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[Intervention Protocol]

Interventions for treating wrist fractures in children

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ABSTRACT

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

To assess the effects (benefits and harms) of interventions for common distal radius fractures in children, including skeletally immature adolescents.

BACKGROUND

Description of the condition

The two forearm bones are the radius and the ulna. Wrist fracture is often used to describe breaks in the distal parts (roughly the distal third) of these bones. Most fractures involve the distal radius, which is the focus of this review. Sometimes they can be accompanied by an adjacent fracture of the ulna. Isolated distal ulna fractures are rare and not considered further here.

Distal radius fractures are the most common fractures in children, amounting to around a quarter to a third of all paediatric fractures (Hedström 2010). Annual incidences of 30 per 10,000 children (aged 0 to 17 years) have been reported in the US during 2009 (Karl 2015). The mean age of children (aged up to 16 years) presenting with these injuries in 2000 at two Edinburgh hospitals was 9.9 years and 55% were boys (Rennie 2007). The distribution of fractures is unimodal for both sexes (Rennie 2007); Hedström 2010 reported peaks at 11 years for girls and 14 years for boys.

Distal radius fractures most commonly result from a fall on an outstretched hand. They vary in severity, complexity and location in relation to the growth plate (physis) and the age of the child. Growth plates are areas of cartilage near the end (epiphysis) of the long bones in children and adolescents. Fractures involving the growth plate are called also physal fractures. Growth-plate fractures of the distal radius are more common in older children (Mizuta 1987). The most frequently used classification of physal injuries is that of Salter and Harris (Salter 1963).

The other three categories of paediatric distal radius fractures commonly described in the literature are: 'buckle' or 'torus' fractures; 'greenstick' fractures and complete or 'off-ended' fractures. These 'metaphyseal' fractures occur in the metaphysis, the area that lies between the shaft (diaphysis) and the growth plate.

Buckle or torus fractures involve compression of only part of the circumference of the cortex (outside part) of the bone. This results in a deformity but not a complete break in the cortex. Buckle fractures are considered stable fractures, with little risk of subsequent deformity (Macnicol 2010; Randsborg 2012; Slongo 2007). They

are by far the most common distal radius fracture (Randsborg 2012; Thimmaiah 2012).

Greenstick fractures are where the bone is broken on one side but only bent (compressed) on the opposite side. This fracture pattern occurs predominantly in the shaft and, strictly speaking, greenstick fractures are not metaphyseal fractures. However, variation in the definition of where distal forearm fractures start can mean that shaft fractures are also included. These are unstable fractures and, like buckle fractures, occur in younger children (Randsborg 2009). Complete metaphyseal fractures are fractures across the bone where both sides of the cortex are disrupted; if displaced, the fractured end fragment is usually displaced dorsally relative to the rest of the bone. These are unstable fractures.

A distal radius fracture is painful, with local tenderness and swelling. There is often deformity in the case of displaced fractures and movement restriction can result. The great majority of distal radius fractures are closed fractures, where the overlying skin and tissues are intact. Open fractures, where the bone has been exposed, are always treated as serious injuries. The presence and type of fracture is determined via X-rays. Most children are treated in emergency care or as outpatients, with around 3% being admitted to hospital (Shah 2015).

Children's bones, especially in younger children, are softer and more pliable than those of adults. This results in distinct fracture patterns in children, such as the buckle and greenstick fractures, where the bone distorts or bends rather than breaking at all or completely. Growth-plate fractures are also specific to children. Conversely, intra-articular fractures (involving disruption of the joint surface) and comminuted (multiple fragmented) fractures are rare in children (Randsborg 2012). Children's bones heal faster than adults' bones and the distal radius has a significant remodelling capacity that occurs with growth of the bone over time. This means that some residual angular deformity and displacement after the fracture has healed can be acceptable in children as the bone will return to a normal shape as it grows over the years. An angulation of 30 degrees will fully remodel within five years in young children (Wilkins 2005), but this capacity is much reduced in older children (Macnicol 2010). Growth-plate fractures of the distal radius also have a large capacity for remodelling (Wilkins 2005). Fractures may also result in overgrowth of the bone. Conversely, damage to the growth plate may result in premature growth-plate closure; this is uncommon in wrist fractures. Surgery may be required to correct deformity resulting from abnormal bone growth (Macnicol 2010; Williams 2005).

