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Effectiveness of school-based behavioural interventions to improve children's oral health by reducing sugar intake and promoting oral hygiene: A rapid review of randomised controlled trials.

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Objective: To evaluate evidence of the effectiveness of school-based behavioural interventions to improve the oral health of children aged 3-18 years in a rapid review of randomised controlled trials (RCTs). ***Methods***: Three independent reviewers searched MEDLINE, EMBASE, Web of Science and other sources between January 2000 and December 2020 for eligible published and unpublished studies in English and extracted data. Primary outcomes were caries increment, plaque levels, gingival health, reported frequency and/or amount of free sugars intake and oral hygiene behaviour. Risk of bias was assessed using the Cochrane criteria. ***Results***: Eight cluster RCTs met the inclusion criteria and had substantial heterogeneity. Three trials assessed caries increment and one found significant reductions in the intervention group. Another trial found similar benefits, but these were limited to children from high socioeconomic groups. The third trial found an increase in dental caries in the intervention group. Three studies reported significant reductions in plaque scores and improvements in gingival health with modest effects. Interventions delivered by peers (at adolescence) or with parents' involvement (at pre-adolescence) showed significant reductions in plaque scores compared to those delivered by dentists or teachers only. Most interventions showed significant improvements in self-reported behaviours. ***Conclusions***: There is limited evidence of clinical benefit to dental health from school-based behavioural interventions. There is a need to conduct well-designed trials of behavioural interventions that are theory-derived and include environmental elements (e.g. supervised toothbrushing). Future trials would benefit from cost-effectiveness analysis and assessment of interventions' effect on oral health inequalities amongst children.

Keywords*: Review, Adolescent, Health behavior, Oral health, School, Child*

Introduction

Despite being a largely preventable disease, dental caries is a global burden that affects over 2.3 billion people (Bernabe *et al.*, 2020). Caries in primary teeth affects 532 million children globally (Bernabe *et al.*, 2020). In England, whilst the burden of tooth decay appears to be decreasing, stark inequalities exist (Public Health England, 2016). Dental caries in children has a high negative impact on the child and family's quality of life (BaniHani *et al.*, 2018; Gilchrist *et al.*, 2015; Jackson *et al.*, 2011; Public Health England, 2017).

Healthy behaviours of limiting the frequency and amount of sugary foods and drinks, and brushing teeth with fluoridated toothpaste twice a day are essential to prevent dental caries (Twetman, 2018; WHO, 2017). If these behaviours are established at an early age, this supports maintenance throughout the life course, supporting lifelong protection against caries. Ideally these behaviours should develop at home. However, for some children healthy behaviours might be more difficult to develop at home, due to socioeconomic and cultural factors that can lead to and may normalise high sugar diets or infrequent toothbrushing (Shaw *et al.*, 2009).

Schools, due to their inclusive nature, provide an ideal setting to deliver population-based interventions that can support children to develop healthy behaviours (Kwan *et al.*, 2005; WHO, 2010). Skills-based approaches align with teaching toothbrushing, with the potential for translating these new skills into twice-daily behaviours in the home environment. Such school-based interventions are called behavioural interventions because they aim to prevent caries and improve child's oral health through supporting the development of independent and habitual healthy behaviours (Cooper *et al.*, 2013). This distinguishes them from other school-based interventions that aim to prevent caries and improve child's oral health through the application of preventative measures such as fluoride varnish and sealants, which do not influence behaviours. School-based behavioural interventions could span the upstream-downstream continuum from downstream interventions (e.g. school health education), to midstream and upstream interventions (e.g. supervised toothbrushing and healthy diet policy, respectively) (Public Health England, 2014).

Recently, a major policy change has taken place in England. Health education (including oral health education) has become a mandatory requirement for all school curricula in both primary and secondary schools in England and will be introduced in the academic year 2020/2021. By the end of primary school, children aged

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10-11 years "should know about dental health, and the benefits of good oral hygiene, including regular check-ups at the dentist" and through continued development in secondary schools, this knowledge is maintained and further expanded upon (Department for Education, 2019).

