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ORIGINAL RESEARCH

Measuring children's distress during burns dressing changes: literature search for measures appropriate for indigenous children in South Africa

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Background: Virtual reality is consistently reported as effective in reducing pain and anxiety in children during burns dressing changes in recent Western studies. Pain scales are a commonly reported outcome measure. Virtual reality is persuasive for all children in distress during medical procedures, because it is a nonaddictive, novel, and inexpensive form of distraction which can be applied repeatedly with good effect. We intend to use virtual reality in South Africa for the many children hospitalized with severe burns from mechanisms rarely seen in the Western world (paraffin/kerosene stoves exploding, electrical fires, shack/township fires, boiling liquid spills). Many severely burnt children are indigenous South Africans who did not speak English, and whose illiteracy levels, cultures, family dynamics, and experiences of pain potentially invalidate the use of conventional pain scales as outcome measures. The purpose of this study was to identify objective measures with sound psychometric properties and strong clinical utility, to assess distress during burns dressing changes in hospitalized indigenous South African children. Choice of measures was constrained by the burns dressing change environment, the ethics of doing no harm whilst measuring distress in vulnerable children, and of capturing valid measures of distress over the entire burns dressing change procedure.

Methods: We conducted two targeted systematic reviews of the literature. All major library databases were searched, and measures with strong psychometric properties and sound clinical utility were sought.

Results: Seven potentially useful measures were identified, ie, child's and caregivers' heart rate, which was measured continuously throughout the procedure, observed physical manifestations of distress using different scales (FLACCs [Face, Legs, Activity, Cry, Consolability Scale] and/or Pain Behavior Checklist), time taken, and number of staff required to complete the procedure, and staff perspectives on the ease of use of the procedure.

Conclusion: These psychometrically sound, clinically useful measures are alternatives to conventional pain scales, and should support valid research into the effectiveness of virtual reality for illiterate children with non-Western cultures and languages.

Keywords: children, burns, distress, anxiety, pain, validity, measurement

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Introduction

This paper outlines the rationale for choosing outcome measures to assess the effectiveness of virtual reality for children with burns undergoing dressing changes at the Red Cross Children's Hospital (RCCH) in Cape Town, South Africa. We have previously reported a profile of burns inpatients at the RCCH.[1] Over 600 children up

to 15 years of age are admitted to the RCCH annually with burns from hot water, explosions, or fires. The criterion for admission to the RCCH is a burn greater than 10% of total body surface area, although all burns involving inhalation, electrical injuries, or face, hands, perineum, or body circumference are admitted. Approximately 1000 other children are treated each year as outpatients. Many burns require extensive skin grafting from nonburnt body parts. Most inpatients are indigenous Xhosa-speaking South African children who, along with their parents, are often poorly educated and illiterate, with minimal exposure to computers. Their home lives are often violent, and they suffer significant impact from human immunodeficiency virus/acquired immune deficiency syndrome, poverty, and community disintegration.[2,3]

The burns treated at the RCCH are rarely seen in the Western world where building standards, occupational health and safety legislation, child protection legislation, and product design have all but eliminated pediatric burns hazards.[1–3] However, in the informal South African townships, many thousands of children live in poorly built shacks with no electricity, running water, or sanitation, with unprotected open-flame cooking, heating, and lighting.[4] Similar situations are reported in other developing countries, including Africa, India, and Southeast Asia.[5–7]

Most burns patients at the RCCH endure serial painful, and prolonged wound dressing changes to prevent infection and promote healing. These procedures can last up to 40 minutes.[1] Despite the standard use of opioid and anxiolytic pharmacological interventions, many children still suffer high levels of distress[8–11] which commence prior to and throughout the burn dressing change. Parents sometimes accompany children to the treatment room and then wait outside, thus becoming partly involved in the procedure. The RCCH has a small contingent of dedicated nurses who undertake daily burns dressings. The children's distress is frequently manifested by extreme behaviors, such as fighting, biting, kicking, and resisting these nurses, as well as screaming and crying. This can hinder efficiency by making the procedure longer and more distressing for everyone involved, and requiring more nursing staff.

