Non-pharmacological interventions for managing dental anxiety in children

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[Intervention Protocol]

Non-pharmacological interventions for managing dental anxiety in children

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

This review aims to assess the effectiveness of non-pharmacological interventions for reducing dental anxiety in children.

BACKGROUND

Description of the condition

Disruptive or non-compliant behaviours are a common manifestation of dental fear, anxiety, or phobia in children (Winer 1982). Dental fear is a normal emotional reaction to one or more specific threatening stimuli in the dental situation. Dental anxiety indicates a state of apprehension that something dreadful is going to happen in relation to dental treatment, and it is usually coupled with a sense of losing control. Dental phobia denotes a severe type of dental anxiety, and is characterised by marked and persistent anxiety in relation to either clearly discernible situations or objects (e.g. drilling, injections) or to the dental situation in general (New Reference; Klingberg 2007). According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), the criteria for diagnosis of a specific phobia are: (i) marked and out of proportion fear within an environmental or situational context to the presence or anticipation of a specific object or situation, (ii) exposure to the phobic stimulus provokes an immediate anxiety response, which may take the form of a situationally bound or situationally predisposed panic attack, (iii) the person recognises that the fear is out of proportion, (iv) the phobic situation(s) is avoided, or else is endured with intense anxiety or distress, and (v) the avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational (or academic) functioning, social activities, or relationships, or there is marked distress about having the phobia (AMA 2013). In addition to the criteria for a specific phobia, the general criteria for a mental disorder, which is common to all Axis I diagnoses, also has to be met. This definition includes the criterion disability (i.e. impairment in one or more important areas of

functioning). Therefore, for a diagnosis of phobia, dental fear or anxiety must result in the individual avoiding the necessary dental treatment completely, or enduring treatment only with dread, and in an adjusted treatment situation (e.g. specialist paediatric dentistry; Klingberg 2008).

The term 'dental fear and anxiety' (DFA) is often used to refer to strong negative feelings associated with dental treatment among children and adolescents, whether or not the criteria for a diagnosis of dental phobia are met. Conversely, dental behaviour management problems (DBMP) are defined by the dentist's experience when treating the patient. It is a collective term for unco-operative and disruptive behaviours, which result in delay of treatment or render treatment impossible, regardless of the type of behaviour or its underlying mechanism (Klingberg 1994).

Based on a review of prevalence studies between 1982 and 2006, Klingberg 2007 reported the prevalence of both DFA and DBMP to be approximately 9% for children in normal populations in Australia, Canada, Europe, and the USA. Recently, higher DFA and DBMP prevalence estimates, ranging from approximately 6% to 29%, have been reported for children in low- and middle-income countries (Abu-Ghazaleh 2011; Akbay Oba 2009; Dogan 2006; Folayan 2004; Paryab 2013; Salem 2012). Given the wide variation in both DFA and DBMP prevalence estimates among children in different geographical areas and settings, it should be recognised that these estimates may be influenced by different measures and cut-off points used by investigators to distinguish between those who are and are not anxious. Nevertheless, girls exhibit DFA and DBMP more frequently than boys (Klingberg 2007). Dental fear and anxiety and DBMP have been related to general fear, and both internalising and externalising behavioural problems (Arnrup 2002; Klingberg 1995; Ten Berge 1999), although these relationships are ambiguous, and the development of these problems has been attributed to several psychological factors (Locker 2001).

Dental treatment frequently involves invasive treatment, multiple injections, and the use of sharp, high-speed cutting instruments, often extended over several visits. Children and adolescents vary considerably in competence, maturity, personality, intellectual capacity, temperament and emotions, experience, oral health, family background, parenting styles, and culture. All of these aspects influence the child's ability to cope with dental treatment, and can pose a great challenge to the treating dentist. It is difficult, if not impossible, to carry out any required clinical or preventive care if a child's behaviour cannot be managed. Therefore, the dentist should identify the factors, both within and outside of the dental setting that may influence DFA and DBMP, so they may select the most appropriate behaviour management interventions, either non-pharmacological or pharmacological, to minimise DFA and DBMP, and deliver high-quality dentistry, whilst also helping the the child develop a positive attitude towards dental health and treatment.

