

Psycho-educational preparation of children for anaesthesia: a review of intervention methods

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Abstract

Objective To systematically review the different methods available for the Psycho-educational preparation of children for anaesthesia induction.

Methods Articles were searched in Academic Search Premier, OvidSP, Web of Science, and PsycINFO. Inclusion criteria were psychological and educational preparation of children for anaesthesia and anxiety reduction. The titles of papers and abstracts were reviewed and full copies of selected papers were scrutinized.

Results Forty-four empirical studies were identified. Twenty-one articles described Preoperative Preparation Programs, Twelve examined the effects of Distractive Techniques and eleven reported the effect of Parental Presence during anaesthesia's induction. Some general characteristics of the different interventions are discussed together with some key psychological and educational factors mediating anxiety in children undergoing anaesthesia.

Conclusion The effectiveness of interventions were linked to several factors. Psychological and contextual aspects are discussed. Psycho-educational activities should be better described when reporting their effectiveness in children's preparation for an anaesthesia.

Practice Implications Patient and family characteristics together with organizational and systemic aspects are described in order to guide the choice of the most appropriate preparation method for diverse health care setting.

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1. Introduction

The initial process of anaesthetization delivers a state of unconsciousness known as “anaesthesia induction”. Most often unconsciousness is reached by intravenous injection of a short-acting anaesthetic agent or via an inhalational procedure [1]. This process can be distressing for both children and parents. In fact, the incidence of clinically significant anxiety during this preoperative period is as frequent as 40-60% [2], and often results in postoperative agitation and adverse behaviours that can persist past hospitalization [3-5].

Research has found several factors to be correlated with the incidence of preoperative anxiety in children. These include daily home routines, unfamiliar situations presented by the hospital setting, medically invasive or diagnostic procedures involving different parts of the child’s body, uncertainty about how the surgery procedure is conducted, fear of pain and separation from parents [6, 7].

In the last two decades surgery techniques, anaesthetic agents and nursing knowledge have greatly improved [8] and most paediatric surgical procedures are now performed as day cases [9] which may increase distress in children as it leaves them with less time to adapt [10, 11].

Children of different ages suffer from different stressors during hospitalisation. Infants (0-1 years old) lack a rational understanding of why surgery is necessary [12, 13] and may feel betrayed by those believed to protect them [14]. The greatest stress from them is probably parental separation [15, 16]. Infants are particularly sensitive to the caregiver’s reaction. In fact, one way infants learn how to behave in an unfamiliar situation is via social referencing, which means they use emotional information gained from a caregiver as a means to evaluate strange situations [17]. This phenomenon applies to anxiety as well. De Rosnay and Cooper

[18] showed how the impact of an infant viewing a socially anxious interaction between his/her mother and a stranger, carried forward to his/her own interactions with that stranger.

Toddlers (1-3 years old), on the other hand, seem to suffer from social isolation and independence restrictions. Limited experience and inadequate knowledge of health care systems can add to a child's feelings of anxiety and fear resulting in an increased vulnerability to the stress of surgery [8, 14, 19]. Preschool children (3-5 years old) cannot use abstract logical thinking [20]. They have a limited concept of time, express fantastical beliefs [21], and may perceive hospitalisation as a punishment for wrong-doing [14].

Common hospital-related stressors at this age include painful procedures, immobilisation and separation from parents [21]. Sensitization of children with previous hospital experiences is often found in younger children and seems to decrease with age [22]. School-age children (6-10 years old) have improved language skills, increased logical thinking and improved perspective taking abilities [23, 24]. These abilities result in the school-aged child experiencing different stressors in a more realistic way. Important issues for those children are their worries relating to the disease, the separation from peers and from families members [21, 25]. Adolescents, on the other hand, demonstrate abstract thinking and can fully understand how their body is functioning, the nature of their problems and the reasons for invasive procedures [22]. They need more privacy and more independence. Common concerns for adolescents include fear of waking during the procedure, pain, and the possibility of death. Fear of loss of control is extremely important to adolescents and can lead to anxiety or distress [26] [27].

Children face hospital-related stressors with different types of coping strategies. A form of adaptation, coping is, in fact, flexible and develops through the lifespan as a joint function of personality and environmental characteristics [28]. Children develop their abilities to cope with fear and stress in several ways, which can be summarized in the following way: while

children younger than four years usually present a prevalence of distraction strategies [29], as they grow, coping shifts to cognitive-based and emotion-focused coping [30, 31]. From age four and up, children also present a good ability to regulate the coping response, according to the stressful situation [29], and to use play as a means to anticipate what is going to happen [32]. From age 6 and up, emotion-focused forms of coping improve [33-35] together with age-related problem solving ability [29]. Another trend increasing with age is the ability to seek social support and to shift from seeking parent-centred help to peer support, especially for emotional problems [36].

In the last two decades there has been an increase in attention on the psychological aspects related to patient well-being [37], children's preoperative anxiety (CPA) and parental anxiety [4]. The response has been that many hospitals have designed new programs that prepare children for medical procedures that require anaesthesia [9]. As noted by Hodges and colleagues [38], a great deal of confusion exists around the term *psycho-educational intervention* and this is merely due to the lack of a clear definition. On the other hand, when assessing interventions that involve the psychological or educational sphere, embracing a linear cause-effect and context-independent medical model often leads to insufficient or incomplete explanations of the observed phenomena [39]. A solution to this problem is suggested by Gutkin and Curtis [40], who affirm that in psychology the fundamental unit of analysis should be the interaction between internal states of the person and external environments. According to Bronfenbrenner's theory [41], such interaction can be effectively appreciated with the analysis of roles, relationships and activities occurring within a microsystem. In coherence with the above-mentioned propositions, throughout this paper we will consider a psycho-educational intervention as any type of action aimed at purposely modifying roles, activities or relationships of the different actors present in a given environment. In a medical setting, such interventions may be shaped in many different ways,

such as providing information, medical play, distractive techniques, and parental presence, and also changing organisational and communication routines in order to better adapt to children's and families' needs.

Numerous studies in children's healthcare discuss the beneficial effects of psycho-educational interventions. The aim of these interventions are many, for example, reduce child and parental anxiety, improve patient coping and cooperation during medical procedures, enhance postoperative recovery, increase patients' self-control and enhance the relationship between patients, families and health care providers [22]. One important mediating factor in the management of the child's anxiety appears to be parental presence at time of anaesthesia induction. The rationale for allowing parents to assist during induction is that the presence of a trusted family member, whom children believe to be a source of protection, guidance, and encouragement, may help alleviate fear and feelings of anxiety and gives the child a feeling of familiarity, even if he is in an unfamiliar environment and surrounded by strangers [42]. Additionally, parents usually have a better knowledge of the child's responses and preferred coping style [43]. The presence of a consistent, responsive, and empathic caregiver ensures psychological holding of the child and eases adaptation to the unknown environment [44].

The present review synthesizes research on interventions based on the psycho-educational preparation of children designed to reduce CPA. In the process, the present review underlines what these interventions are, what the contribution of each intervention is, as well as the methodologies and research design and assessment tools used in them.

2. Method

2.1 Eligibility criteria

Clinical studies analysing different educational and/or psychological interventions for the preparation of children to undergo anaesthesia and for the reduction of related anxiety were included. Participants between 1 month and 14 years of age receiving anaesthesia in a

clinical setting were considered. Any type of educational or psychological intervention was considered for this review (i.e., clown or music therapy, distraction, parental presence at time of induction, informational intervention). The aim of these programs could differ (e.g., reduced anxiety, improved perceived quality of care, patient and family empowerment). Clinical trials comparing only differing pharmaceutical interventions were excluded. Studies aimed at the preparation of children for a medical procedure not necessary involving anaesthesia were excluded. Because the aim of this study was also to account for different assessment methods used, no limitation was imposed on the outcome measures used in the studies.

2.2 Search

Articles were searched in Academic Search Premier, OvidSP, ISI Web of Science, and PsycINFO. These databases were selected because they include studies from multiple scientific disciplines relevant to the investigated topic (e.g., nursing and medical sciences, psychology, sociology, education, anthropology). The selected articles were all written in English. In order to account for dramatic changes in hospitalization practices and anaesthetic procedures during the last two decades, articles published between January 1990 and January 2015 were selected. The keywords ‘children’, ‘preoperative anxiety’, ‘premedication’, ‘hospitalization’, ‘anaesthesia’, ‘induction’, ‘surgery’, ‘preoperative program’, ‘preoperative preparation’, ‘preoperative intervention’, ‘hypnosis’ were used alone and in Boolean combinations. All USA and UK English variations of search terms were used. This search was extended by manually adding relevant articles presented in the reference section of those articles found using the above keyword search.

3. Findings

The initial keyword search generated 293 articles and 26 more were added through references inspection (Fig. 1). The screening of titles and abstracts and the elimination of

duplicates resulted in 51 articles that were read and evaluated. Ultimately, 45 articles were found to be relevant to the research question and the above-mentioned eligibility criteria and were included in this review. These studies were independently assessed by the two authors and when the authors diverged in their assessment, consensus was reached by discussion.

Psycho-Educational interventions for reducing CPA were divided into 3 main categories: Preoperative Preparation Programs, Distractive Techniques and Parental Presence (Table 1). Category assignment was based on what was explicitly written in the article or because it was inferred by the present authors reading of the described intervention.

----- Insert Table 1 about here -----

Intervention categories reflect different theoretical and practical approaches and have been used to organise the review table (Table 2).

----- Insert Table 2 about here -----

A critical analysis was performed on the selected articles, following The PRISMA Method [45], which provides both a structure and a process for systematically reviewing scientific literature. In order to create a proper data set to allow comparison and evaluation of the reviewed articles, two tables were created. Table 3 was organised following the STROBE criteria [46] as suggested by Aujoulat and colleagues [45]. STROBE is a widely used standard created to improve the quality of reporting observational studies. It provides general reporting recommendations in the form of a checklist. Table 4 was created in order to assess other important psychological, pedagogical and organisational issues in the preparation of the patient for anaesthetisation.

----- Insert Table 3 about here -----

----- Insert Table 4 about here -----

3.1 Preoperative Preparation Programs

Twenty-two studies (49 %) were categorized as Preoperative Preparation Programs (PPP).

The therapeutic effects of PPP have been attributed to cognitive and physiological responses, including decreased pain due to muscle relaxation, habituation of body sensations, distraction, altered perception of the event, increased positive reinforcement, and enhanced sense of internal locus of control [22]. Today, the majority of these programmes aim to reduce CPA by giving information to children and actively involving parents, enabling them to anticipate events both on a cognitive and a behavioural level, facilitating the child's and parents' understanding, sense of control, and active coping.

Nineteen of the reviewed programs were delivered by hospital personnel that provided in situ information about what to expect from the hospitalization experience, while the remaining three studies actively involved the family in this process. PPP run at the hospital employed different tools like videos, books, photo files, pamphlets, and it usually provided an orientation tour of the operating room (OR) and the recovery area, where medical equipment pertaining to the planned surgery was presented and demonstrated, either directly or through adult-initiated medical play. This kind of play activity provides children with the opportunity to play with and explore medical topics and equipment they are likely to experience when undergoing anaesthetisation [47]. The aim of such kind of play is to allow the child to become familiar with medical components and, therefore, experience less anxieties, fears, and misconceptions during upcoming medical procedures [48, 49].