A bath bed with a mobile shower head is used for most dressing changes (Figure 1). The dressing change consists of three parts (Figure 2). Firstly, removal of the soiled burn wound dressing (Part 1), secondly, showering and debridement (Part 2), and, lastly, redressing (Part 3). When the child has multiple burnt areas and/or skin grafts, dressings may be changed at two or more sites simultaneously. Nursing staff often need to restrain children physically during the first two parts of the procedure.

Figure 1 A bath bed with a mobile shower head is used for most dressing changes at the Red Cross Children's Hospital in Cape Town, South Africa.

The management of distress in pediatric burns patients is an ongoing challenge. Children who are very anxious prior to a dressing change generally experience greater distress, and if the procedure is repeated, distress levels escalate.[11–13] This makes it difficult to estimate adequate analgesic requirements and to measure distress.[8–15] It is acknowledged worldwide that medication management for painful medical procedures in children could be improved.[14,15]

Our recent systematic review[16] reported consistent evidence that virtual reality successfully distracts adult and adolescents from the reality of burns dressing changes. There is some evidence that virtual reality is similarly effective in Western world children during painful medical procedures,[17–24] including children with burns.[21–24] The burns described in these papers[21–24] were less extensive than the ones for which children are admitted to the RCCH, and consequently the dressing changes were not as complex or lengthy. Given the Western world environment of the research, it is likely that the children were computer-literate and familiar with computer games.[21–24] In all the virtual reality research, subjects acted as their own controls, to address the within-subject nature of pain perception.[1–3]

Figure 2 The three parts of a burn dressing change procedure. Part 1: removal of the soiled burn wound dressing. Part 2: showering and debriding the wound. Part 3: application of new dressings (ointment and bandages). Photographs taken at the Red Cross Children's Hospital in Cape Town, South Africa.

We wanted to test the effectiveness of virtual reality at RCCH for burns inpatients aged 5 years or older. Our experiences, and the virtual reality literature, suggest that virtual reality games could provide an important nonpharmacological distraction to decrease children's distress prior to and during wound dressing procedures.

It is essential that we establish valid measures of distress as outcomes for any virtual reality trial at the RCCH. This is a challenge for a number of reasons. Children's education, literacy, home environments, pain-reporting culture, and indigenous languages make it unlikely that they will understand the notion of numeric, pictorial, or analog pain scales which are reported in current pediatric virtual reality research.[21–24] The children would also need to act as their own controls, hence the measures should be reliable within-child over repeated administrations. Furthermore, the children's distress is likely to be multifaceted and variable throughout each dressing change, related to its regularity and unavoidability, seeing their burnt bodies uncovered, posttraumatic stress related to the burn event, and the frequent absence of parents/caregivers.[11–15] Thus, we hypothesized that unidimensional abstract pain scales may not capture the complexity of the children's distress. Different levels of distress are likely to be associated with each phase of the dressing change. Therefore, children's distress may fluctuate, making it difficult to pinpoint a moment of "worst" or "average" distress (the usual instruction when using visual analog scales). Many children are reported by staff to be so traumatized that it seems unethical to ask them directly to quantify their distress.[11–13] Children are not the only participants in the dressing change procedure. Nursing staff and parents/caregivers will also have important insights into children's behaviors.

We thus established a framework within which to identify potentially useful outcome measures for our virtual reality research:

- Participants – perspectives of the child, parents/caregivers, and nursing staff should be measured regularly (for instance at every dressing change)
- Research requirements – objective measures of pediatric distress which were psychometrically sound, clinically sensitive, and could be ethically and efficiently administered in contained physical spaces
- Comprehensiveness – a suite of measures was needed to capture the range and complexity of children's distress appropriately, and the impact of this on a dressing change.