Fear of dental treatment and anxiety about dental procedures have an impact on quality of life and the quality of the dental treatment performed (Milgrom 2010). Delay in seeking treatment because of dental anxiety often means that conservative treatment options are not viable. The choice of an appropriate non-pharmacological intervention is based on the levels (low, moderate, high or phobic) of dental anxiety exhibited by the child. For children presenting with low levels of DF or DA, approaches that can be adopted include: tell-show-do, voice control, distraction, modelling, memory reconstruction, positive reinforcement, relaxation training, magic tricks, and positive images. Children with moderate levels of DF or DA may require more intensive interventions, such as providing them with information on coping strategies, while children who exhibit DP could benefit from the complementary use of pharmacological and psychological approaches, especially cognitive behavioural therapy (Newton 2012).

Behaviour management needs to be flexible and individualised for each child (Feigal 2001). Most behaviour management techniques require an understanding of the cognitive, emotional, and social development of the child and aim to develop communication between the child, dentist, and parent, where possible (Feigal 1995; Rosenberg 1974). To date, there are few studies that have evaluated the effectiveness of various non-pharmacological interventions for managing dental anxiety in children. One Cochrane review explored the effectiveness of hypnosis (with or without sedation) for behaviour management in children receiving dental treatment, and reported that there was insufficient evidence to support the benefits of hypnosis for behaviour management in children (Al-Harasi 2010). Our review aims to assess the effectiveness of all non-pharmacological interventions in reducing dental anxiety in children.

Description of the intervention

Several non-pharmacological techniques have been proposed for use with children, including:

- Voice control;
- Tell-show-do;
- Positive reinforcement;
- Distraction;
- Non-verbal communication;
- Hand-over-mouth technique (HOM);
- Hand-over-mouth with airway restriction (HOMAR);
- Physical restraint;
- Contingent distraction;
- Contingent escape;
- Modeling;
- Relaxation training;
- Hypnosis;
- Systematic desensitisation and graded exposure;
- Cognitive behavioural therapy;
- Visual pedagogy;
- Memory reconstruction; and

- Others (e.g. magic tricks, positive images, environmental change).

Despite the range of non-pharmacological intervention currently available, they are rarely used in isolation; for instance, tell-show-do, a basic desensitisation technique, is nearly always immediately followed by some form of praise (reinforcement). If this is used as an approximation to an eventual co-operative behaviour, the technique could be termed 'behaviour shaping' (Roberts 2010).
Enhancing control or temporary escape allows the patient to have some degree of control over their situation, and the ability to communicate when they require a rest, are in pain, or need the dentist to stop. Voice control is the modulation of tone, volume, pace, and pitch of voice to control and guide behaviour. Contingent or non-contingent distraction shifts the patient's attention, allowing the dentist to decrease negative perceptions of treatment and avert negative or avoidance behaviour. Modeling relies upon the theory that behaviours are learned from observing and imitating others. By observing a model, a child is able to learn complex behaviour patterns to cope and approach dental treatment without fear (Roberts 2010; Ten Berg 2008).
Cognitive behaviour therapy (CBT) is an example of a brief psychological therapy, which uses both behaviour modification techniques and cognitive restructuring procedures to change disruptive beliefs and behaviours. Behavioural aspects of CBT include learning relaxation skills, conducting mini-experiments, systematic desensitisation, and graded exposure. This aims to reduce anxiety through the gradual presentation of anxiety or fear-inducing stimuli while the child is either in a relaxed state, or in the presence of a neutral or positive stimulus, thus modifying child's response (Gordon 1974; Ten Berg 2008).
Protective stabilisation is defined as restriction of a patient's freedom of movement, with or without the patient's permission, to decrease risk of injury while allowing safe completion of treatment (AAPD 2015-2016). Controversy surrounds the use of protective stabilisation, due to the risks of respiratory compromise, loss of dignity, and potential induction of psychological trauma (Roberts 2010).
Suggestion, visualisation, and hypnosis strategies train patients to be placed, or to place themselves into a level of focused consciousness, so suggestions can be easily adopted. The magic trick, or similar method of gaining a child's attention and admiration, may make a child feel at ease in an unfamiliar scenario, as well as build rapport, and ultimately, lead to positive behaviour.
Regardless of the technique used, its effectiveness greatly depends on how it is applied, including the empathic skills shown by the dental practitioner.