Available evidence to inform such public health policy changes has limitations. There is consistent evidence of the effectiveness of the benefits to child oral health of supervised toothbrushing with fluoride toothpastes in schools (Marinho *et al.*, 2003). However, it is much less clear which school-based interventions would be effective in supporting this behaviour at home; and, very little evidence of the effectiveness of school-based behavioural interventions to control children's dietary sugar. The Cochrane review published by Cooper et al. (2013) assessed the clinical effects of primary school-based behavioural interventions addressing both sugar intake and oral hygiene. However, that review was limited to primary schools and to studies published to 2012. Thus, to address these gaps and to support the introduction of school health education policy changes in England, the present rapid review aimed to review randomised controlled trials (RCTs) that evaluated the effectiveness of school-based behavioural interventions (with or without environmental elements such as daily supervised toothbrushing) in improving children's oral health.

Method

The present review was reported following the PRISMA guidelines (Moher *et al.*, 2009) and registered at PROSPERO platform (CRD42019148407).

This review included RCTs of school-based oral health behavioural interventions versus no intervention, conducted with children aged 3 to 18 years, of both sexes, from any socio-demographic and ethnic backgrounds, with different baseline levels of dental caries and fluoride exposure, and attending primary or secondary schools. Interventions within a school setting that targeted child oral health behaviours related to both sugar intake and oral hygiene (including toothbrushing with fluoride toothpaste, use of fluoride mouthrinse and/or dental flossing) were included. No restrictions were applied on the study country or type of publication (e.g. full journal article, conference abstract and report).

Schools had to be the focal site for delivering the intervention. The intervention could include environmental elements (e.g. daily supervised toothbrushing, healthier school lunches, more water fountains, removing vending machines). It could include multiple methods of delivery and other components that may also occur within the home and/or a clinical setting (e.g. school trips to the dentist to expand on the related learning experience). Control groups received usual health education; that is, the standard health-based education from their current school curriculum.

This review achieved rapidity through including only trials conducted from 2000 onwards and published or reported in English. Trials published before this date were deemed dated due to multiple changes in the curricula for schools, policy and school environments nationally and internationally.

Information on the following primary and secondary outcomes, assessed after a follow up time of one month or more, was sought.

Primary outcomes included:

1. Changes in the prevalence and/or mean number of primary and/or permanent teeth with caries
2. Changes in plaque scores and gingival health for primary and/or permanent teeth (measured by valid clinical indices)
3. Changes in frequency or amount of sugar intake (measured by self-reported measures or by collecting food wrappers)

Secondary outcomes included:

1. Changes in frequency of oral hygiene practices (toothbrushing using fluoridated toothpaste, use of fluoride mouthrinse and/or dental flossing; as measured by self-completed questionnaires or by data tracking toothbrushes)
2. Rates of dental attendance (measured by self-completed questionnaires or extracted from clinical records)
3. Changes related to knowledge regarding oral health, oral hygiene and/or sugar intake (measured by self-completed questionnaires)
4. Changes in attitudes towards oral health, oral hygiene and/or sugar intake (measured by self-completed questionnaires)
5. Changes in oral health-related quality of life (measured by validated scales only)
6. Costs
7. Adverse events

The following databases were searched: MEDLINE via Ovid, EMBASE, The Cochrane Library (Cochrane Central Register of Controlled Trials (CENTRAL)), Web of Science (Science citation expanded), PsycINFO via Ovid, ClinicalTrials.gov and the World Health Organization International Clinical *Trials Registry Platform* from January 2000 through December 2020. Reference lists of included studies were searched for further eligible studies. Experts were contacted to obtain grey literature. The search strategies for different databases combined keywords with medical subject headings (MeSH) terms related to school-based behavioural interventions as well as database-specific filters for controlled trials (wherever available) (Available at https://qmro.qmul.ac.uk/xmlui/handle/123456789/72844).

Titles and abstracts were screened independently by two sets of reviewers (AS/IB and IB/EJ). Full texts were screened when at least one of the authors considered the study as a potentially eligible study. Disagreements between the reviewers were resolved through discussion with the arbiter (EJ).

Data were extracted independently, without blinding of the study authors, by three reviewers (AS, IB and EJ) using a piloted standardised form. Extracted data included demographic characteristics, details of the intervention, comparator and outcome measures, as well as risk of bias in the study. Missing data were requested from authors. Disagreements were resolved through discussion. Risk of bias was assessed using the Cochrane criteria (Higgins *et al.*, 2019).

