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The Impact of Parental Presence on Their Children During Painful Medical Procedures: A Systematic Review

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Abstract

Objective. Whether parental presence during their children’s painful medical procedures is advantageous with regard to children’s pain-related outcomes is questionable. Research on this topic is equivocal, and additional questions, such as whether levels of parental involvement may play a role as well, remain to be addressed. The purpose of this systematic review is to summarize and critically appraise the literature on the impact of parental presence vs absence during their children’s painful medical procedures on the child’s pain-related outcomes. Methods. The review protocol was registered on Prospero (ID CRD42018116614). A systematic search in PubMed, Web of Science, and PsycArticles resulted in 22 eligible studies incorporating 2,157 participants. Studies were considered eligible if they included children (<18 years old) undergoing a painful medical procedure and compared parental presence and/or involvement with parental absence during the procedure. Results. The children’s pain-related outcomes included self-reported pain intensity, self-reported fear, anxiety and distress, observed pain-related behavior, and physiological parameters. Overall, evidence points in the direction of beneficial effects of parental presence vs absence with regard to children’s self-reported pain intensity and physiological parameters, whereas mixed findings were recorded for children’s self-reported fears, anxiety and distress, and observed pain-related behaviors. Conclusions. To provide clear recommendations on how to involve the parent during the procedure, as well as for which type of children and parents parental presence has the best effects, further research is needed, as indicated in this review.

Key words: Child; Procedural Pain; Parent; Parental Presence; Parental Involvement
Introduction
Throughout childhood, children frequently undergo painful medical procedures in pediatric settings, such as immunizations [1]. As such, the needle is a powerful negative symbol for many children [2, 3] and sometimes even leads to needle phobia [4]. Although the benefits of these procedures have been proved in many ways, the pain associated with these procedures may constitute a source of great anxiety and distress to many children [1]. If pain and associated fear are not properly managed, they may lead to future preprocedural anxiety, increased fear of needles, and health care avoidance behaviors [5].

Parents are considered to play a critical role in the pain management of their children. When children undergo a painful medical procedure, parents are often eager to stay with their children to reassure and comfort them [6]. However, whether the presence of parents during such procedures is advantageous in regard to the child’s pain-related outcomes remains inconclusive. Indeed, despite understanding the impact of this costless and often effortless intervention, which is assumed to have an important impact on the child’s pain experience during the procedure as well as on future pain-related behavior, research findings are equivocal [7, 8]. Several benefits of parental presence during their child’s medical procedures have been reported, including reducing child’s fear [9], pain [7, 10, 11], and distress [7, 12], as well as minimizing the need for premedication [13]. Additionally, parental presence has been found to have a positive effect on physiological pain-related outcomes, such as a decrease in children’s respiration rate, blood pressure, and heart rate [7]. In contrast, several studies have also indicated negative consequences of parental presence, such as more crying [14] and increased levels of a child’s behavioral distress [8].

A mixed picture in regard to the effects of parental presence upon a child’s distress and behavioral outcomes was also found in a systematic review of Piira et al. (2004) [15] that examined the role of parental presence in the context of children’s medical procedures. However, since then, many high-quality studies have been performed, making the latter systematic review outdated. In addition, the review protocol was not registered, and the authors did not report any replicable search string, resulting in a lack of transparency and reproducibility. Moreover, it included a mix of painful and nonpainful medical procedures (e.g., inhalational anesthesia induction) and did not specifically focus on child outcomes. Instead, it included a broad spectrum of child, parent, health professional, and procedural outcomes [15]. A more recent systematic review by Pillai Riddell et al. (2015) [16], focusing on the effectiveness of educating individuals involved in vaccination procedures on child outcomes, also found mixed results for the presence of parents during vaccinations. In particular, data in that review supported the presence of parents only for preprocedural distress. However, the scope of the review was limited, as it included only four articles that studied the effect of parental presence vs absence, whereby only child distress behavior could be included as an outcome measure [16].

Furthermore, additional questions remain, such as whether the level of parental involvement could play a role as well, and for which children and parents (e.g., high/low anxiety) parental presence is more or less beneficial. Chambers et al. (2009) [17] reported in their review on psychological interventions for reducing pain and distress during childhood immunizations that parent-led distraction and parent coaching were not effective in reducing children’s pain or distress during immunizations [17]. In addition, two evidence-based clinical practice guidelines about reducing pain for childhood vaccinations are available [18, 19]. These guidelines recommend the presence of parents exclusively on the basis of the review by Pillai Riddell et al. (2015) [16]. Additionally, the authors recommend parent-involved interventions, such as breastfeeding, parent-led distraction, and parent coaching. Knowing that for some painful medical procedures, other than vaccinations, active parent involvement might not be as easy to apply and that in certain hospitals the presence of parents during particular procedures is still not allowed, these guidelines remain rather limited. Importantly, the latter publications [16–19] focus exclusively on immunizations/vaccinations, and information about for which children and parents (e.g., high/low anxiety) parental presence is more or less beneficial is not covered.

Because of the conflicting and outdated evidence about the influence of parental presence vs absence during their children’s painful medical procedures, performing an up-to-date review on this topic is timely. In doing so, the present review will provide a systematic overview of the effects of parental presence vs absence during their children’s painful medical procedures on the child’s pain-related outcomes. In addition, and on the basis of the information provided within the included studies that are answering the primary research question, two subquestions will be addressed: 1) Is there a difference in effect depending on the level of parental involvement (parent being plainly present vs parent being involved in management)? 2) What role do parent variables, child variables, and context play in the appropriateness of parents being present or absent during their children’s painful medical procedures?

Methods
Protocol and Registration
A systematic search of the existing literature was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [20]. The review protocol was registered on
Parental Presence During Children’s Painful Procedures

Propero (https://www.crd.york.ac.uk/prospero/) on December 3, 2018 (ID CRD42018116614).

Eligibility Criteria
Articles were included in the systematic review if they met the following inclusion criteria: 1) Participants were children (≤18 years old) undergoing a painful medical procedure (e.g., needle-induced anesthesia induction, immunization, etc.); 2) articles compared a condition of parental presence with a condition of parental absence; 3) articles reported on child pain-related outcomes (e.g., pain intensity, distress, anxiety, etc.); and 4) articles were full-text reports of original research (abstracts, case reports, reviews, meta-analyses, letters, expert opinions, and editorials were excluded). No a priori restrictions were set for language or year of publication. Studies could include healthy children as well as clinically ill children (i.e., children with a clinical diagnosis such as cancer). Because of pain assessment issues or different/dysfunctional pain processing mechanisms, articles focusing on children with significant developmental disorders (e.g., attention deficit [hyperactivity] disorder) [21, 22], mental or psychological disorders (e.g., anxiety disorders) [22], or chronic pain disorders (e.g., fibromyalgia) [23, 24] were excluded.

Information Sources and Search
A systematic literature search was performed in the electronic databases PubMed, Web of Science, and PsyArticles. The last search update was carried out on August 11, 2021. The search string was based on a combination of key words and Medical Subject Heading (MeSH) terms, overall divided into five groups according to the defined Population, Exposure, Comparator, and Outcomes (PECO) question: (P1) children (≤18 years old), (P2) painful medical procedure, (E1) parent/guardian, (E2) presence/involvement, and (O) child pain-related outcome measure(s). The comparison, predefined as parental absence, was not integrated into the search string to avoid the exclusion of relevant articles. Each database was searched by title, abstract, and keywords. The complete search strategy for all databases is available in Supplementary Data Appendix 1.

Study Selection
First, duplicates were removed through the use of EndNote X9 software (Clarivate Analytics, Philadelphia, PA, USA). Eligibility assessment of the articles was performed independently in a blinded, standardized manner (i.e., blinded for each other’s decision on the inclusion or exclusion of articles until the moment of a consensus meeting) by three independent reviewers (ER, YL, LS) in Rayyan QCRI, a Web application for exploring and filtering searches for eligible studies (https://rayyan.qcri.org/welcome) [25]. All titles and abstracts were screened to identify relevant articles. Next, the full-text versions of all articles were retrieved and evaluated against the inclusion criteria. In addition, the reference lists of the selected articles were screened. In case no full text was available or certain aspects of the research method were unclear (e.g., not clear whether the parent was present vs absent in the control group), the corresponding author was contacted via e-mail. In case an error message was received after the first e-mail or if the author reported that she/he did not (co)author the paper, the second author was contacted. In case of no reply after 2 weeks, a reminder e-mail was sent. In case of no reply after another 2 weeks, the article was excluded. Disagreements between reviewers were resolved by consensus. If no agreement could be reached, a fourth independent reviewer (KI) was consulted.