Given the preponderance of distal radius buckle fractures, the rapid healing and good remodelling capacity of children's distal forearm bones, the vast majority of children with distal radius fractures have a good prognosis with a complete recovery.

Description of the intervention

Treatment for most children with these fractures is non-surgical (Mellstrand-Navarro 2014). Non-surgical treatment primarily involves splintage ranging from support via a simple bandage to full immobilisation in a complete (encircles arm) rigid cast, that may sometimes include the elbow joint. Rigid casts are usually made from materials such as plaster of Paris or one of the forms of fibreglass. Some casts (backslabs) are incomplete, involving only part of the circumference of the arm; these are often applied initially to allow for swelling to subside. More recently, casts can be made of softer more flexible materials. Other types of non-rigid supports, often removable, consist of splints (also called orthoses). Some devices are 'off the shelf' whereas others, such as rigid casts, are 'custom-made' being tailored to the child and requiring specialist application and removal. The duration of splintage varies but is typically around three weeks for stable fractures.

When fractures are displaced beyond a tolerable limit (see [How the intervention might work](#)), closed reduction, where the displaced parts are manipulated through the skin to restore the correct anatomy, is generally performed. Reduction is usually performed under sedation with analgesia, regional anaesthesia or general anaesthetic. Most fractures can be reduced closed and this reduction will be followed by immobilisation in a suitably rigid cast for four to six weeks. In other cases, surgical fixation of the fragments is performed, to prevent re-displacement in the cast (Proctor 1993). This usually comprises percutaneous pinning, where one or two wires are inserted through small incisions in the skin into the bones to secure the bones and stabilise the fracture. This is followed by splintage, typically cast immobilisation.

Surgical open reduction of children's distal radius fractures is rarely performed, being reserved for the most serious and rare injuries such as open fractures, neurovascular injuries and complex intra-articular fractures.

Metalwork inserted into children's distal radius fractures is generally removed. Percutaneous wires are mostly left outside the skin to facilitate removal in the clinic. If buried, a further anaesthetic is required for removal.

Aside from visits to a fracture clinic for monitoring purposes and for removal of rigid casts, children do not usually need rehabilitation interventions, such as physiotherapy. Longer-term follow-up may be recommended for displaced growth-plate fractures to check that growth is proceeding normally.

How the intervention might work

The choice of intervention is influenced primarily by an assessment of the stability and the degree of displacement of the distal radius fracture, taking into account the age of the child and the potential for remodelling. In particular, the concept of tolerable displacement (angulation or linear displacement, or both) is useful in children's fracture practice; it describes an amount of displacement that will reliably remodel to a normal shaped and sized bone (Schneidmüller 2011).

For stable fractures, predominantly buckle fractures, the main aim of treatment is pain relief and protection, including from re-injury. This can be provided with a variety of devices such as a simple bandage, a wrist brace or orthosis, a backslab or a complete cast. One key issue is whether a rigid cast is required or whether it represents over-treatment. Other types of support, which can often be removed at home, may be preferable in terms of convenience and cost-saving. Attendance for removal of casts and the need for routine follow-up are additional considerations in the management of these minor fractures.

All splints aim to hold the fracture in place while healing occurs. They also provide pain relief and protection from further injury. However, rigid casts are cumbersome and inconvenient; in particular, casts need to be kept dry. There is a risk of complications, such as skin problems, especially from poorly fitted casts. The removal of casts using a cast saw can be distressing; injuries are rare, even if a source of litigation (Atrey 2010). There is often short-term stiffness of immobilised joints upon cast removal. The inclusion of the elbow in above elbow casts increases this risk, but may enhance fracture stability for more unstable fractures. Extent and position of cast immobilisation are sources of variation in practice (Webb 2006).

Unstable fractures, whether undisplaced or minimally displaced initially or following reduction or surgery, are considered to require immobilisation to prevent later displacement and deformity. As well as rigid casts made from plaster of Paris or fibreglass, softer casting materials may be used when reinforced at vital points in the cast. Likewise, splints could be used if specifically designed for preventing displacement. A preliminary plaster backslab may be applied to allow for swelling to subside.