Only narrative syntheses of included studies' findings were performed by EJ. Planned quantitative syntheses, sensitivity analyses, subgroup analyses and publication bias assessment could not be performed because of the paucity of trials and heterogeneity in their outcomes (Higgins *et al.*, 2019).

Results

The search yielded 4,513 unique citations. Screening titles and abstracts excluded 4,469 citations, leaving 44 for full-text screening (Figure 1). Eight studies were included in the final review (Table 1).

Characteristics of included studies

All included studies were cluster RCTs. Two of the eight studies took place in Iran, two in India and the remaining four were in Germany, Finland, Taiwan and Pakistan. Children's ages ranged between 5 and 16 years.

School-based behavioural interventions differed across studies and across different arms within the same study. Interventions differed in terms of their design and content, as well as children's group size and/or facilitators (Table 1).

The control group in one study received the intervention after the end of the study (Qadri *et al.*, 2018). The follow up period ranged from one month to 2 years.

With respect to outcomes, three studies measured dental caries in the primary and/or permanent dentition using different indices/scores (DMFT/DMFS, Moller's index and the scores of a *light*-induced fluorescence device). Three studies measured plaque scores using different indices (e.g. Debris index, Sillness and Loe index and modified Sillness and Loe index) and gingival health (e.g. Loe and Sillnes gingival index, CPI bleeding index and Muhlemann-Son sulcus bleeding index). Different self-completed questionnaires were used to measure knowledge, attitudes and reported behaviours related to sugar intake, oral hygiene and dental attendance. Only two studies used validated questionnaires. Due to this heterogeneity in outcome measures used across studies a quantitative synthesis of the findings was not feasible.

Risk of bias in included studies

Due to the nature of interventions at the school level, all studies had a high risk of bias regarding blinding of intervention providers and children (Figures 2 and 3). Low risk of bias was found with respect to incomplete outcome data and selective outcome reporting (6 studies), blinding of outcome assessors (5 studies), random sequence generation (3 studies), allocation concealment (1 studies) and other source of bias related to adjustment for clustering effect (2 studies).

Changes in the prevalence and/or mean number of primary and/or permanent teeth with caries

Three studies reported on dental caries. Two studies measured caries increment (Chachra *et al.*, 2011; Qadri *et al.*, 2018), and one study measured the demineralisation of the occlusal surfaces of permanent premolars and molars (Anttonen *et al.*, 2011). There were inconsistent findings in these studies. Whilst Chachra et al. (2011) reported a significantly lower caries increment in the intervention

