Revista Brasileira de Enfermagem
REBEn

SUPPLEMENTARY EDITION 4
WOMEN'S AND CHILDREN'S HEALTH

REVIEW

Overview of clinical trial protocols for behavioral insomnia in infants

Panorama dos protocolos de ensaios clínicos para insônia comportamental em lactentes

Descripción general de los protocolos de ensayos clínicos para el insomnio conductual en lactantes

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How to cite this article:
Lima RBS, Dias AJL, Barbosa LP. Overview of clinical trial protocols for behavioral insomnia in infants Rev Bras Enferm. 2021;74(Suppl 4):e20200769. https://doi.org/10.1590/0034-7167-2020-0769

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Submission: 08-12-2020 **Approval:** 11-26-2020

ABSTRACT

Objective: to describe the overview of clinical trial protocols for behavioral insomnia in infants. **Methods:** an analytical study that reviewed protocols registered with the International Clinical Trials Registry Platform between August and September 2019, aiming to identify the interventions for behavioral insomnia in infants, the comparators, the main primary, secondary outcomes and their respective measurements. **Results:** eleven protocols registered between 2004 and 2018 were included. Nurses were the main coordinators of protocols (45.5%), with proposals using educational technologies, one-to-one and online follow-up consultations. The main outcome was improvement of infant and maternal sleep patterns. Secondary outcomes were anxiety, depression, and parental sexual satisfaction. To measure them, the following were used: sleep diary (54.5%), actigraphy (45.4%), and the Pittsburgh Sleep Quality Interview (36.3%) and Extended Brief Infant Sleep Questionnaire (27.2%) were used. **Conclusion:** the protocols proposed interventions for independent sleep, aiming at quality of sleep for the whole family.

Descriptors: Sleep; Sleep Initiation and Maintenance Disorders; Infant; Clinical Trial; Clinical Protocols.

RESUMO

Objetivo: descrever o panorama dos protocolos de ensaios clínicos para insônia comportamental em lactentes. **Métodos:** estudo analítico, que revisou protocolos registrados na *International Clinical Trials Registry Platform* entre agosto e setembro de 2019, visando identificar as intervenções para insônia comportamental em lactentes, os comparadores, os principais desfechos primários, secundários e suas respectivas mensurações. **Resultados:** incluíram-se 11 protocolos registrados entre 2004 e 2018. Os enfermeiros foram os principais coordenadores dos protocolos (45,5%), com propostas utilizando tecnologias educacionais, consultas de acompanhamento presencial e *online*, tendo como principal desfecho a melhoria do padrão de sono infantil e materno, e como desfechos secundários, ansiedade, depressão e satisfação sexual parental. Para mensurá-los, foram utilizados o diário do sono (54,5%), o actígrafo (45,4%) e os questionários *Pittsburgh Sleep Quality Interview* (36,3%) e *Extended Brief Infant Sleep Questionnaire* (27,2%). **Conclusão:** os protocolos propuseram intervenções para um sono independente, visando qualidade de sono para toda a família.

Descritores: Sono; Distúrbios do Início e da Manutenção do Sono; Lactente; Ensaio Clínico; Protocolos Clínicos.

RESUMEN

Objetivo: describir el panorama de protocolos de ensayos clínicos para el insomnio conductual en lactantes. **Métodos:** estudio analítico, que revisó los protocolos registrados en la International Clinical Trials Registry Platform entre agosto y septiembre de 2019, con el objetivo de identificar intervenciones para el insomnio conductual en lactantes, los comparadores, los principales desenlaces primarios y secundarios y sus respectivas mediciones. **Resultados:** se incluyeron 11 protocolos registrados entre 2004 y 2018. Las enfermeras fueron las principales coordinadoras de los protocolos (45,5%), con propuestas mediante tecnologías educativas, consultas de seguimiento presencial y online, teniendo como resultado principal la mejora del patrón de sueño infantil y materno, y como resultados secundarios, la ansiedad, la depresión y la satisfacción sexual de los padres. Para medirlos, el diario de sueño (54,5%), el actígrafo (45,4%) y los cuestionarios Pittsburgh Sleep Quality Interview (36,3%) y Extended Brief Infant Sleep Questionnaire (27,2%). **Conclusión:** los protocolos propusieron intervenciones para el sueño independiente, orientadas a la calidad del sueño para toda la familia.

