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Sonic and ultrasonic oscillating devices for the management of pain and dental fear in children or adolescents that require caries removal. A systematic review.

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Sonic and ultrasonic oscillating devices for the management of pain and dental fear in children or adolescents that require caries removal. A systematic review.

Stefano Cianetti[1], Iosief Abraha [2,3], Stefano Pagano[1], Eleonora Lupatelli[1], Guido Lombardo[1]

Author affiliations:

1. Department of Surgical and Biomedical Sciences, Università degli Studi di Perugia, Perugia, Italy

2. Health Planning Service, Regional Health Authority of Umbria, Perugia, Italy
3. Centro Regionale Sangue, Azienda Ospedaliera di Perugia, Perugia, Italy

Corresponding Author:
Iosief Abraha
Health Planning Service
Regional Health Authority of Umbria
Via Mario Angeloni 61
06124 Perugia, Italy
iosief_a@yahoo.it; iabraha@regione.umbria.it

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Abstract

Objectives. To evaluate the effectiveness and degree of acceptance by children and adolescents of the use of oscillating tips compared to rotating drills.

Design Systematic overview of reviews.

Data sources PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane library, and Web of Science (October 2017).

Eligibility criteria Controlled randomized or non-randomised trials that evaluated sonic and ultrasonic oscillating devices vs rotating drill.

Data extraction Eligible studies were selected and data extracted independently by two reviewers. Risk of bias was assessed using the Cochrane method.

Results. Two controlled clinical trials comprising 123 children, aged 2-12 years old were identified. Both trials were at high risk of selection bias and unclear detection bias. In both studies, the percentage of children not feeling pain (or a moderate pain) was higher in the intervention group (oscillating tips) compared to the control group, respectively 89% vs.73.1% ($p<0.001$) and 54% vs. 29.1% ($p<0.001$) using specific pain rating scales. The effectiveness of the removal of caries was only considered in one study, but no statistically significant differences between the two interventions were found.

Conclusions. The evidence based on two low quality studies was insufficient to conclude that use of oscillating tips for the management of pain and dental fear in children or adolescents comparing to rotating drills.

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Strengths and limitations of this study

- This paper addresses systematically the issue of sonic or ultrasonic oscillating devices for the management of pain and dental fear in children or adolescents.
- Cochrane method based risk of bias was used to assess the quality of the studies.
- The number of studies identified was limited.
- A narrative summary of the results is provided as data could not be pooled.

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Introduction

Sonic and Ultrasonic devices are commonly used in dental practices such as, periodontology[1], oral surgery[2]), endodontics[3] and prosthetics[4]. High frequency Ultrasonic devices have been used in conservative dentistry since the 1950s[5]. Sonic and Ultrasonic tips have been declared useful for precise and controlled removal of both caries and unsupported hard tissue free of caries [6]. Sonic and Ultrasonic instruments remove caries by abrading hard and soft dental tissues with oscillating diamond-coated tips. The Ultrasonic tips carry out high frequency linear oscillations, ranging from 6,500 to 40,000 Hz, powered by piezo-driven inserts. Similarly, the Sonic tips also execute low frequency (6,000 Hz) elliptic oscillations generated by an air scaler insert. Both oscillating abrasion systems are cooled with a water spray [5]).

These oscillating tips offer an innovative technique for the removal of caries as a result of several characteristics: (1) minimally invasive cavity preparation; (2) ample visibility of caries during cavity preparation; (3) easy removal of caries located in hard-to-reach areas (i.e., lingual or buccal surfaces of posterior teeth) due to specific angulate shapes of oscillating tips [6]); (4) low frequency of iatrogenic damage to neighbouring teeth when proximal caries are treated[7 8]; (5) low noise level; and (6) low requirement of administration of anaesthesia during patient treatment [6].

Furthermore, oscillating devices could be a clinically relevant solution for patients with a phobia of dentists for whom the sight of traditional drills, and the accompanying noise they produce, trigger significant fear [9-13]. They are also an alternative solution for patients suffering from needle phobia [9 11 13-17]). One case report described one highlighted the conservative ablating capacity of sonic tips during cavity preparation, without damaging the enamel of adjacent teeth [4], while another emphasized the device efficiency, in terms of working time and cost-effectiveness, to remove dental proximal surface caries[18]. When compared to traditional rotating drills, the conservative features of ultrasonic tips were highlighted in addition to their ability, to reduce noise, administration of local

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anaesthesia and, conversely, to improve the approach to caries located in hidden posterior dental surfaces [6].

The need of a systematic review on the effectiveness, safety and young patient's acceptance regarding this new caries removal procedure is large by a large awareness among clinicians on a frequently negative acceptance by children (especially when affected by dental fear) to be treated with traditional rotating drill, that represent a relevant dental anxiety trigger[19].

The aim of this systematic review is to establish the effectiveness of sonic and ultrasonic tips used in the perspective of the management of pain and dental fear in children or adolescents that require caries removal.

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Methods

Criteria for considering studies for this review

Types of studies. Randomized controlled trials (RCTs) and Controlled Clinical Trials (CCTs) without language limitations.

Types of participants. Children and adolescents with caries. Studies carried out on patients affected by specific oral or systemic disease were excluded. Both deciduous and permanent teeth were included, with only restored and non-vital teeth excluded.

Types of interventions. Studies that evaluated sonic and ultrasonic devices to remove caries and to prepare cavities for filling compared to conventional high and/or low speed rotating instruments. No limitations were considered concerning restorative materials used for filling cavities

Types of outcome measures. Primary outcomes: episodes of pain, during and after treatment; dental fear; and removal of caries, confirmed by clinical, radiological or other validated assessment tools [20];. Secondary outcomes: durability of restoration (marginal integrity); recurrent caries; pulpal phlogosis or necrosis; patients' acceptance; patients' preferences; need for anaesthesia; dental practitioner opinion; duration of treatment; costs of intervention; adverse events.

Search methods to identify studies. A systematic literature review was carried out in the most relevant electronic databases (October, 2017) Medline, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane library and Web of Science. Moreover, studies reported in reference lists of obtained articles, in consulted reviews and studies, and listed in the chapter of the most relevant textbook in this field, were screened in order to find additional relevant studies. If multiple publications of a single trial were available, only the first publication was considered, except in the case that additional data was reported, such as delayed outcome results. A search strategy in the abovementioned electronic databases was carried out using a combination of keywords and Medical Subject Headings (MeSH) (**Appendix 1**).

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Selection of studies. Two review authors independently assessed the titles and extracts of all records identified in the electronic databases (SC and EL). The full text of studies potentially fulfilling the inclusion criteria were requested. Disagreement between review authors, regarding any records meeting the inclusion criteria, was resolved by discussion. Where resolution was not possible, a third review author was consulted (SG).

Data extraction and management. Data from included studies was independently extracted by two review authors (SP and RG), and disagreements were resolved by means of discussion or involvement of a third review author (LP). A data extraction sheet (table) was used to collect data. The retrieved data was divided, based on its characteristics, into the following fields: (1) studies (year of publication, country), patients (number of participants, age, gender), intervention (type of oscillating device), comparator (placebo, high or low speed rotating instruments) and outcomes (primary and secondary). Any adverse events reported in the study were recorded. When full texts of studies, potentially meeting the inclusion criteria, were unavailable, the study authors were contacted by e-mail, whenever possible.