Methods

The research design included two targeted literature reviews. The first literature review comprised published studies on the use of virtual reality for children with procedure-related pain, using the search terms "virtual reality", "p(a)ediatric(s)", "children", and procedure-related pain. We used Morris et al[16] as a starting point, because the authors identified and critiqued all relevant studies on the use of virtual reality with pediatric patients up to January 2009. We conducted a further search for new literature published from that date to December 2010. We did not review the more recent literature for study quality, because we were only interested in how distress had been measured. The second literature review searched for recently published secondary evidence describing outcome measures for pediatric pain, using the broad search terms of "p(a)ediatric procedural pain/distress/anxiety" to interrogate the common library databases (Ovid, PubMed, MEDLINE) for recent systematic reviews assessing the psychometric properties and clinical utility of outcome measures of pediatric pain, anxiety, and distress. We sought secondary evidence because it would provide an overview of the types of outcome measures available, the pediatric populations in which these measures had been developed, and the quality of the included studies. We used the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement to assess the methodological quality of the included reviews.[26] For data extraction, we listed the outcome measures recommended in the reviews, and sought further information about their developmental details to assess their appropriateness for 5- to 17-year-olds. For analysis, we developed matrices to record the elements of potentially relevant outcome measures for our research framework (research requirements, participants, and comprehensiveness.

Results

In our first literature review, we identified the review by Morris et al[16] as being of high methodological quality (PRISMA 14, Appendix 1). It identified five studies which included at least some children in our age range of interest (5–17 years), as shown in Table 1. Our search for more recent literature identified three further relevant studies[18,19,25] (Table 1). The most common method for measuring effectiveness of virtual reality in pediatric distress was the use of subjective scales (mostly variations on the visual analog scale) to measure pain, anxiety, and/or distress. In our second literature review, we found two relevant recent reviews of pediatric pain assessment measures[27,28] and two focused

Table 1 Studies identified on the use of virtual reality in pediatric patients (aged 5–17 years), taken from Morris et al[16] and additional literature searches

Study	Age group	Outcome measures
Morris et al[16]		
Das et al[21]	6–16 years	Pain measured by FACES pain scale and visual analog scale
Chan et al[22]	Mean age 6.54 years	Pain measured by FACES pain scale, usability, and modified presence questionnaire
Van Twillert et al[20]	8–65 years	Pain and anxiety measured by visual analog thermometer and Spielberger State-Trait Anxiety Inventory Scale
Sharar et al[23]	6–65 years	Pain measured by 10 point Graphic Rating Scale
Hoffman et al[24]	9–40 years	Pain measured by 10 point Graphic Rating Scale
Additional studies		
Hoffman et al[18]	Two cases (16 and 17 years)	100 mm scales capturing sensory and affective pain ratings, anxiety and subjective estimates of time spent thinking about pain during the procedure
Hoffman et al[19]	9–32 years	Visual analog scales to assess: • Time spent thinking about pain • Unpleasantness • Bothersomeness • Worst pain • Average pain
Mott et al[25]	3–14 years	Pain scores Pulse rates Respiratory rates oxygen saturations recorded preprocedurally, at 10-minute intervals and postprocedurally. Parents graded their child's overall pain score for the dressing change

reviews commissioned by the Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (Ped-IMMPACT, a children's self-report of pain[29] and observational measures of children's pain).[30] The methodological quality of these reviews ranged from 1–14. The PRISMA critical appraisal criteria and relevant scores are shown in Appendix 1.

The reviews differed in scope and purpose, although all used the Society of Paediatric Psychology Assessment Task Force criteria reported by Cohen et al,[28] and all framed the reports of outcome instruments using terminology of "well established", "approaching well-established", and "promising". "Well established" measures were supported by two or more peer-reviewed articles, with sufficient detail in the article to allow replication and evaluation, and psychometric properties were reported in at least one published paper. We extracted information only on those instruments which were reported to be "well established". There was congruence between the reviews in terms of the outcome measures which were reported to be "well established".

With regard to assessment options, three main methods were reported to assess children's pain, anxiety, and distress, ie, self-reported measures from children, observed behaviors using checklists or classifications of distress behavior underpinned by numeric rating scales reported by parents or health care workers, and objective physiological measures.