Descriptores: Sueño; Trastornos del Inicio y del Mantenimiento del Sueño; Lactante; Ensayo Clínico; Protocolos Clínicos.

INTRODUCTION

Sleep has a direct consequence on a child's development, as well as on behavior, learning, mood and higher level cognitive brain functions[1]. During sleep, important neurological and physiological activities of the body occur, with emphasis on the central nervous system maturation, memory consolidation, energy maintenance, thermoregulation, immunity, in addition to protein production and endocrine synthesis, with growth hormones standing out, thyro-stimulant, melatonin, renin, and cortisol[2-3].

However, sleep disorders in childhood are common. About 15 to 35% of Western children experience sleep problems during the first years of life[4]. Among these, the most common in infants (0-2 years) is behavioral insomnia, which can be characterized as difficulty falling asleep when placed in bed or staying asleep throughout the night, in addition to the occurrence of several awakenings and resistance to initiate sleep in the absence of parents[5].

Recognizing the difficulty in dealing with the excessive awakening of children during the night, a study carried out in the United Kingdom found the need for mothers to receive instructions from health professionals about infant sleep[6]. Moreover, it has been found that depression and anxiety are more alarming in mothers when they are in sleep deprivation[7].

Literature presents studies that identify sleep problems in children, especially in premature infants[3] and in preschoolers. For this age group, a systematic review identified obesity, emotional problems and long exposure to electronics as the main factors associated with short sleep duration[8]. For children older than five years, there is a focus on studies for the main sleep pathologies in this phase, such as somnambulism, sleep apnea, and snoring[9]. However, there are few productions that seek to intervene in improving children's sleep, especially when the problems are in the behavioral sphere.

In the case of clinical interventions based on randomized clinical trials, the need arose in recent years to formalize the protocols for this type of research on platforms, in order to avoid selective reports and publication bias. As a result, these platforms have become a fertile setting for previous research and an information bank for analysis in order to identify how researchers in a given area are intervening and whether they actually did what they set out to do in the beginning[10].

Therefore, considering the relevance of the theme and the incipient quantity of clinical trial protocols on the subject, it becomes pertinent to analyze what researchers on the theme of infant sleep have devised to intervene in behavioral insomnia.

OBJECTIVE

To describe the overview of clinical trial protocols for behavioral insomnia in infants.

METHODS

Ethical aspects

This study was conducted on a public domain basis, which does not require submission to a Research Ethics Committee.

Study design

This is an analytical study that reviewed clinical trial protocols in order to list what researchers have used to investigate infant sleep, as well as list primary and secondary outcomes and their respective measurements, in order to examine knowledge gaps and contribute to future research, according to a study developed in Fortaleza-Ceará, Brazil[11]. To guide the conduct of this study, the Preferred Reporting Items for Systematic reviews and Meta-Analyzes (PRISMA)[12]guidelines were followed.

Study protocol

To guide the search, the following guiding question was elaborated: what is the overview of clinical trial protocols for behavioral insomnia in infants? The search for the protocols was carried out through the International Clinical Trials Registry Platform (ICTRP), a platform integrated in the research portal of the World Health Organization (WHO) (www.who.int/ictrp/en/), which compiles the records of clinical trials registered by researchers worldwide.

Data collection took place between August and September 2019, using the Health Sciences Descriptors (DeCS), with corresponding correspondence with the Medical Subject Headings (MeSH). Using the Boolean operator "AND", the search strategy was "Sleep AND Infant", which was applied to the ICTRP home page, using the "phases are all" filter, with no time restrictions, being analyzed the protocols available until the date of the survey.