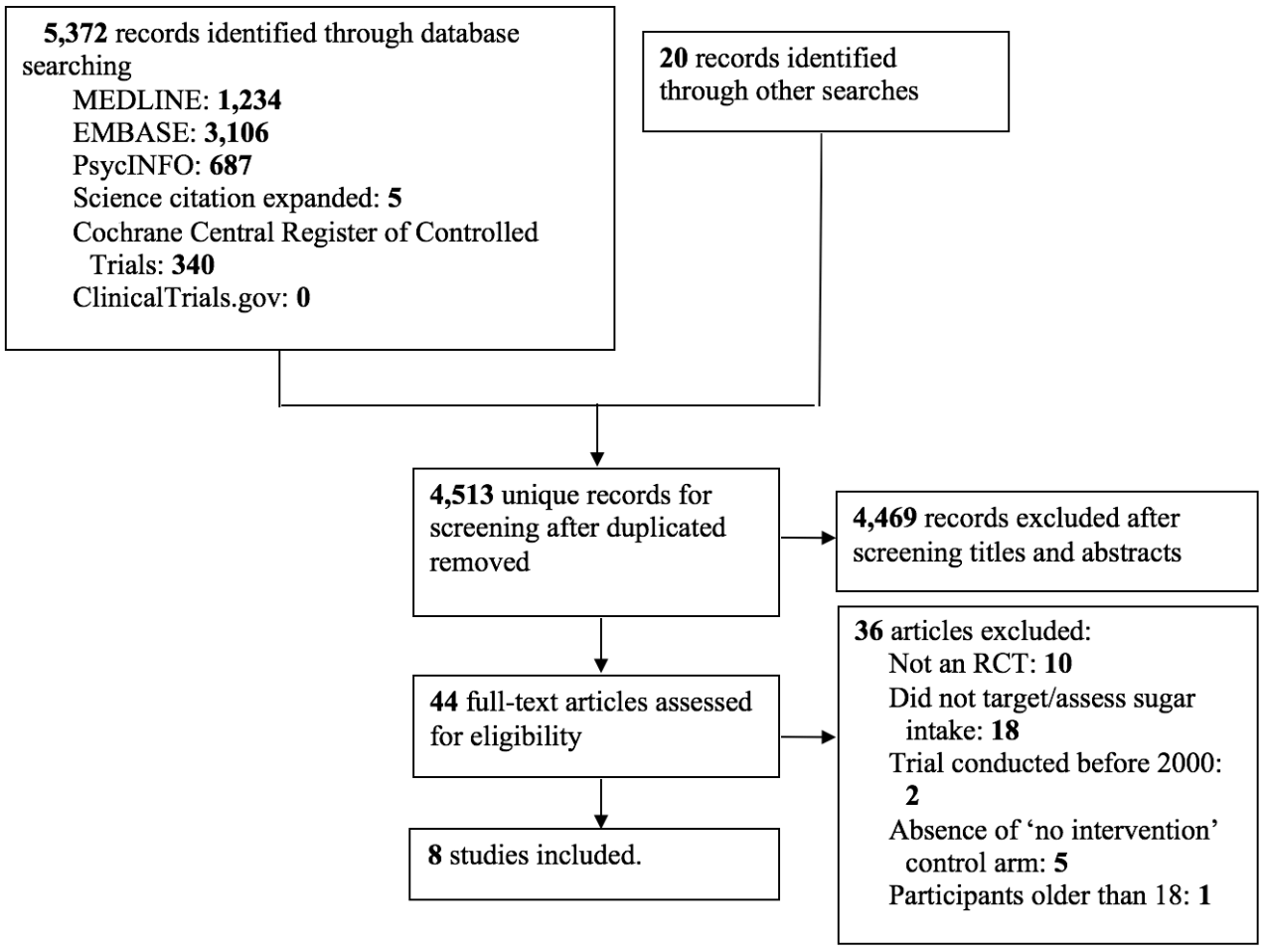

Figure 1. PRISMA Flow diagram of the review's selection of studies.

Table 1. Summary of included cluster randomised controlled trials.

Reference	*Population*	*Sample size (dropouts)*	*Test Group: Number of children and details of intervention*	*Control Group: Number of children and details of usual health education*	*Follow-up duration*	*Outcome(s)*
Haleem et al. (2012), Pakistan	All children (aged 10-11 years) in class six of 40 public and private schools in Karachi.	1,331 (106)	1,007 received a one-hour session based on the social cognitive theory delivered by trained dentists, teachers or peers. Education was based on a booklet, seven pre-tested posters and an oral hygiene demonstration. Topics included sugar intake, oral hygiene, use of fluoride toothpaste and tobacco use. After six months oral health education messages were repeated and reinforced monthly for six months.	324 did not receive the intervention.	2 years	Oral health knowledge, behaviours and oral hygiene status.
Naseri-Salahshour et al. (2019), Iran	All children elementary school in the fourth, fifth and sixth grades in Saveh.	516 (16)	258 received intervention, based on theory of planned behaviors, held three times a week in 45-minute lectures and group discussions. The first session raised students' awareness, the second used role-play and practical work to enhance behavioural control, and the third demonstrated toothbrushing and flossing. Students were given a booklet that detailed dental work, use of toothbrushes and floss, causes of dental caries and harmful foods for the teeth.	258 received the standard training provided by school health coaches.	1 month	Oral health-related awareness, attitudes, and behaviour related to diet, toothbrushing and dental attendance.
Qadri et al. (2018), Germany	All children (aged 9-12 years; with no special needs or systemic disorders) from fifth grade in 18 primary schools in West Pomerania.	854 (114)	336 received intervention based on health literacy and oral health competence using personal, cognitive and social skills, integrated into general health promotion curriculum, delivered by schoolteachers. Topics were oral health, healthy nutrition, health literacy, dealing with pain, healthy recreation, vaccination and smoking. The teachers trained and allowed to convey the information to the students freely.	404 did not receive any intervention until after the end of the study.	19 months	Dental caries and oral health knowledge, attitudes, and practices.
Saied-Moallemi et al. (2009), Iran	All children (aged 9 years) in a representative sample of 16 schools in Tehran.	457 (10)	340 received three types of interventions. Group 1 had 3-4 sessions over one month lasting 30-45 minutes to solve seven puzzles with messages on toothbrushing. There were oral hygiene demonstrations and motivational posters on avoiding sugary snacks. Group 2 received intervention via parents including an oral health leaflet and a brushing diary for supervision. Group 3 received both interventions.	117 did not receive any intervention.	3 months	Plaque levels and gingival health.