Data Collection Process and Data Items
Data were extracted from each included article by the three independent reviewers (ER, YL, LS) and subsequently entered into a shared data extraction sheet in Excel (Microsoft Corp., Redmond, WA, USA). Information was collected from each article on 1) first author, year of publication, study design, and setting; 2) characteristics of study participants (sample size, age, sex, and health status of the children); 3) type of painful medical procedure (e.g., venipuncture, lumbar puncture); 4) study groups (parent absent/present/involved); 5) pain-related outcome measures; 6) level of evidence; and 7) results. To find an answer to our two subquestions, we screened the included articles on studies involving one or more groups of parents who were more involved than just being present, as well as on additional information about variables that may play a role in the differences between parental presence and absence. Any discrepancies were discussed in a consensus meeting with all three reviewers. In case important data were missing or additional data were required, the corresponding author was contacted by e-mail to request the missing or additional data. In case of no reply after 2 weeks, a reminder e-mail was sent. In case of no reply after another 2 weeks, the article was excluded from the review.

Risk of Bias in Individual Studies
The risk-of-bias assessment was performed by the same independent reviewers (ER, YL, LS), who were not aware of each other’s evaluations. After the selected articles had been evaluated, the results of all reviewers were compared. Conflicts were analyzed and discussed. In the event of a disagreement, an additional opinion was provided by a fourth researcher (KI).

Risk-of-bias assessments for all randomized controlled trials (RCTs) were performed with the use of the Cochrane Collaboration’s Tool for Assessing Risk of Bias, as described in the Cochrane Handbook for Systematic Reviews of Interventions [26]. This tool covers six biases: selection bias (random sequence generation...
and allocation concealment), performance bias (blinding of participants and personnel), detection bias for each outcome separately (blinding of outcome assessment), attrition bias (incomplete outcome data), selective reporting bias, and other sources of bias (i.e., bias due to problems not covered elsewhere in the assessment tool). The risk of bias for each domain was judged as “low risk,” “high risk,” or “unclear risk.” Item 3, blinding of participants and personnel, was not included in the final assessment of the studies because of the nature of the intervention (parental presence). As stated in the World Medical Association Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects—each subject involved in medical research and capable of giving informed consent must be adequately informed of the aims and methods of the study [27].

Blinding of personnel and participants was therefore considered impossible and unethical. Blinding of outcome assessment was assessed for each outcome measure separately, with priority given to self-report measures of the child for the final judgment.

For all nonrandomized trials, the risk of bias was assessed with the Newcastle–Ottawa Scale (NOS) for cohort studies, as recommended by the Cochrane Collaboration (http://www.cochrane.org). The NOS uses a star rating system to judge the quality of each study on the basis of three broad perspectives: selection of the study groups, comparability of the groups, and outcome. A maximum of nine stars can be awarded. The last two items of the NOS were not taken into account for the scoring if not applicable to the specific study. No cutoff value of methodological quality was set for inclusion. Finally, for each study, the level of evidence (LoE) was assigned by following the former Evidence-based Guideline Development (EBRO) method [28]. The LoE (EBRO) criteria can be found in Table 1.

Data Synthesis

Although the primary aim was to provide a systematic review of the available findings in the literature (see protocol registration on Prospero [https://www.crd.york.ac.uk/prospero/]), because of the anticipated large variability in study designs and assessed outcomes, we also performed meta-analysis where possible to provide additional information on the average size of the effect. To do so, studies were grouped into subgroups through the use of a similar research design to address the impact of parental presence and with a similar outcome (e.g., self-reported pain intensity) measured at the same time point (preprocedural, during the procedure / immediately after the procedure, or postprocedural). Meta-analyses of data (Comprehensive Meta Analysis [CMA] Version 3) on a subgroup of studies were, however, conducted only in case there were at least three studies that provided necessary data to reduce the risk of nonsignificant findings due to limited power of the meta-analysis test [29, 30] (see also Todd et al. [2018] [31] for a similar approach). Cohen’s d was calculated with postexposure means and standard deviations as an effect size for outcome data. In case no means and/or standard deviations were reported, authors were contacted to provide this information. When no information could be provided, authors used (a conservative estimate of) other statistics (e.g., P values or t value for mean difference) if possible, to allow the calculation of an effect size. (Note: In case a P value <0.001 was reported, a conservative approach of a P value = 0.001 was used). To maintain the independence of the data, whenever necessary, effect sizes were pooled across different sessions (e.g., Cox et al. [2011] [32]). Given the likely heterogeneity between studies, analyses were conducted with random-effects models [33]. Finally, the degree of heterogeneity in effect sizes (significant at P < 0.05) was assessed with Cochran’s Q test [30].

Results

Study Selection

The selection process of the relevant papers is presented in Figure 1. The initial search using PubMed, Web of Science, PsycArticles, and a hand search of reference lists of included articles resulted in 2,968 papers after the removal of duplicates. These articles were screened on titles

Table 1. Grading of the Level of Evidence (LoE) of individual studies (EBRO)

<table>
<thead>
<tr>
<th>LoE</th>
<th>Interventional Studies</th>
<th>Diagnostic Accuracy Studies</th>
<th>Harm, Side Effects, Etiology, Prognosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>Systematic review/meta-analysis of at least two independently conducted studies of A2 level.</td>
<td>Index test compared with reference test (reference standard); cutoffs were defined a priori; independent interpretation of test results; an adequate number of consecutive patients were enrolled, all patients received both tests.</td>
<td>Prospective cohort study of sufficient magnitude and follow-up, adequately controlled for confounding and no selective follow-up.</td>
</tr>
<tr>
<td>A2</td>
<td>Randomized double-blind trial with good study quality and an adequate number of study participants.</td>
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<td></td>
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<tr>
<td>B</td>
<td>Clinical trial, but without all the features mentioned for level A2 (including case-control study, cohort study).</td>
<td>Index test compared with reference test, but without all the features mentioned for level A2.</td>
<td>Prospective cohort study, but without all the features mentioned for level A2 or retrospective cohort study or case-control study.</td>
</tr>
<tr>
<td>C</td>
<td>Noncomparative studies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Expert opinion</td>
<td></td>
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</tbody>
</table>
and abstracts, resulting in 141 articles for full-text screening. Of these articles, an e-mail was sent to the corresponding author of 18 articles to request the full text or missing information. From seven authors [9, 34–39], no response was received, after which those articles were excluded. Another eight authors [40–47] replied to the e-mail, after which the articles were excluded for several reasons (ineligible study design, intervention, or population, or no full text available). Of the remaining three studies [48–50], no contact details could be found, which led to the exclusion of these studies as well. After final screening, 22 articles were included in the systematic review, of which one subgroup of four studies was considered appropriate for meta-analysis (see earlier for criteria) and provided sufficient data (i.e., [7, 10, 11, 32]).

Study Characteristics
Study characteristics of the included studies are presented in Table 2. In total, 2,157 children, with a parent present, absent, or actively involved in some way, were included in this systematic review. None of the children in the included articles suffered from a chronic disease, such as cancer. Two studies [54, 59] investigated preterm babies, and one study [57] included children more than 12 years of age. The age of the children in the remaining 19 studies varied from 0 months to 12 years of age, with a large proportion of children 3 years of age and younger. In 19 of the 22 included articles, the painful procedure comprised a needle puncture procedure, such as a venipuncture, heel stick, immunization, needle-induced general anesthesia, etc. Two articles [54, 59] included endotracheal and/or pharyngeal suctioning procedures, and two articles comprised burn injury procedures, such as hydrotherapy [53] and burn dressing changes [8].