Closed reduction of the displaced (angular or translated) fracture aims to restore the anatomy of the bone. While painful and often requiring anaesthesia, closed reduction may reduce deformity and restore function. However, given the remodelling capabilities of younger children's bone, reduction of less severe angulation or translation may be unnecessary for a successful long-term outcome. Indeed, tolerable displacement may be very extensive; full dorsal displacement of a distal radius fracture in a child aged under 10 years can be successfully treated by immobilisation without reduction because of reliable modelling of the radius (Crawford 2012). However, the extent of what is 'acceptable' deformity will also depend on child, parental and clinician perception, even if eventual correction through remodelling is very likely.

When deemed necessary for stability, supplemental surgical fixation involving metalwork also comes at the risk of complications, such as infection and iatrogenic injuries to nerves, tendons and blood vessels. Wire removal (unless buried) is usually done in a fracture clinic at the same time as removal of the plaster cast. The indications for closed reduction or metalwork insertion (or both) in the context of the good healing and remodelling capabilities of children's distal radius bones are sources of debate (Crawford 2012; Proctor 1993).

Why it is important to do this review

Although distal radius fractures in children have a good prognosis and the vast majority can be treated without surgery, the societal impact is huge given the large numbers involved. The National Institute for Health and Care Excellence (NICE) guidelines published in 2016 estimated that buckle fractures "account for an estimated 500,000 emergency department attendances a year in the UK" (NICE 2016). As well as affecting the child, the impact, including financial, on families can be considerable where caring for the injured child or attendance at hospital requires time off work or making other arrangements (Morris 2006).

There is also considerable variation in practice, such the use of removable splints versus casts for buckle fractures in Canada (Boutis 2014), and of different types of removable splints and bandages in the UK (NICE 2016).

A previous Cochrane Review on this topic, which searched the literature up to October 2007, included 10 trials involving 827 children (Abraham 2008). It reported finding only "limited evidence" to inform on the use of removable splintage for buckle fractures, and on the use of above-elbow casts and use of surgical fixation with percutaneous wiring for displaced fractures. NICE 2016, which searched up to April 2015, reported finding only low or very low quality evidence to inform management decisions for buckle fractures and concluded that the "evidence suggested that soft casts and bandaging were probably the optimal approaches out of the four [bandage, softcast, removable splint and rigid cast] considered." Given the suggested limitations in the evidence so far, it is important to produce an update of the evidence for buckle and other distal radius fractures in children to inform practice and the research agenda.

OBJECTIVES

To assess the effects (benefits and harms) of interventions for common distal radius fractures in children, including skeletally immature adolescents.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials and quasi-randomised controlled trials (method of allocating participants to a treatment that is not strictly random, e.g. by hospital number) that assess interventions for treating distal radius fractures in children.

Types of participants

We will include trials of children with an open distal radius physis who are being treated for an acute distal radius fracture with or without ulna fracture. This will also include skeletally immature adolescents (typically aged under 16 years) with these fractures. This review will focus on the more common types of these fractures. We do not plan to include Galeazzi fractures, which are fractures of the distal radius with disruption of the distal radio-ulnar joint.

While we will exclude trials exclusively on forearm diaphyseal (shaft) fractures, some consideration will be given to the inclusion of mixed populations (shaft and distal radius fracture) in the context of the comparison under test and relative proportions of the two types of fracture.

Types of interventions

We will include all trials testing conservative treatments such as rigid non-removable casts (plaster of Paris; fibreglass) and removable splints, and surgery, primarily involving wire fixation. In setting out comparisons of conservative splintage or casts, our general rule will be to make the control group the more traditional treatment, which typically will be the more cautious and restrictive intervention such as rigid plaster casts.

Our main comparisons will be:

- non-rigid or removable splintage (e.g. splints, non-rigid complete cast, backslab or bandages) or 'no splintage' (analgesia only) versus rigid complete casts for treating buckle and minimally displaced (stable) fractures. Individual trials in the category are likely to compare single interventions such as bandage versus below-elbow cast. We will categorise these into different sub-comparisons under the umbrella comparison;

- bandages and 'off the shelf' removable splints versus backslab and other custom-made devices that require specialist application for treating buckle and minimally displaced (stable) fractures. We will stratify by the different types of splintage in the two categories tested in the individual trials;

- below-elbow versus above-elbow casts after reduction of displaced fractures;

- closed reduction, wire fixation and immobilisation versus closed reduction and cast alone for the treatment of displaced fractures.