Table 1 continued overleaf...

Table 1. Summary of included cluster randomised controlled trials continued...

Reference	*Population*	*Sample size (dropouts)*	*Test Group: Number of children and details of intervention*	*Control Group: Number of children and details of usual health education*	*Follow-up duration*	*Outcome(s)*
Chachra et al. (2011), India	Children (aged 5-16 years) randomly selected from four schools in urban areas of Chandigarh and Panchkula.	972 (0)	(Number not provided) received educational material in the form of albums, short stories and lectures on oral health and the relationship of sugar with caries, as well as toothbrushing demonstrations and fluoride mouth rinse use. Educational materials were tailored to 5-9 and 10-16 year olds. The package was delivered every 15 days over 6 months via dentists (Group 1), teachers (Group 2) and community organisations members (Group 3) trained by dentists.	(Number not provided) did not receive intervention.	6 months	Oral health knowledge, attitudes and practices, and dental caries.
Anttonen et al. (2010), Finland	All 7 grade adolescent children in 12 schools located in three cities.	510 (30); only in relation to the 2 groups that received dietary and oral hygiene instruction as well as the controls	151 received dietary intervention that took advantage of Finland's free school meals and encouraged the reduction of sugar consumption and increased intake of healthier foods, as well as the use of xylitol products after meals. Additionally, this group received oral hygiene instruction.	359 did not receive the intervention.	1 year	Dietary habits, toothbrushing frequency, and changes in the enamel mineralisation.
Vangipuram et al. (2016), India	All adolescents (aged 12-15 years) with no physical or mental disabilities, systemic diseases, or orthodontic treatment, from three public high schools in South Zone-I.	450 (0)	300 received intervention over 6 months. In Group 1, 5 children were given 20-minute oral health education sessions thrice weekly by a dentist using presentations, models, and other interactive learning methods. Once they had retained this knowledge, they delivered it to the whole class. Group 2 received an identical program delivered by a dentist to the whole class directly.	150 did not receive any intervention.	3 and 6 months	Plaque levels, gingival health, oral health knowledge, attitudes, and oral hygiene practices.
Yang et al. (2009), Taiwan	Aboriginal adolescents in two 7th grade classes, which were selected randomly from two schools in Pingtung County.	135 (0)	67 received oral health education weekly 40-minute modules over eight weeks that included lectures, role play, small group discussion and group contests. Topics included understanding teeth and mouth, common diseases, healthy teeth and daily life, and damage from substance abuse.	68 did not receive the intervention.	2 months	Knowledge about oral health, and frequency of sweet consumption and toothbrushing.