Children's self-reports

The reviews synthesized a large amount of primary literature, which indicated that children's self-reports of pain using one-dimensional numeric or analog scales, or diagrams (such as a series of faces), are valid and reliable within-child. Such scales are commonly reported in virtual reality research.[1,18,19,25] However, the self-report instruments were developed on procedural pain suffered by children in the Western world undergoing injections or invasive medical procedures, mostly for cancer. They were assumed to be valid for pediatric burns patients undergoing dressing changes. The scales were generally one-dimensional, which would potentially be insensitive to the gamut of a child's emotions experienced during the multistage burns dressing change process. Thus, all the measures reviewed by Stinson et al,[29] as well as the subjective measures reported by Cohen et al[28] (visual analog scale,[32] OUCHER,[33] and FACES[34] scales, and the Poker Chip tool)[35] were unlikely to be appropriate for research in our environment.

These reviews consolidated our earlier concerns regarding how to apply such scales at the RCCH, particularly in light of Cohen et al[28] who suggested that "pain assessment is limited because of racial and ethnic difference".

Observed behaviors

The reviews reported instruments which purported to classify and score children's observed behaviors related to their distress. Observed behaviors could be measured by research staff or nurses, and some instruments asked for parent/caregiver or nurse perspectives on children's behaviors.

Von Baeyer and Spagrud[30] reported three well-developed observational scales which used video to capture real-time information on distress during a medical procedure and then assessment of the video post-treatment to quantify distress

(Observational Scale of Behavioral Distress Scale,[36] Behavioral Approach-Avoidance and Distress Scale,[37] and Brief Behavioural Distress Scale).[38] Table 2 outlines the "well established" measures of distress identified from the review. These were extracted from Cohen et al,[28] Von Baeyer and Spagrud,[30] and Blount and Loiselle.[27,39–44]

Objective measures

Heart rate was reported by Chalmers et al[45] as a measure of children's pain in an experimental pain paper. The use of heart rate was also reported in the COMFORT scale,[14] which provides classifications for continuous heart rate data to identify physiological stress. A number of process-based objective measures of the dressing change were noted but not specifically explored in the literature. Two which appeared to be appropriate to our study were the time taken to complete the dressing change and the number of nursing staff required to complete the dressing change.

Discussion

Our literature review showed that we could not immediately adopt any one measure with which to assess the effectiveness of virtual reality on children's distress at the RCCH burns unit. Our review framework of participants, research requirements, and comprehensiveness allowed us to consider the specific requirements of our research in our subjects in the burns dressing change environment. However, there were a number of potentially useful objective measures (see Table 3).

Children's self-report

We had already discounted the validity of self-reported pediatric distress using visual analog scales on cultural, ethical, and linguistic grounds, and with regard to the practical difficulties of identifying "worst" or "average" pain during the three-phase, often lengthy, dressing change procedure.

Children's observed behaviors

The physical treatment room environment at RCCH is too small to accommodate video equipment. We believed that it would be problematic to obtain ethical approval to retain copies of sensitive footage for long-term research use, given the extensive nature of the children's burns, their state of undress during the dressing change, and parents' religious and cultural beliefs regarding photographs.

The Varni-Thompson questionnaire,[31] Premature Infant Pain Profile,[42] Parents' Postoperative Pain Measure,[44] and COMFORT[14] scales were not relevant to our pediatric population or dressing change environment, and therefore were not considered further. Whilst the Observational Scale of Behavioral Distress[36] is well reported and has previously been used for burns research,[46] we concur with Von Baeyer

Table 2 Scales used to measure observed behaviors, extracted from Cohen et al,[28] Von Baeyer and Spagrud,[30] and Blount and Loiselle[27]

Scale	Application	Type	Cohen et al[28]	Von Baeyer and Spagrud[30]	Blount and Loiselle[27]
Varni/Thompson[31]	Chronic pain intensity, location, pain qualities via self-report and parent/doctor proxy report	Questionnaire	√		
Observational Scale of Behavioral Distress[36]	Procedural pain and distress	Video and later scoring of distress behaviors	√	√	√
Child-Adult Medical Procedure Interaction Scale[39]	Behavioral distress in children associated with medical procedures	Video and transcripts of conversations scored later for distress behaviors	√		√
Procedure Behavior Checklist[40]	Pain-related distress, fear, and anxiety during medical procedure	Observation	√	√	√
Children's Hospital of Eastern Ontario Pain Scale[41]	Procedural pain	Observation	√	√	√
Premature Infant Pain Profile[42]	Not relevant	Observation	√		
COMFORT[14]	Critical care settings	Observation	√	√	√
Face, Legs, Arms, Cry, Consolability[43]	Postoperative and procedural pain in hospital	Observation		√	√
Parents' Post-Operative Pain Measure[44]	Postoperative pain at home			√	