Secondary comparisons will include the following and any other comparisons of definitive treatment (splints, closed reduction, surgical fixation) tested by randomised controlled trials identified via the search:

- different types of non-rigid splintage, including 'no splintage', for buckle and other stable fractures;

- different durations of cast or splint immobilisation (longer duration will be the control group);

- rigid casts of materials other than plaster of Paris versus plaster of Paris casts;

- above elbow casts with forearm in supination versus neutral versus pronation;

- removal of splintage at home versus at fracture clinic; this may link with delivery of care methods: optional consultation versus fixed formal follow-up at fracture clinic;

- different methods of percutaneous pinning (wire fixation).

We will not include trials comparing different methods of anaesthesia, analgesia or diagnosis.

Types of outcome measures

Primary outcomes

- Physical function using validated measures, such as the Activities Scale for Kids (performance version) (Young 2000), or Paediatric Outcome Data Collection Instrument (PODCI) (Daltroy 1998).

- Treatment failure (composite outcome defined as either the need for a second procedure (further immobilisation, reduction or surgical intervention) or the presence of a symptomatic malunion/unacceptable anatomy (deformity)).

- Serious adverse effects (these are partly comparison dependent): major sustained loss of elbow or wrist (or both) range of movement, infection, nerve or tendon injury, complex regional pain syndrome type 1, compartment syndrome.

Secondary outcomes

- Time to return to normal activities (or interim stages of recovery).

- Wrist pain (visual analogue scale or Faces Pain Scale (Bieri 1990)).

- Minor complications (e.g. short-term wrist or elbow stiffness; skin breakage) and non-routine treatment adjustments (e.g. cast slippage).

- Child (and parent) satisfaction with outcome.

- Child (and parent) satisfaction with treatment; this may be collected in response to the question of whether they would choose the same treatment again.

We will consider grouping outcomes under short-term (less than three months), medium-term (three months to less than 12 months) and longer-term (12 months or longer) follow-up.

We will also record resource use (e.g. number of outpatient visits and routine cast changes; duration of hospitalisation), other costs and findings of included trials reporting cost-effectiveness analysis.

Search methods for identification of studies

Electronic searches

We will search the Cochrane Bone, Joint and Muscle Trauma Group's Specialised Register (to present), the Cochrane Central Register of Controlled Trials (CENTRAL) (current issue), MEDLINE (1946 to present) and Embase (1980 to present). We will also search the [World Health Organization International Clinical Trials Registry Platform Search Portal](#) (WHO ICTRP) and [Clinicaltrials.gov](#) for ongoing and recently completed trials (to present).

In MEDLINE, we will combine subject-specific terms with the sensitivity-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying randomised trials ([Lefebvre 2011](#)) ([Appendix 1](#)). This strategy will be modified for use in CENTRAL and Embase.

We will not apply any language or publication restrictions.

Searching other resources

We will check the reference lists of articles, including guidelines ([NICE 2016](#)) and a previous Cochrane Review ([Abraham 2008](#)). We will search abstracts of the [American Academy of Orthopaedic Surgeons](#) (AAOS) annual meetings, the [Orthopaedic Trauma Association](#) (OTA) annual meetings, the [Bone and Joint Journal \(BJJ\) Orthopaedic Proceedings](#), the [British Society for Surgery of the Hand](#) and the [British Trauma Society](#) (BTS) annual scientific meetings.

Data collection and analysis

Data collection and analysis will be done in accordance with methods specified in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)).

Selection of studies

Two review authors (JE and ZIE) will independently screen all titles and abstracts for potentially eligible studies, for which we will obtain full-text reports where appropriate. The same two review authors will independently perform study selection. Any disagreements regarding the inclusion or exclusion of individual studies will be resolved by discussion or, if necessary, by consulting a third review author (HH or AK). We will contact authors of articles published since 2006 where clarification is required to inform study selection. The final study selection decisions will be discussed among all review authors to ensure a consensus. There will be no masking of the source and authorship of the trial reports.

Data extraction and management

Pairs of review authors will perform independent data extraction of the included trials using a piloted data collection form. The data

collected will include information on study design, study population, interventions and outcomes measurement, and results. Any discrepancies in data extraction will be resolved either by discussion between the two authors or with involvement with another review author. Two review authors (JE and ZIE) will enter initial data into Review Manager 5 ([RevMan 2014](#)).

