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Protocolo de Revisión

Effectiveness of perioperative family-centered educational interventions in the anxiety, pain and behaviors of children/adolescents and their parents: Systematic Review Protocol

Ines Martins Esteves¹, Marcia Silva Coelho², Daniela Cardoso³, Ana Paula Prata⁴, Marcia Pestana-Santos⁵, Margarida Reis Santos⁶.

¹ MSc - Registered Nurse, Abel Salazar Biomedical Sciences Institute – University of Porto, Porto; CINTESIS@RISE – Center for Health Technology and Services Research, Porto, Portugal; Theatre Practitioner, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, United Kingdom; ORCID: 0000-0002-8867-7424

² Registered Nurse, Nursing School of Porto, Porto, Portugal; Baixo Vouga Hospital Centre, Aveiro, Portugal; ORCID: 0000-0002-4885-2064

³ PhD - Junior Researcher, Portugal Centre for Evidence-Based Practice: a JBI Centre of Excellence, Coimbra, Portugal. Health Sciences Research Unit: Nursing (UICISA: E), Nursing School of Coimbra (ESENFC), Coimbra, Portugal; ORCID: 0000-0002-1425-885X

⁴ PhD Coordinator Professor, Nursing School of Porto, CINTESIS@RISE – Center for Health Technology and Services Research, Porto, Portugal; ORCID: 0000-0001-7552-9716

⁵ PhD - Adjunct Professor, Nursing School of Coimbra (ESENFC), Coimbra, Portugal; Health Sciences Research Unit: Nursing (UICISA: E); Portugal Centre for Evidence-Based Practice: a JBI Centre of Excellence, Coimbra, Portugal.; ORCID: 0000-0002-4093-0291

⁶ PhD – Coordinator Professor, Nursing School of Porto; CINTESIS@RISE – Center for Health Technology and Services Research; Abel Salazar Biomedical Sciences Institute – University of Porto, Porto, Portugal; ORCID: 0000-0002-7948-9317

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Correspondencia

Ines Martins Esteves

Bristol Eye Hospital

inesmartinsesteves@gmail.com

ABSTRACT

Introduction: Every year, millions of children and adolescents undergo surgery, 50%-75% of them experience fear and anxiety. Children are particularly susceptible to stress and anxiety surrounding surgery as a result of their cognitive development, previous experiences, and knowledge about healthcare; this leads to additional interventions to prevent and reduce these symptoms.

Objective: To evaluate the effectiveness of family-centered educational interventions in the children's and adolescents' anxiety, pain, and behaviors and their parents' anxiety during the perioperative period.

Methods: This review will follow the Joanna Briggs Institute guidelines for systematic reviews of effectiveness and will consider those studies (experimental and quasi-experimental) in which perioperative educational interventions have been applied to children and adolescents and their parents; these studies measured children and adolescents' pain, anxiety, and behaviors, as well as their parent's anxiety. An initial search of MEDLINE and CINAHL will be followed by a second search for published and unpublished studies from January 2007 on, available in English, Spanish and Portuguese. After all full texts are retrieved, the methodological quality assessment and data extraction will be independently and critically evaluated by two reviewers, and the data will then be presented in a tabular format. An explanatory synthesis will accompany the results. Whenever possible, a meta-analysis will be performed, and a Grading of Recommendations, Assessment, Development, and Evaluation Summary of Findings will be presented.

Expected Results: This review will provide guidance on how family-centred educational interventions can be used as a resource to manage anxiety, pain, and behavior in children, adolescents and their relatives during the perioperative processes.

Keywords: Anxiety; Child; Education; Family; Pain; Perioperative period.

RESUMEN

Eficacia de las intervenciones educativas perioperatorias familiares centradas en la ansiedad, el dolor y las conductas de las personas menores y adolescentes y de sus progenitores: protocolo de revisión sistemática

Introducción: Cada año, millones de personas menores y adolescentes se someten a cirugía, de las cuales entre el 50-75 % experimenta miedo y ansiedad. Las niñas y los niños son particularmente susceptibles al estrés y la ansiedad que rodea a la cirugía, como resultado de su desarrollo cognitivo, experiencias previas y conocimiento de la salud, lo que requiere intervenciones para prevenir y reducir estos síntomas.

Objetivo: Esta revisión tiene como objetivo evaluar la efectividad de las intervenciones educativas familiares centradas en la ansiedad, el dolor y los comportamientos de las personas menores y adolescentes y de sus progenitores en el período perioperatorio.