Assessment of risk of bias in included studies. Two review authors (IA and GL) independently evaluated the risk of bias of all included studies using the Cochrane Collaboration's risk of bias tool (Chapter 8 of the Cochrane Handbook [21]). Disagreements were resolved by discussion and if consensus could not be reached, a third review author (AM) was consulted. The following types of risk of bias were evaluated in each included RCT: random sequence generation (selection bias); allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias) [22], incomplete outcome data (attrition bias) [23 24], selective reporting (reporting bias) [25], [26]. The studies can be classified into: (1) low risk of bias (plausible bias unlikely to seriously alter the results); (2) unclear (plausible bias that raises some doubt about the results); or (3) high risk of bias (plausible bias that seriously weakens confidence in the results).

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Results

Results of the searches.

The electronic database search, identified 373 records up to October 2016. From the entire set of selected records, 111 duplicates were removed and 262 records were screened. After a detailed evaluation of the titles and extracts from the electronic database and manually checking the reference lists of papers, 15 records were considered relevant for a further full text examination [6 18 27-35 18 36 37].

All 15 full texts were obtained and assessed for eligibility. The study screening process is described in **Figure 1**. Thirteen studies, that had potentially met the inclusion criteria, were finally excluded due to their study designs [4 6 18 27 29 32-35 38-40]. Excluded studies with reasons are listed in **Appendix 2**. Only two controlled clinical trials were identified and included in the review[30 31].

Characteristics of included studies.

The two CCTs, had a split mouth format, involving a total of 123 child participants, with ages ranging from 2 to 12 years [30 31].

In the first trial Li and colleagues carried out their clinical trial with a group of 92 Chinese children, aged 3-12, who visited the Peking University Department of Pediatric Dentistry. This split mouth design trial compared oscillating ultrasonic tips with traditional rotating drills in pairs of unspecified teeth (type and overall number for single patient) situated on different sides of the same dental arc and affected by caries with analogous characteristics. One of the two teeth was treated with ultrasonic tips, while the other tooth was treated with a rotating drill. In both cases anaesthesia was not used. The following elements were evaluated in the study: episodes of pain during treatment; dental anxiety (measured in terms of patient's cooperation in the dental chair) and treatment duration. The completeness of caries removal was also assessed at the end of each cavity preparation through visual evaluation and dental exploration (dental tissue texture and color). The

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level of pain felt by the patients during treatment was recorded with a self-reported visual Five Face Rating Scale (varying from 0, absence of discomfort, to 5, severe pain). The level of both anxiety and collaboration shown by paediatric patients in the dental chair was assessed using a modified three level Venham Clinical Rating Scale (ranging from 0, for full cooperation without patient anxiety, to 2 for a completely uncooperative and highly anxious patient). During three follow-up visits conducted after one week, 3 months and 6 months, the level of sensitivity felt by patients on the restored molars (integrity and duration) was also evaluated (**Table 1**).

In the second trial, Chomyszyn-Gajewska and colleagues evaluated an ultrasonic powered tip, in combination with a micro-abrasive suspension (silicon-carbide, grain-size 40-50 νm), compared to a traditional drill. The trial was performed on 31 children, aged 7-11, who visited the Department of Pediatric Dentistry of Cracow University, with at least two occlusal decayed permanent molars, one on each side of the two upper and lower dental arcs (split mouth design). 31 right-side molars were treated with a traditional high speed drill, and the same number of left-side molars were treated with ultrasonic-powered tips. Overall, sixty-two occlusal caries were treated without anaesthesia. In both the intervention and control groups, teeth were matched concerning caries depth (Diagnodent, Kavo-Dental) and type of treated tooth (maxillary or mandibular molars). The patients with a high level of dental anxiety (determined with the self-reported Cora Dental Anxiety Scale before beginning treatment), and patients with a history of uncooperative behaviour or disability, were excluded from the study. The evaluated outcomes included episodes of pain during treatment and duration of treatment. The level of pain experienced by each patient during treatment was recorded using the following two self-reported scales: (1) the Hochman Scale (a verbal scale) or (2) a Facial Expression Scale (a visual five face scale). Both scales rated the pain experienced in five levels ranging from no pain (level 0) to severe pain (level 5). The procedures and diagnostic tools used to assess the complete removal of caries at the end of each cavity preparation were not described (**Table 1**).

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Quality assessment of the body of evidence

By default the two included trials were not randomised and were considered ta high risk of selection bias. In addition, none of the studies reported whether the outcome assessor was blinded and were judged unclear in terms of detection bias. No concern was identified in terms of attrition bias as well as selective reporting bias. Basic characteristics of the patient population were similar between the groups. Figure 2 describes the risk of bias of the two trials.

Effects of interventions

In the Li 2010 [31] study both devices effectively removed caries. In terms of discomfort, a statistically significantly higher percentage of paediatric patients (n=81/93; 89.2%) experienced a comfortable or slightly uncomfortable sensation (for values within the first three levels of the Five Faces Rating Scale) during treatment with ultrasonic tips than a traditional drill (n=68/93; 73.1%) (Wilcoxon signed ranks test, Z=4.357, P<0.001). Concerning dental anxiety, the percentage of children showing positive cooperation with the dentist was significantly higher when an ultrasonic tip was used (n=54/93; 58.1%) than with a traditional drill (n=42/93;45%) (Wilcoxon signed ranks test, Z=3.742 , P<0.001). Moreover, an overwhelmingly higher percentage of paediatric patients (88.2%) preferred to be treated with ultrasonic devices for future dental care. In terms of treatment duration the traditional drill was statistically significantly faster at ablation compared to the ultrasonic tip (average time: 3,5 SD 2.3 min with versus 4 SD 2.5 min; P<0.05).

In Chomyszyn-Gajewska 2006 [30], no data on the effectiveness of the two interventions to remove caries was reported. Concerning discomfort, when the verbal Hochman Scale was employed, seventeen out of thirty-one participants (54%) treated with an ultrasonic tip, and abrasive suspension, did not feel any degree of pain compared to only nine participants (29.1%) treated with a traditional drill (Wilcoxon signed ranks test, z= 3.34; p<0.001). Similarly, when the visual Facial Expression Scale was used, 15 paediatric patients (49%) treated with a traditional drill, did not report any pain or discomfort compared to six patients (22%) treated with an ultrasonic tip and

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abrasive suspension ($p<0.001$). A higher level of pain perception was found among females than males, regardless of the intervention (Hochman Verbal Scale $t=2.42$; $p<0.018$; Facial Expressing Scale $t=1.83$; $p<0.072$). In terms of length of time to prepare cavities, drills were significantly faster (3.9-5.5 minutes) compared to ultrasonic tips (9-16.8 minutes) ($t= 3.91$; $P<0.0002$).

None of the studies evaluated the following outcomes: durability of restoration (marginal integrity), recurrent caries, need for anaesthesia, pulpal phlogosis or necrosis, dental practitioner opinion, costs of intervention and adverse events.

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Discussion

This systematic review assessed the evidence whether oscillating tips could provide advantage in terms of management of pain and anxiety for children and adolescents that receive dental treatment caries removal. The evidence based on two low quality studies was insufficient to conclude that use of f sonic and ultrasonic device for the management of pain and dental fear in children or adolescents comparing to rotating drills.

Despite the proven effectiveness of traditional low and high speed rotating instruments to remove caries and to prepare cavities for filling, these instruments could be inappropriate when a certain strata of the population with evident dental anxiety (12.2-20%), such as young children, are treated by dentists[41]. In many cases, the use of traditional rotating burs to remove caries, is combined with local administration of anaesthesia. Anaesthetic injection notoriously represents one of the most significant dental anxiety triggers, reducing compliance with dental treatment [9 11 13-17]. Furthermore, sight of the traditional rotating drill, as well as the vibration and noise felt by patients during treatment, represents another important dental anxiety stimulus that could be avoided by new approaches and alternative devices used in the management of caries[9-13].