Assessment of risk of bias in included studies

Pairs of review authors will perform independent risk of bias assessment of the same included trials that they collected data for. We will use the Cochrane 'Risk of bias' tool ([Higgins 2011](#)). Inter-rater differences will be resolved by discussion or by involvement by a third review author. We will assess the following domains:

- random sequence generation;
- allocation concealment;
- blinding of participants and personnel;
- blinding of outcome assessment;
- completeness of outcome data;
- selective reporting;
- other sources of bias.

We will consider subjective and functional outcomes (e.g. physical function, pain, satisfaction) and 'hard' outcomes (complications, treatment failure) separately in our assessment of blinding and completeness of outcome data. We will assess two additional sources of other bias: bias resulting from major imbalances in key baseline characteristics (e.g. age, gender, type of fracture); and performance bias such as resulting from lack of comparability in the experience of care providers.

Studies will be judged to be at 'high', 'low' or 'unclear' risk of bias for each domain assessed. We will judge the risk of bias across studies as follows:

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

Measures of treatment effect

For dichotomous outcomes, we will express treatment effect as risk ratios (RR) and 95% confidence interval (CI) and present continuous outcomes as mean differences (MD) and 95% CI. Where studies report the same continuous outcome measured in different ways or scales, we plan to use the standardised mean difference (SMD) when pooling their data. For continuous outcomes, we will present final scores in preference to change scores.

Unit of analysis issues

We anticipate that the individual child will be the unit of randomisation and analysis, and that children with bilateral distal radius fractures will be very rare. Should unit of analysis issues arise from the inclusion of many children with bilateral fractures and where appropriate adjustments have not been made, we will conduct sensitivity analyses to explore the potential effects of the incorrect analysis, including where pooled with data from other trials, where practical. We will be alert to the unit of analysis issues relating to outcome reporting at different follow-up times and the presentation of outcomes, such as total complications, by the number of outcomes rather than participants with these outcomes.

Dealing with missing data

We will contact study authors of reports available since 2006 for missing data, such as for missing denominators and standard deviations. We will use intention-to-treat analysis where possible. Where feasible, we will calculate missing standard deviations from other data (standard errors, 95% CIs, exact P values). We will not impute missing standard deviations. We will note any instances where data have been extracted from graphs.

Assessment of heterogeneity

The decision to pool the results of individual studies will depend on an assessment of clinical and methodological heterogeneity. If we consider studies sufficiently homogeneous for data pooling, we will assess statistical heterogeneity by visual inspection of the forest plots, and using the Chi^2 test with a significance level at P value less than 0.1 and the I^2 statistic. We will base our interpretation of the I^2 statistic results on those suggested by Higgins 2011 (Section 9.5.2):

- 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 (very substantial) heterogeneity.

Assessment of reporting biases

We will attempt to reduce the impact of reporting bias by conducting an extensive literature search that includes inspection of unpublished trials, including conference abstracts and trial registries. If there are more than 10 studies included in a meta-analysis, we will explore potential publication bias by generating a funnel plot. The magnitude of publication bias will be initially determined by visual inspection of the asymmetry of the funnel plot. If this appears asymmetric, we will perform a linear regression of intervention effect estimate against its standard error, weighted by the inverse of the variance of the intervention effect estimate (Egger 1997). A P value of less than 0.1 could be an indication of a publication bias or small-study effects.

Data synthesis

Where appropriate, we will pool results of comparable studies using both fixed-effect and random-effects models. We will decide the choice of the model to report by careful consideration of the extent of heterogeneity and whether it can be explained, in addition to other factors, such as the number and size of included studies. We will use 95% CIs throughout. We will consider not pooling data where there is considerable heterogeneity (I^2 statistic value of greater than 75%) that cannot be explained by the diversity of methodological or clinical features among trials. Where it is inappropriate to pool data, we will still present trial data in the analyses or tables for illustrative purposes and report these in the text.

Where possible, we will stratify by basic fracture type where trial populations include several categories of distal radius fracture. Similarly, we will stratify by different categories of splintage or 'no splintage', where appropriate.

Subgroup analysis and investigation of heterogeneity

To investigate the influence of effect modifiers on results, we plan the following subgroup analyses where sufficient data are available.