Métodos: Esta revisión seguirá las pautas del Instituto Joanna Briggs para revisiones sistemáticas de efectividad y considerará estudios experimentales y cuasiexperimentales en los que las intervenciones educativas perioperatorias para medir el dolor, la ansiedad y los comportamientos en niñas, niños y adolescentes y la ansiedad de sus progenitores. Se ha realizado una búsqueda inicial limitada de MEDLINE y CINAHL. Además, una segunda búsqueda de estudios publicados y no publicados de enero de 2007 disponibles en inglés, español y portugués. Una vez recuperados los textos completos, dos revisores evaluarán críticamente, de forma independiente, la calidad metodológica y la extracción de

datos y se presentarán en forma de tabla. Una síntesis narrativa acompañará a los resultados y, si es posible, se realizará un metanálisis y se presentará un Grading of Recommendations, Assessment, Development and Evaluation.

Resultados esperados: Esta revisión brindará orientación sobre cómo las intervenciones educativas centradas en la familia pueden usarse como un recurso para controlar la ansiedad, el dolor y el comportamiento en niñas, niños, adolescentes y sus familias en el contexto perioperatorio.

Palabras clave: Ansiedad; Dolor; Educación; Familia; Niño; Periodo perioperatorio.

RESUMO

Efetividade das intervenções educativas perioperatórias centradas na família na ansiedade, dor e comportamento de crianças/adolescentes e seus pais: protocolo de revisão sistemática

Introdução: Todos os anos, milhões de crianças e adolescentes são submetidos a cirurgias e 50-75% apresentam medo e ansiedade. Crianças/adolescentes são particularmente suscetíveis ao stress e ansiedade em torno da cirurgia devido ao seu desenvolvimento cognitivo, experiências anteriores e conhecimento que possuem sobre os cuidados de saúde, necessitando de intervenções para a prevenção/redução destes sintomas.

Objetivo: Avaliar a eficácia de intervenções educacionais centradas na família na ansiedade, dor e comportamentos de crianças/adolescentes e ansiedade dos pais no período perioperatório.

Métodos: Esta revisão seguirá a metodologia do Instituto Joanna Briggs para revisões sistemáticas de eficácia e considerará estudos (experimentais e quase-experimentais) em que as intervenções educacionais perioperatórias tenham sido aplicadas a crianças/adolescentes e seus pais e avaliadas a dor, ansiedade e comportamento em crianças/adolescentes e ansiedade dos pais como resultados. Uma pesquisa inicial limitada de MEDLINE e CINAHL foi realizada. Será seguida por uma segunda busca por estudos publicados e não publicados de janeiro de 2007 disponíveis em inglês, espanhol e português. Após a recuperação dos textos completos, a avaliação da qualidade metodológica e a extração de dados serão avaliadas de forma crítica e independente por dois revisores e apresentadas em forma de tabela. Uma síntese narrativa acompanhará os resultados e, se possível, uma meta-análise será realizada e um resumo das Grading of Recommendations, Assessment, Development and Evaluation apresentado.

Resultados esperados: Esta revisão fornecerá orientações sobre como as intervenções educativas centradas na família podem ser utilizadas como um recurso para gestão da ansiedade, dor e comportamento em crianças, adolescentes e suas famílias no contexto perioperatório.

Palavras-chave: Ansiedade; Criança; Dor; Educação; Família; Período perioperatório.

INTRODUCTION

The perioperative care comprises the preoperative, intraoperative, and postoperative care.¹ Even though these care phases differ, they are interconnected as they influence one another. The way the family reacts to and perceives the surgical event directly affects the

level of anxiety and the behavior of the child/adolescent during the perioperative journey.²

Anxiety is defined as apprehensiveness or anticipation of future events, accompanied by a feeling of worry and an autonomic response.³ Based on this definition, parental perioperative anxiety has been reported as very common

(74.2%)⁴ and nearly 50% to 75% of children/adolescents undergoing surgery experience fear and anxiety during the preoperative period.⁵

Preoperative anxiety has been associated with higher analgesia doses in the postoperative period, as well as behavioral disorders, such as sleep disturbances, eating and emotional disorders.⁶ These outcomes are related to the need of prolonged postoperative care and an overall negative experience for the family.⁷ Therefore parental anxiety can be reflected in the anxiety of their children/adolescent.⁸ Parental anxiety is measured progressively during the perioperative journey of their child.⁹ and has also been linked to negative behavioral changes of the child following surgery, including nightmares, separation anxiety, eating problems, and fear.⁸