Sonic and ultrasonic tips are potentially useful tools to non-pharmacologically manage dental anxiety, supporting the patients' oral health status improvement and reducing the recourse to more complicated procedures, such as conscious sedation or general anaesthesia. These oscillating devices belong to a diverse group of so-called "micro-traumatic" tools to remove caries that include several other alternative devices/approaches to rotating instruments. The most noteworthy are Atraumatic Restorative Techniques (ART)[42] , chemo chemical removal of caries[43], lasers[44], air abrasion and polymer rotary burs [45]. Moreover, sonic and ultrasonic ablation methods constitute an interesting intervention for the new ultraconservative approach to caries, which removes a minimal amount of non - decayed mineralized dental tissue (minimally invasive dentistry) [5 46]. These new ultraconservative interventions are warranted by the introduction, in clinical practice, of

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adhesive filling materials that have revolutionized the formerly well-established rules of amalgam cavity fillings[47].

In an observational study 1,060 Brasilian dental practitioners, certified to use ultrasonic devices, were asked to fill in a questionnaire, sent via e-mail, to specify the frequency of local anesthesia use, degree of patients' sensitivity, tip wear and dental tissue preservation during ablation procedures, whilst comparing ultrasonic tips with a high speed rotating drill. Almost 60% of the interviewed dentists declared using 30% less local anaesthesia in cases when they employed ultrasonic tips to ablate caries. The use of sonic tips was considered a more conservative method than traditional approaches by a higher percentage of dentists (48% vs. 25%). Moreover, the dentists described the sonic tips as being better accepted than a traditional drill, by a higher percentage of patients (62.5% vs. 21.9%), with lower discomfort in terms of vibration and noise. Problems were referred about the durability of ultrasonic tips, in terms of wear and/or fracture [33].

Unfortunately, the high expectations regarding the use of oscillating devices to remove caries were not completely supported by data from published clinical studies. Our systematic literature review identified only two CCTs which were exposed to selection bias probably to detection bias [30 31]. Therefore, the potential positive features of oscillating tips, in terms of caries removal and ultraconservative preparation of cavities, in addition to low pain, decreased discomfort and reduced anxiety induction, remain clinically limited and further well designed randomised studies are needed.

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Footnotes

Contributors: SC, SP, EL, and GL conceived the original idea. IA and GL designed the study. GL and IA designed the search strategies. SC and GL performed the search and screened titled and abstracts independently. SP and GL performed data abstraction. IA and EL performed assessment of quality. SC and GL drafted the manuscript. IA, SP and EL revised critically the manuscript. All the authors approved the final version of the manuscript.

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Competing interests None.

Data sharing statement No additional data are available.

Figure Caption

Figure 1. Literature search flow chart.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

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Table 1. Characteristics of included studies

Study ID	Study design	Participants	Treatment	Outcomes	Funding
Chomyszyn-Gajewska 2006	Controlled Clinical Trial (split mouth study) One centre	31 children, 62 teeth and 62 caries (Poland); Age (range): 7-11 years; *Baseline*: Patients at least two occlusally decayed permanent molars, one on each side of the two upper and lower dental arcs; *Inclusion criteria*: Children without systemic diseases with couples of decayed permanent molars (one for each maxillary or mandibular dental arc side) with matching caries depth assessed by means of Diagnodent (Kavo-Dental); *Exclusion criteria*: Highly anxious patients (self-reported Cora Dental Anxiety Scale before beginning treatment), and patients with a history of uncooperative behaviour or disability.	*Experimental*: Ultrasonic device (Vector system); oscillating frequency: not reported; *Control*: Traditional rotating drills	*Primary:* Caries removal; Episodes of pain (scale used: Hochman Scale or a Facial Expression Scale; Dental Fear (measured through Cora Dental Anxiety Scale). *Secondary:* Need for anaesthesia; Duration of treatment	No funding was declared by the authors to support their study
Li 2006	Controlled Clinical Trial (split mouth study) One centre	93 children; 186 teeth and 186 caries (China) Age (range): 3-12 years; *Baseline*: Patients with at least two decayed teeth in the same dental arc; *Inclusion criteria*: Children without systemic diseases with at least two decayed teeth showing carious lesions of equivalent degree; *Exclusion criteria*: Clinical and radiological endodontic lesions.	*Experimental*: Ultrasonic device (KaVo Soniflex Line), oscillating frequency: 6500 Hz; *Control*: High and low speed rotating drills.	*Primary:* Caries removal (assessed trough visual and instrumental (dental explorer) examination); Episodes of pain (recorded with a self-reported visual Five Face Rating Scale); Dental Fear (assessed using a modified three level Venham Clinical Rating Scale); *Secondary:* Post operative patients' sensitivity; Patients' acceptance; Patients' preferences;. Duration of treatment	No funding was declared by the authors to support their study

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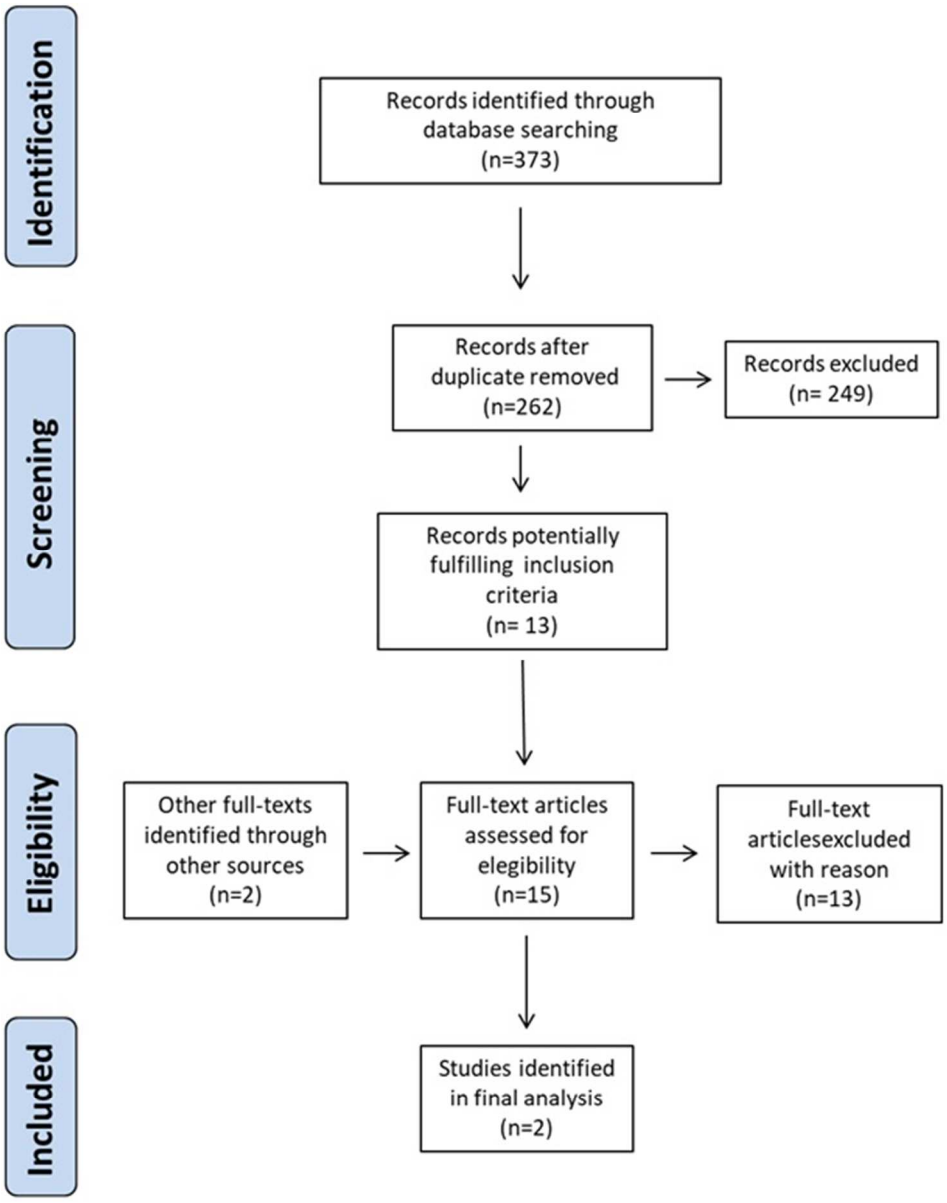
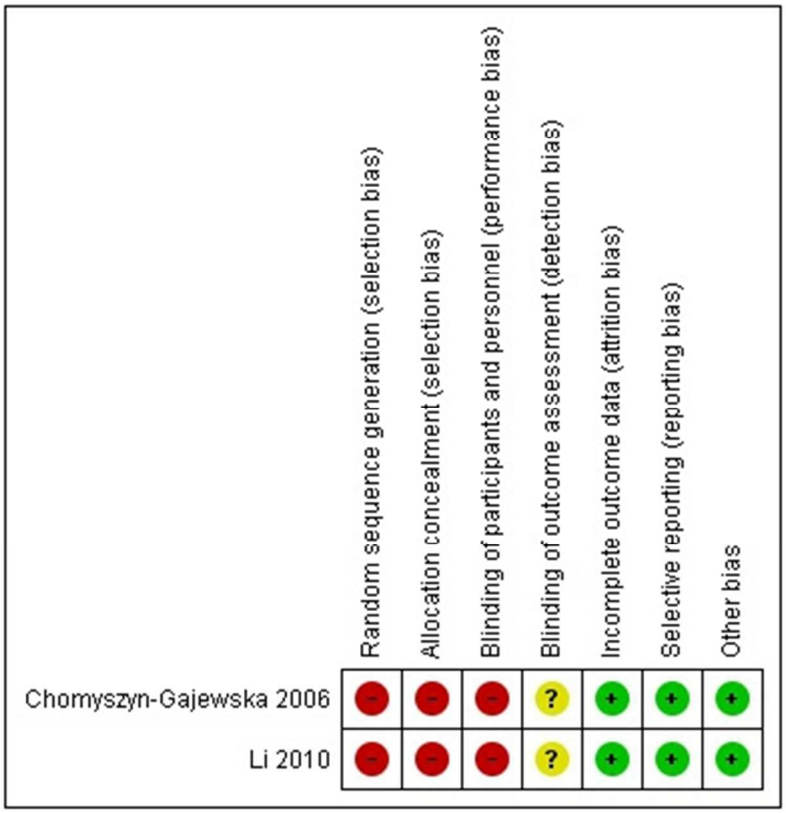


