.
</td>
</tr>
<tr>
<td colspan="9">Author conclusions: It is possible to control caries disease with non-operative treatment based on individualized disease activity. Moreover, the possibility to control dental caries lesions including non-cavitated and cavitated was demonstrated. It is, therefore possible to enforce a non-invasive practice even in occlusal surfaces in place of traditional therapy based on invasive procedures to control the disease.
Reviewer comments: The results of this study are prone to bias for a number of reasons. The schools were not randomly allocated to test and control groups. There was no blind outcome assessment. The authors do not state how many of the eligible children consented to participate in the study nor do they give the numbers of children in the test and control group at baseline. Although the children in the two study groups had similar caries experience at baseline, it is unclear how similar the two groups are in relation to other characteristics e.g. mean age, socioeconomic status, toothbrushing habits. The control group had more FPMs erupted and fewer FPM in functional occlusion than the test group which could lead the control group being at higher risk of developing decay.</td>
</tr>
</table>

•

Author **Morgan MV, Campain AC, Adams GG, Crowley SJ, Wright FAC.**

Title **The efficacy and effectiveness of a primary preventive programme in non-fluoridated areas of Victoria, Australia. *Community Dental Health* 1998; 15: 263–271.**

<table>
<tr><th>Study Type</th><th>Evidence Level</th><th>No. of participants</th><th>Patient characteristics</th><th>Study Duration</th><th>Intervention</th><th>Comparison</th><th>Outcome measure</th><th>Results</th></tr>
<tr>
<td>RCT Cluster randomised</td>
<td>1+</td>
<td>522
Baseline:
Test 256
Control 266
3 years:
Test 207
Control 238

Drop-outs:
Test 19.1%
Control 10.5%</td>
<td>Children aged 12-13 years and considered at high risk of developing dental caries.
All selected schools classified as disadvantaged.
<0.1mg/l F in public water supply</td>
<td>3 years</td>
<td>Baseline and annual dental examinations
Annual oral hygiene education programme
Weekly F mouthrinse (0.2% neutral NaF)
Annual application/ replacement/repair of FS</td>
<td>Baseline and annual dental examinations
Annual oral hygiene education programme</td>
<td>DMF by tooth surface</td>
<td>
<table>
<tr><th colspan="3">Estimated annual rate of increase (%) in DMF score</th></tr>
<tr><td></td><td>Test</td><td>Control</td></tr>
<tr><td>Pit and fissures</td><td>4.2</td><td>13.8</td></tr>
<tr><td>Smooth surface</td><td>14.1</td><td>26.5</td></tr>
<tr><td>All surfaces</td><td>7.4</td><td>17.4</td></tr>
</table>
All differences highly statistically significant p<0.001
</td>
</tr>
<tr><td colspan="9">Author conclusions: “A comprehensive preventive dental programme introduced into adolescent populations at high risk of developing dental caries can result in significant improvements in their dental health. Further research is required to clarify the public health impact of school-based fluoride mouthrinsing.”</td></tr>
</table>

Author **Tapias MA, De Miguel G, Jiménez-Garcia R, González A, Dominguez V.**

Title **Incidence of caries in an infant population in Mostoles, Madrid. Evaluation of a preventive program after 7.5 years of follow-up. *Int J Paediatr Dent* 2001; 11 (6): 440–446.**

Study Type	Evidence Level	No. of participants	Patient characteristics	Study Duration	Intervention	Comparison	Outcome measure	Results
CCT	2-	**Baseline:** Study group: 655 children from 10 schools (1 private) within the basic zone of the healthcare centre. Control group: 298 children from 5 public schools outside the zone of the healthcare centre. **End of study:** Study group 547 Control group 237 **Losses to follow-up:** Study group 16% Control group 20%	Children attending schools in the town of Mostoles, Madrid, Spain aged 6 years at baseline followed-up for 7.5 years. Only those who attended the schools throughout the follow-up period were included in the analysis.	7.5 years	**School:** Health education, toothbrushing, plaque control, and weekly rinsing with 0.2% NaF supervised by teachers(first 5 years only) **Healthcare centre:** Dental health education to children and parents, dental examinations and for those 'at risk' : (DMFT>1, dft>3, deep grooves on occlusal surfaces, enamel defects and fractured incisors) fluoride gel applications and FS for FPMs.	No access to the preventive measures offered in the dental health programme.	Relative risk (RR) Preventive fraction (PF)	RR 0.68 (95%CI 0.6-0.78) PF 32% (95% CI 22-40)

Author conclusions: The preventive program is effective after 7.5 years and shows a particular preventive effect on permanent teeth.

Reviewer comments: The study was not randomized but the baseline characteristics reveal no significant differences between the groups with respect to sex, social class and caries. Outcome assessment does not appear to have been 'blind' to group allocation. In fact the authors provide no details on who conducted the examinations and whether there was training and calibration of the dental examiners.