Three studies were classified as Family-centred preparation programs because they emphasized the importance of the parent as a mediator in the child's preparation. In two separate studies, Kain and Fortier [50] [51] adopted a family-centred program called ADVANCE (Anxiety-reduction, Distraction, Video modelling and education, Adding parents, No excessive reassurance, Coaching and Exposure/Shaping). Parents were instructed how to help their children during hospitalization, how to distract them before and during anaesthesia induction and how to use the induction mask kit to let the children become

familiar with the induction process. The ADVANCE program has been found to have a positive effect in reducing the incidence of postoperative delirium, shortened discharge time and reduced analgesics use post surgery in comparison with the ordinary use of midazolam or with a simple use of parental presence. One of the Family-centred preparation programs was home-based and was usually run one week before surgery [52]. In this program, parents received a video and an auxiliary workbook to be used at home. The video showed a 5-year old boy who was in hospital for an inguinal hernia and the auxiliary workbook presented guidelines and exercises for preparing the child at home.

3.2 Distractive Techniques

Twelve studies (27%) examined the effects of Distractive Techniques (DT) on CPA. DT attempt to reduce CPA by diverting children's attention to other pleasant stimuli. Five studies used self-administered tools to draw children's attention away from medical procedures. Some self-administered tools employ standard and predetermined stimuli like videogames or cartoons, while others present more unstructured stimuli, such as a toy or a playroom, where the child is free to self-determine in detail how to exploit the stimuli. Golden, Pagala [53] found that giving a toy before the anaesthesia induction is an easy, safe and economical way of reducing CPA and may reduce the dose of midazolam necessary to decrease anxiety. Similar results were reported by Patel, Schieble [54] who investigated the use of an hand-held videogame in the holding area and by Lee, Lee [55] who reported that children who watched animated cartoons in the waiting areas had significantly lower anxiety scores than those in the control group. According to Lee, Lee [55], waiting areas that are equipped with toys, games, and other compelling activities help the children refocus their attention and decrease stress during the waiting periods.

Clowns were used as a means of distraction in five studies. Hospital clowns attempt to give children a joyful experience, by stimulating healthy emotions and by mitigating adverse

effects of a hospital stay [56]. In general Clown-based programs appear to positively affect children's anxiety levels, but there are some unresolved issues. None of the five reviewed studies about clown-based programmes gave specific details of the distraction activity presented. Vagnoli, Caprilli [57] reported that even if the majority of the medical staff recognized the effectiveness of this technique (78%), only a fraction were in favour of continuing the activity (28%) because it was believed that the presence of the clown interfered with the work of the medical practitioners. The authors conclude that medical personnel could be better informed regarding the benefits of the therapy. Golan, Tighe [58] found that when the anaesthetic mask was applied to the child's face, their anxiety levels were higher when accompanied by the clown than those children receiving oral midazolam or no intervention.

Music-based programs have also been studied and used in treating anxiety in hospitalized patients. A study by Kain [59], involved a complex, interactive music therapy session whose aim was to reduce children's preoperative anxiety through a process the authors described as "emotional projection" of feelings into stimuli and situations presented through song that allowed physical release by playing of instruments or making physical movements to music. This study did not prove the efficacy of music therapy as children who were treated with midazolam at anaesthesia induction were significantly less anxious than children in the music therapy and control groups. However, the authors found a "therapist effect" such that the music therapist and not the therapy was the key factor in reducing anxiety. The authors concluded that the intervention is quite expensive and recommends future research to identify the population that may benefit from music therapy. One study also investigated the use of hypnosis [60]. Hypnosis is defined as an altered state of consciousness characterised by concentrated but focused attention. The hypnotic intervention was carried out 30 minutes before surgery by the anaesthesiologist who would come in the

child's room and establish a 'hypnotic relation' taking into account some of the child's personal belongings in the room and talking about the child's fear or favourite games. The hypnotic state was then maintained until the induction of anaesthesia. The authors found this intervention more effective than midazolam for preoperative anxiety.

3.3 Parental Presence

Eleven studies (24%) report on the effect of parental presence (PP) during anaesthesia induction. These studies give a poor description of the specific tasks or roles parents may have during this step. During this intervention parents are usually informed about the procedure and then are allowed to accompany their child into the OR, comforting him while he falls asleep during anaesthesia induction [15, 61]. Following induction, the parent is escorted back into the waiting room by a nurse or a Child Life Therapist [62]. When an infant is being operating, parents may be allow to hold him during induction [61, 62]. This group of studies often presents heterogeneous and inconclusive results. Some studies have found that children benefit from PP (e.g. [63, 64]), although that benefit was only with specific cohorts, i.e., children older than 4 years, children who have a low baseline activity level as assessed by temperament, and children with parents who had a low trait anxiety (e.g [3]). Other studies have found that PP does not positively affect child's anxiety (e.g. [61, 65, 66]).

One of the main variables determining PP's effectiveness is the parent's anxiety level. Letting an overly anxious parent into the OR not only does not benefit an anxious child but also actually increases anxiety in a calm child [64]. In a study by Bevan, Johnston [65], children accompanied into the OR by parents who in the waiting area had resulted extremely anxious (VAS = 77.2 ± 16.7), turned out to be more upset than those having a calm parent (VAS = 15.9 ± 12.6). Additionally, the high level of preoperative parental anxiety was reflected in the child's negative behaviour and fears one week after operation. The presence

of calm parents, according to Bevan, Johnston [65], Palermo, Tripi [61] and Wright, Stewart [66], seems to have no impact on children's anxiety, while Messeri, Caprilli [63] and Kain, Caldwell-Andrews [64] found PP to be to be beneficial for the child.

The relationship between PP, premedication and the reduction of CPA is not clear. Kain, Mayes [3] found that PP does not extend the duration of induction, nor prolong the time to discharge, has not effect on the use of postoperative analgesic and does not influence postoperative nausea and vomiting. According to the authors, premedication with midazolam was significantly more effective in reducing CPA. In subsequent research, Kain, Mayes [15] found that combining midazolam with PP was not better at reducing CPA than midazolam alone, while Messeri, Caprilli [63] found that adding midazolam to PP wasn't better at reducing CPA than PP alone. Just to make matters even less clear Arai, Ito [62] found that PP at anaesthesia induction enhances the effects of midazolam on child behaviour at emergence from anaesthesia. Children of all ages do not benefit equally from parental presence at anaesthesia induction. Kain, Mayes [3] found that children under 4 years of age were more anxious during induction in the presence of their parent than children who were alone. The group of children who benefited the most from PP at induction were those older than 4 years of age, with a low level of activity and with a parent with low trait level anxiety.

When parental self-efficacy has been assessed, studies generally report that parents wish to accompany the child into the OR when offered this option and report that they helped their child post-surgery [67]. Anaesthesiologists, however, have differing views regarding the value of PP during induction. In a study by Kain, Mayes [15], 68% of parents believed that their presence had made the anaesthetists' job easier, while the majority of anaesthesiologists believed that parents had either no effect (38%) or made the job more difficult (21%).

4. Discussion and conclusion

4.1 Discussion

Each intervention type has its own benefits and limits. Anxiety and behavioural reactions relating to anaesthesia induction have a composite and multifactorial origin [3]. The plethora of variables at play in the process make it difficult to isolate accurately single mediating factors, which can be comparatively reviewed in table 3 and 4. At a general level, some methodological aspects can be noted from these two tables.

First, 90% of the presented studies employ validated tools, as can be seen from Table 4. Additionally, as can be seen in Table 3, all the reported studies present a satisfactory introduction and key methodological description, with only one study failing to give account of the study size and two studies failing to fully present the statistical method employed. In addition, the presentation of the results reach the STROBE standard [46] in a large majority of cases. Some more in-depth analysis of data is presented by 26 studies. In terms of the discussion of the results, limitation of the study is discussed only in 29 studies, and only 25 of them address generalizability issues.

Secondly, as can be seen in Table 4, psychometrical accuracy is not accompanied by the same level of precision in the presentation and evaluation of more educational and individual variables. It seems as if the method to reduce anxiety and prepare children for an operation has been evaluated objectively, but not as a multifactorial intervention subject to different subjective interpretations. This has led researchers to neglect some bioecological and personal variables that should be considered when running a psycho-educational activity [41]. Those subjective variables are cultural, contextual, or individual perception of the intervention and should include different actors such as parents, ill children, nurses, doctors, and those actively in charge of running the intervention. Some characteristics of each of the three types of the Psycho-educational preparation methods are discussed below in more detail.

Preoperative Preparation Programs represent half of the reviewed articles. Some programs show that when parents are properly informed and involved in the caring process of their children, they become more emotionally available for them. However, as shown by several reviewed studies, specific family differences at play are quite diverse and include culture, rules of affect and emotional display, assertiveness, and ability to ask for information from the medical team. Only the role of parent's anxiety has been extensively investigated as a moderating factor so far. Preoperative preparation should begin with the assessment of the child and parents' current level of understanding of planned procedures and of their emotional response to them. Several other dimensions should then be evaluated, such as the child's developmental level and the coping style, the patient and parents' understanding of the medical condition and planned procedures [68-70]. This is also related to the current emotional, cognitive, and physical symptoms of the patients, as well as previous hospital experiences. Children familiarized with hospitalization may benefit the most from preparations that includes not only procedural information but also coping skills training like relaxation exercises [22, 71]. For preschool children (3-5 years old), picture books explaining surgery and medical play kits are generally considered good tools for promoting understanding. Medical play accompanied with a simple and reassuring language represents a valid way to allow the child to express anxiety and to become familiar with the equipment that will be used during their hospitalization [72]. Hospital tours, preoperative classes, and medical play showing surgical procedures can help school-age children (6-10 years old) understand the meaning and reasons for therapy [73]. Adolescents may benefit from viewing peer-modelling videotapes. They need to be actively involved in the decisional processes and need to feel listened to when expressing concerns or requests.

Another important aspect to be assessed is the method in which information is best processed by the patient and their caregivers (verbal, visual, written, sensory), together with

the family composition and specific coping styles, which often appear to be linked with cultural aspects [74]. When stress and pain reach their peak level, relaxation techniques and coping strategies can be used in combination with parents' active involvement. Another important factor to be taken into consideration when programming a preoperative preparation is timing. In younger children (3-5 yrs.), anxiety levels are managed most effectively with preparation the night before surgery, whereas older children (5-12 yrs.) respond optimally when the information is presented one week before surgery [70]. On the other hand, when time before surgery and the age of children allow this, preparatory materials can be sent directly at home [52]. This method is also accompanied by a high rate of satisfaction of the caregivers involved.

Distractive Techniques may be self-administered by the child (e.g., videogame, watch TV, play with a toy) or may involve external personnel. Self administered techniques are free from effects deriving from an external actor performing the distraction and are either stable over contexts or are directly self-regulated by the child himself. Clowning and music therapy, on the other hand, require an external performer and in this case, the risk of a bias connected to the specific characteristics of the therapist should be assessed by the research.