It is important to clarify that despite anxiety and pain are related and influence one another in the perioperative period,⁹ they are distinct concepts.⁶ Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage.¹⁰ In this regard, poorly managed postoperative pain is associated with longer recovery, increased risk of complications, prolonged hospitalization, unplanned readmissions, and chronic post-surgical pain with an incidence of 38% up to one year after surgery.¹¹

Child/adolescent behavior will be the observable response or action to the perioperative experience. A number of postoperative behavioral changes such as sleep problems, eating and emotional disorders (depression and fear) have been reported (up to 60%)¹² and, in some cases, this can result in developmental regression, particularly in younger children.¹³

Concerning care programs, there is the family-centered care, which is a philosophy of care for children and their families that is planned around the dyad.¹⁴ Even though the first steps towards family-centered care in pediatrics were

taken by John Bowlby (1944), it was not until the 60s and 70s (post-World War II) that Bowlby's theories were turned into practice by James Robertson.¹⁴ However, family-centered pre-surgical preparation programs for children undergoing surgery emerged and became prominent until 2007.¹⁵ Later, in 2010, Dr. Chorney and Dr. Kain proposed the first perioperative family-centered care framework.⁷ A family-centered perioperative care approach that allows both children/adolescents and parents' participation offer a positive experience for everyone, and it has shown to decrease perioperative anxiety.^{15,16}

Pre-surgical preparation programs focused on the family as a whole have implications for postoperative results, namely in children/adolescents and parents' anxiety, children/adolescents' pain, as well as in the incidence of delirium, consumption of analgesics, and recovery time.^{15,17,18} These programs consist of providing relevant information and preparation to the forthcoming surgical procedure to both child/adolescent and their parents about the expected pre and postoperative period and the signs and symptoms that may result from the surgical intervention.¹⁹ The involvement of both, parents and children, in preoperative education can have significant benefits in the anxiety, engagement, understanding, and overall satisfaction along the surgical process.²⁰

Generally applied in the preoperative period, educational interventions can take different forms: verbal, written, or both. Books, pamphlets, guides, teaching programs or sessions (whether face-to-face, via web or audio), games, videos, and DVDs are examples of educational interventions.²¹⁻²⁴

Systematic reviews published on the topic evaluated the effectiveness of educational programs in children (2-12 years old) in their anxiety and other negative emotions²⁵ and the effectiveness of audiovisual interventions at reducing preoperative anxiety in

children/adolescents under 18 years of age.²² In both reviews, educational interventions reduced anxiety (primary outcome) effectively^{22,25}; the authors reported that children aged 4 to 6 years old or older benefit more from these programs, whereas younger children have the reverse effect.²⁵

However, none of those systematic reviews, have evaluated the effectiveness of the educational interventions using the family-centered care approach to manage anxiety, pain, children's behaviors and their parents' anxiety during the perioperative period. Therefore, it is necessary to summarize and evaluate these findings in order to provide and facilitate evidence-based information for the decision-making process of healthcare professionals who work regularly with children, adolescents, and their families in the perioperative setting.

A preliminary search on PROSPERO, MEDLINE, CINAHAL, the Cochrane Database of Systematic Reviews, and the *JB* Evidence Synthesis was conducted on March 5th 2021, and no current or underway systematic reviews on the topic were identified.

The objective of this systematic review is to evaluate the effectiveness of family-centered educational interventions in the anxiety, pain, and behaviors of children/adolescents and in their parents' anxiety during the perioperative period.

Review questions: What is the level of effectiveness of family-centered educational interventions in the anxiety, pain, and behaviors of children/adolescents during the perioperative period? What is the level of effectiveness of family-centered educational interventions in parents' anxiety during the perioperative period?

METHODS

This review will consider studies which include parents and their children/adolescents – 3 to 19

years old – undergoing elective or scheduled surgery (any type of surgery) under general anesthesia. Only three-year-old and older children will be included as they understand simple language, are capable of communicating autonomously, and benefit from therapeutic play.²⁶ Outpatient surgeries will also be included. Children/adolescents undergoing local or regional anesthesia will be excluded.

Regarding the interventions, the present review will consider studies that evaluate the effectiveness of family-centered educational interventions performed with children/adolescents and their parents during the perioperative period. The educative interventions may include any printed, written material such as books, booklets, or guides; also, teaching sessions or programs (virtual or on-site), games, videos, or DVDs. There are no limitations to the type of delivery or frequency, of the intervention. The comparison term may include routine/standard preoperative care, or others.