Risk of Bias of Included Studies
Results for the assessment of risk of bias are reported in Tables 3 and 4. The three independent researchers (ER, YL, LS) agreed in most cases (82.4%). After a consensus meeting for the discrepancies, the reviewers reached consensus for 96.9% of the items. The opinion of a fourth
### Table 2. Characteristics of studies included in the systematic review (N = 22)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Design</th>
<th>Setting</th>
<th>Study Population</th>
<th>Painful Procedure</th>
<th>Exposure</th>
<th>Child Pain-Related Outcomes</th>
<th>LoE</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al-Abbass TM, 2016 [11]</td>
<td>RCT</td>
<td>Emergency department pediatric hospital Amman (Jordan)</td>
<td>N = 102 (4–9 yo) 54 boys, 48 girls Dehydration signs due to diarrhea, vomiting and/or poor fluid intake</td>
<td>VP</td>
<td>PP (n = 53) PA (n = 49)</td>
<td>Pain intensity (WBS)</td>
<td>B</td>
<td>Pain intensity with PP&lt;PA (P = 0.002) SQ1:/ SQ2:/</td>
</tr>
<tr>
<td>Axelin A, 2006 [45]</td>
<td>RCT (crossover with 2-day interval)</td>
<td>NICU at Turku University Hospital (Finland)</td>
<td>N = 20 (preterm infants; 6–37 days PNA; 24–33 weeks GA) 8 boys, 12 girls Preterm infants without major congenital anomalies, but need for regular endotracheal/pharyngeal succioning</td>
<td>Endotracheal/pharyngeal succioning</td>
<td>FTP (PP) (n = 20) CC (PA) (n = 20)</td>
<td>Pain behavior (NIPS)</td>
<td>B</td>
<td>Highest NIPS score FTP&lt;CC (P &lt; 0.001). One minute after succioning procedure, the sign. diff. in NIPS scores had disappeared (P = 0.084). HR or SpO2 FTP vs CC n.s. Time to calm down after succioning FTP&lt;CC (P = 0.024) SQ1:/ SQ2: Relation parent variables (gender, age, nr. of older children, previous NICU experiences, how often visited NICU, how many times taken part in child’s care), and NIPS score reductions n.s. FTP still sign. effect on NIPS scores with duration of succioning as covarate</td>
</tr>
<tr>
<td>Axelin A, 2009 [46]</td>
<td>RCT (crossover)</td>
<td>NICU at Turku University Hospital (Finland)</td>
<td>N = 20 (preterm infants; 28–32 weeks PCA) 12 boys, 8 girls Preterm infants without need for continuous positive airway pressure, regular blood sampling, major congenital anomalies or neurological impairment</td>
<td>Heel stick, pharyngeal succioning</td>
<td>FTP (PP) Oral glucose (PA) Placebo (PA) Opioid (PA)</td>
<td>Pain behavior (PIPP and NIPS) Physiological parameters (ECG, SpO2, RR)</td>
<td>B</td>
<td>Heel stick: PIPP oral glucose&lt; placebo (P ≤ 0.001), FTP&lt;placebo (P = 0.004), oxycodone vs placebo n.s. (P = 0.693), NIPS FTP&lt;placebo (P ≤ 0.001), oxycodone&lt;placebo (P = 0.018), oral glucose vs placebo n.s. (P = 0.072) Pharyngeal succioning: PIPP oral glucose&lt;placebo (P = 0.014), FTP&lt;placebo (P = 0.034), oxycodone vs placebo n.s. (P = 0.339), NIPS FTP&lt;placebo (P = 0.001), oral glucose and oxycodone vs placebo n.s. (P = 0.642; P = 0.290)</td>
</tr>
<tr>
<td>Reference</td>
<td>Design</td>
<td>Setting</td>
<td>Study Population</td>
<td>Painful Procedure</td>
<td>Exposure</td>
<td>Child Pain-Related Outcomes</td>
<td>LoE</td>
<td>Results</td>
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<tr>
<td>Bauchner H, 1996 [51]</td>
<td>RCT</td>
<td>Pediatric emergency department Boston City Hospital (USA)</td>
<td>N = 435 (&lt;3 yo) 182 boys, 248 girls, sex of 5 others missing</td>
<td>VP, IV cannulation, urethral catheterization</td>
<td>PI (PP + given instructions on how to help their child) (n = 153)</td>
<td>B</td>
<td>Computerized analysis of cry</td>
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<td></td>
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<td>Seen in the PED for VP, IV cannulation, urethral catheterization</td>
<td></td>
<td>PP (no instructions) (n = 147)</td>
<td>B</td>
<td>Pain (3-point categorical scale)</td>
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<td>PA (n = 131)</td>
<td>B</td>
<td>SQ1:/SQ2: PI vs PP vs PA n.s. for most cry variables and pain</td>
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<td></td>
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<td></td>
<td>B</td>
<td>SQ1: PI vs PP n.s.</td>
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<td>B</td>
<td>SQ2: Clinician rating child pain in PI successful &lt; (PI unsuccessful + PP) (P = 0.036)</td>
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<td></td>
<td>B</td>
<td>Parent ratings child pain PI successful vs (PI unsuccessful + PP) n.s. (P = 0.249)</td>
<td></td>
</tr>
<tr>
<td>Broome ME, 1989 [52]</td>
<td>RCT</td>
<td>Health screening clinic (USA)</td>
<td>N = 138 (3–9 yo) 63 boys, 75 girls Participating in a health screening before the beginning of the school year</td>
<td>Interview followed by immunization</td>
<td>MA for interview and immunization (n = 26)</td>
<td>B</td>
<td>Distress behavior (CBORS)</td>
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<td>MP for immunization only (n = 38)</td>
<td>B</td>
<td>SQ1:/SQ2: Distress MP vs MA n.s. (P = 0.38)</td>
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<td></td>
<td>MP for interview only (n = 21)</td>
<td>B</td>
<td>Parenting style: Child distress behavior with authoritative parents &lt; authoritarian parents, permissive parents, unresponsive parents during immunization, whether MP or MA</td>
<td></td>
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<td></td>
<td>MP for interview and immunization (n = 53)</td>
<td>B</td>
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<td>PP (n = 47)</td>
<td>B</td>
<td>Behavior PP vs PA n.s. in T1 and T2, only sign. worse behavior in PP group in (painless) habitation session (dentist rating only) (P = 0.007)</td>
<td></td>
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<td></td>
<td>PA (n = 43)</td>
<td>B</td>
<td>Pain/discomfort PP vs PA n.s. in T1 &amp; T2</td>
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<td></td>
<td>B</td>
<td>SQ1:/SQ2: Child anxiety: low-anxiety children pain/discomfort PA&gt;PP (P = 0.037). High-anxiety children pain/discomfort PA vs PA n.s.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>B</td>
<td>High-anxiety children behavior sign. better with PA in habitation (P = 0.029) session and T2 (P = 0.009)</td>
<td></td>
</tr>
<tr>
<td>Cox ICJ, 2011 [27]</td>
<td>RCT</td>
<td>Secondary pediatric dental-care clinic Utrecht (Netherlands)</td>
<td>N = 90 (4–12 yo) 45 boys, 45 girls Referred by family dentist to pediatric dental practice because of extensive caries, behavior management problems, young age or dentist being uncomfortable treating the child</td>
<td>First habituation session, followed by local anesthesia in T1 and T2</td>
<td>Anxiety and cooperative behavior (modified Venham Scale) Pain/discomfort (WBS)</td>
<td>B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference</td>
<td>Design</td>
<td>Setting</td>
<td>Study Population</td>
<td>Painful Procedure</td>
<td>Exposure</td>
<td>Child Pain-Related Outcomes</td>
<td>LoE</td>
<td>Results</td>
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<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Doctor ME, 1994</td>
<td>RCT</td>
<td>Burn Center, Children’s Hospital Denver (USA)</td>
<td>N = 28 (≤ 3yo) Requiring hydrotherapy for burn injuries</td>
<td>Burn injury hydrotherapy</td>
<td>PP (n = 14) PA (supported by staff member) (n = 14)</td>
<td>Behavior (overall pain, anxiety, distress) (BRC Global response (GRS))</td>
<td>B</td>
<td>Behavior PP vs PA n.s. Global response PP vs PA n.s. SQ1/ SQ2/</td>
</tr>
<tr>
<td>Foertsch CE, 1996</td>
<td>N-RCT</td>
<td>Shriner’s Burn Unit in Boston University of Iowa Burn Treatment Center (USA)</td>
<td>N = 23 (3–12 yo) TBSA burned 2–30% 3 successive burn dressing changes (S1, S2, S3)</td>
<td>1. (n = 15): PP if and when they wished 2. (n = 8): PA</td>
<td>Distress behavior (OSBD)</td>
<td>Distress behavior PP &gt; PA (S1 P = 0.003; S2 P = 0.04; S3 P = 0.01)</td>
<td>B</td>
<td>Period 2 (parent leaves the room): OSBD total and HR PA &gt; PP (P &lt; 0.01; P &lt; 0.05) Period 3 (injection): Distress behavior (FBRS &amp; OSBD): PP vs PA n.s. HR. PP vs PA n.s. SQ1/ SQ2/ Period 2: Child age: younger children showed higher OSBD total scores, only in PA condition (P &lt; 0.01); younger children had higher HR, only in PA condition (P &lt; 0.001) Period 3: distress behavior (OSBD &amp; FBRS) PP &gt; PA for older children only (P &lt; 0.05) After entering the treatment room, but before VP, crying MP &gt; MA Overall stress NR SQ1/ SQ2: After entering the treatment room, but before VP, crying MP &gt; MA, regardless of child age Number of very upset or turbulent children during pre-induction and induction period PP &lt; PA (P &lt; 0.001) Delayed response PP vs PA n.s. SQ1/ SQ2/</td>
</tr>
<tr>
<td>Gonzalez JC, 1989</td>
<td>RCT</td>
<td>Pediatric primary care clinic University Miami/Jackson Memorial Center (USA)</td>
<td>N = 47 (13 mo–7y9mo) 23 boys, 24 girls Seen for routine examinations and injections</td>
<td>Injection (immunization or antibiotics)</td>
<td>PP (n = 23) PA (n = 24)</td>
<td>Distress behavior (FBRS, OSBD) Physiological parameters (HR)</td>
<td>B</td>
<td>(continued)</td>
</tr>
<tr>
<td>Gross MA, 1983</td>
<td>RCT</td>
<td>Hospital clinical laboratory (USA)</td>
<td>N = 54 (4–10 yo) (N = 24 4–6 yo, N = 30 7–10 yo) 36 boys, 18 girls Referred to a hospital clinical laboratory for VP blood sampling</td>
<td>VP</td>
<td>MP (n = 27) MA (n = 27) (4–6 yo: MP (n = 12), MA (n = 12); 7–10 yo: MP (n = 15), MA (n = 15))</td>
<td>Behavior (crying, escape, resistance, aggression) Overall stress (anchored scale 1–5)</td>
<td>B</td>
<td>(continued)</td>
</tr>
<tr>
<td>Hannallah RS, 1983</td>
<td>N-RCT</td>
<td>Montréal Children’s Hospital (Canada)</td>
<td>N = 100 (1–5 yo) 64 boys, 36 girls Scheduled for outpatient surgery</td>
<td>Anesthesia induction (needle)</td>
<td>PP (n = 50) PA (n = 50)</td>
<td>Behavior/mood on a scale of 1 to 5 Delayed response (PHBQ)</td>
<td>B</td>
<td>(continued)</td>
</tr>
<tr>
<td>Reference</td>
<td>Design</td>
<td>Setting</td>
<td>Study Population</td>
<td>Painful Procedure</td>
<td>Exposure</td>
<td>Child Pain-Related Outcomes</td>
<td>LoE</td>
<td>Results</td>
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</tr>
<tr>
<td>Johnston CC, 1988 [54]</td>
<td>RCT</td>
<td>Montréal Children’s Hospital Research Institute (Canada)</td>
<td>N = 134 (2–8 yo) 85 boys, 49 girls Day surgery patients, free of any major cognitive deficits.</td>
<td>Anesthesia induction (needle)</td>
<td>PP (n = 67) PA (n = 67)</td>
<td>Fears of hospital (HFI) Behavioral upset/mood (GMS) Posttraumatic behavior</td>
<td>B</td>
<td>Parental Presence During Children’s Painful Procedures</td>
</tr>
<tr>
<td>Matziou V, 2013 [7]</td>
<td>RCT</td>
<td>Pediatric clinic at Kyriakou Children’s Hospital Athens (Greece)</td>
<td>N = 130 (7–10 yo) 66 boys, 64 girls Diagnosis or treatment requiring a VP, no cancer or other chronic illness</td>
<td>VP</td>
<td>PP (n = 43) Toy/PA (n = 44) No toy/PA (n = 43)</td>
<td>Pain (verbal NRS) Anxiety (STAI-C) Physiological parameters (RR, HR, BP)</td>
<td>B</td>
<td>Parental Presence During Children’s Painful Procedures</td>
</tr>
<tr>
<td>O’Laughlin E, 1995 [55]</td>
<td>RCT</td>
<td>Private pediatric practice (USA)</td>
<td>N = 36 (4.8–5.7 yo) 19 boys, 17 girls Seen for routine well-child examinations and immunizations</td>
<td>Immunization</td>
<td>MP/routine (n=? MP/watch (n=? MP/coach (n = 7) MA (n=?</td>
<td>Distress behavior (expressive, resistant, nonverbal) Distress (global ratings on a 1–9 Likert scale)</td>
<td>B</td>
<td>Parental Presence During Children’s Painful Procedures</td>
</tr>
<tr>
<td>Ozcetin M, 2011 [56]</td>
<td>RCT</td>
<td>Pediatric outpatient clinic (China)</td>
<td>N = 135 (3–6 yo) 73 boys, 62 girls Admitted to pediatric outpatient clinic for VP, no psychomotor or chronic disorders</td>
<td>VP</td>
<td>PP (n = 68), PA (accompanied by staff member) (n = 67)</td>
<td>Pain (WBS) Physiological parameters (HR, RR)</td>
<td>B</td>
<td>Parental Presence During Children’s Painful Procedures</td>
</tr>
</tbody>
</table>