How the intervention might work

Major consequences of a child's unco-operative behaviour in a dental setting include delays or early termination of treatment, or decreased quality of care (Allen 1988). The above-mentioned non-pharmacological interventions have been proposed in an attempt to help the child overcome DFA and DBMP, and learn about and understand dental procedures in a way that minimises their anxiety (Allen 1987; Allen 1992; Kuhn 1994; Peretz 1996a; Peretz 1996b; Peretz 1999). The use of these basic psychological techniques during dental treatment has been found to be effective in reducing children's dental anxiety, which could potentially facilitate their acceptance of what may occur in the dental environment (Folayan 2003). This may be by gradually exposing them to potentially anxiety-inducing experiences, helping them feel more in control by providing them with communication strategies, gaining their attention or distracting them, providing positive or negative reinforcement to minimise disruptive behaviour and strengthen desired behaviours, and focusing on building a more trusting relationship with their dentist and the dental team. Reducing a child's anxiety without using a pharmacological intervention means less threat to their general health, less obstruction to the delivery of timely dental health care in the present, and the likelihood of better compliance with clinical advice and preventive care in the future. Therefore, non-pharmacological interventions are recommended by paediatric dental organisations (AAPD 2015-2016; Roberts 2010).
Non-pharmacological interventions, can be theoretically grouped into: (i) communication skills, rapport, and trust building, (ii) behaviour-modification techniques, (iii) cognitive behavioural therapy, and (iv) physical restraints (Appukuttan 2016).

Communication skills, rapport, and trust building

Verbal communication

The clinician (or another member of the dental team) should aim to establish an empathetic relationship with the patient, and create a non-threatening perception of the dental environment. To achieve this, it is essential that clinicians have a sound knowledge of the child's cognitive processes, and pay attention to their emotions (Bandura 1969). To devlop a trusting relationship with the young patient, the dentist should establish a direct approach by communicating with them in a friendly, calm, and non-judgmental manner (Marci 2007), using comprehensible vocabulary and avoiding negative phrases (Corah 1988). A two-way communication between child and dentist allows the child to exhibit their skills for coping with a dental visit (Marci 2007).

Non-verbal communication

Non-verbal communication, such as positive eye contact and friendly facial expressions are essential to achieve an empathetic relationship between child and dentist.

Behaviour-modification techniques

These techniques, which are based on learning theories, are a set of interventions used to modify the disruptive or unco-operative patients' behaviour in the dental office (Pavlov 1927; Skinner 1938; Bandura 1969).

Voice control

It is classified as a negative behaviour reinforcement (punishment) technique, characterised by loud and firm commands from the dentist towards the unco-operative patient (Greenbaum 1988). Phrases such as "open your mouth and stop crying" expressed in a firm and loud tone, with the dentist showing a dissatisfied expression can be useful to reduce the child's disruptive behaviour during treatment (Pinkham 1991).

Tell, show, do

This is the most commonly used technique, where the patient is introduced to the treatment through a gradual procedure. In the 'tell' phase, the patient is well informed on the various steps of the treatment procedure. In the 'show' phase, they become familiar with the treatment armamentarium, by either looking at them or touching them. Subsequently, in the 'do' phase, the dentist begins the treatment, without any change to the previous explanation and demonstration (Buchanan 2003; Kantaputra 2007; Wright 1991).

Signalling

This is to allow the patient to communicate with the dental team during any phase of the treatment by means of previously-established signals with specific meanings. The patient, by raising a hand or a finger can communicate their wish to stop the treatment (for rest breaks), or notify the dentist of any unpleasant feelings. The relationship of trust is greatly improved by the clinician responding promptly and appropriately to the young patient's signals (Armfield 2013).