Table 3 A list of potential measures of distress to assess the effectiveness of virtual reality during burns dressings in pediatric patients

	Child	Parent	Health care provider
Perspectives on pain experienced	CAMPIS-SF	Proxy reports FACES scale or other visual analog	Ease of completing dressing change Comparison of individual child behaviors compared with "usual" for similar children/similar burns CAMPIS-SF
Classifications, types, and frequencies of behavior			FLACC PBCL
Objective measures	Heart rate	Heart rate	Time taken for procedure to be completed Number of staff required

Abbreviations: CAMPIS-SF, Child-Adult Medical Procedure Interaction Scale-Short Form; FLACC, Face, Legs, Arms, Cry, Consolability; PBCL, Procedure Behavior Checklist.

and Spagrud[30] that it poses too large a burden for regular use in our setting, particularly considering the physical limitations of the environment, and the cultural and religious contexts of videoing these children whilst in distress. We similarly discounted the CAMPIS (Child-Adult Medical Procedure Interaction Scale).[39] However, the CAMPIS-Short Form (SF) scale[39] was potentially useful. This scale has been validated by comparing it with the Observational Scale of Behavioural Distress[36] and the Behavioral Approach-Avoidance and Distress Scale.[37] The CAMPIS-SF scale involves an independent observer recording four dimensions of children's and caregivers' responses to the child's distress in relation to a medical procedure. The instrument uses a five-point Likert scale for rating the frequency of each dimension over the total observation period, ie, none or one (1), minimal or few (2), moderate or adequate (3), substantial or considerable (4), and maximum or nearly continuous (5). The child dimensions are coping and distress, and the caregiver dimensions are coping-promoting and distress-promoting. However, the development and validation of the CAMPIS-SF was based on procedural pain associated with injections, and thus this scale may not capture the extent of distress during burns dressing change procedures at the RCCH. Thus, we also discounted this instrument. Three possible observational outcome instruments remained (see Table 2).

The Procedure Behavior Checklist (PBCL)[40] was initially developed for children aged 6–18 years. It uses eight behaviors to evaluate medical procedure-related pain and anxiety. The reviews included in this research universally reported this instrument to have sound psychometric properties. It has been used in interventional studies of different procedures (bone marrow aspiration, lumbar puncture, radiation therapy, and immunization). The behaviors comprise muscle tension, screaming, crying, restraint used, pain verbalized, anxiety verbalized, verbal stalling, and physical resistance. An advantage of the PBCL is that it separately scores three phases of a procedure (prior to, preparation for, and delivery). This could be adapted to our needs. Behaviors are scored based on occurrence (1 if present and 0 if absent, for a possible total score ranging from 0 to 8 per treatment phase) and intensity (scale of 1 to 5, where 1 indicates "very mild" and 5 indicates "extremely intense", for a possible total score ranging from 0 to 40 per phase). The PBCL score is derived from the three occurrence subscores and the three intensity subscores.

The Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)[41] is widely reported and has sound psychometric properties. Scores range from 4 to 13, with scores 4–6 indicating no pain. This instrument has been used in studies of general surgery, myringotomy and ear tube insertion, bladder nerve stimulation, closed fracture reduction, intravenous cannulation, sickle cell episodes, circumcision, and immunizations.

The Face, Legs, Arms, Cry, Consolability (FLACC)[43] scale is an instrument that uses items similar to CHEOPS but with a 0–10 metric. It is reported as imposing a low burden whilst having sound psychometric properties. It has been used in studies of postoperative pain, minor noninvasive procedures, ear, nose, and throat operations, and is routinely used at the RCCH.

Thus, it seemed sensible for us to collect pilot data using these three scales (PBLC, CHEOPS, and FLACC) administered independently, and then compare their clinical utility and scores in order to identify the most appropriate measure for our virtual reality research. The literature indicates that parent and health care provider reports of children's perceived distress rarely correlate with children's self-reports of pain.[25] This is because parents (and health care workers) bring their own distress to the perception of child distress, and may overestimate the child's responses if they are the sole respondents. Thus, we did not include specific parent/caregiver/health care provider perspectives on children's distress.