Literature search flow chart

160x204mm (96 x 96 DPI)



Risk of bias summary: review authors' judgements about each risk of bias item for each included study

103x107mm (96 x 96 DPI)

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Appendix 1. Complete list of key words used to search the most relevant databases for the studies to be included in the present review.

Minimally invasive dentistry caries		
Dental Caries/therapy*	AND	Ultrasonic Therapy/instrumentation*
Dental Cavity Preparation/instrumentation*	AND	Ultrasonic Therapy/instrumentation*
Dental Cavity Preparation/methods	AND	Ultrasonic Therapy/instrumentation*
Tooth Preparation/instrumentation*	AND	Ultrasonic Therapy/instrumentation*
Dental Caries/therapy*	AND	Oscillometry/instrumentation
Dental Cavity Preparation/instrumentation*	AND	Oscillometry/instrumentation
Dental Cavity Preparation/methods	AND	Oscillometry/instrumentation
Tooth Preparation/instrumentation*	AND	Oscillometry/instrumentation
Dental Caries/therapy*	AND	Sonic
Dental Cavity Preparation/instrumentation*	AND	Sonic
Dental Cavity Preparation/methods	AND	Sonic
Tooth Preparation/instrumentation*	AND	Sonic
Dental Caries/therapy*	AND	Ultrasonic Therapy/adverse effects
Dental Cavity Preparation/instrumentation*	AND	Ultrasonic Therapy/adverse effects
Dental Cavity Preparation/methods	AND	Ultrasonic Therapy/adverse effects
Dental Caries/therapy*	AND	Sonication
Dental Cavity Preparation/instrumentation*	AND	Sonication
Dental Cavity Preparation/methods	AND	Sonication
Tooth Preparation/instrumentation*	AND	Sonication
Dental Caries/therapy*	AND	Oscillometry/adverse effects
Dental Cavity Preparation/instrumentation*	AND	Oscillometry/adverse effects
Dental Cavity Preparation/methods	AND	Oscillometry/adverse effects
Tooth Preparation/instrumentation*	AND	Oscillometry/adverse effects
Dental Caries/therapy*	AND	Sonoabrasive

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Dental Cavity Preparation/instrumentation*	AND	Sonoabrasive
Dental Cavity Preparation/methods	AND	Sonoabrasive
Tooth Preparation/instrumentation*	AND	Sonoabrasive

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Appendix 2. The reasons leading to the exclusion of retrieved full texts.

n.	Author	Reason for Exclusion
1	Banerjee 2000	Literature narrative review
2	Josgrilberg 2007	In vitro study
3	Haase 1998	Case report
4	Koczarski 2007	Case report
5	Koubi 2008	Descriptive study
6	Mota 2013	Descriptive study
7	Ntovas 2017	Literature narrative review
8	Predebon 2006	Observational study)
9	Sheets 2002	Case report
10	Tassery 2013	Descriptive study
11	Thomas 2012	Descriptive study
12	Wicht 2002	In vitro study
13	Yildirim 2010	In vitro study

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Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	na
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6 and appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	na

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Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	na
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	8
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	8-9
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	10
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	10-11
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	na
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	10
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	na
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	12
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	12-13
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	14

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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Sonic and ultrasonic oscillating devices for the management of pain and dental fear in children or adolescents that require caries removal: A systematic review.

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Sonic and ultrasonic oscillating devices for the management of pain and dental fear in children or adolescents that require caries removal: a systematic review.

Stefano Cianetti[1], Iosief Abraha [2,3], Stefano Pagano[1], Eleonora Lupatelli[1], Guido Lombardo[1]

Author affiliations:

1. *Department of Surgical and Biomedical Sciences, Università degli Studi di Perugia, Perugia, Italy*
2. *Health Planning Service, Regional Health Authority of Umbria, Perugia, Italy*
3. *Innovation and Development, Agenzia Nazionale per i Servizi Sanitari Regionali (Age.Na.S.), Rome, Italy*

Corresponding Author:
Iosief Abraha
Health Planning Service
Regional Health Authority of Umbria
Via Mario Angeloni 61
06124 Perugia, Italy
iosief_a@yahoo.it; iabraha@regione.umbria.it

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Abstract

Objectives. To evaluate the effectiveness and degree of acceptance by children and adolescents of the use of oscillating tips compared to rotating drills.

Design. Systematic review.

Data sources. PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Library, and Web of Science (October 2017).

Eligibility criteria. Controlled randomized or non-randomized trials that evaluated sonic and ultrasonic oscillating devices vs. rotating drill.

Data extraction. Eligible studies were selected and data extracted independently by two reviewers. Risk of bias was assessed using the Cochrane Method.