Positive reinforcement

This technique is based on the clinician's reinforcement manifestations to encourage any positive effort by the patient to collaborate during treatment with encouraging phrases (using a positive voice modulation), such as "thank you for helping me by keeping your mouth wide open", or physical manifestation, such as a smile. Positive reinforcement represents, for anxious patients, a moment of escape from the fear-inducing situations related to dental treatment (Kuhn 1994). When positive behaviour is sustained throughout the entire visit, the patient might also receive a reward, e.g. sticker badge, toy, etc. (Roberts 2010).

Relaxation training

This intervention requires well-developed learning skills, and therefore, is deemed potentially useful only for older patients. The relaxation techniques are based on the hypothesis that a person cannot be anxious at the same time as they are physically relaxed (Armfield 2013). These techniques work on muscle tension, joint mobility, or breathing by producing feedback feelings in order to reduce a patient's anxiety level.

Breathing relaxation

This is a breath conditioning technique (mainly involves engaging the diaphragm muscle), characterised by an increased depth in both inhalation and exhalation, and a reduced breath frequency for an established range of time (e.g. two to four minutes). This type of breathing provides more oxygen to the body, thus reducing the heart rate (Milgron 2009). Breathing relaxation is easy to perform, and can be adopted by anxious patients in the dental chair immediately before the treatment, or at home (Armfield 2013).

Distraction

This is the psychological procedure of diverting the patient's attention from the threatening stimuli (e.g. dental treatment). Visual or auditory stimuli can be useful in modifying behaviour, particularly in patients showing mild or moderate traits of anxiety in the dental chair (Corah 1981; Lahmann 2008). Some commonly used distractors in the dental office include magic tricks, toys, cartoons, or movies, music. They can be given either in the waiting room or during dental treatment (Bentsen 2001; Hoffman 2001).

Modelling

This is based on the principle that a patient can be conditioned to exhibit positive behaviour after observing the behaviour of another patient, an older sibling, or family member in a similar situation (e.g. in the dental chair) (Roberts 2010; Shapiro 2007). This intervention should be used as a preventative approach with the anxious patient before their first dental treatment begins (Greenbaum 1988).

Guided imagery

The patient, seated in the dental chair, is asked to use their imagination skills to focus on pleasant places (e.g. beach or mountain scenery). This consciously encourages their psyche to reach a state of relaxation and well-being. The emotional well-being guides the body to a complete physical relaxation. This, combined with a positive suggestion, reduces the anxiety-inducing symptoms. The images during this relaxation procedure can be evoked from the dentist or independently chosen by the patient. Nevertheless, in both cases, the imagined scenery must be rich in detail,and include colours, smells, and sounds (Armfield 2013).

Hypnosis

The dentist aims to establish a psychological interaction with the patients to reduce their peripheral awareness, by focusing their attention on evoked ideas and images, in order to condition their perceptions, feelings, thoughts, and consequently, their behaviour (Lynn 2015; Montgomery 2000).

Systematic desensitisation

This intervention is composed of three phases. In the first phase, the dental practitioner invites the patient to indicate the most fearful conditions among those imagined during treatment. In addition, the patient is asked to define the order of severity of the perceived threatening dental stimuli. The second phase is characterised by teaching the patient relaxation techniques. The third phase is focused on progressive exposure to the treatment, by beginning with the simplest and least painful (or entirely painless) interventions, to the more complicated treatments, sometimes causing pain, and inducing anxiety (Farhat-McHayleh 2009; Wolpe 1954).

The following two relaxation techniques, due to their complexity, are used often in children.

Progressive muscle relaxation

The patient is asked to focus his attention on a progressive sequence of muscles (e.g. four groups) corresponding to different anatomical areas. The most commonly used Jacobson's technique requires that within each muscle group, individual muscles are tensed for five to seven seconds, and subsequently relaxed for 20 seconds (Bracke 2010).

Functional relaxation therapy

This technique is characterised by joint small-wide movements of several sequentially involved bones, such as the lower jaw, head and neck, shoulders, and backbone. A sequence of movements performed in different directions (forward-back, lateral, and rotational) for three to five seconds. Each joint movement is followed by a pause during which the patient can focus his attention on the resulting body postural changes. These body exercises are deemed to induce functional relaxation through positive stimulation of the autonomic nervous system (Loew 2001; Lahmann 2008).