Objective measures

Pulse rate and respiration were reported by Mott et al as measures of distress.[25] The child's heart rate (beats per minute), measured every 5 seconds using a Polar model chest strap and watch was reported as a measure of distress in an experimental paper by Chalmers et al.[45] Heart rate was expressed as mean values over the time that the experimental pain (cold) was tolerated. Grossi Porto and Junqueira [47] demonstrated that a Polar model heart rate monitor provided time-domain variability of heart interval series (R–Ri) similar to that provided by a conventional electrocardiogram. In our research setting, heart rate could be measured noninvasively using a heart rate monitor that records continuous information which could be downloaded later for analysis. Heart rate could be classified using the domains of the COMFORT scale.[14] Heart rate also appears to be a useful measure of distress for parents/caregivers as well, and could be collected whilst they wait for their child outside the burns dressing room.

Two process-based objective measures of the dressing change identified from the literature potentially reflected the within-child efficiency of the dressing change procedure related to the child's distress. Thus, we could record the time taken to complete the dressing change (from the time the child leaves the bed until completion of the procedure) and the number of nursing staff required to complete the dressing change.

The RCCH nurses are a constant factor in the burns dressing change procedure, and they get to know children well during their time in hospital. Thus, they could provide contextual information to enhance our understanding of measures of observed behaviors and objective measures.

Conclusion

Virtual reality has strong evidence of effectiveness in distracting Western children and alleviating their distress during painful burns dressing change procedures. Whether it is similarly effective for indigenous African children with extensive burns, who are from different cultures, illiterate, non-English-speaking, and with no experience of computers, is yet to be determined. The influences of culture, language, illiteracy, and familiarity with computers in our children underpinned our concerns about the validity of using the self-report scales in current pediatric virtual reality research. Our research framework of considering the participants, research requirements, and comprehensiveness assisted us to sort through the range of alternative measures of pediatric distress reported in the literature.

Considering our analysis framework, our proposed measures of pediatric distress for virtual reality research at the RCCH considers the perspectives of all participants in the burns dressing change procedure. The measures we have identified as potentially useful are psychometrically sound and clinically appropriate. The measures are also comprehensive, in that they measure different aspects of children's distress prior to and during burns dressing changes. Our chosen measures are:

Child's observed behaviors

These include FLACCs, PBCL, or CHEOPS. These three measures will be assessed in a preliminary (pilot) study to correlate scores and to consider clinical utility. This will assist us in identifying the most appropriate observed behavior measure for our virtual reality research.

Objective measures

- Child's heart rate measured over short time periods (eg, every 5 seconds)
- Parent's heart rate measured in the same manner whilst they are outside the treatment room during the dressing change
- Time taken to complete the dressing change from the time the child leaves his/her bed
- Number of staff required to complete the dressing change.

Subjective measures for context

Nurse perspectives on the efficiency of each dressing change will be captured using semistructured interviews at the completion of the dressing change procedure.

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Disclosure

The authors report no conflicts of interest in this work.

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Appendices

Appendix 1 PRISMA checklist for Von Baeyer and Spagrud[30]

Section/topic	Item number	Checklist item	Reported on page number(s)
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, interventions, study appraisal and synthesis methods, results, limitations, conclusions, and implications of key findings, systematic review	No
Introduction			
Rationale	5	Describe the rationale for the review in the context of what is already known	2
Objectives	4	Provide an explicit statement of questions being addressed with reference to PICOS	2
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (such as web address), and, if available, provide registration information including registration number	No
Eligibility criteria	6	Specify study characteristics (such as PICOS, length of follow-up) and report characteristics (such as years considered, language, publication status) used as criteria for eligibility, giving rationale	6,7
Information sources	7	Describe all information sources (such as databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	5
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	No
Study selection	9	State the process for selecting studies (that is, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	5,6
Data collection process	10	Describe method of data extraction from reports (such as 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 (such as PICOS, funding sources) and any assumptions and simplifications made	5
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	No
Summary measures	13	State the principal summary measures (such as risk ratio, difference in means)	1
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (such as I^2 statistic) for each meta-analysis	4
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting within studies)	2
Additional analyses	16	Describe methods of additional analyses (such as sensitivity or subgroup analyses, metaregression), if done, indicating which were prespecified	No
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	No
Study characteristics	18	For each study, present characteristics for which data were extracted (such as study size, PICOS, follow-up period) and provide the citations	No
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)	No
Results of individual studies	20	For all outcomes considered (benefits or harms), present for each study (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a Forest plot	NA
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	No
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	No