Results. Two controlled clinical trials comprising 123 children aged 2-12 years old were identified. Both trials were at high risk of selection bias and unclear risk of detection bias. In one trial, pain due to the use of oscillating drill resulted lower than employing rotating drill (Verbal Hochman Scale: RR 0.64 (95%CI 0.41 to 1.00) ; Visual Facial Expression Scale: RR 0.64 (95%CI 0.44 to 0.94)). In another study, compared to traditional drill ultrasonic tip was associated with a lower level of patient's discomfort (RR 0.40 (95%CI 0.20 to 0.79)) but not with dental anxiety (RR 1.29 (95%CI 0.97 to 1.71)). The effectiveness of the removal of caries as well as fillings durability were only considered in one study, but no statistically significant differences were found between the two interventions.

Conclusions. The evidence based on two low quality studies was insufficient to conclude that the use of oscillating tips for the management of pain and dental fear in children or adolescents comparing to rotating drills was more effective.

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Strengths and limitations of this study

- This paper addresses systematically the issue of sonic or ultrasonic oscillating devices for the management of pain and dental fear in children or adolescents.
- Cochrane Method based risk of bias was used to assess the quality of the studies.
- The number of studies identified was limited.
- A narrative summary of the results is provided as data could not be pooled.

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Introduction

Sonic and ultrasonic devices are commonly used in dental practices such as, periodontology[1], oral surgery[2], endodontics[3] and prosthetics[4]. High frequency ultrasonic devices have been used in conservative dentistry since the 1950s[5]. Sonic and ultrasonic tips have been declared useful for precise and controlled removal of both caries and unsupported hard tissue free of caries [6]. Sonic and ultrasonic instruments remove caries by abrading hard and soft dental tissues with oscillating diamond-coated tips. The ultrasonic tips carry out high frequency linear oscillations, ranging from 6,500 to 40,000 Hz, powered by piezo-driven inserts. Similarly, the sonic tips also execute low frequency (6,000 Hz) elliptic oscillations generated by an air scaler insert. Both oscillating abrasion systems are cooled with a water spray [5].

These oscillating tips offer an innovative technique for the removal of caries as a result of several characteristics: (1) minimally invasive cavity preparation; (2) ample visibility of caries during cavity preparation; (3) easy removal of caries located in hard-to-reach areas (i.e., lingual or buccal surfaces of posterior teeth) due to specific angulate shapes of oscillating tips [6]; (4) low frequency of iatrogenic damage to neighbouring teeth when proximal caries are treated[7 8]; (5) low noise level; and (6) low requirement of administration of anaesthesia during patient treatment [6].

Despite the proven effectiveness of traditional low and high speed rotating instruments to remove caries and to prepare cavities for dental fillings, these instruments could be inappropriate when a certain strata of the population with evident dental anxiety (12 – 20%), such as young children, are treated by dentists [9]. In many cases, the use of traditional rotating burs to remove caries is combined with local administration of anaesthesia. Anaesthetic injection notoriously represents one of the most significant dental anxiety triggers, reducing compliance with dental treatment [10-16].

Furthermore, sight of the traditional rotating drill, as well as the vibration and noise felt by patients during treatment, represents another important dental anxiety stimulus that could be avoided by new approaches and alternative devices used in the management of caries [10 11 14 17 18].

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Sonic and ultrasonic devices belong to an alternative group of so-called "micro-traumatic" tools to remove caries that include several other alternative devices/approaches to rotating instruments. The most noteworthy are Atraumatic Restorative Techniques (ART)[19], chemo chemical removal of caries[20], lasers[21], air abrasion and polymer rotary burs[22].Oscillating devices, therefore, are potentially useful tools to treat caries with a "psychological micro-invasive approach" reducing the recourse to more complicated pharmacological procedures, such as conscious sedation or general anaesthesia. It is well reported that psychological condition impacts the children's' and adolescents' oral health status[10 13 23 24], by conditioning their dental service attendance as well as their compliance with treatment[17 25-29]. Hence, sonic and ultrasonic ablation devices can be attractive alternative tools with which to overcome concerns regarding dental anxiety.

The aim of the present investigation was to systematically review the current available literature comparing the use of sonic or ultrasonic devices to rotating drills for the management of pain and dental fear in children or adolescents who require caries removal.

Review scientific question

The primary research question was "Are sonic and ultrasonic devices effective in the management of pain and dental fear in children and adolescents who require caries removal?" The population of interest was children or adolescents who required caries removal. The intervention of interest was any oscillating tip that was compared to standard drills whereas the primary outcomes were pain and dental anxiety.

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Methods

Criteria for considering studies for this review

Types of studies. Randomized controlled trials (RCTs) and Controlled Clinical Trials (CCTs) without language limitations.

Types of participants. Children and adolescents with caries. Studies carried out on patients affected by specific oral or systemic diseases were excluded. Both deciduous and permanent teeth were included, with only restored and non-vital teeth excluded.

Types of interventions. Studies that evaluated sonic and ultrasonic devices to remove caries and to prepare cavities for fillings compared to conventional high and/or low speed rotating instruments. No limitations were considered concerning restorative materials used for filling cavities.

Types of outcome measures. Primary outcomes: episodes of pain and discomfort during and after treatment; dental fear; and removal of caries as confirmed by clinical, radiological or other validated assessment tools [30]. Secondary outcomes: durability of restoration (marginal integrity); recurrent caries; pulpal phlogosis or necrosis; patients' acceptance of treatment; patients' preferences; need for anaesthesia; dental practitioner assessment; duration of treatment; costs of intervention; adverse events.

Search methods to identify studies.

A systematic literature review was carried out in the most relevant electronic databases (October, 2017): Medline, the Cochrane Central Register of Controlled Trials (CENTRAL), the Cochrane Library and Web of Science.

Moreover, studies reported in reference lists of obtained articles (reviews and/or studies) and listed in the chapter of the most relevant textbooks in this field, were screened in order to find additional relevant studies. If multiple publications of a single trial were available, only the first publication was considered, except in cases where additional data was reported, such as delayed outcome

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results. A search strategy in the above-mentioned electronic databases was carried out using a combination of keywords and Medical Subject Headings (MeSH) (**Appendix 1**).

Selection of studies

Two review authors independently assessed the titles and extracts of all records identified in the electronic databases (SC and EL). The full text of studies potentially fulfilling the inclusion criteria were requested. Disagreement between review authors, regarding any records meeting the inclusion criteria, was resolved by discussion. Where resolution was not possible, a third review author was consulted (SG).

Data extraction and management

Data from included studies was independently extracted by two review authors (SP and RG), and disagreements were resolved by means of discussion or involvement of a third review author (LP). A data extraction sheet (table) was used to collect data. The retrieved data was divided, based on its characteristics, into the following fields: (1) studies (year of publication, country); patients (number of participants, age, gender); intervention (type of oscillating device); comparator (placebo, high or low speed rotating instruments) and outcomes (primary and secondary). Any adverse events reported in the study were recorded. When full texts of studies potentially meeting the inclusion criteria were unavailable, the study authors were contacted by e-mail whenever possible.

Assessment of risk of bias in included studies

Two review authors (IA and GL) independently evaluated the risk of bias of all included studies using the Cochrane Collaboration's risk of bias tool (Chapter 8 of the Cochrane Handbook [31]). Disagreements were resolved by discussion and if consensus could not be reached, a third review author (AM) was consulted. The following types of risk of bias were evaluated in each included RCT: random sequence generation (selection bias); allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias)[32], incomplete outcome data (attrition bias) [33 34], selective reporting (reporting bias)[35]

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[36]. The studies can be classified into (1) low risk of bias (plausible bias unlikely to seriously alter the results), (2) unclear (plausible bias that raises some doubt about the results), or (3) high risk of bias (plausible bias that seriously weakens confidence in the results).