(continued)
<table>
<thead>
<tr>
<th>Reference</th>
<th>Design</th>
<th>Setting</th>
<th>Study Population</th>
<th>Painful Procedure</th>
<th>Exposure</th>
<th>Child Pain-Related Outcomes</th>
<th>LoE</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ozdogan HK, 2017 [57]</td>
<td>N-RCT</td>
<td>Adana Numune Training and Research Hospital (Turkey)</td>
<td>N = 48 (5–12 yo) 21 boys, 27 girls ASA I</td>
<td>Anesthesia induction (needle)</td>
<td>MP (n = 24) MA (n = 24)</td>
<td>Anxiety (STAIC) Stress level (salivary cortisol levels)</td>
<td>B</td>
<td>Anxiety (trait + state): MP vs MA n.s. Salivary cortisol levels MA &gt; MP after induction (P = 0.001) and in recovery room (P = 0.02) SQ1:/ SQ2:/</td>
</tr>
<tr>
<td>Sağlik DS, 2019 [10]</td>
<td>RCT</td>
<td>Pediatric emergency department—outpatient clinic- of Istanbul University (Turkey)</td>
<td>N = 111 (9–12 yo) 49 boys, 62 girls Undergoing invasive procedures, no mental and/or physical health problems Blood withdrawal, vascular access, IM injection, IV injection</td>
<td>PI (n = 40), PP (n = 40), PA (n = 31)</td>
<td>Anxiety (STAIC) Pain (VAS)</td>
<td>B</td>
<td>Pain PA &gt; PI &amp; PP (P &lt; 0.001) SQ1: pain PI = PP (n.s.) SQ2: Parent T-anxiety sign, affected child pain before (P = 0.042) and during (P = 0.019) procedure, and child T-anxiety (P = 0.025) in PA group. Weak positive sign relationship between T-anxiety parents and preprocedural pain (P = 0.025) and T-anxiety (P = 0.044) of children in all 3 groups.</td>
<td></td>
</tr>
<tr>
<td>Shaw EG, 1982 [58]</td>
<td>RCT</td>
<td>Regular visit to pediatrician (USA)</td>
<td>Study 1: N = 20 (18 mo) 13 boys, 7 girls Study 2: N = 20 (5 yo) 11 boys, 9 girls Seen for routine well-child examinations and immunizations Immunization</td>
<td>MP (n = 10) MA (n = 10) in both studies</td>
<td>Behavior (modified FBR5 + behavior coding per 20-s interval)</td>
<td>B</td>
<td>Study 1: FBR5 only sign, diff. for interval 3 (mother leaves) (MP&lt;MA, P &lt; 0.02) and interval 6 (injection) (MP&gt;MA, P &lt; 0.05) Coding: Interval 3: crying MP&lt;MA (P &lt; 0.01); Interval 6: MP vs MA n.s. Study 2: FBR5 MA&lt;MP (P &lt; 0.05) for interval 8 (injection) and 9 (immediately afterwards). Coding: sign, diff. (P &lt; 0.01) only for amount of crying (interval 8) and fussing (interval 9) SQ1:/ SQ2:/</td>
<td></td>
</tr>
<tr>
<td>Sun Y, 2017 [49]</td>
<td>N-RCT</td>
<td>Affiliated Hospital of Hebei University of Engineering (China)</td>
<td>N = 172 (4–6 yo) 85 boys, 87 girls Suffering from facial trauma ASA I or II Debridement and soft tissue reconstruction with local anesthesia</td>
<td>PP (n = 88) PA (n = 84)</td>
<td>Anxiety (VAS)</td>
<td>B</td>
<td>Average anxiety PP&lt;PA (P &lt; 0.05). Preoperative anxiety PP vs PA n.s. Postoperative anxiety PP&lt;PA (P &lt; 0.05) SQ1:/ SQ2:/</td>
<td></td>
</tr>
<tr>
<td>Reference</td>
<td>Design</td>
<td>Setting</td>
<td>Study Population</td>
<td>Painful Procedure</td>
<td>Exposure</td>
<td>Child Pain-Related Outcomes</td>
<td>LoE</td>
<td>Results</td>
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</tr>
<tr>
<td>Tantikul C, 2014 [50]</td>
<td>N-RCT</td>
<td>Royal Thau Army Medical Department, Phramongkutklao Hospital (Thailand)</td>
<td>N = 72 (&lt; 4 yo) 41 boys, 31 girls Pneumonia, acute gastroenteritis, sepsis, acute bronchitis, febrile convulsion</td>
<td>VP or IV cannulation</td>
<td>PP (and given instructions) (n = 22) PA-A (n = 22) PA-B (n = 28)</td>
<td>Pain (FPS) B</td>
<td>Despite of being calm when parents performed very well in calming their children with talk, touch, and maintaining eye contact, all children with PP cried. Further group differences NR SQ1:/ SQ2:/&gt; Wolfram RW, 1996 [47]</td>
<td>RCT</td>
</tr>
</tbody>
</table>