Cognitive behavioural therapy

Anxious patients often have unrealistic expectations about dental treatment. Cognitive therapy is a goal-orientated talking therapy, with the objective of altering and restructuring the child's negative beliefs, to reduce their dental anxiety and improve the control of negative thoughts (Kendall 2006). The objective is to allow children to learn new self-management skills that they can use to overcome specific threatening stimuli in the dental situation. Children learn about the inter-relationship between thoughts, feelings and behaviour, and how they can change how they feel by putting into practice what they have learned (Dumitrache 2014; Williams 2002). This complex intervention requires the involvement of specific therapists (e.g. psychologists), who teach the patients to manage their anxiety by developing new skills (Getka 1992; Heaton 2013). This allows for a better communication of their personal opinions, feelings, and needs during dental treatment (Wide 2013). Cognitive therapy often requires the presence of parents or carers, together with their anxious children (Williams 2002). Behaviour modification therapies, such as relaxation techniques, guided imaginary practice, and gradual exposure to treatment are usually associated with cognitive restructuring (Appukuttan 2016).

Physical restraints

This technique is used in only some countries. In order to restrict movement, the patient may be strapped to a papoose board, or be held by their parents, and if necessary, by additional dental team members. Restraint techniques are also called 'protective stabilization'; one of the most common restraint techniques is the "hand-over-mouth exercise" (Roberts 2010). The American Academy of Pediatric Dentistry recommends that the use of restraints should be limited to rare, critical clinical situations where "no other alternatives are available" (e.g. life-threatening situations without any possibility of obtaining minimal patient co-operation), due to their inhumane and unacceptable features (Weaver 2010) .

Why it is important to do this review

Cochrane Oral Health undertook an extensive prioritisation exercise in 2014 to identify a core portfolio of titles that were the most clinically important ones to maintain on the Cochrane Library (Worthington 2015). The paediatric dentistry expert panel identified this review topic as a priority (Cochrane Oral Health priority review portfolio).

Children should be able to enjoy the benefits of dental treatment without experiencing unnecessary distress. Dental fear and anxiety and DBMP may have major and long-lasting implications for children and their families, which are as follows.

- They exhibit a higher caries experience compared to children with low levels of dental anxiety (Nicolas 2010; Rantavuori 2004; Townend 2000; Versloot 2004).
- They are difficult to treat and require more time, resulting in a stressful and unpleasant experience for the child, parent and the treating dentist (Moore 2001).
- They are much more likely to resist, delay, or avoid dental visits, which is an important influencing factor for parents who fail to take their children to the dentist, thus resulting in failed or missed appointments (Hallberg 2008).

- There are financial implications for providing dental treatment to these children (Weinstein 2008). Dental practices, which operate on a fee-per-service basis, may be reluctant to treat these children, hence referring them to secondary or tertiary dental care services (Harris 2008). This results in longer waiting times, potentially leading to more extensive dental problems. They may eventually require more complex treatment with the aid of pharmacological interventions, namely, intravenous sedation, conscious sedation, or general anaesthesia (Armfield 2013).
- This results in neglected dental care and increased unmet need in adulthood (Berggren 2001). They are more likely to be symptomatic, rather than proactive, users of dental services in adulthood (Poulton 2001).

It is important that non-pharmacological interventions delivered by dentists are evidence based; therefore, this review could help identify the specific interventions that are effective for the different levels of dental anxiety in children. Furthermore, this could help in developing guidelines and training dental practitioners in such techniques.

OBJECTIVES

This review aims to assess the effectiveness of non-pharmacological interventions for reducing dental anxiety in children.

METHODS

Criteria for considering studies for this review

Types of studies

We will only include randomised control trials (RCTs) with parallel design.
We will exclude cross-over studies because of potential for a carry-over effect.