Measures of treatment effect and data synthesis

Where possible, for dichotomous outcomes we calculated risk ratios (RR) with 95% confidence intervals (CI) for each trial; for continuous data we calculated mean difference (MD). In the case of studies of split-mouth design, we planned to calculate log risk ratio and standard error separately for each outcome.

We planned to combined data from split-mouth studies with data from parallel-group trials using the method suggested by Elbourne[37], employing the generic inverse variance method available in Review Manager 5. Due to heterogeneity of the data it was not possible to conduct any meta-analysis.

Unit of analysis issues

We planned to handle any unit of analysis issues in split-mouth trials according to the recommendations of Section 16.4 of the Cochrane Handbook for Systematic Reviews of Interventions[31].

Patient and Public Involvement

Patients and the Public were not directly involved. This was a retrospective study based on the consultation of electronic medical literature.

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Results

Results of the searches.

The electronic database search identified 373 records up to October 2017. From the entire set of selected records, 111 duplicates were removed and 262 records were screened. After a detailed evaluation of the titles and extracts from the electronic database and manually checking the reference lists of papers, 15 records were considered relevant for a further full text examination[6 38-49]. All 15 full texts were obtained and assessed for eligibility. The study screening process is described in **Figure 1**. Thirteen studies, that had potentially met the inclusion criteria, were finally excluded due to their study designs [4 6 38 40 42 44-47 50-52]. Excluded studies with reasons for their exclusion are listed in **Appendix 2**. Only two controlled clinical trials were identified and included in the review[41 43]. Agreement of selection and quality appraisal procedures between the reviewers was almost perfect (κ>0.94).

Characteristics of included studies.

The two CCTs had a split mouth design, involving a total of 123 child participants with ages ranging from 2 to 12 years [41 43].

The first study was carried out in China and it involved 72 children, aged 3-12, who visited the Peking University Department of Paediatric Dentistry[43]. This split mouth design trial compared oscillating ultrasonic tips with traditional rotating drills in pairs of unspecified analogous teeth situated on different sides of the same dental arc and affected by caries with similar characteristics. Overall 186 teeth were treated, 93 with ultrasonic tip (intervention group) and 93 with traditional rotating instruments (control group). Of the overall 186 treated dental elements, 156 were primary teeth while 30 were permanent teeth. In each patient at least one pair of teeth was treated. In both groups anaesthesia was not used. The following elements were evaluated in the study: episodes of pain during treatment; dental anxiety (measured in terms of the patient's cooperation in the dental chair) and treatment duration. The completeness of caries removal was also assessed at the end of

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each cavity preparation through visual evaluation and dental exploration (dental tissue texture and colour). The level of pain felt by the patients during treatment was recorded with a self-reported visual Five Face Rating Scale, varying from 0 (absence of pain) to 4 (severe pain). The level of both anxiety and collaboration shown by paediatric patients in the dental chair was assessed using a modified three level Venham Rating Scales for Anxiety and Uncooperative Behavior ranging from 0 (for full cooperation without patient anxiety) to 2 (for a completely uncooperative and highly anxious patient). During three follow-up visits conducted after one week, at 3 months and at 6 months, the level of sensitivity felt by patients on the restored molars (integrity and duration) was also evaluated (**Table 1**).

The second trial was conducted in Poland and included 31 children, aged 7-11, who visited the Department of Paediatric Dentistry of Cracow University, with at least two occlusal decayed permanent molars, one on each side of the two upper and lower dental arcs (split mouth design)[41]. Chomyszyn-Gajewska and colleagues evaluated an ultrasonic powered tip, in combination with a micro-abrasive suspension (silicon-carbide, grain-size 40-50 vm), compared to a traditional drill. In this trial thirty one right-side molars were treated with a traditional high speed drill, and the same number of left-side molars were treated with ultrasonic-powered tips. Overall, 62 occlusal caries were treated without anaesthesia. In both the intervention and control groups, teeth were matched concerning caries depth (Diagnodent, Kavo-Dental) and type of treated tooth (maxillary or mandibular molars). The patients with a high level of dental anxiety (determined with the self-reported Cora Dental Anxiety Scale before beginning treatment) and patients with a history of uncooperative behaviour or disability were excluded from the study. The evaluated outcomes included episodes of pain during treatment and the duration of treatment. The level of pain experienced by each patient during treatment was recorded using the following two self-reported scales: (1) the Hochman Scale (a verbal scale) or (2) a Facial Expression Scale (a visual five face scale). Both scales rated the pain experienced in five levels ranging from no pain (level 0) to severe

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pain (level 5). The procedures and diagnostic tools used to assess the complete removal of caries at the end of each cavity preparation were not described (**Table 1**).

Quality assessment of the body of evidence.

By default, the two included trials were not randomized and were considered at high risk of selection bias. In addition, none of the studies reported whether the outcome assessor was blinded and were judged unclear in terms of detection bias. No concern was identified in terms of attrition bias as well as selective reporting bias. Basic characteristics of the patient population were similar between the groups. **Figure 2** describes the risk of bias of the two trials.

Effects of interventions.

Dental caries removal

This outcome was reported only by Li and co-authors[43]. In this studies no cases of residual caries were described in either intervention group. Analysis did not show any difference between the sonic and standard drill (1 study, 93 treated caries in each group, RR 1.00 (95%CI 0.98, 1.02)).

Dental Anxiety

This outcome was reported only by Li and co-authors[43]. In this study the dental anxiety was measured together with patient cooperation forming the following single outcome: dental anxiety and patient's cooperation. The percentage of children showing dental anxiety and negative cooperation with the dentist was lower when an ultrasonic tip (n=39/93; 42%) was used than when a traditional drill was used (n=51/93; 55%) but the difference was not statistically significant (RR 0.78 (95%CI 0.58 to 1.03)).

Pain

This outcome was considered only by Chomyszyn-Gajewska and co-authors' trial[41]**.** When the Verbal Hochman Scale was employed, 14 out of 31 participants (45%) treated with an ultrasonic tip and abrasive suspension reported pain compared to 22 participants (71%) treated with a traditional

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drill (RR 0.64 (95%CI 0.41 to 1.00) ; P = 0.05). Similarly, when the Visual Facial Expression Scale was used, 16 paediatric patients (50%) treated with a traditional drill reported pain or discomfort compared to 25 patients (22%) treated with an ultrasonic tip and abrasive suspension (RR 0.64 (95%CI 0.44 to 0.94); P = 0.02).

Discomfort

Only Li and co-authors reported on this outcome[43]. Patient discomfort during dental treatment was usually due to sight, noise or vibration related to use of ablating instruments. In the intervention group (ultrasonic tip), children experienced moderate or high uncomfortable sensation (for values within the latest two levels of the Five Faces Rating Scale) in 10 out of overall 93 (11%) during treatment. Conversely, in the control group (traditional rotating drill) children felt a comfortable or slightly uncomfortable experience only in 25 out of 93 (27%) of the cases. A statistically significantly difference was found between these two compared instruments in terms of discomfort, with a better performance in favour of ultrasonic tip (RR 0.40 (95%CI 0.20 to 0.79); P = 0.008)].

Patients' preference

Of the two included studies, only Li and co-authors[43] demonstrated an overwhelmingly higher percentage of paediatric patients (88.2%) who preferred to be treated with ultrasonic devices for future dental care. Conversely, only a lower percentage of study participants (11.8 %) chose the traditional rotating drill. In the other study, no data on this outcome were reported.

Duration of treatment

In Li and co-authors' study, the traditional drill was statistically significantly faster at ablation compared to the ultrasonic tip (average time: 3,5 SD 2.3 min with versus 4 SD 2.5 min; P<0.05). Likewise, Chomyszyn-Gajewska and co-authors demonstrated that in terms of length of time to prepare cavities, rotating drills were significantly faster (3.9 during treatment for dentinal caries just beyond the amelo-dentinal junction; 5.5 minutes during treatment for dentinal caries advancing for at least half the depth of the dentine) compared to ultrasonic tips (9 to 16.8 minutes) (P<0.0002).