(*Continued*)

Appendix 1 (*Continued*)

Section/topic	Item number	Checklist item	Reported on page number(s)
Additional analysis	23	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, metaregression, see item 16)	No
Discussion			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (such as health care providers, users, and policy makers)	7
Limitations	25	Discuss limitations at study and outcome level (such as risk of bias), and at review level (such as incomplete retrieval of identified research, reporting bias)	No
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	10
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (such as supply of data) and role of funders for the systematic review	10

Abbreviations: PICOS, participants, interventions, comparisons, outcomes, and study design; NA, not available.

Appendix 2 PRISMA checklist for Stinson et al[29]

Section/topic	Item number	Checklist item	Reported on page number
Title			
Title	1	Identify the report as a systematic review, meta-analysis, or both	143
Abstract			
Structured summary	2	Provide a structured summary including, as applicable, background, objectives, data sources, study eligibility criteria, participants, interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings, systematic review	143
Introduction			
Rationale	5	Describe the rationale for the review in the context of what is already known	144 (Introduction)
Objectives	4	Provide an explicit statement of questions being addressed with reference to PICOS	144 (SR of outcomes; no intervention required)
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (such as web address), and, if available, provide registration information including registration number	No
Eligibility criteria	6	Specify study characteristics (such as PICOS, length of follow-up) and report characteristics (such as years considered, language, publication status) used as criteria for eligibility, giving rationale	144
Information sources	7	Describe all information sources (such as databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	144
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	No
Study selection	9	State the process for selecting studies (that is, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	145
Data collection process	10	Describe method of data extraction from reports (such as piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	145
Data items	11	List and define all variables for which data were sought (such as PICOS, funding sources) and any assumptions and simplifications made	145
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	145

(*Continued*)

Appendix 2 (*Continued*)

Section/topic	Item number	Checklist item	Reported on page number
Summary measures	13	State the principal summary measures (such as risk ratio, difference in means)	No
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (such as I^2 statistic) for each meta-analysis	No
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting within studies)	No
Additional analyses	16	Describe methods of additional analyses (such as sensitivity or subgroup analyses, metaregression), if done, indicating which were prespecified	No
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	No
Study characteristics	18	For each study, present characteristics for which data were extracted (such as study size, PICOS, follow-up period) and provide the citations	No
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)	No
Results of individual studies	20	For all outcomes considered (benefits or harms), present for each study (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a Forest plot	No (results are presented for individual outcomes not for individual studies)
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	No
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	No
Additional analysis	23	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, metaregression, see item 16)	No/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 (such as health care providers, users, and policy makers)	No
Limitations	25	Discuss limitations at study and outcome level (such as risk of bias), and at review level (such as incomplete retrieval of identified research, reporting bias)	No
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	No
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (such as supply of data) and role of funders for the systematic review	No (but unsure, could be funded by Ped-IMMPACT group but it is unclear)

Abbreviations: PICOS, participants, interventions, comparisons, outcomes, and study design; NA, not available; Ped-IMMPACT, Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials.