We will consider studies in this review that address the following outcomes for children/adolescents:

- Pain as it is assessed by any validated instrument such as, but not limited to, the Visual Analogue Scale (VAS), the FLACC Behavioral Pain Scale, and the Numerical Pain Assessment Scale.
- Anxiety as it is assessed by any validated instrument such as, but not limited to, the Modified Yale Preoperative Anxiety Scale (mYPAS), The State-Trait Anxiety Inventory for Children (STAIC), or the Visual Analogue Scale for Anxiety (VAS-A).
- Behaviors, such as sleep and emotional disorders, as they are assessed by any validated instrument such as, but not limited to, Children's Emotional Manifestation Scale (CMES) for emotional behaviors, Post Hospitalization Behavioral Questionnaire for Ambulatory Surgery.

This review will consider studies that include the following outcomes for parents:

- Anxiety as it is assessed by any validated instrument such as, but not limited to, The State-Trait Anxiety Inventory for Adults (STAI).

Study designs will include experimental and quasi-experimental designs, such as randomized controlled trials, non-randomized controlled trials, and before and after studies.

The proposed systematic review will be conducted following the JBI methodology for systematic reviews of effectiveness²⁷ and the PRISMA model for organizing the information found.²⁸ This review has been registered with PROSPERO (CDR42020211574).

The search strategy will aim to locate both published and unpublished studies. An initial limited search of MEDLINE (PubMed) and CINAHL (EBSCOhost) was undertaken to identify articles on the topic. The words in the titles and abstracts of relevant articles and the index terms used to describe the articles were used to develop a full search strategy for MEDLINE (PubMed) (Table 1).

The search strategy, including all identified keywords and index terms, will be adapted for each information source included. The reference lists of all studies selected for critical appraisal will be screened for additional studies.

Studies published in English, Spanish, and Portuguese that were published from January 1st, 2007 on will be included. There is no geographical or cultural limitation for the acceptance of studies.

The databases to be used include MEDLINE (PubMed), CINAHL (EBSCOhost), PsycINFO (EBSCOhost), Cochrane Central Register of Controlled Trials (EBSCOhost), and SciELO. Sources of unpublished studies and gray literature to be reviewed include OpenGrey, Open Access Theses and Dissertations, and *Repositório Científico de Acesso Aberto em Portugal* (RCAAP).

Following the bibliographical search, all identified citations will be classified and uploaded to EndNote X9.3 (Clarivate Analytics, PA, USA), where all duplicates will be removed. Following a prescreening, titles and abstracts will then be screened by two independent reviewers (IE, MC) to assess them according to the inclusion criteria. Potentially relevant studies will be fully retrieved, and their citation details will be imported to the JBI System for a Unified Management, Assessment, and Review of Information.³⁰ The full text of selected citations will be assessed in detail against the inclusion criteria by two independent reviewers (IE, MC). Reasons for excluding full-text studies that do not meet the inclusion criteria will be recorded and reported in the systematic review. Any disagreements between the reviewers at each stage of the study selection process will be resolved through discussion or through the judgement of a third reviewer (MPS). The search and study selection and inclusion process results will be disclosed in the final systematic review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.²⁷

Eligible studies will be critically appraised by two independent reviewers (IE, MC) in terms of methodological quality of the review; this will be done by using standardized critical appraisal instruments from JBI for experimental and quasi-experimental studies. Authors of papers will be contacted to request missing or additional data for clarification, when required. The results of this critical appraisal will be reported in a table with its corresponding explanation.

Following the critical appraisal, studies that do not meet a certain quality threshold (7-13 indicators answered in the affirmative for RCTS and 6-9 for quasi-experimental studies) will be excluded.