ASA I = perfectly healthy patient without long-term medication use; ASA II = patient with a minor disorder, for which medication may be required (however, the condition does not affect daily life); A-state = state anxiety; A-trait = trait anxiety; BRC = behavioral rating checklist; CBORS = Child Behavior Observation Rating Scale; CC = control care; CFSS-DS = Dental Subscale of Children’s Fear Survey Schedule; CHEOPS = Children’s Hospital of Eastern Ontario Pain Scale; diff. = difference; ECG = electrocardiogram; ED = emergency department; FBRs = Frankl Behavior Rating Scale; FPS = Faces Pain Scale; FTP = facilitated tucking by parents; GA = gestational age; GMS = general mood scale; GRS = global response scale; HFI = Hospital Fears Inventory; IM = intramuscular; IV = intravenous; MA = maternal absence; mo = months old; MP = maternal presence; NICU = neonatal intensive care unit; NIPS = Neonatal Infant Pain Scale; nr. = number; NR = not reported; N-RCT = nonrandomized clinical trial; NRS = numeric rating scale; n.s. = nonsignificant; OSBD = Observational Scale of Behavioral Distress; PA = parental absence; PCA = postconceptional age; PED = pediatric emergency department; PI = parental involvement; PIPP = Premature Infant Pain Profile; PNA = postnatal age; PP = parental presence; S1 = session 1; S2 = session 2; S3 = session 3; sign. = significant; SpO2 = oxygen saturation; SQ1 = subquestion 1; SQ2 = subquestion 2: the role of parent variables, role of child variables, role of context; STAIC = State-Trait Anxiety Inventory for Children; T1 = treatment 1; T2 = treatment 2; TBSA = total body surface area affected by a burn; VAS = visual analog scale; VP = venipuncture; WBS = Wong-Baker Faces Pain Rating Scale; yo = years old.
researcher (KI) for the remaining five conflicts was decisive. The methodological quality of RCTs was moderate overall, with high risks of varying biases across the included studies. “Incomplete outcome data” was considered the domain with the least risk of bias overall, with eight (47.06%) studies rated as low, nine (52%) as unclear, and zero (0%) as high. Only one study had a low risk on each of the assessed domains [7]. The overall methodological quality of nonrandomized trials was moderate to high. Three of these five studies scored the maximum number of stars. For three nonrandomized studies [8, 51, 58], criteria 8 and 9 of the NOS were not evaluated, as a follow-up was not applicable. Detailed information on the assessments of methodological quality can be found in Supplementary Data Appendix 2. As none of the included studies can be considered double-blinded for the previously mentioned reason, according to the criteria of the EBRO method, all 22 articles were scored with a LoE of B: Comparative study, but not with all characteristics as mentioned under A2 (this includes patient–control research, cohort study). The LoE assessments can be found in Table 2.

Table 3. Assessment of methodological quality—Cochrane Collaboration’s Tool for assessing risk of bias (N = 17)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Random Sequence Generation</th>
<th>Allocation Concealment</th>
<th>Blinding of Outcome Assessment</th>
<th>Incomplete Outcome Data</th>
<th>Selective Reporting</th>
<th>Other Sources of Bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al-Abbas TM, 2016 [11]</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Axelin A, 2006 [45]</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Bauchner H, 1996 [51]</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Broome ME, 1989 [52]</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Cox ICJ, 2011 [27]</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Doctor ME, 1994 [48]</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
</tr>
<tr>
<td>Gonzalez JC, 1989 [53]</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>Low</td>
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</tr>
<tr>
<td>Gross MA, 1983 [14]</td>
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<td>Low</td>
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<tr>
<td>Johnston CC, 1988 [54]</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low</td>
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<td>Low</td>
</tr>
<tr>
<td>O’Laughlin E, 1995 [55]</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Ozcetin M, 2011 [56]</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
<td>High</td>
<td>High</td>
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<tr>
<td>Shaw EG, 1982 [58]</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Wolfram RW, 1996 [47]</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td>Wolfram RW, 1997 [12]</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
</tr>
</tbody>
</table>

Low = low risk of bias; unclear = lack of information or uncertainty about potential bias; high = high risk of bias.

Item 3 of the Cochrane Collaboration’s Tool for Assessing Risk of Bias (blinding of participants and personnel) was not included in the final assessment of the studies.

Table 4. Assessment of methodological quality—Newcastle-Ottawa Scale (cohort studies) (N = 5)

<table>
<thead>
<tr>
<th>Reference</th>
<th>Selection</th>
<th>Comparability</th>
<th>Outcome</th>
<th>No. of Stars</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foertsch CE, 1996 [8]</td>
<td>*</td>
<td>*</td>
<td>/</td>
<td>4/7</td>
</tr>
<tr>
<td>Hannallah RS, 1983 [13]</td>
<td>* * * *</td>
<td>*</td>
<td>*</td>
<td>7/9</td>
</tr>
<tr>
<td>Ozdogan HK, 2017 [53]</td>
<td>* * * *</td>
<td>*</td>
<td>*</td>
<td>9/9</td>
</tr>
<tr>
<td>Sun Y, 2017 [49]</td>
<td>* * * *</td>
<td>*</td>
<td>/</td>
<td>7/7</td>
</tr>
<tr>
<td>Tantikul C, 2014 [50]</td>
<td>* * * *</td>
<td>*</td>
<td>/</td>
<td>7/7</td>
</tr>
</tbody>
</table>

* = criterion fulfilled; / = criterion not evaluated.

Selection.
1. Representativeness of the exposed cohort.
2. Selection of nonexposed cohort.
3. Ascertainment of exposure.
4. Demonstration that outcome of interest was not present at start of study.

Comparability.
1. Comparability of cohorts on the basis of the design or analysis.

Outcome.
1. Assessment of outcome.
2. Was follow-up long enough for outcomes to occur?
3. Adequacy of follow-up of cohorts.
Results of Individual Studies
What Are the Effects of Parental Presence vs Absence During Children’s Painful Medical Procedures on Children’s Pain-Related Outcomes?
In general, a diversity of experimental designs and outcome measures was found in the included studies, prohibiting an overall meta-analysis. Therefore, a subdivision was made in the study findings on the basis of the outcome, i.e., self-reported pain intensity, self-reported fear, anxiety and distress, observed pain-related behavior, and physiological pain-related parameters. After the outcome measures were grouped into these four outcome groups, on the basis of reflecting conceptually similar outcomes with overlapping measurement content, only self-reported pain intensity, the primary outcome of this review, appeared to be appropriate for a meta-analytic approach. For the remaining outcome groups, meta-analysis was not appropriate because of highly diverging study designs, measuring moments, and outcome constructs, as well as the lack of necessary data. Therefore, it was decided to follow the initial aim of this review for these outcomes, i.e., an in-depth review.

Self-Reported Pain Intensity. Four studies [7, 10, 11, 32] measured child self-reported pain intensity in children with ages varying between 4 and 12 years. Three of four studies (75%) [7, 10, 11] reported a significant beneficial effect of parental presence vs parental absence on child pain intensity during the procedure, whereas the remaining study [32] did not find a significant difference for child pain intensity during or after the painful procedure. To provide an index of the strength of the effect, all four studies were included in a meta-analysis. One study [7] presented data on more than two parent-absent groups, i.e., parent absent with toy and parent absent without toy. Only the latter group was included, as it provides the pure effect of parental absence. Furthermore, only self-reported scores for pain during the painful procedure were taken into account. Results of this meta-analysis indicated a significant effect \( d \approx -0.493, 95\% \text{ confidence interval } [CI] -0.891 \text{ to } -0.095 \text{) in favor of parental presence. Heterogeneity testing revealed significant heterogeneity } (Q = 10.193, \text{df } (Q) = 3, P = 0.017) \text{ between the studies. However, because of the relatively small number of studies in each meta-analysis, inspection of funnels plots was not appropriate [56] and therefore not undertaken.}

Self-Reported Fear, Anxiety, and Distress. Six studies [7, 10, 52, 55, 57, 58] looked at child self-reported fear, anxiety, or distress as an outcome measure. Johnston et al. (1988) [52] interviewed 2- to 8-year-old children about their fears of hospitals at four time points (during a preoperative visit, in the waiting room just before induction, 1 week postoperatively, and 4 weeks postoperatively). No significant differences were found between the parent-present and parent-absent group at any of the time points. Two studies [10, 55] measured trait and state anxiety preoperatively, reporting no significant differences with parental presence compared with parental absence. Matziou et al. (2013) [7] measured trait and state anxiety in children 7 to 10 years of age immediately after venipuncture. Parental presence resulted in significantly less trait and state anxiety when compared with parental absence. Finally, two studies [57, 58] measured self-reported anxiety/distress in children 4–6 and 8–18 years old, respectively. Both studies reported significantly less anxiety and distress, measured postoperatively, when the parent had been present during the procedure than when the parent had been absent.

In conclusion, mixed findings were found with regard to self-reported fear, anxiety, and distress. Evidence points as much in the direction of beneficial effects of parental presence (vs absence) as in the direction of no significant differences between both conditions with regard to children’s self-reported fear, anxiety, and distress. Importantly, however, none of these studies shows overall adverse effects of parental presence before, during, or after a painful medical procedure on children’s self-reported fear, anxiety, or distress.

Observed Pain-Related Behavior. A total of 16 studies reported outcomes with regard to pain-related behavior, assessed by the parent, a research assistant, or a health care practitioner (via, e.g., facial expressions, crying, etc.). Four studies [12, 13, 54, 59] found significantly beneficial effects for the presence of the parent(s). Two crossover RCTs assessed pain behavior of preterm infants during endotracheal/pharyngeal suctioning [54, 59] and heel stick [54]. The first study [59] showed that “facilitated tucking by parents” (FTP) significantly alleviated the behavioral pain of preterm infants during suctioning and decreased the time to calm down after the procedure when compared with control care (parents absent). Nevertheless, the significant difference in behavioral pain was short-lived, disappearing 1 minute after the procedure. In line with these findings, the second study [54] also showed significantly less pain behavior in the FTP group than in the oral water (parent-absent) group during heel stick and suctioning. In the study of Hannallah et al. (1983) [13], 1- to 5-year-old children’s distress behavior during anesthesia induction was measured at four stages (waiting room, before induction, during induction, and after induction). Results indicated that the number of upset/turbulent children was significantly lower when the parents were present. A similar favorable effect for parental presence was found in the study of Wolfram et al. (1997) [12], where young children’s distress behavior was scored from videotapes of the venipunctures.