The fact that clown-based programs have not always been well received by practitioners and even parents may be due to the fact that the clown attitude is that of an order-breaker [75], and in some specific settings like an OR or a waiting area such an attitude may not be the most appropriate one. Additionally, the specific type of action performed by the clown is an important confounding variable. For instance, if a clown plays magic tricks or makes soap-bubbles then this becomes the distracting factor and one could question what is the effective need for the clown itself. The specific actions performed by clowns are not documented in the reviewed studies. These features need to be better investigated and documented in future research.

Music has been used in a variety of medical settings for issues including pain and anxiety management, cancer-related care, psychiatric problems, and stress reduction [59]. While the relaxing effects of music have been objectively observed with physiological measures [76], its effectiveness as a preoperative distraction technique has not been confirmed by the study reviewed here. The study by Kain, Caldwell-Andrews [59] proves that a therapist effect may well be present in music therapy and this kind of variable should be examined in other studies involving external actors. All these techniques requiring the support of an external practitioner (i.e., clowning, music therapy, adult-initiated hypnosis) impact on the staff and incurs organisational cost and, therefore, their deployment should be carefully evaluated. The success of these techniques heavily rely on the therapist's ability to perform. When they are also poorly explained on the report, a high degree of objectivity and reproducibility is lost.

As shown by table 4, items 9 to 14, when a distraction technique is self-administered, it is usually associated with lower costs and represents an easy method to reduce anxiety at anaesthesia induction, especially when preparation time is limited. Such techniques may be used in combination with other interventions such as premedication, considering the evidences that a good distracting process may decrease the dose of drugs necessary to reduce CPA. For toddlers, modelling and/or distraction can often be used effectively [22, 27]. Distraction techniques that require the interventions of additional personnel should be carefully evaluated, as the effectiveness of this extra organisational and economical cost has not been proven superior to one of the other self-administered tools presented here. When preparation time is limited, distraction techniques may be more effective than other methods (LeRoy et al. 2003).

Concerning **Parental Presence**, this type of intervention has not always proven to be beneficial. We believe that the great number of variables involved in the process call for a

more systemically approach when evaluating experimental effects of PP on CPA. Future studies should offer a better description of the different tasks or roles parents may take during anaesthesia induction. “Parents” and “child” cannot be seen as a uniform variable. For instance the child's age, family culture, baseline anxiety levels of the child and parents, use of premedication, type of surgery, type of anaesthesia induction, and even experience and preferences of the anaesthetist have all been found to influence the outcome of PP [77]. A research study by Vessey and colleagues [78] specifically investigated parents’ reaction to anaesthesia induction of the child. The most upsetting factors for parents were: separation from the child after induction; seeing the child becoming limp during induction; observing the child's distress prior to induction; and remembering past negative experiences. Mothers reported a higher degree of upset than fathers. Having a single child and being employed in health care correlated with greater upset. The anaesthetist's view of parental upset only correlated with maternal self-assessment. Another research on PP at time of induction shows that in terms of parental perceived self-efficacy parents usually believe their presence at time of induction to be helpful both to their child and to the anaesthesia care providers [79]. However more objective measures of parental anxiety show that this can affect not only parents’ motivation but also their ability to be effective aids to their children [67].

4.2. Conclusion

When the WHO [80] view of health promotion is applied to young people in hospitals, it calls for better professional networking and a better understanding of the developmental needs of children [81], and requires the development of patient education interventions aimed to promote children’s active health and empowerment [37].

The present review revealed that linear and univariate cause-effect research design often leads to inconclusive or partial results. This happens because all the individual variables such as child temperament and attachment style, family culture and socio economic status, attitudes of the medical caregivers, skills of the professionals in charge of the child's preparations, are often overlooked. A more systemic approach, for example Bronfenbrenner's bioecological theory and process-person-context-time (PPCT) model for conceptualizing integrated developmental system and designing research related to human development [41] could effectively guide future research. Future studies should focus on a better documentation of the activity involved in the preparation with a clear definition of roles, relationships, timing, and a clear description of the social and cultural context in which the activity is carried out. As outlined by Table 4, some aspects such as the account of a "therapist effect" and a better customisation of the intervention based on the child's preferences could be added in the future. In line with a narrative medicine approach, the report of more psychological perceptions of the preparation activity by different actors involved should be further developed.

4.3 Practice Implications

Children's healthy functioning and resilience is related to their perception of care and involvement with their surrounding environment [82] as well as with a plethora of protecting factors at different systemic levels [83]. Today's health care practitioners cannot be focused only on the curing of an illness but need to adopt an holistic approach caring for paediatric patients. Increasing children's resilience is essential, in line with WHO recommendation that defines health as "A state of complete physical, mental, and social well-being not merely the absence of disease" [84].

The first main message therefore for practitioners is that preoperative preparation can and should be done for children. Anxiety reduction and coping with the stress related to the incumbent operation should be one of the therapeutic objectives of the hospital. Some of the reviewed studies showed that even the incidence of postoperative problems can be reduced with preoperative preparation.

Practitioners can choose from a plethora of different activities to prepare children undergoing anaesthesia and even their parents. Some of the activities presented here can also be combined, but it should be noted that too much information may also have a counterproductive effect.

Education and proper preparation may contribute to transforming a potentially negative and harmful experience into a formative and empowering one. Good psycho-education preparation helps the child to gain sense of the experience and replaces a feeling of powerlessness with a sense of mastery, thanks to active and effective coping skills. The choice of the proper preparation should be guided by several criteria and is related to the objective of the preparation. While anxiety reduction is often the common ground, several other variables may appear. Is cost-control also a necessity? Does the hospital also need to monitor and improve parents' satisfaction and good perception of the care? Is there a need also to improve the child's perception of the procedure? Is there the need to choose a practice that is also well accepted by the practitioners? Each of these questions leads one to different preparation methods as documented in this review and the proper choice should be carefully considered given the context.

In order to properly set a psycho-educational preparation for anaesthesia, practitioner's assessment of the temperament, culture and psychological functioning of each individual child is crucial. Children have different ways of seeking information and expressing emotions; they may present with specific phobias and have different abilities for

relieving anxiety through play and all these need to be assessed. This means that while active involvement of the child is always important, the preparation procedure should be tailored to the child's specific characteristics.

Indeed, family is the main learning and modelling source for children and has a great influence when educating them about the reasons for hospitalisation, how to face the medical procedures and how to deal with their emotional states. Therefore, the assessment of parental experiences, emotions, and attitudes should also be a part of routine preoperative paediatric evaluation. As suggested by Himes and Munyer [85], inexperienced and anxious parents could be managed with an education and information programme providing information about commonly experienced emotions during induction and offering reassurance about the procedure and the physical and emotional responses of the child. Other items that may be included in parent's instruction may be an overview on the sequence of the medical-related events in anticipation of the sensory experiences of the child. This kind of information may be given in situ by a practitioner or may be provided ahead of the operation with written material. Also, allowing parents to actively take part in the explanation of the procedures to the child through play techniques may be helpful, and this too can begin at home with the submission of preparation materials, such as a video link on the web and brochures and activity books to be completed together with the child. Information given to children should include the fact that anaesthesia is a very deep type of sleep in which you cannot feel anything, that the child will get the anaesthesia during the entire operation to make sure he/she stays asleep and that he/she will wake up only once the medicine has stopped, that the anaesthetist will stay with the child the entire time to monitor his/her sleep and to make sure he/she is comfortable, that nothing can be eaten or drunk before the operation, that one's parents will be with the child (or in a room near the child, depending on how the local hospital is organised) when he/she goes to sleep and when he/she wakes up [86].

The researches reviewed here show that parental participation at induction is still a controversial matter. Outcomes of such activity are heterogeneous and subject to great variance. Practitioners should therefore carefully evaluate the decision to allow parent to accompany children into the OR. This practice should be initiated only if there is a general consensus among the hospital staff, if a local organisation allows such activity to be easily conducted, and if parental involvement is a key objective of hospital care. In this case, to make parents more self-confident and, therefore, provide good support for their children, families should be offered adequate information on what the surgical experience will involve and how to behave [42]. For instance, parents could be encouraged to actively talk to their child during induction, read them their favourite story, talk about a favourite child's activity they are going to do when the operation is over, sing the child a lullaby, etc. With this kind of preparation, parents may participate in the anaesthesia induction in a manner that is beneficial not only for children but also for themselves.

In organisational terms, practitioners should be aware of the fact that preoperative preparation of a child involves teamwork and a complex caring system. It is therefore crucial that the whole ward's team of different professionals in charge of the child's care have a voice and feel committed in the development and implementation of the programme [87]. Especially, the opinions and comments of those professionals who would be affected by the changes in the routines should be heard. Interpersonal differences among professionals involved in the processes of anaesthetisation and keeping the child calm appear to represent an important and sometimes even significant mediating variable and yet they have seldom been investigated. Teamwork ensures that the new practice is subject to systematic, steady, and continuing application and evaluation.

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Table 1

Psycho-Educational Interventions categories in the reduction of preoperative anxiety in children.

Intervent. Type	# Articles	Aim	Sub Category (# articles)	Description	Rationale
Preoperative Preparation Programs (PPP)	22	Reducing preoperative anxiety by giving information and teaching children coping skills to manage stress or anxiety.	Preoperative preparation run at the hospital (19). Family-centred preparation program (3), of which one is run at home by parents.	Children (and sometimes parents) are given a verbal, written or multimedia description of the procedure and are told what to expect; a video or a comic book is sometimes used to present the anaesthesia procedure. Play activities with medical equipment and peer-modelling are often used to prepare the subject to the use of specific instruments (e.g., breathing mask, oximeter). A tour of the relevant hospital rooms (e.g., pre-anaesthesia, recovery) may be given. Relaxation techniques and coping skills are taught children for managing stress.	The main background is the theory of stress and coping [88]. Coping refers the cognitive, emotional, and behavioural response used to deal with stressful situations. Providing relevant information to children and teaching them coping skills, allows them to process, prepare for and understand the anaesthesia induction procedure gaining a sense of mastery over the stressful event.
Distractive Techniques (DT)	12	Redirecting child's attention from the stressful event to relaxing or entertaining stimuli.	Self-administered tools such as toys, watch TV, videogame (5) Clown-based programs (5) Music-based programs (1) Hypnosis (1)	Children are exposed to distracting stimuli such as videogames, toys, cartoons, clowns, and music or even virtual reality glasses. This draws their attention away from the stressful environment.	Engaging children's attention with distractions allows them to escape from what is happening, forgetting the surrounding, and refocusing attention on positive stimuli.
Parental Presence (PP)	11	Reducing anxiety-allowing parent to accompany their children during the anaesthesia induction.		Parents accompany their children during anaesthesia induction and comfort them during the procedure as they fall asleep.	Informed and calm parents can help children deal with stressful situations connected to the anaesthetisation, reinforcing their internal coping strategies. According to the Theory of Attachment [89] [90], parents are considered the primary source of affection for the child and the best option for comforting during distress. Parents act as mediator for emotion regulation of the stressed child. This in turns empowers the child's coping abilities.