Protocols that addressed behavioral interventions to improve sleep in infants (children aged 0 to two years) or infants and mothers were included. Records of behavioral interventions to improve the sleep of preterm infants, those addressing only maternal sleep and records of behavioral interventions for neurological disorders were excluded.

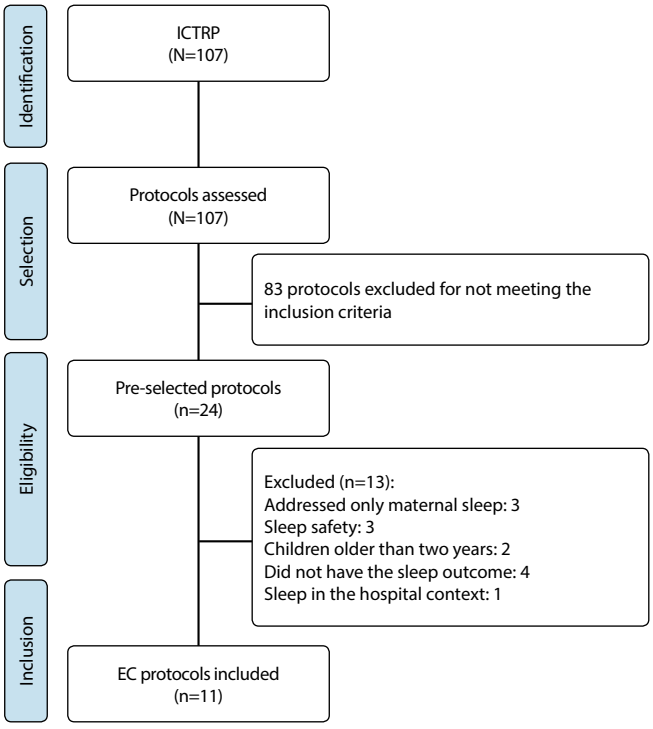
Considering the protocols, the following information was extracted: public title, registration year, country and institution, goal, intervention, comparator, measures for the primary outcome, and measures for secondary outcomes.

Data analysis

Protocol search and selection were carried out by two independent researchers. Initially, localized records were pre-selected by reading title and basic information contained in the ICTRP platform; when doubts arose regarding the eligibility of the works' content, these were pre-selected for further full analysis, being included or excluded by consensus. After defining the sample and extracting the data, they were described and analyzed in literature in search of possible gaps on the topic.

RESULTS

The search selected 107 protocols, of which 24 were pre-selected, based on the eligibility criteria, which were analyzed on the ICTRP page and in the registration base of the country of registration; 13 were excluded, so that the final sample resulted in 11 records. Figure 1 presents the process of study selection.



Note: ICTRP - International Clinical Trials Registry Platform; EC - Clinical trial.
Figure 1 - Flowchart of the screening process for clinical trial protocols for final selection, 2019

The included protocols were registered from 2004 to 2018, with only one registration in 2005, 2012, 2015 and 2017; two in 2004 and 2016; and three, in 2018. As for the countries of origin, the protocols came from Australia (n=3/27.3%), Canada (n=2/18.2%), the United States (n=2/18.2%), from Iran (n=2/18.2%), the United Kingdom (n=1/9.1%) and Brazil (n=1/9.1%).

The professional category that registered the most clinical trials with proposed interventions for infants' sleep was nursing (n=5/45.5%) so that four of these were only for this category and one was in partnership with psychology. Then, the professional category with the most intervention proposals was medicine (n=3/27.3%), followed by psychology (n=1/9.1%). In two records, it was not possible to identify the professional category of which the study coordinators were part.