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Durability of restoration

Of the two studies, only Li and co-authors considered the durability of restoration[43]. They found that all 93 dental fillings in both intervention and control groups resulted kept inside their cavities at one week, 3 months or 6 months. Moreover, in this study also the dental sensibility was considered such sign of filling integrity over time. One out of 93 filled teeth in the intervention group versus 4 out of 93 restored teeth in the control group resulted with a certain degree of sensibility at 6 months after treatment control visit

Other outcomes

None of the studies evaluated the following outcomes: recurrent caries, need for anaesthesia, pulpal phlogosis or necrosis, dental practitioner opinion, costs of intervention and adverse events.

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Discussion

Summary of findings

The use of oscillating devices for caries removal is becoming more common among dental practitioners [45]. Unfortunately, the high expectations regarding the use of oscillating devices to remove caries were not completely supported by data from published clinical studies. Only a few methodologically low quality clinical studies described the effectiveness of oscillating devices to manage caries. Therefore, the potential positive features of oscillating tips, in terms of caries removal and ultraconservative preparation of cavities, in addition to low pain, decreased discomfort and reduced anxiety induction, remain clinically unproven.

Strength and limitation

To provide a comprehensive synthesis of the evidence about oscillating devices for the management of dental fear we systematically searched studies available in four electronic databases and search references of relevant studies. In addition, we used we assessed the methodological quality of the trial using the risk of bias method of the Cochrane Collaboration. Another strength of the present review was the adoption of a systematic and transparent method, and the use of duplicate, independent approach of the reviewers for study selection, data abstraction and data interpretation. We acknowledge several limitation of our study. Despite a systematic literature review, only two Controlled Clinical Trials were found, both of which were considered to have unclear or high risk of selection, detection and attrition biases [41 43]. In addition, in one trial Li and co-authors rated both the cooperation level and anxiety shown by children in the dental chair by using a modified version of a rating scale named Venham Rating Scales for Anxiety and Uncooperative Behavior. Usually, all rating scales (based on a dentist assessment) are considered a valid tool to perform a child's behaviour cooperation assessment rather than an anxiety evaluation[53]. The above-mentioned Venham Rating Scale represents an exception to this rule. This scale, indeed, is composed of two subscales: an Anxiety Rating Scale to measure dental fear and a Behavior Rathing Scale to evaluate

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the child's cooperation. The reliability and validity of this scale has been directly demonstrated by Venhnam some years after its realization [54]. However, in the Li and co-authors' study, as well-outlined before, a modified version of Venham Rating Scales for Anxiety and Uncooperative Behavior (composed of only one scale) was used and no validation studies about that were found. Consequently, unresolved concerns remain about the validity of anxiety and cooperation values measured in the Li and co-authors' study.

In the second trial, Chomyszyn-Gajewska and co-authors[41] excluded from their study sample dental anxious and/or uncooperative children, whereas those represent the target population of greatest interest for the present review. This particular group of patients, indeed, is the one most advantaged by anxiety management procedures. Therefore, data derived from only non-anxious and dental care compliant patients (for whom ordinarily no anxiety management is required) generate doubts on their value in terms of applicability (indirectness)[55] and relevance to improve the clinical practice. However, when children are considered during treatment of dental caries, they should be always deemed as at risk of developing dental fear particularly when they are younger[9 56]. Unpleasant experiences, particularly when pain was felt during the earliest dental visits, represent an extremely relevant risk factor for children to develop dental anxiety[25 57-59] that should be carefully avoided with an adequate dentist-child relationship.

Moreover, both trials presented a split mouth design that might be considered a particular type of crossover study. In both study designs the same patient is treated at two different times (one decayed tooth on each side of the mouth, one at a time) with alternating intervention and control devices for caries removal. The crossover study presents two relevant advantages over the most commonly adopted parallel study design: (1) the need of a lower sample size to obtain the same level of precision and statistical power, (2) a more accurate comparison between two different interventions due to the fact that single patient variations are lower than between different patients. However crossover design could present a risk of a "carryover effect" biasing the results. This

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effect is that the emotional impact of the patient's first dental visit lingering in his or her memory, might affect perception of a second intervention and influence his or her pain perception[60]

Conclusions

The lack of available literature with a high methodological quality prevented us from answering the main question of this systematic review. The effectiveness of sonic and ultrasonic tips for managing pain and dental fear in children and adolescents who required caries removal remains, therefore, unproven and further research is required.

Footnotes

Contributors: SC, SP, EL, and GL conceived the original idea. IA and GL designed the study. GL and IA designed the search strategies. SC and GL performed the search and screened titled and abstracts independently. SP and GL performed data abstraction. IA and EL performed assessment of quality. SC and GL drafted the manuscript. IA, SP and EL revised critically the manuscript. All the authors approved the final version of the manuscript.

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Competing interests None.

Data sharing statement No additional data are available.

Figure Caption

Figure 1. Literature search flow chart.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

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Table 1. Characteristics of included studies

Study ID	Study design	Participants	Treatment	Outcomes	Funding
Chomyszyn-Gajewska 2006	Controlled Clinical Trial (split mouth study) One centre	31 children, 62 teeth and 62 caries (Poland); Age (range): 7-11 years; *Baseline*: Patients at least two occlusally decayed permanent molars, one on each side of the two upper and lower dental arcs; *Inclusion criteria*: Children without systemic diseases with couples of decayed permanent molars (one for each maxillary or mandibular dental arc side) with matching caries depth assessed by means of Diagnodent (Kavo-Dental); *Exclusion criteria*: Highly anxious patients (self-reported Cora Dental Anxiety Scale before beginning treatment), and patients with a history of uncooperative behaviour or disability.	*Experimental*: Ultrasonic device (Vector system); oscillating frequency: not reported; *Control*: Traditional rotating drills	*Primary:* Caries removal; Episodes of pain (scale used: Hochman Scale or a Facial Expression Scale; Dental Fear (measured through Cora Dental Anxiety Scale). *Secondary:* Need for anaesthesia; Duration of treatment	No funding was declared by the authors to support their study
Li 2010	Controlled Clinical Trial (split mouth study) One centre	72 children; 186 teeth and 186 caries (China) Age (range): 3-12 years; *Baseline*: Patients with at least two decayed teeth in the same dental arc; *Inclusion criteria*: Children without systemic diseases with at least two decayed teeth showing carious lesions of equivalent degree; *Exclusion criteria*: Clinical and radiological endodontic lesions.	*Experimental*: Ultrasonic device (KaVo Soniflex Line), oscillating frequency: 6500 Hz; *Control*: High and low speed rotating drills.	*Primary:* Caries removal (assessed trough visual and instrumental (dental explorer) examination); Episodes of pain (recorded with a self-reported visual Five Face Rating Scale); Dental Fear (assessed using a modified three level Venham Clinical Rating Scale); *Secondary:* Post operative patients' sensitivity; Patients' acceptance; Patients' preferences;. Duration of treatment	No funding was declared by the authors to support their study