Next, four studies [8, 14, 60, 61] found rather adverse effects for the presence of parents during their children’s painful medical procedures. Foertsch et al. (1996) [8] showed significantly higher levels of behavioral distress in three successive burn dressing changes when parents were present vs absent. Seven years earlier, Gonzalez et al. (1989) [60] indicated significantly more distress
behavior with parents present, but this was only in the older children (mean age 5 years 6 months old). Additional analysis of this study indicated that only the amount of crying was significantly different. For the total group, no significant differences were found. These adverse findings for parental presence confirm results from earlier research conducted in the 1980s. The study performed by Shaw et al. in 1982 [61] was divided into two substudies (study one: 18-month-olds; study two: 5-year-olds). In study one, modified Frankl Behavior Rating Scale (FBRS) scores were significantly lower (indicating more positive behavior) in the mother-present condition than in the mother-absent condition at the moment that the mother had to leave the room in the latter group, whereas during the actual injection, the opposite was found. With regard to six dichotomous coded behaviors in this study, results showed significantly more crying at the separation moment (mother leaves in the mother-absent condition) in the mother-present group but no significant differences between both groups during injection. In study two, significantly fewer negative FBRS ratings were found in the mother-absent condition during and immediately after injection. For the coded behaviors, only for the amount of crying and fussing was a significant difference found, respectively during the injection and immediately after injection, again in favor of the mother-absent condition [61]. Finally, distress behavior (crying, escape, resistance, and aggression) of 4- to 10-year-old children was also measured in the study of Gross et al. (1983) [14]. They indicated that after entering the treatment room, but before the actual start of the puncture procedure, the children showed significantly more crying in the parent-present group. Nevertheless, no further differences were found between the groups.

The remaining eight studies [32, 51–53, 62–65] did not find significant differences between parent-present and parent-absent groups. Three studies in which the child’s pain intensity was scored by the parent and physician [62], parent and research assistant [51], or an experienced anesthetist [63] found no significant differences for parental presence vs absence. One of these studies [62] also performed a computerized analysis of cry variables (e.g., the level of energy) but found no significant differences between the parent-present and parent-absent groups. In the RCT of Broome et al. (1989) [64] in healthy 3- to 9-year-old children, no significant differences were found for child distress behavior with parents present vs absent during immunization. Another study [52] measured the global mood of children during anesthesia induction and found no significant difference for the presence of parents compared with the absence of parents. In line with these findings, Doctor (1994) [53] found no significant differences for distress behavior (overall pain, anxiety, and distress) or global response in children (≤3-year-olds) undergoing painful wound care procedures. In an RCT [65] comparing four groups (mother-present routine, mother-present watching, mother-present as coach, mother-absent), seven distress behaviors were coded dichotomously, seven of which were found with regard to parental presence vs any of the parent-present conditions. Cox et al. (2011) [32] assessed observed anxiety and cooperative behavior by the dentist and parent during two dental treatment sessions with local anesthesia. Again, no significant differences between parent-present and parent-absent groups could be identified for this outcome measure.

Finally, two studies [13, 52] also looked at children’s posttraumatic behavior. Hannallah et al. (1983) [13] measured children’s delayed response 2 weeks after surgery with the Post-Hospitalization Behavior Questionnaire. In the study of Johnston et al. (1988) [52], parents assessed posttraumatic behavior on a behavior scale at 1 week and 4 weeks postoperatively. Neither study found a significant difference for parental presence vs absence.

In sum, evidence is again mixed with regard to the impact of parental presence vs absence on observed pain-related behavior in children. It should be noted that disadvantageous effects of parental presence vs absence were found in only a minority of the studies. Of additional interest, preliminary research findings indicate that parental presence vs absence has no significant influence on children’s posttraumatic behavior.

**Physiological Parameters.** Six studies [7, 54, 55, 59, 60, 63] measured pain-related physiological outcome measures. Heart rate (HR) was gauged in four studies [7, 59, 60, 63], of which two [59, 60] reported no significant differences when the parent was present compared with absent during the painful procedure. The other two studies [7, 63] showed a significantly lower HR when the parent was present during the painful procedure. Of interest, further results of study [60] indicated that the children’s HR was significantly higher in the parent-absent group at the moment the parent had left the room. Respiration rate (RR) was measured in two studies [7, 63], both showing a significantly lower RR with the parent present than with the parent absent. Only one study [7] measured 7- to 10-year-old children’s blood pressure (BP), describing a significantly lower BP when the parent was present. Additionally, salivary cortisol levels were measured in one study [55] in children 5 to 12 years of age. Salivary cortisol levels in this study significantly increased in the mother-absent group after induction and in the recovery room when compared with those in the mother-present group. Adverse effects in preterm infants, meaning desaturation (SpO2 < 85), bradycardia (HR < 100), or both, were described in the study of Axelin et al. (2009) [54], showing much more adverse effects in the parent-absent conditions (21.25% for oral glucose, 12.5% for oral water) when compared with the parent-present condition (5% for FTP) and with oxycodone (5%). To conclude, most evidence points in the direction of beneficial effects for parental presence compared with absence during their children’s...
painless medical procedures with regard to children’s physiological parameters, such as HR, RR, BP, salivary cortisol levels, and adverse effects (SpO₂ < 85, HR < 100, or both).

Is There a Difference in Effect Depending on the Level of Parental Involvement?
Only three studies [10, 62, 65] incorporated an additional group of parents. A study by O’Laughlin and Ridley-Johnson (1995) [65] in 4- to 5-year-olds included four groups: 1) mother absent, 2) mother watches, 3) mother present with noninstructed high involvement, and 4) mother present and trained as coping coach. The mothers of the coach group were asked to select one specific distraction method together with the child and to start applying it when the nurse picked up the needle until the needle was removed. The results of this study provided support for the second condition (watch), because these children exhibited the least amount of expressive distress behavior (cry/scream, fuss/whine, verbal pain, and request for emotional support) before and during immunization compared with the children in the third condition (routine) (P < 0.05). Besides, no further group differences were found for expressive or resistant behavior. In a study by Bauchner et al. (1996) [62] in young children (<3-year-olds) a comparison was made between three groups: 1) parent absent, 2) parent present without instructions and 3) parent present and given instruction on how to calm and relax the child. In this third group, the parent was asked to sit down at the head of the bed and to talk to, touch, and maintain eye contact with the child. No differences were found between the groups in terms of child cry variables or in terms of child pain ratings by clinicians and parents. A third study [10] investigated the differences between three groups of 9- to 12-year-old children: 1) parents absent, 2) parents present without being involved in the management of the child, and 3) parents involved by holding their children’s arms during blood withdrawal, vascular access, and intravenous injection, by holding their legs during intramuscular injections, and by continued communication during the procedure. Results showed significantly higher child pain levels in the parent-absent group during the procedure than in the parent-involved and parent-present groups. No differences between the parent-involved and parent-present groups were reported.

In sum, and unexpectedly, results of these studies overall indicate no important differences between parental involvement and conditions in which the parent is merely present. In only one article [65], a condition in which mothers were just watching without being actively involved was reported as more favorable than conditions in which the mothers were actively involved with either no instructions or being trained to coach their child during the procedure, but this was the case for only one of the three measured distress behaviors (i.e., expressive distress behavior).

What Role Do Child, Parent, and Context Variables Play in the Appropriateness of Parents Being Present or Absent During Children’s Medical Procedures?
With regard to child variables, one study [32] found that low-anxiety children reported significantly more pain/discomfort in absence of their parents than the children who were accompanied by their parents. On the other hand, no significant pain/discomfort differences were found in the high-anxiety group when parents were present or absent. Furthermore, according to the dentists’ ratings, the high-anxiety children behaved significantly more relaxed in the (painless) habituation session and second treatment session when the parent was absent. Looking at children’s age, Gonzalez et al. (1989) [60] reported that younger children (13 months to 4 years of age) showed higher behavioral distress (P < 0.01) and higher HR (P < 0.001) only in the parent-absent condition, at the moment the parent left. At the moment of the injection, the opposite effect was found for the older children (4- to 7-year-olds), including more distress behavior in the parent-present condition (P < 0.05), but not for the younger ones. Three other studies [12, 14, 57] found no differences with regard to the age of the child. Two studies [12, 57] also considered other child variables, such as sex, race, number of previous venipunctures, emergency department visits within 6 months of venipuncture, previously witnessed venipunctures, and duration of the suctioning procedure, but found no associated differences for these variables for child distress behavior with regard to parental presence vs absence.