To compose the interventions, the protocols presented 12 different types of isolated technologies, which were divided, in this study, into two categories: hard technologies (n=7/58.3%) and soft technologies (n=5/41.7%). Hard technologies comprised the use of leaflets (n=2), manual (n=1), Standard Operating Protocol (SOP) (n=1), application (n=1), educational game (n=1), compact disc (CD) (n=1). Soft technologies included home visits (n=1), one-to-one training with parents (n=1), the presence of a sleep specialist during the intervention (n=2), follow-up by text message (n=3), and the use of gradual extinction techniques with instructions to place babies still sleepy in the crib, leave the room and keep returning periodically (n=6).

Chart 1 presents the combined technologies to compose the interventions as well as the comparators for each one. It also presents the outcomes and forms of measurements for each proposal, highlighting the most frequent primary outcome, which was the improvement in the quality of infant and maternal sleep, measured by the decrease in awakenings, total duration of night sleep. Of the 11 protocols, the most frequent secondary outcomes were parents' level of stress, depression, fatigue, and anxiety. As for measurements, the use of a sleep diary (n=6/54.5%), actigraphy (n=5/45.4%) and the Pittsburgh Sleep Quality Interview (n=4/36.3%) and Extended Brief Infant Sleep Questionnaire (n=3/27.2%) questionnaires were the most frequent.

Chart 1- Characterization of protocols regarding interventions, comparator, and outcome measures, 2019

Protocol title (ICTRP), Country and year of registration	**Interventions**	**Comparisons**	**Outcomes and Primary Measures**	**Outcomes and Secondary Measures**
Effect Of An Educational-Behavioral Program About Infant Sleep Country: Iran Year: 2018	Lecture on general education and behavioral techniques * for infant sleep for about 90 minutes.	30-minute lecture on child safety and sleep safety	- Amount of infant and maternal sleep, measured by the mother's and baby's sleep diary. - Quality of maternal sleep, measured by Pittsburgh Sleep Quality Interview (PSQI).	- Postnatal depression, measured by Edinburgh Postnatal Depression Scale (EPDS); - Maternal anxiety, measured by State Trait Anxiety; - Sexual satisfaction, measured by Hudson's Sexual Dysfunction Questionnaire).
The Efficacy of the Nanit-Insights App in Improving Infant Sleep Country: United States Year: 2018	Application that provides parents with personalized sleep recommendations based on the baby's stage of development and weekly sleep data.	Monitoring without application	- Quality of infant sleep, assessed by videosomnography and Extended Brief Infant Sleep Questionnaire.	- Quality of parents' sleep, measured by Pittsburgh Sleep Quality Index; and sleep duration, number of awakenings, time to wake up and night visits by parents, confirmed by videosomnography; - Parental humor, measured by the Clinically Useful Depression Outcome Scale.
Infant Behavioral Sleep Intervention: Comparative Efficacy Country: United States Year: 2018	(1) Routine adjustment + help from a sleep specialist + protocol of what parents do for children to start sleeping and in all possible awakenings at night; (2) Routine adjustment + help from a sleep specialist + protocol just to initiate sleep.	Monitoring	-Quality of children's sleep, measured by the Children's Sleep Questionnaire (ISQ).	- Duration of sleep, number of nighttime awakenings, assessed by sleep diary + videosomnography); - Parents' stress assessed by self-report; - Parental humor, measured by the Profile of Mood State); - Parents' sleep, measured by the Pittsburgh Sleep Quality Index).