Table 2

Overview of Psycho-Educational Interventions studies for the reduction of preoperative anxiety in children.

#	Authors (Date)	Design	Type	Research Question	# Subject (Age range)	Assessment			Main Results
						<i>Self-report (target)</i>	<i>Observational (target)</i>	<i>Physiological (target)</i>	
1.	Bevan et al. (1990) [65]	QEx	PP	What are the effects of anaesthesia induction and surgery on the child's mood and on parents' anxiety, when they are allowed to be present at induction?	134 (2-10 yr.)	HFI (c) PQ (p) VAS (p)	GMS (c) BQ (c)		The presence of a parent is not always beneficial. Almost half of the parents of this study were extremely anxious [VAS 81.7± 18.7] and their children were more upset [GMS 4.5± 1.5] in comparison with children [GMS 3.4± 1.6] accompanied by calm parents [VAS 31.2± 33.5]. The presence or absence of "calm" parents at induction made no difference to children [GMS 3.4± 1.6 and 3.5± 1.8]. Level of parental anxiety preoperatively was found in children's behaviour and fears one week later.
2.	Kain, Mayes, and Caramico (1996) [70]	CS	PPP	What are the effects of a preoperative preparation program aimed at reducing anxiety in children and their parents before elective surgery?	143 (2-10 yr.)	VPT (c) VAS (c&p)	EASI (c) CARS (c) PHBQ (c) VAS* (c) VAS (c)		The program was more effective for 6-years-old children who were prepared at least 5 to 7 days before surgery than for children who did not receive the intervention and for children who received the intervention one day prior to surgery [VAS 47±13 vs. 54±14 vs. 63±22, p=0.04]. Parents of 6-years-old children who received the program more than 5 to 7 days before surgery were less anxious than parents who received the program 1 day before surgery [VAS 78±24 vs. 23±9, p=0.02]. At the preoperative holding area, 3-years-old children and younger were more anxious than children who did not receive the intervention [VAS 46±17 vs. 25±14, p=0.001]; at separation before the OR, these children were more anxious if they received the intervention [VAS 23±13 vs. 36±18, p=0.03] Children more emotionally labile (upper quartile of EASI-emotionality) who received the intervention were more anxious, both at preoperative holding area [VAS 34±19 vs. 51±16, p=0.03] and on separation before entering the OR [VAS 13±8 vs. 41±19, p=0.01], than children more emotionally stable (lower quartile of EASI).

3.	Kain, Mayes, Caramico, et al. (1996) [3]	RCT	PP	Does PP during the anaesthesia induction, reduce children's anxiety and long-term problematic behaviours? Which factor predicts the children-parent pairs that will benefit most from PP at induction?	84 (1-6 yr.)	STAI (p&a)	VAS (c&p) VAS* (c) YPAS (c) CARS(c) EASI (c) PHBQ (c)	BP (p&a) HR (p&a) Cortisol (c)	PP at induction did not affect the duration or the efficacy of the induction or the stress level of the anaesthetists. Anaesthetists believed that few parents were helpful for their child (12%) and made their job easier (31%); on the contrary, 90% of the parents felt helpful to their child, and 68% felt supportive to the work of the medical personnel. PP was not associated with the decrease of postoperative behavioural problems of the child. Children under 4 yr. were more anxious during induction in the presence of their parent [serum cortisol 96± 32 µg/ml vs. 77± 26 µg/ml, unadjusted p= 0.049, adjusted Tukey's p= 0.42]. Children older than 4 yr. [serum cortisol 70± 5 µg/ml vs. 131± 22 µg/ml, adjusted Tukey's p= 0.001] children with a low level of activity [lower 25% of the EASI activity: serum cortisol 69± 7 µg/ml vs. 105± 14 µg/ml, adjusted Tukey's p= 0.05] and children with a parent with low trait anxiety level [lower 25% of the STAI: serum cortisol 71± 8 µg/ml vs. 116± 18 µg/ml, adjusted Tukey's p= 0.02] presented lower level of serum cortisol than children under 4 yr., children with an high level of activity and children with a parent with high trait anxiety.
4.	Kain, Caramico, et al. (1998) [91]	RCT	PPP	Is an extensive preoperative preparation program, for children undergoing surgery, more effective than a limited preoperative preparation program?	75 (2-12 yr.)	STAI (p) MBSS (p) VPT (c) CC (c)	EASI (c) VAS (c) YPAS (c) PHBQ (c)	BP (p) HR (p) Cortisol (c)	Children and parents, who received an extensive behavioural program presented less anxiety during the preoperative period but only in low-stress moments, like preoperative holding. The program had not effect during in high-stress periods, like anaesthesia induction. Children who rated higher in positively coping strategies (r=0.43, p=0.03) benefited more from the interventions. Parents who received the extensive program resulted less anxious in the holding area [STAI 44±12.2, p=0.047] and presented lower diastolic blood pressure [72 (61-68), p=0.003] and lower systolic blood pressure [119 (110-145), p=0.01].
5.	Kain, Mayes, et al. (1998) [92]	RCT	PP	Which intervention between a pharmacological intervention (premedication with midazolam) and PP is more effective in	93 (2-8 yr.)	STAI (p) MBSS (p) CC (c)	m-YPAS (c) PBRS (c) ICC (c) PHBQ (c)		Oral midazolam before surgery is a more effective intervention than PP for reducing the child's preoperative anxiety [PBRS 0 (0-1) vs. 4 (0-5), p= 0.02]. In addition, premedicated children were more compliant during anaesthesia induction. Parents in the midazolam group were the least anxious after separation [STAI 43± 12] while parents in the parental-

				reducing preoperative anxiety in children?			presence group were the most anxious [STAI 50± 10, p = 0.048].
6.	(Margolis et al., 1998) [93]	RCT	PPP	What is the effect of preoperative teaching at induction and postoperatively?	143 (2-6 yr.)	PHBQ (c) GMS (c)	<p>Children's anxiety increased from holding area to OR entry and mask application.</p> <p>In the group of children aged 4 to 6 years, at mask application experimental group showed less anxiety [GMS 2.3±1.7] than the control group [GMS 2.7±2.0]; contrariwise, in the group of children aged 2 to 4 years, at mask application the experimental group showed more anxiety [GMS 3.4±2.0] than children in the control group [GMS 3.0±2.0] (all p < 0.0001).</p> <p>Postoperatively, children in the control group showed higher aggression [PHBQ 8.8±2.4 to 9.0±3.0] than children in the experimental group [PHBQ 8.4±2.0 to 8.0±2.0] (p = 0.05). The increase in aggression was more pronounced in the 2 to 4 years group: in the control group, PHBQ increased up to 9.5 (2.7) while in the experimental group there was a ceiling of 7.7 (1.9), (All p < 0.008).</p> <p>83% of the parents in the intervention group felt the preparation received by them and their child was exhaustive, compared with 66% of parents in the control group (p < 0.05).</p>
7.	Hatava et al. (2000) [12]	Coh	PPP	Does a new information program increase retrieval of information and reduce anxiety before surgery?	160 (2-10 yr.)	Adh1 (p, c) Adh2 (p, c)	<p>Children and parents who received the new information program had a better acquisition of knowledge about the events of the preoperative period (p<0.001).</p> <p>Older children (> 5 yr.) were less frightened by the pre-anaesthetic preparation [odds ratio of not expressing fear = 3.52 (1.35, 9.15) (p<0.01)] and anaesthesia induction [odds ratio= 5.57 (1.74, 17.8) (p<0.001)] than the younger one.</p> <p>Older children (>5 yr.) without previous medical experience presented a less negative attitude toward premedication than those with this experience [p<0.001].</p> <p>Informed children (<5 yr.) with previous hospital experience presented less fear of anaesthesia induction than children of [p<0.05].</p> <p>Parents of younger children and of children with previous hospital experience, who received the new program, presented less negative emotions at anaesthesia induction than parents in conventional group [p=0.06, odds ratio = 2.58</p>

								(0.76,8.70)].
8.	Zelikovsky et al. (2000) [71]	RCT	PPP	Does the intervention package designed for this study effectively reduce children's distress during voiding cystourethrogram procedures?	40 (3-7 yr.)	FACES (c)	CAMPIS-R (c) PTR (c)	Intervention group presented more coping behaviours and fewer distress behaviours than children in the standard care condition, during both catheterization [CAMPIS-R t(38) = -1.80, p<.05 and t(38)= 1.82, p<.05] and voiding [CAMPIS-R t(38)= -2.93, p<.005 and t(38)= 1.86, p<.05]. Children who were more scared presented more distress behaviours [FACES r= .39, p<.01], fewer coping behaviours [FACES r= -.37, p<.01] and higher levels of pain [FACES r= .42, p<.005]. Younger children reported more distress behaviours [FACES r= -.55, p<.0001 and lower coping behaviours [FACES r= -.50, p<.0001]. Parents and technicians found children who had previous hospital experiences less cooperative [r= -.32, p<.05 and r= -.34, p<.05].
9.	Kain et al. (2000) [15]	RCT	PP	Is the combination of PP and sedative premedication more effective than sedative premedication alone, in reducing anxiety in children and their parents, and in improving parental satisfaction and compliance of the child?	103 (2-8 yr.)	STAI (p) Adh3 (p)	m-YPAS (c) ICC (c)	PP at anaesthesia induction, in addition to 0.5 mg/kg oral midazolam, has no additive effect in reducing children's anxiety, nor did it improve the child's compliance during the induction process. Parents who accompanied their children into the OR were less anxious after separation [STAI 43± 11 vs. 48± 12 F(2,93)= 4.46, p= 0.037] and more satisfied with the overall hospital organization [0.43± 0.26 vs. -0.28± 1.2, p= 0.046].
10.	Palermo et al. (2000) [61]	RCT	PP	How do children and parents respond to PP during the anaesthesia's induction?	73 (1-12 mo.)	STAI (p) HCAQ (p) PPQ (p)	RCD (c)	PP had no impact on infants' distress during induction [RCD 2.0± 0.5 vs. 1.8± 0.5]. Parental anxiety level pre- and post-surgery, health care attitudes pre and post-surgery, and satisfaction with the surgical experience were the same for the parents present at induction and for the parents who were not present.
11.	Felder-Puig et al. (2003) [13]	RCT	PPP	Does the presented new book for surgery preparation reduce the effects of anxiety and distress in children?	400 fam. w. 2-10 yr. c.	STAI (p)	Adh4 (c)	Mothers who received the preparation book experienced less anxiety before surgery than mothers in the control group [STAI 42.11±10.75 vs. 45.97±11.48, p<0.01]. After surgery, mothers of both groups were less anxious without differences. Children who received the book resulted less worried than those in the control group did, even if the levels of distress