Types of participants

We will include all children and adolescents up to 16 years of age, with varying levels of dental anxiety (low, moderate, high (phobic)). We will include children having any dental treatment (simple restorative treatment with or without local anaesthetic (LA), simple extractions, or management of dental trauma (e.g. repositioning of tooth, splinting, removal of pulp (nerve) from tooth), and orthodontic treatment), regardless of their baseline anxiety. Furthermore, we will include children receiving dental treatment with or without any sedative agent (sedation could be inhalation, oral, or intravenous).
We will exclude children with a medical condition or syndrome that could potentially influence their behaviour in a dental setting.

Types of interventions

Test group: any non-pharmacological technique with or without any sedative agent (sedation could be inhalation, oral, or intravenous).
Control group: no intervention, or sedative agent alone.
Any sedation (inhalation, oral, or intravenous) must be identical in the test and control group so that the only difference between the groups is the addition of a non-pharmacological intervention.
A previous Cochrane review explored the effects of hypnosis (with or without sedation) for behaviour management of children receiving dental care to allow successful completion of treatment, and reported that there was insufficient evidence to support the use of hypnosis in paediatric dentistry (Al-Harasi 2010). To update this evidence, we will incorporate RCTs assessing hypnosis in our review.

Types of outcome measures

Primary outcomes

- Difference in post-treatment anxiety between test and control groups (scales used may vary between studies)

Secondary outcomes

- Differences in behaviour between test and control groups (scales used may vary between studies)
- Completion of the planned dental treatment (yes or no)
- Adverse events

Search methods for identification of studies

Cochrane Oral Health's Information Specialist will conduct systematic searches for randomised controlled trials and controlled clinical trials. Due to the Cochrane Embase Project to identify all clinical trials on the database and add them to CENTRAL, only recent months of the Embase database will be searched. Please see the 'How to search' page on the Cochrane Oral Health website for more information. No restrictions will be placed on the language or date of publication when searching the electronic databases.

Electronic searches

We will search the following databases for relevant trials:

- Cochrane Oral Health's Trials Register;
- the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library;
- MEDLINE Ovid (from 1946 onwards);
- Embase Ovid (previous 6 months to date).

The subject strategies for databases will be modelled on the search strategy designed for MEDLINE Ovid in Appendix 1. Where appropriate, this will be combined with subject strategy adaptations of the highly sensitive search strategy designed by Cochrane for identifying randomised controlled trials and controlled clinical trials (as described in the *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0, Box 6.4.b. (Lefebvre 2011)).

Searching other resources

We will search the following trials registries:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (ClinicalTrials.gov);
- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch).

We will check the bibliographies of included studies and any relevant systematic reviews identified, for further references to relevant trials.

We will not perform a separate search for adverse effects of interventions used for the treatment of dental anxiety. We will consider only adverse effects described in included studies.

Data collection and analysis

Selection of studies

Two review authors will independently screen the titles and abstracts identified during the electronic searches. We will attempt to retrieve full-text copies of any articles appearing to meet our inclusion criteria, or those that have insufficient information in the title or abstract. Two review authors will then independently assess each full-text paper to confirm eligibility. We will resolve any disagreements on eligibility through discussion. If there is still disagreement, we will consult a third review author in order to reach consensus.

When assessing the full-text articles, we will discard any studies that clearly do not meet our inclusion criteria. We will undertake manual searching of reference lists. We will record all other studies (i.e. those that would initially be assumed to be eligible) that do not meet the inclusion criteria, along with reasons for exclusion, in the 'Characteristics of excluded studies' table.

Data extraction and management

Two review authors will independently extract data from each included study using a predetermined data extraction form, which we will pilot on a small number of studies to determine any issues that may arise. Where details are unclear or information is missing from the study report, we will attempt to contact the study authors, if feasible. We will resolve any disagreements through discussion, and consult a third review author to reach consensus if necessary. We will record the following data for each included study in the 'Characteristics of included studies' table.

- Trial design, location (i.e. country), setting (i.e. general practice, specialist practice, or hospital-based dental clinic), number of centres, recruitment period, trial registry number.
- Inclusion and exclusion criteria, age and gender of participants, number randomised and analysed, anxiety levels (low, moderate, or high (phobic)).
- Detailed description of the intervention and comparator, including timing, duration, and information on compliance with the intervention.
- Details of the outcomes reported, including timing (follow-up period) and method of assessment.
- Details of sample size calculations, funding sources, declarations and conflicts of interest, and any other information worth noting.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias of each included study using the domain-based, two-part tool described in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will contact study authors for clarification or missing information, where necessary and feasible. We will resolve any disagreements through discussion, consulting a third review author to achieve consensus, when necessary.