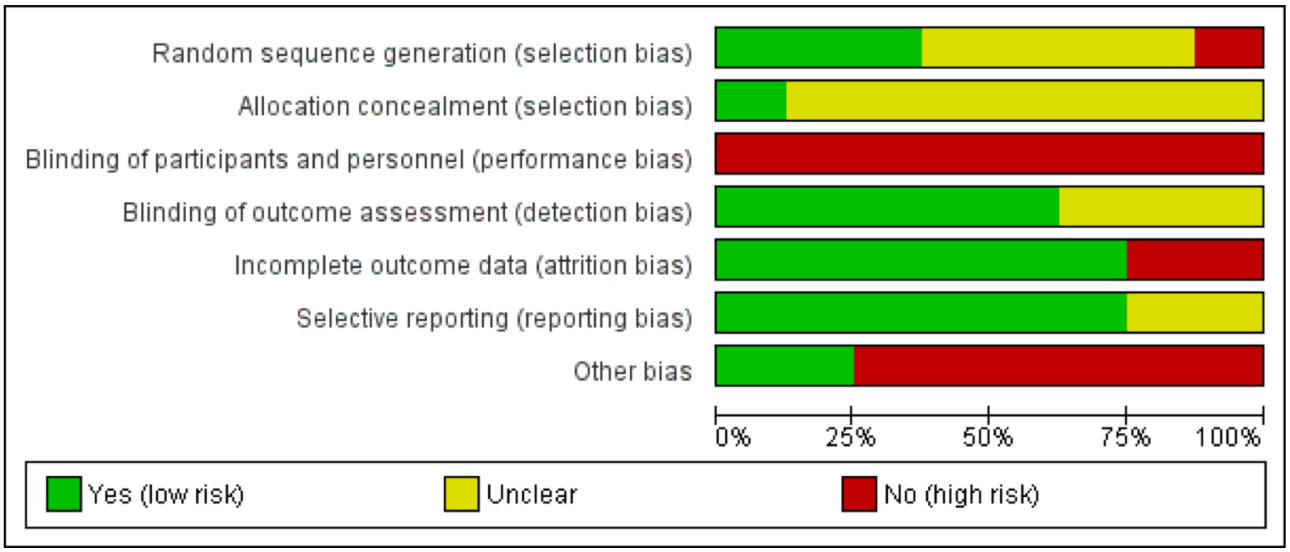

Figure 2. Risk of bias in eight included studies.

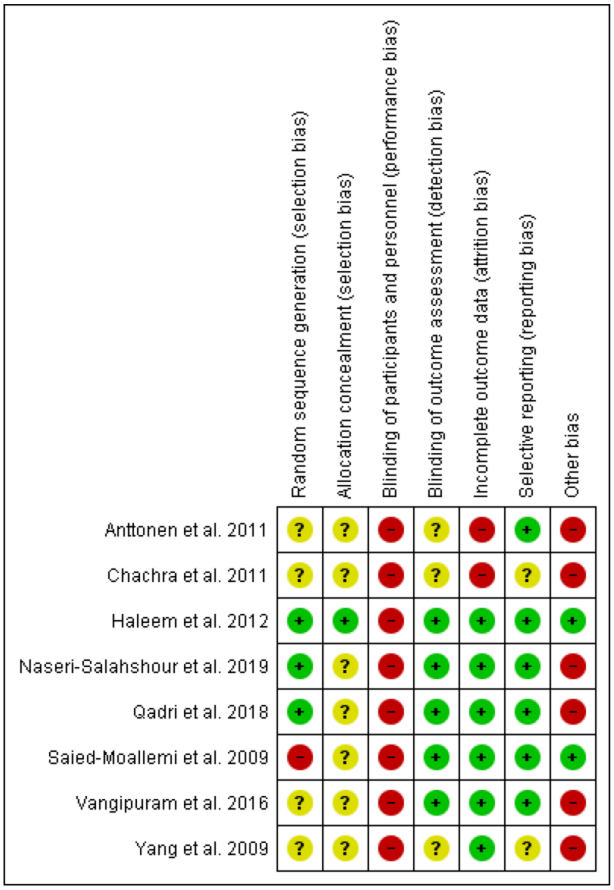

Figure 3. Risk of bias for individual studies.

groups compared to the control group, Anttonen et al. (2011) reported contrary results showing significantly more demineralisation in the intervention than the control group. Furthermore, Qadri et al. (2018) did not find a significant difference in caries increment between their intervention and control groups. Yet, when their findings were adjusted for age, gender and socioeconomic position, a significant difference emerged, and a lower caries increment was found in children from high socioeconomic position.

Changes in plaque scores and gingival health for primary and/or permanent teeth

Three studies reported significant changes in plaque scores and gingival health (Olubunmi and Olushola, 2013; Saied-Moallemi *et al.*, 2009; Vangipuram *et al.*, 2016). Interventions delivered by peers (at adolescence) or with parents' involvement (at pre-adolescence) showed a reduction in plaque scores and better gingival health than those delivered by dentists / teachers or without parents' involvement, respectively (Saied-Moallemi *et al.*, 2009; Vangipuram *et al.*, 2016).