								for both groups were higher after surgery than before. 96% of mothers in the experimental group found the book to be helpful and 91% of them felt better informed and prepared for surgery and hospitalization Nurses observed that informed mothers were more actively involved in their children's care (80%) than mothers in the control group (67%).
12.	Kain et al. (2004) [59]	RCT	DT	Is interactive music therapy effective in reducing preoperative anxiety in children?	123 (3-7 yr.)	STAI (p)	m-YPAS (c) EASI (c) ICC (c)	Children who received music therapy were as anxious as children who did not received it [m-YPAS 33.8± 12.2, 31.2± 10.5, 33.2± 13.1, p= 0.61]. At separation to the OR and on entrance to the OR, children who received music therapy from Therapist 2 were significantly less anxious than children who received music therapy from Therapist 1 were. This therapist effect did not continue at time of the anaesthesia induction.
13.	Messeri et al. (2004) [63]	Obs	PP	What are the effects of both premedication and PP on preoperative anxiety?	39 (2-14 yr.) and parents	STAI (p) Adh5 (c&p)	RCB (c)	A reaction of less stress in children during anaesthesia induction was moderated by the presence of the mother (86% of children "no stress" in comparison to the presence of the father 50% of children "no stress"), low anxiety level of the parent, and the age of the child itself (<5 yr. 65% "no stress", ≥ 5 yr. 94% "no stress"). Children of parents with high anxiety levels were more stressed during induction. Parents judged their own presence during the anaesthesia induction as a positive event to their child.
14.	Campbell et al. (2005) [94]	RCT	PPP	How effective are two preparation packages aimed at facilitating coping behaviours in children undergoing dental general anaesthetic induction and recovery?	198 (3-10 yr.)	VAS (c)	MCDAS (c)	The computer preparation package seemed to facilitate children's coping behaviour at anaesthetic induction [median (coping) VAS score of 1 range (0-10)]. Children in the cartoon group were the most distressed at recovery [median (coping) VAS score of 4 range (0-10)].
15.	Vagnoli et al. (2005) [57]	RPS	DT	Does the presence of clowns reduce preoperative anxiety in children undergoing minor surgery?	40 (5-12 yr.)	STAI (p) Adh6 (ph) Adh7 (cl)	m-YPAS (c)	The presence of clowns together with one of the parents during the anaesthesia induction proved to be an effective intervention for reducing the anxiety of the child in comparison to the presence of only one parent [m-YPAS 37.50± 21.48 vs. 68.25± 28.42, p= .000]. Children who interacted with the clowns presented the same degree of anxiety in the induction room and in the waiting room [m-YPAS 30.95± 11.34, p= .254 and 37.50± 21.48, p=

								.000] The majority of the staff recognized the effectiveness of this technique (78%) but only few were in favour of continuing it (28%).
16.	Caldwell - Andrews et al. (2005) [67]	Obs	PP	Does parental motivation for presence during anaesthesia induction significantly influence children anxiety?	289 mother-child (2-12 yr.) dyads	MMPI (p) STAI (p) MBSC(p)	m-YPAS (c)	Children of mothers who presented high desire and low hesitancy to enter the OR, were more anxious as compared with children whose mothers were less motivated to accompany the child [m-YPAS 64.8± 28.8 vs. 51.4± 28.8, p= 0.02]. Highly motivated mothers reported higher state anxiety than lesser motivated mothers [STAI 44.4± 10.6 vs. 39.8± 9.7, p= 0.007]. Also mother with low hesitancy resulted more anxious than mother with high hesitancy [STAI 46.2± 9.9 vs. 39.2± 9.7, p= 0.0001].
17.	Calipel et al. (2005) [60]	RCT	DT	Is hypnosis more effective in reducing preoperative anxiety in children than Midazolam?	50 (2-11 yr.)		m-YPAS (c) PHBQ (c)	The group of children which received Midazolam had an increase in anxiety from arrival in the department [m-YPAS 42, (p<0.05)] to the application of the facemask [m-YPAS 52, (p<0.05)]. They also showed higher anxiety when the facemask was placed [m-YPAS 52, (p=0.04)], in comparison with the group of children who received hypnosis [m-YPAS 40, (p= 0.04)].
18.	Golden et al. (2006) [53]	RCT	DT	Does giving a small toy to a child decrease anxiety and apprehension in association with oral premedication?	100 (3-6 yr.)		m-YPAS (c)	Giving a toy reduced preoperative anxiety in children enhanced their acceptance of midazolam. Children in the no-toy group had an increase in the m-YPAS score from 28 at baseline to 42 during the administration of midazolam in comparison to the toy group (decrease from 33 to 23).
19.	Patel et al. (2006) [54]	RCT	DT	What are the effects of a hand-held video game in reducing preoperative anxiety in children?	112 (4-12) yr.		m-YPAS (c) PHBQ (c)	Children (4-12 years) who played with a hand-held Video Game had less anxiety at anaesthesia induction compared both with children who had only their parents present, and with children who received oral midazolam [m-YPAS 41.7± 4.1 vs. 51.5± 4.0 vs. 53.9± 2.7, p< 0.01]. Children in the 4-5 years subgroup of the Video Game group had the lowest change in m-YPAS scores compared with Midazolam and PP groups. Patients in the subgroup 6-9 years showed the least level of anxiety across all three groups (22% vs. 60% vs. 57%).
20.	Kain et al. (2006)	Coh	PP	What are the child-parent dyads that will benefit from parental	568 (2-12 yr.)	STAI (p)	EASI (c) m-YPAS (c)	Authorizing an overly anxious parent into the OR does not appear to benefit an anxious child [m-YPAS 71.0± 23 (53) vs. 66.6± 27 (26), p= 0.490] and even increases anxiety in a

	[64]			presence at induction?					calm child [m-YPAS 52.4± 28 (55) vs. 39.4± 21 (75), p= 0.002] Letting calm parents in the OR will benefit anxious children [m-YPAS 51.9± 24 (47) vs. 64.6± 26 (28), p= 0.39] and will not change the anxiety level of children who were calm in the preoperative holding area [m-YPAS 39.9± 22 (63) vs. 34.7± 20 (68), p= 0.150].
21.	Li et al. (2007) [95]	RCT	PPP	What are the effects of therapeutic play on anxiety outcomes of children undergoing day surgery?	203 (7-12 yr.)	CSAS-C (c) VAS** (c)	CEMS (c)		Children in the therapeutic playgroup presented less anxiety level both after the intervention [CSAS-C 34.36, 8.09 vs. 38.60, 8.53] and in the postoperative period [CSAS-C 33.58, 5.90 vs. 36.16, 5.60], comparing with the children who received the routine information preparation. No differences were found between the two groups in postoperative pain [VAS 4.19, 1.18 vs. 4.47, 1.24].
22.	Kain et al. (2007) [50]	RCT	PPP	Is a behaviourally oriented perioperative preparation program that targets the family as a whole (ADVANCE), effective in reducing preoperative anxiety in children?	408 (2-12yr.)	STAI (p) MBSS (p)	m-YPAS (c) RCEB (c)		The ADVANCE program reduced children's anxiety before surgery [m-YPAS 31±12, p=0.001] in comparison with children in the control group [m-YPAS 36±16, p=0.001], in the PP group [m-YPAS 35±16, p=0.001] and in the midazolam group [m-YPAS 37±17, p=0.001]. At anaesthesia induction, children who received ADVANCE presented lower levels of anxiety [m-YPAS 43±23, p=0.018] than children in the control group [m-YPAS 52±26, p=0.018] and in the PP group [m-YPAS 50±26, p=0.018], but similar levels to the midazolam group [m-YPAS 40±24, p=0.018]. ADVANCE reduced the incidence of postoperative delirium (10%), shortened discharge time [min 108±46, p=0.040], and reduced using of analgesics after surgery [$\mu\text{g}/\text{kg}$ 0.41±1, p=0.016].
23.	Arai et al. (2007) [62]	RCT	PP	Is a combination of mother presence and midazolam premedication more effective than midazolam premedication alone or mother presence alone, in improving pre-anaesthetic and emergence from anaesthesia in children?	60 (1-3 yr.)		RCQM (c) RCE (c)	BP(c) ECG(c) SO2 (c) ETCO2 (c)	PP during anaesthesia induction (PPIA) did not enhance the effect of oral midazolam on the quality of induction [Midazolam 2(1-3), PPIA 3(2-3), Midazolam+PPIA 2(1-3), p< 0.001]. PPIA enhanced the effect of oral Midazolam on emergence behaviour of children undergoing general anaesthesia [Midazolam 4(2-5), PPIA 4(2-5), Midazolam+PPIA 3(2-4), p< 0.001].

24.	(Li & Lopez, 2008) [96]	RCT	PPP	Is therapeutic play effective in preparing children and their parents for paediatric Surgery?	203 (7-12 yr.)	CSAS-C (c) STAI (p) PPSQ (p)		<p>The results showed that children in the experimental group reported significantly lower state anxiety scores in the preoperative period [CSAS-C 34.36±8.08] and in the postoperative period [33.58±5.89] than children in the control group [CSAS-C 38.60±8.52 and 36.16±5.60]; p = 0.001 and p = 0.002, respectively.</p> <p>Parents in the experimental group reported significantly lower state anxiety scores in the preoperative period [STAI 39.90±9.36] and in the postoperative period [STAI 36.57±7.65] than parents in the control group [STAI 44.04±9.56, and 39.13±8.71]; p = 0.002 and p = 0.030, respectively.</p> <p>Additionally, parents in the experimental group reported significantly higher levels of satisfaction [PPSQ 27.28±2.35] than parents in the control group [PPSQ 25.90±2.13, (p = 0.001)].</p>
25.	MacLaren & Kain (2008) [72]	RCT	PPP	What are the effects of a modelling and exposure intervention on children's anxiety and compliance during anaesthesia induction?	112 (2-7yr.)	STAI(p)	m-YPAS(c) ICC (c)	<p>Children who received the modelling intervention were more compliant during the anaesthesia and presented smaller increases in anxiety than children who did not receive it (7.0% vs. 26.8%).</p> <p>Both groups showed increases in anxiety when separated from parents but children who did not receive the intervention, showed higher levels [effect of group on change in m-YPAS score from separation to induction, F(1,101) = 6.32, p<0.02].</p> <p>This intervention did not affect parents' anxiety.</p>
26.	Golan et al. (2009) [58]	RCT	DT	Do trained professional clowns relieve preoperative anxiety in children?	65 (3-8 yr.)	STAI (p)	m-YPAS (c)	<p>The presence of trained clowns reduced the preoperative anxiety in children [m-YPAS 28.3± 12.7, p= 0.01] and when they were accompanied to the OR [m-YPAS 37.3± 12.3, p=0.005].</p> <p>When the anaesthetic mask was applied to children's face, the level of anxiety in the children accompanied by clowns reached its peak [m-YPAS 62.7± 14.6] and was greater than in children receiving either oral midazolam [m-YPAS 49.9± 16.0] or no intervention [m-YPAS 54.4± 21.6].</p>
27.	(Karabulut & Arıkan, 2009) [97]	QEx	PPP	What are the effect of different training programs in decreasing anxiety of mothers and children before and after the operation?	90 children (9-12 yr.) and their mothers	STAI (p) Adh12 (c, p)		<p>Children in the experimental group (VCD) and in the Booklet one group were less anxious 24 hours before surgery [23.93 (SS=2.92), (p < 0.01) and 28.60 (SS= 3.92), (p > 0.05)] and 24 hours after [22.23 (SS=1.19), (p < 0.01) and 27.40 (SS= 3.94), (p > 0.05)], than children in the Control group [before 40.37 (SS=5.68), and after 30.50 (SS=7.08), (p</p>