With regard to parent variables, parents’ successfulness in implementing the intervention, parental fears, and parenting style appear to be factors that may be important in the decision about whether to have the parent present during painful medical procedures. Bauchner et al. (1996) [62] performed a re-analysis of clinician and parent ratings of the child’s pain, based on the parent’s ability to successfully implement all aspects of the intervention (talk to, touch, maintain eye contact), and found that clinicians rated the children’s pain significantly lower for children whose parents successfully implemented the intervention than for children whose parents did not. A similar re-analysis of the parent ratings showed no significant differences.

Two studies [10, 52] looked at the influence of parents’ fears or anxiety. Significant positive correlations were shown between the parent’s preoperative fears and the child’s fears and mood in the waiting room. However, no significant differences in child anxiety or behavioral upset during the procedure were found with regard to high-anxiety vs low-anxiety parents in both groups (parent-absent and parent-present) [52]. Sağlık et al. (2019) [10] reported that parental trait-anxiety was significantly positively related to child pain before and during puncture procedures and to children’s trait-anxiety when the parent was absent. Furthermore, a
significant positive association was identified between parental trait-anxiety and preprocedural pain and trait-anxiety of children in all three groups (parental involvement, parental presence, parental absence).

Finally, an interesting finding about parenting styles was reported in the study of Broome et al. (1989) [64]. Children of authoritative parents exhibited significantly less distress than children of authoritarian, permissive, and unresponsive parents during immunization, regardless of whether the mother was present or not. Other parent variables, such as sex, age, number of older children, previous neonatal intensive care unit experiences, number of neonatal intensive care unit visits, and how often they have taken part in the child’s care, did not affect child pain (NIPS scores) reduction between the groups in one study [59].

In sum, some child variables (e.g., baseline anxiety and age) and parent variables (e.g., how successfully they implement all aspects of the intervention and their level of anxiety) seem to play an important role in explaining differences between parent-present and parent-absent conditions. However, these findings are preliminary and largely based on only one or two studies. Further research is needed to gain more insight into the role of specific child and parent variables in the context of this topic.

**Discussion**

The aim of this systematic literature review was to determine the effects of parental presence vs absence during their children’s painful procedures on child pain-related outcomes. Furthermore, two subquestions were addressed, i.e., differences in effect depending on the level of parental involvement, and the role of child, parent, and context variables in the appropriateness of parental presence. Overall, evidence points in the direction of beneficial effects of parental presence vs absence with regard to children’s self-reported pain intensity and physiological parameters, whereas mixed findings were recorded with regard to children’s self-reported fears, anxiety, and distress and observed pain-related behaviors. Importantly, however, none of the included studies reported adverse effects of parental presence with respect to children’s self-reported pain, self-reported fear, anxiety or distress, and physiological pain-related outcomes.

For our primary outcome, self-reported pain intensity, most studies (75%) investigating the effect of parental presence on children’s self-reported pain intensity [7, 10, 11] reported significant beneficial results for the presence of the parent. One study [32] found no significant difference for parental presence vs absence, but it is important to take into account the habituation session in this study that preceded the subsequent painful treatment sessions, where the parent was already present/absent without a painful intervention taking place. In sum, evidence points to beneficial effects of the presence of parents vs absence with regard to children’s self-reported pain ($d = -0.493$, 95% CI $[-0.891$ to $-0.095]$) during painful medical procedures, which was considered the most important child pain-related outcome within the present systematic review.

With regard to the child’s self-reported fears, anxiety, and distress, 50% of the studies addressing these outcomes [7, 57, 58] identified significantly beneficial effects for parental presence, whereas the other 50% [10, 52, 55] failed to show significant differences. However, two RCTs [10, 52] within the latter three studies showed a high risk of bias with regard to random sequence generation and allocation concealment, whereas the two RCTs [7, 57] within the three studies reporting beneficial effects for parental presence were given a low risk of bias on both domains. One of these RCTs [7] was even given a low risk of bias on each domain of the Cochrane Collaboration’s Tool. In addition, the three studies [10, 52, 55] that reported no differences measured anxiety preoperatively, with two of them [10, 32] not clearly reporting for the parent-absent condition whether the parent was still present in the room or not. Taking into account the risk of bias for these studies and the fact that none of these studies shows overall adverse effects of parental presence before, during, or after a painful medical procedure, we can cautiously assume that parental presence has a positive influence on children’s self-reported fears, anxiety, and distress.

Our review provides a mixed picture with regard to pain-related behavior observed by others (i.e., the parent, research assistant, or health care practitioner). Fifty percent [32, 51–53, 62–63] of the studies investigating the effect of parental presence on the observed pain-related behavior of children found no significant differences between the parent-present and parent-absent conditions. In three [32, 51, 62] of eight studies (37.5%) reporting no significant differences, behavior ratings were partly performed by the parents. Knowing that the interpretation of parent proxy measurements may contain bias, these study findings should be treated with caution [66]. The remaining eight studies showed a 50/50 distribution in terms of showing significant beneficial [12, 13, 54, 59] vs disadvantageous [8, 14, 60, 61] effects of parental presence vs absence. However, the four studies [12, 13, 54, 59] that showed significantly beneficial effects for parental presence on children’s distress behavior also showed these beneficial effects during the painful procedures (i.e., not only before or after the procedure). This is in contrast with the findings of Pillai Riddell et al. (2015) [16], who reported advantageous effects for parental presence only before the start of the painful procedure. These findings [16] need to be put into perspective. Some studies (e.g., [61]) indeed show beneficial effects of parental presence before the start of the procedure but state that parents are better absent during the actual procedure. However, children’s behavior before the procedure was scored at a time when the parents in the parent-
absent group left the room and thus at a conscious separation moment between the child and parent. This may have led to a direct increase in distress in the child, compared with a parent-absent condition in which the parent was not accompanying the child from the beginning. Additionally, in some studies (e.g., [14]), less crying is interpreted as a beneficial outcome. However, caution is needed, as it may also imply expressive suppression in the presence of an unfamiliar person, such as a health care practitioner [67, 68].

The majority of studies (66.67%) that explored physiological outcomes (e.g., HR, RR, BP) reported significantly better outcomes when the parent was present during the painful medical procedures [7,54,55,63]. Two studies that measured children’s HR [59, 60] found no significant differences between the parent-present and parent-absent groups. One study [7] that reported beneficial effects of parental presence vs absence upon children’s HR, RR, and BP was given a low risk of bias on each domain and so was assumed to be free of bias. In sum, we carefully conclude that the presence of parents also has beneficial effects on physiological pain-related outcome measures in the child. To the best of our knowledge, only one other systematic review [15] on parental presence included physiological parameters as an outcome of interest. However, the importance of these outcome measures should not be underestimated. Measuring salivary cortisol levels, for example, is a noninvasive and reliable method to reflect the stress response of children in a fast and direct manner [69–71]. However, knowing that distress is just a type of negative emotion that could interfere in painful procedures [72], it should be considered separately from other negative emotions, such as the pain experience itself. Therefore, a combination of self-reported pain and distress, behavioral distress measurements, and physiological parameters such as salivary cortisol assessment might be a recommended method to provide a more complete biobehavioral picture of the impact of parental presence vs absence on child pain-related outcomes.

The variation in timing of both the parent–child separation and the assessment of the child’s behavior and especially the underreporting of this matter across the included studies seem to play an important role in explaining the heterogeneity of the study findings within the present review. In addition, a possible reason why some studies on the main research question did not find beneficial effects of parental presence could be particular features of parent–child interaction during painful medical procedures, which were not taken into account in the majority of included studies. For instance, parental protective or pain-attending behaviors, such as excessive reassurance and solicitousness, are shown to elicit more pain and distress in the child [73–75]. However, research nonetheless shows that children have a strong preference for the presence of their parent(s) during vaccinations [18, 60]. Drawing from a patient-centered care perspective as well as findings from the present review, it would be advisable to invite the parents to be present during painful medical procedures with their child, but further research is needed to identify for which type of children and parents (e.g., low/high anxiety) parental presence has the best effects.

Differences Depending on the Level of Parental Involvement

No convincing conclusions could be drawn with regard to this first subquestion. One study [65] showed that a condition in which the parents were asked to just watch without interacting with the child was preferable, because the children in this group showed the least expressive behavior before and during immunization. However, the only significant difference was found between the routine condition, with noninstructed high maternal involvement, and the watch condition, with children in the routine condition exhibiting more expressive behavior than children in the watch condition. In addition, the results of this study need to be interpreted with caution because of a high risk of bias on five of the six scored domains, resulting in a very low evidential value. However, this subquestion was not the focus of the present systematic review, which may have resulted in missing studies that could have provided a clearer answer to this question. For example, an interesting observation was made by Felt et al. (2000) [76] in infants of 2 to 24 months of age undergoing immunizations. Not only was the group of parents who received information on techniques to help their infant at immunization more likely to use a behavioral technique with their infant before immunization than the standard care parents, but also the infants’ distress was less pronounced at immunization, the infants were thought by their parents to feel more comfortable, and the infants’ salivary cortisol levels were lower for 1 hour after the immunization procedure. A systematic literature review focusing exclusively on this subquestion is recommended in order to form suggestions on which ways of active parental involvement (e.g., parents present and just watching vs parents present and having received instructions on how to interact with the child during the procedure) are desirable for advantageous pain-related outcomes in the child.