We will complete a 'Risk of bias' table for each included study. For each domain of risk of bias, we will first describe what was reported to have happened in the study. This will provide the rationale for our judgement of whether that domain is at low, high, or unclear risk of bias.

We will assess the following domains:

- sequence generation (selection bias);
- allocation concealment (selection bias);
- blinding of participants and personnel (performance bias).

Although this is not possible in our studies, we will acknowledge any resulting bias.

- blinding of outcome assessment (detection bias);
- incomplete outcome data (attrition bias);
- selective outcome reporting (reporting bias);
- other bias.

We will categorise the overall risk of bias of individual studies as low, high, or unclear risk of bias according to the following criteria:

- low risk of bias (plausible bias unlikely to seriously alter the results) if all domains are at low risk of bias;
- high risk of bias (plausible bias that seriously weakens confidence in the results) if one or more domains are at high risk of bias; or
- unclear risk of bias (plausible bias that raises some doubt about the results) if one or more domains are at unclear risk of bias.

We will also present the 'Risk of bias' summary graphically.

Measures of treatment effect

For dichotomous outcomes (e.g. was the planned dental treatment completed: yes or no), we will express the estimate of effect as a risk ratio (RR) with 95% confidence interval (CI).
For continuous outcomes (e.g. behaviour or anxiety measured on a continuous scale), where studies use the same scale, we will use the mean values and standard deviations (SDs) reported in the studies, in order to express the estimate of effect as mean difference (MD) with 95% CI. Where different scales are used, we will consider expressing the treatment effect as standardised mean difference (SMD) with 95% CI.

Unit of analysis issues

The participant will be the unit of analysis.

Dealing with missing data

Where feasible, we will attempt to contact the authors of included studies for clarification or missing data. We will use the methods described in Section 7.7.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* to estimate missing SDs (Higgins 2011). We will not use any other statistical methods or perform any further imputation to account for missing data.

Assessment of heterogeneity

If a sufficient number of studies are included in any meta-analyses, we will assess clinical heterogeneity by examining the characteristics of the studies, the similarity between types of participants, interventions, and outcomes. We will also assess heterogeneity statistically using a Chi² test, where $P < 0.1$ indicates statistically significant heterogeneity, and by visual inspection of the forest plot (overlap of CIs). We will quantify heterogeneity using the I^2 statistic. A guide to interpretation of the I^2 statistic given in Section 9.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions* is as follows (Higgins 2011):

- 0% to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

Assessment of reporting biases

If at least 10 studies are included in a meta-analysis, we will assess publication bias according to the recommendations on testing for funnel plot asymmetry (Egger 1997), as described in Section 10.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If asymmetry is identified, we will examine possible causes.

Data synthesis

We will only carry out meta-analyses where there are studies of similar comparisons reporting the same outcomes. We will combine RRs for dichotomous data, and MDs (or SMDs where different scales have been reported) for continuous data. Our general approach will be to use a random-effects model. With this approach, the CIs for the average intervention effect will be wider than those that would be obtained using a fixed-effect approach, leading to a more conservative interpretation.
We will use an additional table to report the results from studies not suitable for inclusion in a meta-analysis.

Subgroup analysis and investigation of heterogeneity

We will carry out subgroup analyses according to:

- age: we will use the age bands used by in the British National Formulary: younger than 5 years of age, 6 to 12 years, between 12 and 16 years of age (BNF 2007);
- gender (male and female);
- planned dental treatment (e.g. restorative treatment, extractions, management of dental trauma, orthodontic treatment);
- low, moderate, or high (phobic) levels of anxiety.