							< 0.05)]. In the same way, mothers in the VCD group and mothers in the Booklet one showed low anxiety levels 24 hours before surgery [34.07 (SS=7.80), (p < 0.01) and 36.93 (SS=8.42), (p < 0.01)] and 24 hours after [28.93 (SS=5.85), (p < 0.01) and 28.20 (SS=4.80), (p<0.01)], than mothers in the control group [before 54.23 (SS=7.03), (p > 0.05) and after 31.33 (SS=9.97), (p > 0.05)].
28.	Wakimiz u et al. (2009) [52]	RCT	PPP	Can a Family-centred preparation program run at home prior to surgery reduce anxiety in children?	158 (3-6 yr.)	Wong-Baker FACES (c) STAI (p) Adh8 (p)	91.7% of caregivers in the experimental group are satisfied with this Family-centred preparation program run at home; This preparation program significantly reduced the preoperative anxiety of the children [FACES 1.30±1.42 vs. 2.06±1.89, p=0.02]. Parents' levels of anxiety in the experimental group have resulted lower than anxiety's level in the parents of the control group at all stages.
29.	(Fernandes & Arriaga, 2010) [98]	RCT	DT	Can a clown-based program reduce preoperative worries and the affective responses of children undergoing minor surgery?	70 (5-12 yr.)	CSWQ (c) SAM (c) STAI (p) EAS (c)	Children in the clown group reported less worries than those in the control group [CSWQ = 0.85, SD = 0.45 vs. CSWQ = 1.95, SD = 0.67]. Children in the clown group reported a higher positive affect [SAM = 8.14; SD = 1.19] than those in the control group [SAM = 6.06; SD = 1.59], all p < 0.001). Children in the clown group expressed lower arousal [SAM = 1.66; SD = 0.69] than those in the control group [SAM = 3.36; SD = 1.77] and experienced a significant reduction in arousal between the pre-operative [SAM = 3.53; SD = 2.55] and the post-operative phase [SAM = 1.49; SD = 1.24], (all p < 0.001). Anxiety was lower for parents in the clown group [STAI = 1.80; SD = 0.38] than for those in the control group [STAI = 2.14; SD = 0.46], all p < 0.001.
30.	(Hosseinpour & Memarza deh, 2010) [99]	RCT	DT	Is a playroom next to the operating room efficient in reducing preoperative anxiety in children?	200 (children over the age of 4 year. Male mean age of 4.33±1.5. female 3.87±1.2)	m-YPAS (c)	Preoperative anxiety decreased significantly in all categories of the m-YPAS: children in the playroom group showed more activity (for example "looking around, curious, playing with toys, reading" 64% Vs 20%, p = 0.001), did more reading (56% Vs 16%, p = 0.001), asked more questions, did more comments and laughing than children in the control group. They also presented less stress ("happy, smiling" 52% Vs 8%, p = 0.001), and they were more alert and looked around occasionally (52% Vs 12%, p=0.001). Finally children in the playroom group were busy playing and staid

								more without parents (34% vs 14%, p = 0.001) than children in the control group.
31.	Vagnoli et al. (2010) [100]	RCT	DT	Which is the most effective intervention, between PP, clowns and premedication, in reducing preoperative anxiety?	75 (5-12 yr.)	STAI (p)	m-YPAS (c)	PP in conjunction with clown was more efficient in reducing anxiety in children than PP alone or associated with midazolam, both in the waiting room [m-YPAS 29.48± 10.47 (23-62) vs. 34.96± 14.39 (23-68) vs. 37.40± 13.13 (23-63)] and at time of induction room [m-YPAS 33.16± 18.82 (23-100) vs. 65.40± 24.97 (32-100) vs. 49.72±22.86 (23-96)]. Parents who knew that their children were premedicated were more reassured [STAI 37.40± 13.13 (41-77)] than parents who simply accompanied their children in the OR [STAI 58.32± 9.32 (41-72)] and than parents whose children received the support of clowns [STAI 58.52± 12.73 (41-85)].
32.	Wright et al. (2010) [66]	RCT	PP	Does PP alleviate anxiety in children undergoing outpatient surgery?	61(3-6 yr.)		m-YPAS (c)	PP had no effect on child's anxiety at time of induction [m-YPAS 54.18± 27.90 vs. 52.75± 24.27]. A difference was noted with the parental absence group when children were separated from their parents [m-YPAS 38.87± 20.89 vs. 26.71± 6.72]. Decreased anxiety in the PP group was short-lived and did not persist at time of induction a few minutes later.
33.	Fortier et al. (2011) [51]	RCT	PPP	What are the key effective components of ADVANCE on reducing preoperative anxiety in children?	96 (2-10 yr.)	STAI (p)	EASI (c) m-YPAS (c) Adh9 (p)	Greater parental adherence to ADVANCE was associated with lower child anxiety before surgery [m-YPAS 37.5±17.8 vs. 52.8±25.7, p=0.01]. Additionally children's anxiety seemed to remain stable and low throughout the preoperative period. Practicing with the anaesthesia mask at home and the use of distraction in the holding area were the two components which had more impact on children's anxiety. Those children whose parents were not complainant to these intervention components presented an increased anxiety from holding area to the introduction of anaesthesia mask [m-YPAS 50.4±23.4, p= 0.01 and 59.8±28.7, p=0.02].
34.	Vaezzadeh et al. (2011) [73]	RCT	PPP	What are the effects of performing preoperative preparation program on children's anxiety?	122 (7-12 yr.)	SSAS-c (c)		Using therapeutic play before surgery is an effective method to decreasing children's anxiety: after the intervention children in the experimental group resulted less anxious than children in the control group [SSAS-c 31.44 (5.87) vs. 38.31 (7.44), p= 0.001].
35.	Fincher et al. (2012) [101]	RCT	PPP	What are the effects of a structured preoperative preparation on child	73 (3-12 yr.)	STAI(p)	EASI (c) m-YPAS (c) FLACC (c) FPS-R (c)	Both groups of children experienced increasing in anxiety. Parents' anxiety decreased in the preoperative preparation group [-2.32, CI -4.06 to -0.56, p= 0.009] compared with the group that did not receive any preparation, but there were no

				and parent state anxiety, child behavioural changes and parent satisfaction?			PHBQ (c)	differences in their satisfaction. The preparation was beneficial in reducing postoperative pain but there were no differences in post-hospital behaviour between the two groups.
36.	Lee et al. (2012) [55]	RCT	DT	What are the beneficial effects of viewing an animated cartoon and playing with a favourite toy on preoperative anxiety in children?	130 (3-7 yr.)		m-YPAS (c) VAS (c)	Children who watched animated cartoons (group 3) in the OR had significantly lower anxiety scores than the children in the control (group 1) and toy groups (group 2) [m-YPAS 31.8± 8.8 vs. 57.4± 18.1 vs. 43.6± 16.1, p<0.05]. Also parents of children in group 3, at time of the operation, reported the lowest scores in comparison with parents of group 1 and group 2 [VAS 3.2± 2.4 vs. 6.1± 2.7 vs. 5.2± 2.6, p<0.05].
37.	(Cuzzocrea et al., 2013) [102]	RCT	PPP	Is this psychological preoperative program effective in reducing preoperative anxiety and in promoting compliance in children undergoing surgical procedures?	0 (3-12 yr.) and their parents	APAIS (p) Adh10 (p)	m-YPAS (c) ICC (c) Adh11 (c)	Children in the experimental group showed less anxiety in the preoperative room [m-YPAS 33.88±11.7, (P = 0.002)] and at induction of anaesthesia [m-YPAS 41.72±21.48, (p=0.0001)] than children in the control group [m-YPAS 49.68 ±20.13 and m-YPAS 71.68± 24.02]. Children in the experimental group had less oppositional behaviours during the induction of anaesthesia [ICC 1.48± 2.74, (p = 0.0001)] than children in the control group [ICC 3.6 ±2.6 and ICC 4.9 ±3.14]. Mother of children in the experimental group showed a significant reduction in anxiety [APAIS T1 14.44 ±4.25 and T2 12.96 ±4.79, (p = 0.004)] and in information need [Adh10 T1 8 ±1.71 and T2 6.60 ±2.45, (p = 0.001)]. Mothers of children in the experimental group showed a significantly higher satisfaction [Adh11= 19.36 ± 1.4, (p = 0.0001)] and judged as significantly more effective the program proposed to prepare their children [Adh11=19.16 ±1.59, (P = 0.0001)] than mothers of control group [Adh11= 8.88 ± 0.88 and 9.04 ± 0.88].
38.	(Kerimoglu et al., 2013) [103]	RPS	DT	Is behavioural distraction with video glasses more efficient than oral midazolam in managing preoperative anxiety in children?	96 (4-9 yr.)		m-YPAS (c) HR (c)	Significant difference was seen at time to transport to OR, with the lowest median anxiety scores recorded in the Video Glasses group (VG) [m-YPAS 28.3 (23.3–40.0) vs Midazolam Group (M) 36.7 (26.7–51.7) and vs Group which received both interventions (M+VG) 31.7 (23.3–36.7)], all p = 0.04. Increase in anxiety was observed between 20 min before OR and Induction time in the M group [m-YPAS from 36.7 (23.3–45.8), (p = 0.04) to 45.0 (32.5–56.7), (p = 0.11)] and M + VG group [m-YPAS from 33.3 (23.3–42.5), (p = 0.04)