Changes in frequency or amount of sugar intake

Five studies collected self-reported data on the frequency of sugar intake or the practice of consuming chocolates, biscuits and soft drinks (Chachra *et al.*, 2011; Haleem *et al.*, 2012; Naseri-Salahshour *et al.*, 2019; Vangipuram *et al.*, 2016; Yang *et al.*, 2009). All studies reported a significant reduction in self-reported sugar intake in the intervention compared to the control groups. Interventions delivered by peers showed more reduction in sugar intake compared to interventions delivered by dentists or teachers (Haleem *et al.*, 2012; Vangipuram *et al.*, 2016).

Changes in frequency of oral hygiene practices

Six studies reported on oral hygiene practices, such as the frequency, time and equipment of toothbrushing as well as the use of fluoride toothpaste. Five studies reported significant improvement in oral hygiene practices in the intervention groups compared to the control group (Chachra *et al.*, 2011; Haleem *et al.*, 2012; Naseri-Salahshour *et al.*, 2019; Vangipuram *et al.*, 2016; Yang *et al.*, 2009). Only one study reported a reduction in the frequency of toothbrushing in the intervention group compared to the control group (Anttonen *et al.*, 2011).

Rates of dental attendance

One study reported on dental attendance, showing a significant increase in self-reported dental attendance in the intervention group compared to the control group (Naseri-Salahshour *et al.*, 2019).

Changes in knowledge regarding oral health, sugar intake and/or oral hygiene

Five studies assessed differences in knowledge related to oral health, sugar intake and/or oral hygiene (Chachra *et al.*, 2011; Haleem *et al.*, 2012; Naseri-Salahshour *et al.*, 2019; Vangipuram *et al.*, 2016; Yang *et al.*, 2009). All five found significant improvements in such knowledge in the intervention compared to the control groups.

Changes in attitudes towards oral health, sugar intake and/or oral hygiene

Two studies measured attitudes towards oral health, sugar intake and/or oral hygiene (Naseri-Salahshour *et al.*, 2019; Vangipuram *et al.*, 2016). Both studies reported significant improvements in attitudes in the intervention compared to the control groups.

Changes in oral health-related quality of life

None of the studies reported on oral health-related quality of life.

Costs

None of the studies included information related to the costs of intervention.

Adverse events

No adverse events were reported in the included studies.

Discussion

This review found limited evidence regarding the clinical benefits of school-based behavioural interventions. The risk of bias in included studies was considered serious as none of them was scored as low risk for blinding the healthcare providers and children. However, this would be difficult to achieve due to the nature of the interventions.

There was inconsistency across the included studies in relation to the effect of behavioural interventions on dental caries. The study that reported an increase in molar demineralisation scored low risk of bias on one domain only, indicating poor quality (Anttonen *et al.*, 2011). The study that reported a lower caries increment in the intervention groups compared to the controls did not score low risk of bias on any domain and used a somewhat dated dental caries index, limiting comparisons (Chachra *et al.*, 2011). The third study, which used the common DMFT/DMFS indices to measure caries increment, reported a non-significant difference in caries increment between the intervention and control group (Qadri *et al.*, 2018). However, when these findings were adjusted for age, gender and socioeconomic position, significant differences were found with children of high socioeconomic position benefitting compared to their counterparts of middle and low socioeconomic position. This highlights the potential that school-based behavioural interventions may increase the gap in oral health amongst children from different socioeconomic backgrounds.

Measuring definitive dental outcomes such as dental caries or periodontitis, both of which can take years to develop, can be challenging. Three studies included surrogate outcomes by measuring plaque and gingival health. It is possible to align changes in dental plaque with future changes in dental caries. In children with high caries levels, abundant anterior plaque is often found and this association relates to infrequent toothbrushing leading to inadequate fluoride exposure for caries prevention. Therefore, reductions in plaque on anterior teeth may be a useful indicator of fluoride application, thereby forming a surrogate to health outcome. Nevertheless, future studies should consider including dental caries as a primary outcome. There is a more direct relationship for gingival bleeding as a surrogate for periodontitis. Higher reductions were observed in gingival bleeding in two studies (Saied-Moallemi *et al.*, 2009; Vangipuram *et al.*, 2016).