To be continued

Chart 1

Protocol title (ICTRP), Country and year of registration	**Interventions**	**Comparisons**	**Outcomes and Primary Measures**	**Outcomes and Secondary Measures**
Comparison of behavioral sleep interventions to reduce infant sleep disturbances and improve parental mental health Country: Australia Year: 2017	(1) Information leaflet on sleep physiology + nursing instruction to perform the gradual extinction technique; (2) Information leaflet on sleep physiology + instruction on how to teach children to sleep independently + not to leave the room and attend to children when asked.	Information leaflet on sleep physiology + instruction to answer questionnaires	- Night awakenings, assessed by actigraphy and parental self-report; - Levels of parental depression assessed, measured by Edinburgh Post Natal Depression.	- Attachment levels between parents and baby, measured by the Parental Attachment Questionnaire (PAQ); - Wear level, measured by the intervention participants' withdrawal); - Parents' stress levels, measured by Subjective Stress Scale (SUDS); - Babies' stress level measured by salivary cortisol.
Infant Sleep Hygiene Counseling Trial Country: Brazil Year: 2016	(1) Home visit for routine adjustment, sleep environment, sleep self-regulation practices and guidance for babies to be placed in the crib while still sleepy; (2) Actigraphy + home visit, intervention guidelines 1, sleep diary monitoring and telephone calls.	Home visits and delivery of material on breastfeeding	- Number of hours in a row in night sleep, measured by Brief Infant Sleep Questionnaire (BISQ).	- Linear growth, measured by anthropometry; - Neurocognitive development, measured by Intergrowth Neurodevelopment Assessment tool - INTER-NDA and the Oxford Neurodevelopment Assessment tool - OX-NDA).
Play2Sleep: Using Play to Improve Infant Sleep Country: Canada Year: 2016	Intervention through Play2Sleep Game with each parent separately. A recording is made, stimulating the bond between the parents and a leaflet on infant sleep is delivered.	Handout only	- Number of nighttime awakenings, measured by Brief Infant Sleep Questionnaire (BISQ).	- Parental depression, measured by Edinburgh Postnatal Depression Scale (EPDS); - Parental sense of competence, measured by Parental Sense of Competence (PSOC) Scale; - Marital satisfaction, measured by Dyadic Adjustment Scale (DAS-4); - Parent-child interactions, measured by Parent-Child Interaction Teaching Scale (PCITS); - Cognition of parents about baby sleep, measured by the Maternal Cognitions about Infant Sleep Questionnaire (MCISQ).
The impact of education on the fatigue and sleep disorders in the mother and infant in the postpartum period Country: Iran Year: 2015	(1) One-to-one training on the tenth day after birth (30-45 minutes) + daily text messages for 60 days. (2) Delivery of a CD with guidance on sleep on the tenth day after birth + daily text messages for 60 days.	Visit to answer the instruments, on the tenth and sixty days after birth	- Children's sleep quality: assessed by a sleep diary; - Quality of mothers' sleep, measured by Pittsburgh Sleep Quality. - Maternal fatigue: measured by Fatigue Intensity Questionnaire.	Not mentioned
A randomized controlled trial of behavioral interventions for infant sleep disturbance Country: Australia Year: 2012	Gradual extinction (placing the child awake in the crib, leaving the room and returning to warm up periodically), with routine adjustment and 24-hour follow-up for seven days.	Sleep education about time, naps and sleep environment in a 50-minute individual class	Sleep duration assessed by the sleep diary and actigraphy.	Child stress level assessed by salivary cortisol.
Tips for Infant and Parent Sleep (TIPS) Country: Canada Year: 2005	Behavioral interventions * + sleep hygiene guidelines by nurses in the immediate postpartum period.	Follow-up only	- Duration of night sleep, assessed by a sleep diary and actigraphy; - Duration of naps: field diary and actigraphy; - Duration of maternal sleep: field diary and actigraphy.	- Morning and night fatigue, measured by Fatigue Visual Analogue Scale Fatigue (VAS); - Child sleep disorder, measured by General Sleep Disturbance Scale (GSDS). - Depressive symptoms, measured by Edinburgh Postnatal Depression Scale (EPDS); - Maternal anxiety, measured by State-Trait Anxiety Inventory, state-anxiety subscale.
Impact of an infant sleep parenting intervention at age 6 months on infant sleep problems at ages 6 to 12 months and maternal psychological and physical wellbeing Country: Australia Year: 2004	Behavioral interventions* by nurses to improve nighttime awakenings and facilitate the onset of sleep, through gradual extinction and follow-up for 60 days.	Usual assistance of maternal and child health nurses	Maternal report of decreased sleep problems	- Psychological, physical and maternal well-being; - Amount and quality of maternal sleep. (form of measurement not mentioned).