									to 41.7 (28.3–56.7), (p = 0.11)] but not in the VG group [m-YPAS from 33.3 (25.0–40.0), (p = 0.04) to 33.3 (25.0–45.8), (p = 0.11)].
39.	(Lee et al., 2013) [104]	RCT	PPP	Can a preoperative preparation program using smartphone application in the reduce preoperative anxiety in children?	120 children (1-10 yr.)		m-YPAS (c)		Children in the midazolam group (M) had lower mean m-YPAS values in the preoperative holding area [6.38 ± 5.79 , 5.46 ± 5.74 , $p = 0.063$] compared to children who received the smartphone application program (S) [59.2 ± 17.6 ($p = 0.063$)] and children who received both the interventions (S+M) [58.3 ± 17.5 , ($p = 0.063$)]. 5 minutes after the intervention S+M group showed the lowest level of anxiety [m-YPAS 26.0 ± 3.4 , Vs M= 41.0 ± 7.0 Vs S= 36.4 ± 7.3 , ($p < 0.01$)]. Again, after entry into the operating room children in S+M group presented less anxiety [m-YPAS 30.2 ± 3.5] than children in M group [m-YPAS 44.8 ± 6.5] and in S group [m-YPAS 38.6 ± 6.4], all $p < 0.01$.
40.	(Tunney & Boore, 2013) [105]	QEx	PPP	Is a storybook efficient in reducing the level of anxiety in children undergoing tonsillectomy and adenoidectomy?	80 children (5-11 yr.)		CD: H (c) HFRS (c) [DA SISTEMA RE ANCHE IN LEGENDA]		Children in the experimental group showed a reduction of the anxiety level from pre-test [HFRS (30.03 ± 12.99), ($p = 0.001$)] [CD:H (79.40 ± 23.90), ($p = 0.011$)] to post-test [HFRS (25.13 ± 12.63), ($p = 0.001$)] [CD:H (70.58 ± 24.82), ($p = 0.011$)]. The storybook was more efficient in reducing anxiety for female in the Experimental group [HFRS (32.20 ± 28.48), ($p = 0.035$)] [CD:H (81.52 ± 69.43), ($p = 0.004$)] and for 7-year-old children in the experimental group [HFRS (38.00 ± 26.67), ($p = 0.001$)] [CD:H (76.83 ± 60.17), ($p = 0.050$)].
41.	(Dionigi et al., 2014) [106]	RCT	DT	Does clown intervention significantly reduce children's preoperative anxiety?	77 children (2-12 yr.) and their parents	STAI (p)	m-YPAS (c)		Children in the control group [m-YPAS 33 (23–97), ($p = 0.004$)] showed less anxiety compared to the Experimental Group (CG) [m-YPAS 50 (23–97)] when in the waiting room. Anxiety in parents showed no significant differences in the waiting room between Control Group and Experimental Group. Children in the Experimental Group showed a statistically significant reduction of anxiety between scores in the waiting room [m-YPAS 50 (23–97), ($p < 0.01$)] and preoperating room [m-YPAS 33 (23–83), ($p < 0.01$)].
42.	(Fernandes et al., 2014)	RCT	PPP	What is the impact of an educational multimedia	90 (8-12 yr.)	SAM (c) CSWQ (c) STAI (p)	EAS (c)	HR (c) BP (c)	Children in the educational multimedia group reported lower level of worries about hospitalization, medical procedures, illness and negative consequences [CSWQ 0.46 ± 0.18]

	[107]			intervention on the cognitive, emotional, and physiological responses of children undergoing surgery?				than those in the control [CSWQ 1.91±0.86] and in the group who received an entertainment with a Videogame [CSWQ 1.56±.73], all p < 0.001.
43.	(Karimi et al., 2014) [108]	RCT	PPP	Is an orientated tour efficient in reducing children's anxiety before elective surgeries?	70 (5-11 yr.)	CD: H (c)		Total anxiety score in children showed a decrease in the intervention group [CD: H from 71.03±15.65 to 59.83±18.22, (p □ 0.001)]. In the control group, instead, there was an increase in anxiety in children [CD: H from 69.97±20.72 to 78.14±18.29, (p = 0.001)]
44.	(Rasti et al., 2014) [109]	RCT	PP	What are the effect of parental presence on anxiety during anaesthesia induction in children undergoing surgery?	60 (2-11 yr.)		m-YPAS (c)	Children's anxiety after the operation in the experimental [m-YPAS 59.44±15.81] and control [m-YPAS 67.39±13.97] groups were different from each other (p < 0.05). The total score of children's anxiety before and after the operation in the experimental [m-YPAS -8.39±22.95] and control [m-YPAS -3±16.45] differed from each other (p > 0.05).
45.	(He et al., 2015) [110]	RCT	PPP	Does a therapeutic play intervention reduce perioperative anxiety, negative emotional manifestation and postoperative pain in children who undergo inpatient elective surgery?	53 pairs of children (6-14 yr.)	SAS-C (c) NRS (c)	CEMS (c)	Both experimental and control group showed a statistically significant time effect of percentage change of perioperative state anxiety levels (F = 3.260, p < 0.05). No Perioperative anxiety statistically significant group effect and interaction effect was fund. Children in the experimental group had significantly lower CEMS mean scores before anaesthesia induction than those in the control group (F = 13.452, p < 0.01) Maximum pain score around 24-hour postsurgery in the experimental group was 1.5 points lower (2.11 vs. 3.60) than the one in the control group. This difference was statistically significant (F = 10.536, p < 0.01).

Study Design: Coh = Cohort study; CS=Cross-Sectional Study; Obs=Observational Study; QEx = Quasi experimental design; RCT= Randomized controlled Trial; RPS=Randomized Prospective study;

Assessment target: c=children; p=parent; a=anaesthetist; ph=physicians; cl=clowns.

Assessment instruments:

Adh1= Ad Hoc *Self-rating questionnaire A*; Measure of parents' and children's experiences of preoperative care.

Adh2= Ad Hoc *Self-rating questionnaire B*; Measure of children's and parents' emotional experience of premedication, operation theatre, pre-anaesthetic preparation and induction.

Adh3 = Ad Hoc *Satisfaction Questionnaire*; Measure of parental satisfaction.

Adh4= Ad Hoc *Short checklist*; for the assessment of fluctuating mood states of children.

Adh5= Ad Hoc Questionnaires (two) for the assessment of parents' and children's specific behavioural areas.

Adh6= Ad Hoc *Questionnaire for Health Professionals*; for the assessment of physicians' opinion on clowns.
Adh7= Ad Hoc *Clown Effectiveness Self-Evaluation Form*; for the self-assessment of clowns' interaction with children.
Adh8= Ad Hoc Likert scale for the assessment of caregivers' satisfaction.
Adh9= Ad Hoc Scale for the assessment of Parental Adherence to the components of the ADVANCE intervention.
Adh10= Ad hoc SEQ questionnaire about the psychological intervention offered.
Adh11= Ad Hoc m-ICC to assess the compliance of the child at the admission during the sampling.
Adh12= questionnaire form to have information about the child and mother as well as state anxiety inventory for the children and adults.
APAIS= *Amsterdam Pre-operative Anxiety and Information Scale*; assess level of anxiety of the child, related to surgery [111].
BQ= *Behavior Questionnaire*; Measure of children's behavioural changes due to the hospital experience [112].
BP= *Blood Pressure*; Measure of blood pressure.
CAMPIS-R= *Child-Adult Medical Procedures Interaction Scale*; Measure of children's coping and distress behaviours [113].
CARs= *Clinical Anxiety Rating Scale*; Measure of child's anxiety [114].
CC = *Coping Cards*; Measure of children's strategies for coping with fear [34].
CD: H= *Child Drawing: Hospital instrument*; This instrument was designed to assess children's anxiety in hospital from the child's point of view [115].
CEMS= *The children's emotional manifestation scale*; Measure of children's observable emotional behaviours [116].
CPaD = *Children, Parents and Distraction*; Used to predict which parents could successfully provide high-quality distraction to their children after receiving brief standard distraction training (basic distraction) and which children would respond well to their parents' distraction efforts [117, 118].
CHEOPS= *Children's Hospital of Eastern Ontario Pain Scale*; Measure of children's pain intensity [119].
Cortisol= *Serum Cortisol Analysis*; Measure of plasma cortisol concentration.
CSAS-C= *Chinese version of the state anxiety scale for children*; Measure of children's anxiety [120].
CSWQ= *Child Surgery Worries Questionnaire*; Self reporting measure used to evaluate children's preoperative worries [121].
DCI= *Distraction Coaching Index*; Behavioral observation scale that measures the frequency and quality of distraction coaching [122].
EASI= *Emotionally, Activity, Sociability, Impulsivity*; Measure of child's temperament [123].
EAS-TS= *Child Temperament: Emotionality Activity Sociability Temperament Survey*; Used to assess temperament of the child through parental report [123] [124].
Wong-Baker FACES= *Wong-Baker Rating Scale*; Measure of children's anxiety [125].
ECG= *Electrocardiogram*.
ETCO₂= *End-Tidal CO₂*; Measure of exhaled CO₂.
FACES= *Children's Self-report Measure of fear and pain* [126].
FLACC= *Faces Legs Activity Cry Consolability scale*; Measure of children's pain [127].
FPS-R= *Faces Pain Scale Revised*; Measure of children's pain [128].
GMS= *Global Mood Scale*; Measure of children's mood at induction [129].
HCAQ= *Health Care Attitudes Questionnaire*; Measure of parental health care attitudes [130].
HFI= *Hospital Fears Inventory*; Measure of children's fears [131].
HFRS= *The Hospital Fears Rating Scale*; State Measure of children's hospital related anxiety [132].
HR= *Heart rate*; Measure of heart rate.
ICC= *Induction Compliance Checklist Instrument of Child Temperament*; Measure of children's cooperation at anaesthesia induction [92].
MAP= *Mean Arterial Blood Pressure*; Measure of mean arterial blood pressure.
MBSC= *Miller Behavioral Style Scale*; Measure of parental coping style [133].
MBSS = *Monitor Blunter Style Scale*; Measure of parental coping style [133].
MCDAS= *Modified Child Dental Anxiety Scale*; Measure of children's anxiety [134].
MMPI= *Motivation for PP during Induction of Anaesthesia Scale*; Measure for the assessment of parental motivation, [67].

m-YPAS= *Modified Yale Preoperative Anxiety Scale*, Measure of children's anxiety [135].
Oucher= Self-report of pain intensity for children aged 3–12 years [136].
PAED=*Pediatric Anaesthesia Emergence Delirium*; is a validated 5-item measure of emergence delirium that assesses specific behavioural components that are distinct from pain [137].
PBRS =*Procedural Behavior Rating Scale*; Measure of children's behaviour during stressful medical procedures [138].
PPSQ=*The Postoperative Parents' Satisfaction Questionnaire*; measuring the parents' perceptions and opinions of the interventions received preoperatively [139].
PRCD= *Parent Report of Child Distress*; Perception of Procedures Questionnaire used to measure parent perception of child distress [140].
OSBD-R= *Observation Scale of Behavioral Distress-Revised*; an objective observation scale that consists of operationally defined behaviours indicative of distress in children during medical procedures [141].
PHBQ=*Post-hospitalization-Behavior-Questionnaire*; Measure of behavioural changes in children after hospitalization [112].
PPQ= *Perception of Procedures Questionnaire (modified)*; measure of parental satisfaction of medical procedures [140].
PQ =*Parents' Questionnaire* measure of parental anxiety in relationship to the child's hospitalization, previous general anxiety and the way in which the parent has prepared the child for surgery [142].
PTR= *Parent and Technician Report*; a Likert scale for the assessment of children's fears and pain [143].
RCB= *Rating of child's behaviour* A modified Likert scale for the assessment of the child's behaviour [144].
RCD= *Rating of child's Distress*; A modified Likert scale for the assessment of children's distress, [144].
RCE= *Rating of child's Emergence Behavior* Ad Hoc Likert scale for assessing children's emergence behaviour, [145, 146].
RCEB= *Rating of Child's Emergence Behaviour*; A Likert scale for the assessment of children's emergence behaviour [147].
RCQM= *Rating of child's Quality of Mask Induction*; Ad Hoc Likert scale for assessing children's quality of mask induction,[145, 148].
RR= *Respiratory Rate*; Measure of respiratory rate.
SAM= *The Self-Assessment Manikin*; Used to evaluate children's feelings of arousal and valence (i.e., pleasant/unpleasant emotions) [149].
SO2= *Haemoglobin Oxygen Saturation*; Measure of Oxygen saturation.
SSAS-c = *The Spielberger State Anxiety Scale for children*, Measure of children anxiety [150].
STAI = *State-Trait Anxiety Inventory*; Anxiety Inventory for adults [151].
VAS = *Visual Analog Scale*, observational or self-report scale for anxiety, can be used for children or adults, [152]. VAS has been used: (*) for children's previous medical encounters; and (**) for children's pain level.
VPT = *Venham Picture Test*; Anxiety test for children [153].
YPAS= *Yale Preoperative Anxiety Scale*; Measure of children anxiety [154].