Self-reported oral health knowledge, attitudes and behaviours may be considered distal surrogates for health outcomes. Unfortunately, self-reported outcomes are susceptible to reporting and social acceptability bias. Whilst self-reported oral hygiene data can be triangulated with clinical data on plaque and gingival health, such triangulation is not feasible for self-reported sugar intake data as none of the studies collected additional sugar-related data such as those extracted from food wrappers to allow triangulation.

Overall completeness and applicability of evidence

All behavioural interventions assessed by the included studies were downstream (educational) interventions, without any environmental elements. The latter could include supervised toothbrushing and the provision of healthy foods, drinks and free water at school. The effectiveness of school-based behavioural programmes may be strengthened by including environmental elements to reduce dental caries and inequalities in children's oral health. The effectiveness of supervised toothbrushing programmes has been established (Marinho *et al.*, 2003), with potential reductions in inequalities (Blair *et al.*, 2015; Kidd *et al.,* 2020). The costs of including environmental elements could act as a barrier. Behavioural interventions need to be reviewed in structure, content and delivery to reduce the potential problem that they could increase inequality in oral health between children.

Only two studies utilised theory in the design of their interventions. It is important to consider strengthening future interventions by using theoretical frameworks that will assist both in development, delivery and evaluation of school-based behavioural programmes for children in primary and secondary schools. The potential benefit of peer-led delivery should be explored in future studies.

The present review has a number of limitations. Due to authors' non-response, risks of bias could not be verified. The included studies were limited in quality and quantity with heterogeneous reporting outcomes. Thus, meta-analysis could not quantitatively synthesise the outcome data. Additionally, planned sensitivity, subgroup and publication bias analyses could not be performed. Poor reporting of the intervention design and content in some of the studies was a further limitation. Only studies that targeted both sugar intake and oral hygiene were considered. School-based behavioural interventions that targeted sugar intake only to reduce childhood obesity were not included. Yet, a recent systematic review of the effectiveness of such interventions in reducing the intake of sugar-sweetened beverages and body mass index

among children aged 4 to 16 years found no significant reduction in either of these outcomes (Abdel Rahman *et al.*, 2018). Furthermore, this review only included studies published in English after 2000. However, the landscape for the educational systems has changed appreciably since then, making older studies potentially irrelevant. The latter were included in a previous Cochrane review that highlighted the limited evidence related the effectiveness of primary school-based behavioural intervention on children's oral health (Cooper *et al.*, 2013).

Compared to Cooper et al. (2013), this review included behavioural interventions in primary and secondary schools as well as those with or without environmental elements. Findings in both reviews suggest that school-based behavioural interventions might improve oral hygiene and oral health related knowledge and practices. With respect to dental caries, our findings have some similarity with Cooper et al. The latter identified one study showing a mild protective effect of behavioural interventions on dental caries. This review also found one study with a similar benefit. Additionally, we identified two further studies, one of which did not show similar benefit and the other one found benefit confined to children of high socioeconomic position. Our findings are in line with those of de Silva et al. (2016) on community-based interventions to promote child oral health. The latter also noted that studies were generally of poor methodological quality. Oral health education alone may show little or no effect on dental caries. Oral health education in combination with supervised toothbrushing with fluoridated toothpaste may show a beneficial effect on dental caries in primary teeth and a small effect on dental caries in permanent teeth. With respect to gingival health, positive impacts were reported in the included studies. The latter finding was not supported by the review by Stein et al. (2018), which included only RCTs with educational interventions delivered by oral health professionals. Traditional oral health educational interventions were only effective in reducing plaque in the short term, but not gingivitis.

Conclusion

There is limited evidence of the clinical benefit to dental health from school-based behavioural interventions. However, behavioural interventions did improve oral hygiene amongst primary and secondary schoolchildren. Most interventions showed significant improvements in self-reported behaviours.

This review adds to the evidence that informs the introduction of interventions to support policy regarding school-based health education. Of concern, is a potential impact of increasing socioeconomic inequalities in oral health amongst children, which although found only in one study in relation to dental caries, highlights the need to conduct an RCT with low risk of bias to identify any differences in clinical outcomes by socioeconomic group. Future studies that include environmental elements in addition to the educational elements would add to the evidence base. The educational element of the intervention should also be derived from behaviour change theory. Analyses should include inequalities in clinical outcomes as well as cost-effectiveness.

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