Appendix 3 PRISMA checklist for Blount and Loiselle[27]

Section/topic	Item number	Checklist item	Reported on page number
Title			
Title	1	Identify the report as a systematic review, meta-analysis, or both	No
Abstract			
Structured summary	2	Provide a structured summary including, as applicable, background, objectives, data sources, study eligibility criteria, participants, interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings, systematic review	No
Introduction			
Rationale	5	Describe the rationale for the review in the context of what is already known	47

(*Continued*)

Appendix 3 (*Continued*)

Section/topic	Item number	Checklist item	Reported on page number
Methods			
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS)	No
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (such as web address), and, if available, provide registration information including registration number	No
Eligibility criteria	6	Specify study characteristics (such as PICOS, length of follow-up) and report characteristics (such as years considered, language, publication status) used as criteria for eligibility, giving rationale	No
Information sources	7	Describe all information sources (such as databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	No
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	No
Study selection	9	State the process for selecting studies (that is, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	No
Data collection process	10	Describe method of data extraction from reports (such as piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	No
Data items	11	List and define all variables for which data were sought (such as PICOS, funding sources) and any assumptions and simplifications made	No
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	No
Summary measures	13	State the principal summary measures (such as risk ratio, difference in means)	No
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (such as I^2 statistic) for each meta-analysis	No
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting within studies)	No
Additional analyses	16	Describe methods of additional analyses (such as sensitivity or subgroup analyses, metaregression), if done, indicating which were prespecified	No
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	No
Study characteristics	18	For each study, present characteristics for which data were extracted (such as study size, PICOS, follow-up period) and provide the citations	No
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)	No
Results of individual studies	20	For all outcomes considered (benefits or harms), present for each study (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a Forest plot	No
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	No
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	No
Additional analysis	23	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, metaregression, see item 16)	No
Discussion			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (such as health care providers, users, and policy makers)	No
Limitations	25	Discuss limitations at study and outcome level (such as risk of bias), and at review level (such as incomplete retrieval of identified research, reporting bias)	No
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	51
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (such as supply of data) and role of funders for the systematic review	No

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Abbreviation: PICOS, participants, interventions, comparisons, outcomes, and study design.

Appendix 4 PRISMA checklist for Cohen et al[28]

Section/topic	Item number	Checklist item	Reported on page number
Title			
Title	1	Identify the report as a systematic review, meta-analysis, or both	No
Abstract			
Structured summary	2	Provide a structured summary including, as applicable, background, objectives, data sources, study eligibility criteria, participants, interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings, systematic review	No (methods section not adequate)
Introduction			
Rationale	5	Describe the rationale for the review in the context of what is already known	939,940
Objectives	4	Provide an explicit statement of questions being addressed with reference to PICOS	No
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (such as web address), and, if available, provide registration information including registration number	No
Eligibility criteria	6	Specify study characteristics (such as PICOS, length of follow-up) and report characteristics (such as years considered, language, publication status) used as criteria for eligibility, giving rationale	No (not in detail)
Information sources	7	Describe all information sources (such as databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	No
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	No
Study selection	9	State the process for selecting studies (that is, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	No
Data collection process	10	Describe method of data extraction from reports (such as piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	No
Data items	11	List and define all variables for which data were sought (such as PICOS, funding sources) and any assumptions and simplifications made	No
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	No (outcomes were assessed but not individual studies)
Summary measures	13	State the principal summary measures (such as risk ratio, difference in means)	No
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (such as I^2 statistic) for each meta-analysis	No (synthesis was performed individual outcomes as well established, approaching well established and promising assessment)
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting within studies)	No
Additional analyses	16	Describe methods of additional analyses (such as sensitivity or subgroup analyses, metaregression), if done, indicating which were pre-specified	No
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	No
Study characteristics	18	For each study, present characteristics for which data were extracted (such as study size, PICOS, follow-up period) and provide the citations	No (presented information as per outcome not per study)
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).	No
Results of individual studies	20	For all outcomes considered (benefits or harms), present for each study (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a Forest plot	No

(*Continued*)

Appendix 4 (*Continued*)

Section/topic	Item number	Checklist item	Reported on page number
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	No
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	No
Additional analysis	23	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, metaregression, see item 16)	No (Subgroup analysis: Table 1: given individual outcome results and psychometrics only)
Discussion			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (such as health care providers, users, and policy makers)	No
Limitations	25	Discuss limitations at study and outcome level (such as risk of bias), and at review level (such as incomplete retrieval of identified research, reporting bias)	No
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	949
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (such as supply of data) and role of funders for the systematic review	No

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Abbreviation: PICOS, participants, interventions, comparisons, outcomes, and study design.