Sensitivity analysis

It will not be possible to test the robustness of the results by performing sensitivity analyses based on excluding studies at unclear or high risk of bias, as studies are likely to be rated as being at high risk of bias due to lack of blinding of participants and personnel. If any meta-analyses include several small studies and a single very large study, we will undertake a sensitivity analysis comparing the effect estimates from both random-effects and fixed-effect models. If these are different, we will report on both analyses as part of the results section, and we will consider possible interpretation.

Presentation of main results

We will produce a 'Summary of findings' table for each comparison. We will use GRADE methods and the GRADEpro GDT online tool for developing 'Summary of findings' tables (GRADE 2004; GRADEpro GDT 2014). We will assess the quality of the body of evidence for each comparison and outcome by considering the overall risk of bias of the included studies, the directness

of the evidence, the consistency of the results, the precision of the estimates, and the risk of publication bias. We will categorise the quality of each body of evidence as high, moderate, low, or very low.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE Ovid search strategy

1. DENTAL ANXIETY/
2. ANXIETY DISORDERS/
3. PHOBIC DISORDERS/
4. PANIC DISORDER/
5. or/2-4
6. (dental or dentist$ or mouth$ or tooth or teeth).ti,ab.
7. 5 and 6
8. ((dental or dentist$ or mouth$ or oral) adj5 (anxiet$ or anxious$ or apprehensive$ or fear$ or fright$ or phobi$ or panic$ or (disrupt$ adj3 (behavior or behaviour)))).ti,ab.
9. 1 or 7 or 8
10. Reinforcement, verbal/
11. Patient compliance/
12. Psychotherapy/
13. Hypnosis, dental/
14. Autogenic training/
15. Behavior therapy/
16. Color therapy/
17. Music therapy/
18. Play therapy/
19. exp Mind-Body Therapies/
20. Relaxation techniques/
21. (cognitiv$ adj6 (intervention$ or therap$ or treat$ or technique$ or behaviour$ or behavior$)).ti,ab.
22. ((behavior$ or behaviour$) adj6 (intervention$ or therap$ or treat$ or technique$)).ti,ab.
23. ((auditory and distract$) or (audiovisual$ adj6 distract$) or ((visual$ or music$ or verbal$) adj6 distract$)).ti,ab.
24. (((color$ or colour$ or music$ or play$) adj6 therap$) or (verbal$ adj6 encourag$) or "positive reinforc$" or reward$ or reassur$ or "tell show do" or "show tell do").ti,ab.
25. (hypnosis or hypnotic$ or image$).ti,ab.
26. Reinforcement, positive/
27. Nonverbal communication/
28. ((non-verbal or nonverbal) adj2 communicat$).ti,ab.
29. hand-over-mouth.ti,ab.
30. Restraint, physical/
31. ((restrain$ or immobili$ or restrict$ or hold$) and physical$).ti,ab.
32. (contingent adj (distract$ or escap$)).ti,ab.
33. ((desensiti$ and psychocol$) or (relax$ adj6 (train$ or technique$ or therap$ or hypnotherap$)) or (therap$ adj6 touch$) or (massage$ or "breathing exercise$") or (model$ and psychol$)).ti,ab.
34. (desensit$ adj3 systematic$).ti,ab.
35. (visual$ adj5 pedagog$).ti,ab.
36. or/10-35
37. exp child/
38. (child$ or adolescen$ or youth$ or teen$ or preteen$ or pre-teen$).ti,ab.
39. 37 or 38
40. 9 and 36 and 39

This search retrieved 135 references from MEDLINE Ovid when combined with the Cochrane Highly Sensitive Search Strategy (CHSSS) for identifying randomised trials in MEDLINE: sensitivity-maximising version (2008 revision) as referenced in Chapter 6.4.11.1 and detailed in box 6.4.c of the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011).

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.

3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1-8
10. exp animals/ not humans.sh.
11. 9 not 10

WHAT'S NEW

Date	Event	Description
14 June 2017	Amended	Minor edit to Data synthesis section.

CONTRIBUTIONS OF AUTHORS

Robert Anthonappa: wrote the Background and Methods sections.

Paul Ashley: provided a clinical perspective.

Debbie Bonetti: provided a psychological perspective.

Guido Lombardo: wrote the Background section.

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