Table 1*Search strategy conducted on MEDLINE (PubMed). April 13th, 2021*

Search	Query	Records retrieved
#1	adolescen*[Title/Abstract] OR teen*[Title/Abstract] OR youth[Title/Abstract] OR child*[Title/Abstract] OR paediatric*[Title/Abstract] OR pediatric*[Title/Abstract] OR parent*[Title/Abstract] OR mother*[Title/Abstract] OR father*[Title/Abstract] OR "early adulthood"[Title/Abstract] OR "young adulthood"[Title/Abstract] OR Family[Title/Abstract] OR Caregiver*[Title/Abstract] OR Care-giver[Title/Abstract] OR Carer*[Title/Abstract]	2,942,362
#2	Surg*[Title/Abstract] OR "pre-operative"[Title/Abstract] OR Preoperative[Title/Abstract] OR Perioperative[Title/Abstract] OR postoperative[Title/Abstract]	2,358,782
#3	"audiovisual aids"[Title/Abstract] OR book* OR multimedia* OR hypermedia OR pamphlet* OR education OR "teaching session"[Title/Abstract] OR DVD OR "digital versatile disc"[Title/Abstract] OR video* OR leaflet* OR "non-pharmacological intervention"[Title/Abstract] OR "nonpharmacological intervention"[Title/Abstract] OR "Complementary Therapy"[Title/Abstract] OR "family centered care"[Title/Abstract] OR "family centred care"[Title/Abstract]	2,095,378
#4	pain*[Title/Abstract] OR anxiety[Title/Abstract] OR behaviour[Title/Abstract] OR behavior[Title/Abstract] OR STAI[Title/Abstract] OR "FLACC"[Title/Abstract] OR "visual analog scale"[Title/Abstract]	1,784,997
#5	"Adolescent"[Mesh] OR "Minors"[Mesh] OR "Child"[Mesh:NoExp] OR "Child, Preschool"[Mesh] OR "Family"[Mesh:NoExp] OR "Parents"[Mesh] OR "Mothers"[Mesh] OR "Fathers"[Mesh] OR "Caregivers"[Mesh:NoExp]	3,209,023
#6	"Elective Surgical Procedures"[Mesh] OR "Surgical Procedures, Operative"[Mesh:NoExp] OR "preoperative care"[Mesh] OR "perioperative care"[Mesh] OR "postoperative care"[Mesh]	217,009
#7	"Hypermedia"[Mesh] OR "Education"[Mesh:NoExp] OR "Teaching"[Mesh:NoExp] OR "Teaching Materials"[Mesh:NoExp] OR "Audiovisual Aids"[Mesh:NoExp] OR "Multimedia"[Mesh] OR "Videotape Recording"[Mesh] OR "Books"[Mesh:NoExp] OR "Pamphlets"[Mesh:NoExp] OR "Complementary Therapies"[Mesh:NoExp]	117,172
#8	"Pain"[Mesh:NoExp] OR "Pain, Postoperative"[Mesh:NoExp] OR "Anxiety"[Mesh:NoExp] OR "Acute Pain"[Mesh] OR "Behavior"[Mesh:NoExp]	288,558
#9	#1 OR #5	4,711,539
#10	#2 OR #6	2,414,594
#11	#3 OR #7	2,110,674
#12	#4 OR #8	1,855,885
#13	#9 AND #10 AND #11 AND #12	4,751
#14	Filters: Limited to from 2007/01/01	3,219
#15	Languages: English, Spanish and Portuguese	3,103

This decision will be based on the reviewers' overall quality assessment and the risk of bias. If a limited quantity of eligible studies is found due to the low number of publications or low methodological quality, the reviewers will include all studies that meet the inclusion criteria and discuss their limitations and methodological weaknesses.

Data will be extracted from studies included in the review by two independent reviewers using the standardized JBI data extraction tool available at JBI SUMARI.²⁹ The data extracted will include specific details about the considered population (children or adolescents and their parents), study methods, interventions (specifically, educational interventions), and outcomes of significance to the review question (anxiety and pain in children or adolescents and parental anxiety). Any disagreements that arise between the reviewers (IE, MC) will be resolved through discussion or through a third reviewer (MPS). Authors of papers will be notified when missing or additional data is needed. All selected studies, regardless of their assessment of methodological quality, will be presented in a table exported from JBI SUMARI.²⁹

Whenever possible, studies will be pooled with statistical meta-analysis using JBI SUMARI.²⁹ The effect sizes will be expressed as either odds ratios (for dichotomous data) or weighted (or standardized) final post-intervention mean differences (for continuous data), and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard χ^2 and I^2 tests. The use of a random or fixed effects model and method for meta-analysis will be based on Tufanaru and colleagues.²⁷ Subgroup analyses, if appropriate, will also be considered. Wherever possible, the data will be grouped, taking into account the pediatric age groups (children or adolescents). If this is not possible, children and adolescents will be integrated into

the same group. Where statistical pooling is not possible, findings will be presented textually, tables and figures will be included to aid data presentation.

The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach for grading the certainty of evidence will be followed, and a Summary of Findings (SoF) will be created using GRADEPro software (McMaster University, ON, Canada).³⁰ The Summary of Findings will present the following information when needed: absolute risks for the treatment and control, estimates of relative risk, and a ranking of the evidence quality based on the risk of bias, directness, heterogeneity, precision, and the risk of publication bias of the reviewed results. The outcomes reported in the Summary of Findings for children/adolescents will be anxiety, pain, and behaviors, and the outcomes for parents will be anxiety.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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