- Type of fracture - this will depend partly on the comparison. Subgroups will be:
 - incomplete metaphyseal fractures (buckle and torus);
 - undisplaced complete metaphyseal fractures (this may contain some fractures classified by authors as 'greenstick');
 - displaced complete metaphyseal fractures (this may contain some fractures classified by authors as 'greenstick');
 - physeal fractures (Salter-Harris 1 and 2);
 - articular fractures (Salter-Harris 3 and 4).
- Fracture of distal radius only versus fracture of distal radius and associated ulna fracture.
- Age: up to five years, six to 10 years and over 11 years.
- Different categories of splintage, including 'no splintage'.

This will depend on the comparison. We envisage that the categorisation for the intervention group for the first comparison will be 'no splintage', bandage, softcasts, and removable splints.

We will investigate whether the results of subgroups are significantly different by inspecting the overlap of CIs and performing the test for subgroup differences available in Review Manager 5 (RevMan 2014).

Sensitivity analysis

We will undertake sensitivity analyses to assess whether the results of the review are robust to the decisions made during the review process. We plan to examine the effects on the review findings of:

- excluding trials at high or unclear risk of bias, either overall or selection bias reflecting inadequate or lack of allocation concealment;
- excluding trials reported in abstracts only;

- excluding trials not reporting radiographic confirmation of buckle or other undisplaced fractures;
- excluding mixed population trials with data from radial shaft fractures;
- adjusting for missing data (to be detailed at the review stage);
- different interpretations of data where there are potential or known unit of analysis issues; and
- using fixed-effect versus random-effects models for pooling.

We will report any sensitivity analyses in the text and, if numerous, by producing summary tables.

Assessing the quality of the evidence and 'Summary of findings' tables

We will use the GRADE approach to assess the quality of evidence related to all outcomes listed in the [Types of outcome measures \(Schünemann 2011\)](#). The four levels of evidence certainty are 'high', 'moderate', 'low' or 'very low'. Quality may be downgraded due to study limitations (risk of bias), imprecision, inconsistency, indirectness or publication bias.

Where there is sufficient evidence, we will prepare 'Summary of findings' tables for our main comparisons; these will present the results for each primary outcome and first three listed secondary outcomes. We will present functional outcome at short-term and either medium- or long-term depending on data availability. Two review authors will independently produce 'Summary of findings' tables using the GRADEpro GDT software ([GRADEpro GDT 2015](#)).

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* Indicates the major publication for the study

APPENDICES

Appendix I. Search strategies

MEDLINE (Ovid Online)

1 Radius Fractures/ or Ulna Fractures/

2 (distal or metaphys* or epiphys* or torus or wrist).tw.

3 1 and 2

4 Wrist Injuries/ or Forearm Injuries/

5 exp Fractures, Bone/

6 fracture*.tw.

7 5 or 6

8 4 and 7

9 (ulna* or radius or radial or forearm*).tw.

10 2 and 7 and 9

11 (wrist* or buckle or torus).tw.

12 7 and 11

13 3 or 8 or 10 or 12

14 (infan* or newborn* or new-born* or perinat* or neonat* or baby or baby* or babies or toddler* or minors or minors* or boy or boys or boyfriend or boyhood or girl* or kid or kids or child or child* or children* or schoolchild* or schoolchild or school child* or adolescen* or juvenil* or youth* or teen* or pubescen* or pediatric* or paediatric* or peadiatric* or school* or prematur* or preterm*).mp,jn.

15 13 and 14

16 Randomized controlled trial.pt.

17 Controlled clinical trial.pt.

18 randomized.ab.

19 placebo.ab.

20 Drug therapy.fs.

21 randomly.ab.

22 trial.ab.

23 groups.ab.

24 or/16-23

25 exp Animals/ not Humans/

26 24 not 25

27 15 and 26

Line 14: modified version of the paediatric search filter developed and validated by [Leclercq 2013](#)

Lines 16-26: sensitivity-maximising version of the Cochrane Highly Sensitive Search Strategy for identifying randomised trials ([Lefebvre 2011](#))

CONTRIBUTIONS OF AUTHORS

HH initiated the protocol and wrote the first draft of the background and inclusion criteria. HH is the guarantor of the protocol.

JE developed the search strategy and drafted the search methods section.

ZIE wrote the first draft of the methods section.

AK and JH provided clinical oversight and revised the protocol for clinical content.

All authors commented on early drafts and approved the final version.

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All authors have no interests to declare.

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