Table 3.
Methodological description of the included studies (STROBE method).

Authors (date)	Bevan et al. (1990)	Kain et al. (1996a)	Kain et al. (1996b)	Kain et al. (1998a)	Kain et al. (1998b)	(Margolis et al., 1998)	Hatava et al. (2000)	Zelikovsky et al. (2000)	Kain et al. (2000)	Palermo et al. (2000)	Felder-Puig et al. (2003)	Kain et al. (2004)	Messeri et al. (2004)	Campbell et al. (2005)	Vagnoli et al. (2005)	Caldwell-Andrews et al. (2005)	Calipel et al. (2005)	Golden et al. (2006)	Patel et al. (2006)	Kain et al. (2006)	Li et al. (2007)	Kain et al. (2007)	Arai et al. (2007)	(Li & Lopez, 2008)	MacLaren & Kain (2008)	Golan et al. (2009)	(Karabulut & Arkan, 2009)	Wakimizu et al. (2009)	(Fernandes & Arriaga, 2010)	(Hosseinpour & Memarza, 2010)	Vagnoli et al. (2010)	Wright et al. (2010)	Fortier et al. (2011)	Vaezzadeh et al. (2011)	Fincher et al. (2012)	Lee et al. (2012)	(Cuzzocrea et al., 2013)	(Kerimoglu et al., 2013)	(Lee et al., 2013)	Tunney & Boore (2013)	(Dionigi et al., 2014)	(Fernandes et al., 2014)	(Karimi et al., 2014)	(Rasti et al., 2014)	(He et al., 2015)			
Reference #	[65]	[70]	[3]	[91]	[92]	[93]	[12]	[71]	[15]	[61]	[13]	[59]	[63]	[94]	[57]	[67]	[60]	[53]	[54]	[64]	[95]	[50]	[62]	[96]	[72]	[58]	[97]	[52]	[98]	[99]	[100]	[66]	[51]	[73]	[101]	[55]	[102]	[103]	[104]	[105]	[106]	[107]	[108]	[109]	[110]			
Study #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45			
Title and abstract																																																
(1) Title/abstract	0	1	1	0	0	1	0	0	0	0	1	1	0	1	1	0	1	0	1	1	0	1	1	1	0	1	1	1	0	0	0	1	1	1	0	1	0	0	1	1	1	1	0	1	0	1		
Introduction																																																
(2) Background	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1		
(3) Objectives	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
Methods																																																
(4) Study design	0	1	1	1	1	1	0	0	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	0	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	
(5) Setting	1	1	1	0	1	1	1	0	1	0	0	0	1	0	0	0	0	0	0	0	1	1	0	0	0	0	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	0	1	1	1
(6) Inclusion criteria	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
(7) Variables	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
(8) Data sources	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
(9) Bias	1	0	1	1	0	1	0	0	1	0	1	0	0	1	1	1	1	1	1	1	0	0	1	0	1	0	0	0	1	0	0	0	0	0	1	0	1	1	1	1	1	1	1	1	1	0	0	1
(10) Study size	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
(11) Quantitative variables	1	1	1	1	1	0	1	0	1	0	0	1	0	1	0	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
(12) Statistical methods	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Results																																																
(13) Participants	1	1	1	1	1	1	1	0	1	1	1	0	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	
(14) Descriptive data	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	0	1	1	0	1	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	0
(15) Outcome data	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
(16) Main results	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
(17) Other analysis	1	1	1	1	1	0	1	1	1	0	0	1	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0	1	1	1	1	1	0	1	1	0	0	0	0	1	1	1	1	1	1	0	0	1
Discussion																																																
(18) Key results	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	
(19) Limitations	0	0	1	1	1	0	1	0	1	0	0	1	0	1	0	1	1	1	1	1	0	1	0	1	1	0	1	0	1	0	1	0	1	1	0	1	1	1	1	1	1	1	1	1	1	0	0	1
(20) Interpretation	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
(21) Generalizability	1	1	1	1	1	1	1	1	1	0	1	0	0	0	0	0	1	0	0	1	1	1	0	1	1	0	0	1	1	0	0	1	0	1	1	0	1	1	0	0	0	0	1	1	0	0	1	
(22) Funding	0	0	0	0	0	1	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total score	17	18	21	18	18	18	18	14	19	12	17	15	15	17	17	16	18	13	16	16	16	16	21	14	16	16	14	15	18	17	11	17	19	16	17	17	18	15	19	17	17	20	17	16	14	19		

Table 4.
Overview of additional relevant qualitative and quantitative aspects.

Authors (date)	[65]	[70]	[3]	[91]	[92]	[93]	[12]	[71]	[15]	[61]	[13]	[59]	[63]	[94]	[57]	[67]	[60]	[53]	[54]	[64]	[95]	[50]	[62]	[96]	[72]	[58]	[97]	[52]	[98]	[99]	[100]	[66]	[51]	[73]	[101]	[55]	[102]	[103]	[104]	[105]	[106]	[107]	[108]	[109]	[110]					
Reference #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45					
Biocological and educational variables																																																		
(1) "Therapist" effect	0	0	1	0	0	0	0	0	0	0	0	1	0	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
(2) Parental psychological characteristics	1	1	1	1	1	0	0	0	1	1	1	1	1	0	1	1	0	0	0	1	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
(2) Family culture	0	1	1	0	0	0	1	1	1	1	1	1	0	0	1	1	0	0	0	1	0	1	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
(3) Patient previous hospital experiences	0	1	1	1	0	1	1	0	1	0	1	1	0	0	1	0	0	1	1	0	1	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
(4) Adjustment based on children's age, gender...	0	1	1	1	0	0	1	1	1	0	1	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0	1	1	0	0	1	1	0	0	0	0		
(5) Customisation based on child's preferences	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0			
Research design and tools																																																		
(6) Control Group	1	1	1	0	1	1	0	1	0	1	1	1	0	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
(7) Validated Tools	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
(8) Ad Hoc tools	0	0	0	0	0	0	1	0	1	0	1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Organisation of the intervention																																																		
(9) Initial setup on the intervention (easy/medium/hard)	e*	h	h	h	h	m	e	h	h	e	h*	m*	h	m*	e*	h	e*	e*	e*	e*	h	h	e*	h	e	e*	e	h	e*	e	e	h	h	e	h	e	e	e*	e	e*	e	h*	e	e	e*	e	h			
(10) On going execution of intervention (easy/medium/hard)	e*	m*	m*	m*	m*	h*	m*	m*	m*	e*	h*	m*	e*	e*	e*	e*	m*	e*	e*	e*	e*	h	h	e*	h	e	e*	e	h	e*	e	e	h	h	e	h	e	e	e*	e	e*	e	h*	e	e	e*	e	h		
(11) N of sbj actively involved in intervention	P	1*	P	1*	P	1	2	2	P	P	1	2	P	0	2	P	4	1	0	P	2	3	P	1	1	2	1	1	3	1*	3	P	3	1	2	0	1	0	0	2	0	1	0	P	1	1				
(12) Intervention organisation burdens on hospital staff	0	1§	1	1§	1§	1	1	1	1§	0	1	0	1	1	0	1	0	1	1	1	0	1	1§	0	1	0	0	0	0	1	0	0	1§	1	1§	1	1§	1	1	1	1	1	1	1	1	1	1	1		
(13) Intervention execution burdens on hospital staff	1	1§	1	1§	1§	1	1	1	1§	1	1	1	1	1	1	1	1	1	1	1	1	1	1§	1	1	0	0	1	0	1	1	1	1§	1	1§	1	1	1	1	1	1	1	1	1	1	1	1	1		
(14) Intervention requires extra staff	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
(15) Equipment involved ¹	x	me	me	ma me	me	b	me	me	me	x	b	m	x	ma	x	x	Hp	t	ma	x	me	b t ma me	x	ma me	me	x	ma b*	ma b	x	t ma	x	x	ma b t	me	ma me	ma	ma me	vg ma	ma	b	x	ma	d	x	ma me					
(16) Location ²	H	H	H	H	H	hm	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	hm	H	H	H	H	H	hm	H	H	H	H	hm&H	H	H	H	H	H	H	H	hm&H	H	H	H	H	h/hm				
(17) Time of intervention before surgery	30m*	1d-10d	1w	1d-10d	2-7d	1-3d	1d	1h*	1-7d	30m*	1d	1h*	30m*	1h*	30m*	30m*	30m	30m*	30m*	30m*	1w	2-7d	30m*	1w	1h*	30m*	1d	1w	30m*	30m	30m*	90m	2-7d	1d	1-10d	1d	1d	1d	30m*	1d	1w*	30m*	30m*	1h*	1h*	3-7d				
(18) Duration of the preparation	15m*	1h*	15m*	40m	15m*	£	1h*	1h	1h*	15m*	30m*	25m*	15m*	30m*	15m	15m*	15m*	8m	20m	15m*	1h	20m	15m*	1h	40m*	20-30m	20m*	£	15m	30m	15m	15m*	20m	1h	1h	15m*	30m	15m	10m*	30m*	15m*	15m	30m*	15m*	1h					
Evaluation																																																		
(19) Parent's perception	1	0	1	0	1	1	0	0	1	1	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0			
(20) Children's perception	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
(21) Physician's perception	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
(22) Nurses perception	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
(23) Actor of the intervention perception ("therapist")	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
(24) Parent physiologic measure	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
(25) Child physiologic measure	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
(26) Parent psychological measure	1	1	1	1	1	1	0	1	0	1	1	1	1	1	1	1	0	0	0	0	1	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	
(27) Child psychological measure	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	

* = This value was not indicated in the paper and has been estimated by the present authors;

§ = The activity is run by a child life Specialist

£ = Duration of the intervention is set by the child himself

Setup and Execution of the intervention:

- "e*" = easy
- "m" = medium
- "h" = hard

- Equipment:**
- "x" = No equipment indicated but an extra person was present (parent or clown)
 - "me" = medical equipment (medical play)
 - "ma" = multimedia application such as video player, computer, cartoon, video game, photo file.
 - "b" = booklet or pamphlet
 - "t" = toys
 - "vg" = video glasses
 - "d" = drawing set

- Location**
- "H" = hospital
 - "hm" = home
 - "H/mm" = hospital or home
 - "H&hm" = both hospital and home

Figure 1
Flow scheme of inclusion process (PRISMA guidelines) [45].