To be continued

Chart 1 (concluded)

Protocol title (ICTRP), Country and year of registration	Interventions	Comparisons	Outcomes and Primary Measures	Outcomes and Secondary Measures
A randomized controlled trial to compare alternative strategies for preventing infant crying and sleeping problems in the first 3 months of life Country: United Kingdom Year: 2004	(1) Sleep education to intervene in the sleep environment, reinforced feeding at the end of the night, and teaching the baby to sleep in the crib; (2) Sleep education + educational manual + visit by health visitors.	Standard visit by health visitors, offered by the government	Number of nights without awakening per week (between 10 p.m. and 5 a.m.).	Not mentioned

*Note: *Behavioral technique/intervention: strategies that aim to teach the baby to fall asleep independently.*

DISCUSSION

This study presented a synthesis of the protocols on the international platform of clinical trials about child sleep, whose intervention proposals used techniques and technologies with the aim of improving quality of sleep. Despite the platform's dimension, it was observed that interventions aimed at full-term infants born and without comorbidities are still incipient. In Brazil, there is only one registered intervention proposal.

In this study, it was identified that among the hard technologies used to compose the interventions, educational technologies figured prominently, which, in the scope of health, have developed an important role to assist health professionals, mainly nurses, and clients in care and understanding of any injury. In the case of the pediatric public, literature presents different educational technologies aimed at parents and caregivers, with the objective of assisting in child care[13-15].

With regard to soft technologies, mainly focused on the relationship between patient and professional, it appears that one-to-one consultations are consolidated in the health field[16]. However, some of the interventions analyzed in this study proposed, in addition to consultation, follow-ups carried out through home visits or text messages. These strategies are relevant, as they provide a closer relationship between professional and client, in addition to corroborating the intervention to be executed in the way it was designed[17]. Additionally, interventions aimed at improving children's sleep tend to generate insecurity and anxiety in parents, which can be mitigated by periodic monitoring by a qualified professional[18].

Recognizing the importance of soft and hard technologies in care, Brazilian nurses built a care plan as an intervention to guide nursing consultations for children aged 12 to 18 months, with altered sleep patterns. Among the interventions listed, rituals before sleep, routine adjustments during the day, incentive for children to start sleeping independently stand out[18].

Considering the ways to lead children to sleep, there are discrepancies in literature, both by national[19] and international[20] authors, as there are lines of thought that defend independence for children's sleep, focusing on sleep quality of the whole family and others that emphasize sleep with attachment, like the shared bed, based on the formation of emotionally healthy children[21].

The interventions of the protocols analyzed presented proposals with a focus on sleep independence, evidenced by the gradual extinction technique and guidelines for placing babies still sleepy in the crib as the most prevalent strategies. The gradual extinction technique consists of putting the baby to sleep in the place chosen by parents, ignoring the crying and keep returning to calm babies down in periodic times. According to a study carried out in Australia, this technique does not increase salivary cortisol levels, indicating that it does not generate stress in babies[20].

On the other hand, a reflective study, based on several sciences (nursing, psychology, anthropology, among others), presents subsidized conclusions in cultural and evolutionary aspects, defending the touch and the presence of parents with their babies at sleep time. It is said that co-bed (shared bed) practices contribute to improving and lasting sleep, prolonging breastfeeding time and decreasing cortisol levels. Moreover, they raise reflections that the independence that babies need to fall asleep are reflections of the desire of parents who want some free time for themselves[21].