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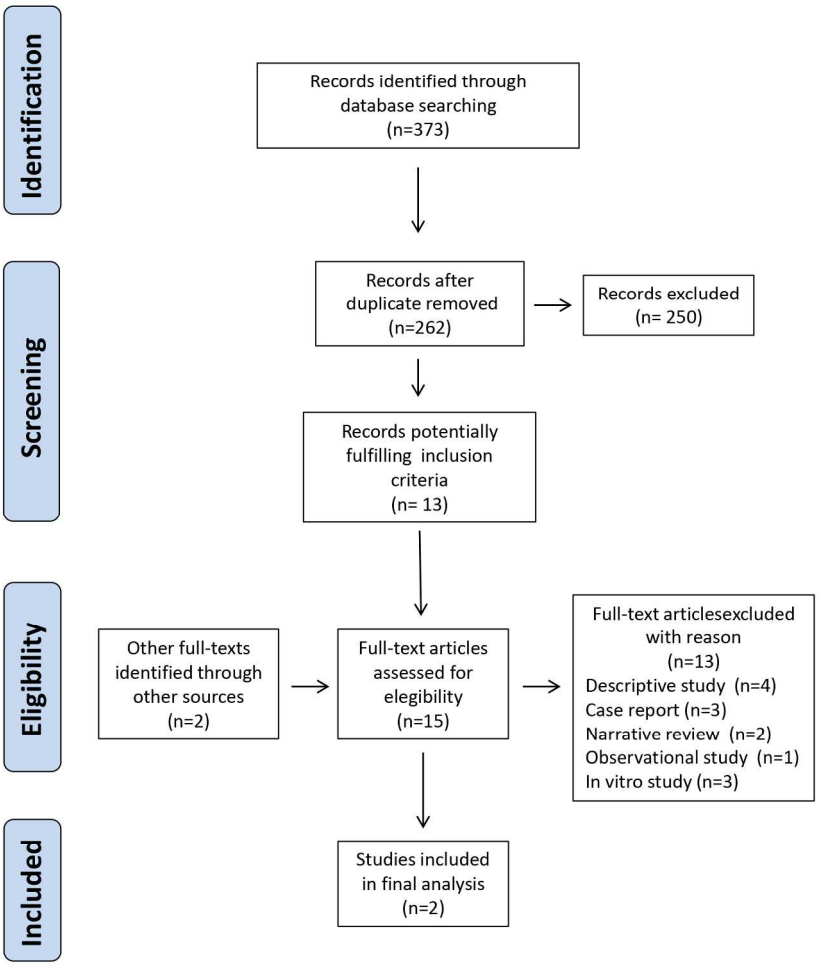

Literature search flow chart.

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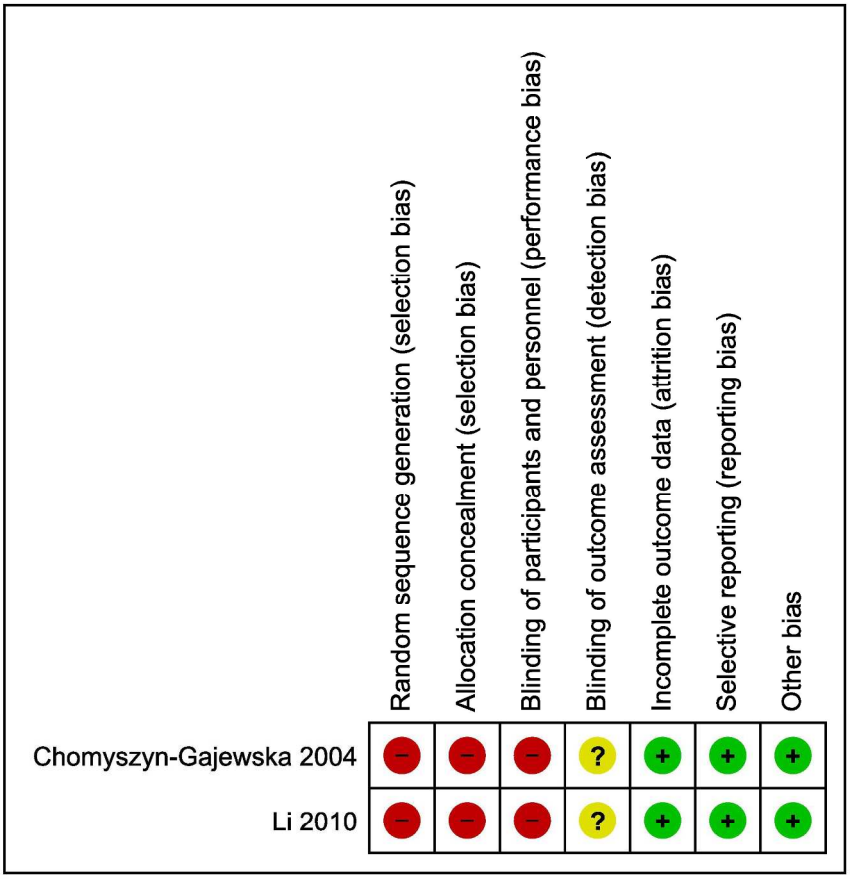

Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

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Appendix 1. Complete list of key words used to search the most relevant databases for the studies to be included in the present review.

Minimally invasive dentistry caries		
Dental Caries/therapy*	AND	Ultrasonic Therapy/instrumentation*
Dental Cavity Preparation/instrumentation*	AND	Ultrasonic Therapy/instrumentation*
Dental Cavity Preparation/methods	AND	Ultrasonic Therapy/instrumentation*
Tooth Preparation/instrumentation*	AND	Ultrasonic Therapy/instrumentation*
Dental Caries/therapy*	AND	Oscillometry/instrumentation
Dental Cavity Preparation/instrumentation*	AND	Oscillometry/instrumentation
Dental Cavity Preparation/methods	AND	Oscillometry/instrumentation
Tooth Preparation/instrumentation*	AND	Oscillometry/instrumentation
Dental Caries/therapy*	AND	Sonic
Dental Cavity Preparation/instrumentation*	AND	Sonic
Dental Cavity Preparation/methods	AND	Sonic
Tooth Preparation/instrumentation*	AND	Sonic
Dental Caries/therapy*	AND	Ultrasonic Therapy/adverse effects
Dental Cavity Preparation/instrumentation*	AND	Ultrasonic Therapy/adverse effects
Dental Cavity Preparation/methods	AND	Ultrasonic Therapy/adverse effects
Dental Caries/therapy*	AND	Sonication
Dental Cavity Preparation/instrumentation*	AND	Sonication
Dental Cavity Preparation/methods	AND	Sonication
Tooth Preparation/instrumentation*	AND	Sonication
Dental Caries/therapy*	AND	Oscillometry/adverse effects
Dental Cavity Preparation/instrumentation*	AND	Oscillometry/adverse effects
Dental Cavity Preparation/methods	AND	Oscillometry/adverse effects
Tooth Preparation/instrumentation*	AND	Oscillometry/adverse effects
Dental Caries/therapy*	AND	Sonoabrasive

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Dental Cavity Preparation/instrumentation*	AND	Sonoabrasive
Dental Cavity Preparation/methods	AND	Sonoabrasive
Tooth Preparation/instrumentation*	AND	Sonoabrasive

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Appendix 2. The reasons leading to the exclusion of retrieved full texts.

n.	Author	Reason for Exclusion
1	Banerjee 2000	Literature narrative review
2	Josgrilberg 2007	In vitro study
3	Haase 1998	Case report
4	Koczarski 2007	Case report
5	Koubi 2008	Descriptive study
6	Mota 2013	Descriptive study
7	Ntovas 2017	Literature narrative review
8	Predebon 2006	Observational study)
9	Sheets 2002	Case report
10	Tassery 2013	Descriptive study
11	Thomas 2012	Descriptive study
12	Wicht 2002	In vitro study
13	Yildirim 2010	In vitro study

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	na
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6 and appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	7
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8

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PRISMA 2009 Checklist

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	na
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	9-10
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	11
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	11-13
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	na
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	11
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	na
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	14-15
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	16
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	16

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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