Role of Child, Parent, and Context Variables

Baseline anxiety and age of the child appeared to be important child variables explaining differences between the parent-present and parent-absent conditions. Low-anxiety children were found to report significantly more discomfort during a painful dental treatment in the absence of their parent compared with when they were accompanied by their parent, while the dentist rated high-anxiety children’s behavior significantly better when their parent was absent during a habituation session as well as a painful treatment session [32]. A possible
explanation for this may be that the anxious behavior of high-anxiety children triggers more pain-attending behavior in the parent, such as extremely reassuring the child, which in turn is associated with more pain behavior and distress in the child [73, 75, 77]. Low-anxiety children, on the other hand, might provoke rather non-pain-attending (coping-promoting) behavior in the parent, which could promote child adaptive coping [78, 79]. Future research might reveal whether it is more beneficial for high-anxiety children to not allow the parent into the operating room, whereas for low-anxiety children, the presence of the parent results in less anxiety and distress during the procedure. With regard to the age of the child, younger children (1–4 years old) seem to show more distress behavior and have a higher HR if the parent leaves the room in a parent-absent condition. When the painful procedure takes place, the opposite is true for older children (4–7 years old), whereas more negative behavior is seen if the parent is present [60]. In summary, it seems to be advantageous to have a parent present during a painful medical procedure, especially for low-anxiety and younger children.

With regard to parent variables, it is shown that the presence of parents is particularly beneficial for the child’s pain experience when parents successfully implement the intervention aspects that are instructed to them, such as talking to, touching, and maintaining eye contact with the child [52], and when the parent himself has low trait-anxiety [10]. The latter especially was an expected finding, as multiple studies have shown that parental attitudes, responses, and beliefs can influence a child’s pain experience and management [80–83]. Indeed, a recently proposed affective motivational theoretical model on inter-personal pain dynamics [84] posits that varying levels of parents’ self-oriented distress (i.e., feelings of personal distress when witnessing their child’s negative experience) account for observed differential effects of similar types of caregiving behavior. In particular, in the absence of adequate distress regulation, parental protective or pain-attending responses, such as extremely reassuring and comforting the child, may negatively impact child pain outcomes, whereas similar behavior may exert more beneficial effects when accompanied by low levels of parental distress. The effect of parental non-pain-attending responses (e.g., distracting the child with humor, singing, etc.) may likewise depend on whether or not such behavior is accompanied by high levels of parental distress. Possible explanatory mechanisms are described, such as parental self-oriented distress inducing an enhanced self-focus and impeding the parent’s sensitivity to the child’s needs and adjusting their behavior accordingly [83, 85]. Parents with lower feelings of distress, on the other hand, might be able to engage in pain-related behavior that is more attuned to the needs of the child. In addition, non-verbal quality characteristics of the parent’s behavior (e.g., facial expressions, tone of voice, interpersonal distance, etc. [86–89]) that may subtly differ depending on their associated level of distress may profoundly affect child pain-related outcomes. Indeed, findings have demonstrated that tone of voice and facial expressions are central in understanding the impact of reassurance on children’s behavior during painful medical procedures [90].

**Review Limitations and Strengths**

Some limitations to this review must be taken into consideration. First, a limitation of this field of research is the lack of blinding of participants and personnel. As a result,Item 3 of the Cochrane Collaboration’s Tool for Assessing Risk of Bias (blinding of participants and personnel) was not included in the assessment of methodological quality of the included RCTs. Second, a large variety of outcome measures were found throughout the studies, with a large variety of measuring instruments and measuring moments. Because of this, an overall meta-analysis was not possible. The fact that very few studies reported the exact moment of the measurement (e.g., preprocedural: parent already gone or parent still present in both groups) did not facilitate the interpretation of the results, while it might be exactly this variation in timing of measurements that may explain mixed study findings within the present review. Third, the quality of measuring instruments in the included studies was rather variable, and multiple studies did not describe any information about the psychometric properties of the measuring instruments used. Fourth, many of the included studies are older literature, and selective outcome reporting was prevalent, which may impact the findings of this review. Some studies lacked data in the Methods or Results sections (e.g., number of participants per group, number of girls/boys), and because of the dates of the studies, the authors could not be contacted (deceased or no contact details could be found), did not respond to both e-mails (first e-mail and reminder), or did not have the data files available anymore. To reduce the risk of bias of future research into the effects of parental presence during their children’s painful medical procedures, the exact randomization procedure should be described in detail, and the exact results, with means and standard deviations for each group, need to be reported in the article. Fifth, as both RCTs and nonrandomized clinical trials were included in the present systematic review, a possible bias across the overall study population might exist. Families participating in an RCT might be slightly different systematically from families participating in a nonrandomized clinical trial. This could be even more true in case parents are offered the option of selecting their group assignment or decline participation when they do not agree with the group to which they were allocated. Additionally, some studies included in the present review that described themselves as RCTs may not be fully considered as being randomized (e.g., O’Laughlin and Ridley-Johnson (1995) [63]). In sum, the above
issues appear to be significant limitations of the existing literature. Sixth, it needs to be remarked that both sub-questions were not the focus of the present systematic review, so it is assumed that a number of relevant articles about these topics, providing more insight into the effect of different levels of parental involvement and the role of child and parent variables, were not included in this study collection. In addition, our review focused on child pain-related outcomes only. However, we are aware of the fact that parent, clinician, and procedural outcomes are not to be overlooked, but this decision was made from a patient-centered care point of view.

Despite the limitations mentioned above, the present systematic review pushes the field forward and contributes significantly to our understanding of the effects of parental presence during painful medical procedures on pain-related outcomes in children. This review is, to the best of our knowledge, the first systematic review focusing on the effects of parental presence vs absence during children’s painful medical procedures on child pain-related outcomes. Compared with the most recent reviews covering this topic [15, 16], 10 [7, 10, 11, 32, 51, 54, 55, 58, 59, 63] and 18 [7, 8, 10–14, 32, 51–55, 57–59, 62, 63] new and recent studies, respectively, were included within this review. To focus on acute painful medical experiences, nonpainful medical procedures such as mask-induced anesthesia were disregarded, in contrast to a previous systematic review [15] on that topic. In addition, the present review also provides preliminary insights into some child and parent factors that may moderate the effect of parental presence vs absence on pain-related outcomes in children and also on how the parent can or should be involved in the pain management of the child to optimize child pain-related outcomes. These preliminary findings provide immediate indications for further investigation.

**Recommendations for Future Research**

Recommendations for improving the quality of future clinical trials and examining the effects of parental presence vs absence on child pain-related outcomes include a well-considered randomization method that is not interrupted by the wishes of the parents or other parties involved and that remains adequately hidden from both the participant and the researchers until the moment of the painful procedure itself. However, although RCTs are considered the gold standard to answer research questions such as the main one of the present review, a valuable challenge could be to design rigorous, high-quality, and ethically responsible studies that could be conducted in more naturalistic circumstances (e.g., a patient-centered approach in deciding on parental presence vs absence) and therefore better reflect the clinical reality of painful medical procedures in children. Furthermore, it seems that the effect of parental presence vs absence also depends on the moment of the measurement (e.g., measuring when the parent has to leave the room vs measuring when the parent is absent from the beginning). We strongly recommend that future studies report very clearly when the parent leaves the room and when the measurement is performed and even additionally investigate whether a conscious separation moment between parent and child does or does not increase the child’s anxiety even more than when the parent is absent from the beginning. Next, measuring instruments should be adapted to the age and related cognitive, intellectual, and emotional development of the participating children. Therefore, it is advisable to consult guidelines, such as the PediIMMPACT recommendations [91] and the VAPAIN statement [92], in order to select the appropriate outcome domains and accompanying measuring instruments in a well-considered manner. Moreover, a combination of self-reported pain and distress, behavioral distress measurements, and physiological parameters such as salivary cortisol assessment may provide a more complete biobehavioral picture of the impact of parental presence on child pain-related outcomes. To be able to properly answer the two highly important sub-questions formulated in this review, which may allow the understanding of mixed research findings, it is desirable to include one or two additional groups in which the parent is actively involved. For example, the parent may be given specific instructions on how to hold the child and maintain eye contact during the procedure, and in an additional group, the parent may be asked to distract the child throughout the procedure. Moreover, additional analyses on the impact of child and parent variables (e.g., age, sex, baseline anxiety, level of distress, verbal and nonverbal behavioral characteristics, etc.) and context variables (e.g., duration of the procedure, clinical setting, sex of the health care practitioner, moment of measuring, etc.), may provide more clarity about the situations in which it is more or less advisable for the parent to be present/involved during the procedure.

**Conclusions**

Evidence within the present review demonstrates beneficial effects of parental presence during painful medical procedures with regard to children’s self-reported pain and physiological outcomes, but it shows mixed findings with regard to children’s self-reported fear, anxiety, and distress and observed pain-related behavior in children from 0 to 18 years old. To provide clear recommendations on how to involve the parent during the procedure, as well as for which types of children and parents parental presence has the best effects, further research is needed, as indicated in this review.

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Supplementary Data
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