When considering attachment, intervention for mothers of babies at risk of unsafe attachment found that the regulation of cortisol in 12-month-old babies significantly improved after mothers were taught to increase sensitivity and responsiveness to babies' needs[22]. Similarly, a study carried out with babies aged one to three months showed less cortisol activity when mothers were more emotionally available (calm, non-hostile and sensitive to the baby's signs) during sleeping routines[23].

However, for mothers to be calm and available to care for their babies, it is also necessary that babies are not deprived of sleep, as this can drastically interfere with self-control, thus negatively impacting stress regulation in babies. In healthy adults, partial sleep deprivation for five to six hours can result in daytime sleepiness and negative mood and, when continued for one to two weeks, can lead to cognitive impairments equivalent to sleep deprivation for 48 hours straight[24].

This can be corroborated by a study conducted with 10,000 English women in the postpartum period, which showed that participants with depression, anxiety, sleep problems and who frequently breastfed had a significantly higher risk (OR 2.99) to develop fatigue[25]. Additionally, a systematic review showed a potential association between sleep deprivation and suicidal thoughts[26].

Given the above, understanding the interfaces of psychic aspects in relation to infant sleep becomes relevant to elucidate the best intervention strategies for each family context. In this sense, the clinical trial protocols presented in this study signaled

the need to assess anxiety, depression, and marital satisfaction levels as secondary outcomes, in addition to improving the quality of children's and parental sleep.

In order for these measurements to be carried out, the protocols listed different instruments and the strategies to be used. Among these, the Pittsburgh Sleep Quality Interview and the Extended Brief Infant Sleep Questionaire stood out, both already translated and adapted to Brazilian Portuguese[27-28]. In addition to the instruments presented in this study, a review published in Brazil showed a compilation of instruments available and used internationally to measure changes in infant sleep[29].

In addition to the psychometric measures, the protocols presented the actigraph and the field diary as an alternative to monitor children's sleep patterns. The actigraph suggests objective measurement of sleep, since from its interpretation it is possible to estimate total time, beginning and end of sleep and time of wakefulness, while the sleep diary is configured as a qualitative strategy of systematic notes made by parents and other caregivers about what happens to the child during the day related to sleep[30].

Considering the findings of this article, it is understood that there are different approaches to infant sleep as well as different ways of measuring sleep patterns. However, the completeness of children's sleep, which runs through self-regulatory issues, needs to be studied, considering parenting habits, with regard to mental health and cultural habits. Therefore, in order to intervene in this perspective, a deep knowledge about the family situation is necessary.

From this, further studies are suggested that try to intervene in improving the infant sleep pattern, considering attachment, neurological and psychological development, in addition to family dynamics. It is believed that the best strategies are those that consider the need for children sleep according to the stages of child development and are striking for strengthening bonds between caregivers and children, this being the main gap observed by the present study.

Study limitations

This study was limited to analyzing protocols that correspond to proposals for clinical trials, the purpose of which was to find out what researchers on the theme of infant sleep devised. However, the results of these studies and their methodological quality were not measured.

Contributions to nursing

Primary care nurses, during their care practice, deal with concerns on the part of mothers about the sleep of their children, who generally do not have any neurological alterations that prevent them from having quality sleep. Most complaints are associated with behavior. Therefore, this study aimed to raise the main interventions used in order to guide the practice and also to encourage researchers in child health to conduct more research considering this aspect of child development.

CONCLUSION

This study showed that nursing was a profession with the greatest expression in the protocols of clinical trials that proposed to intervene in infants' behavioral insomnia, using mainly educational technologies and consultations followed by periodic monitoring. The main primary outcome addressed in the proposed interventions was an improvement in infants and/or maternal sleep pattern, and the secondary ones were related to psychic issues, such as anxiety, depression, and parental sexual satisfaction. These outcomes were measured mainly by psychometric instruments, actigraphy and a sleep diary. Such findings signaled that the protocols proposed interventions for babies to fall asleep independently so that they and the other family members had better sleep patterns. However, the literature already presents controversial approaches, which leads to the development of more studies on the topic.

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