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The effectiveness of massage in relieving colic in infants  
A Systematic Review of the Literature  
O efeito da massagem no alívio da cólica do lactente  
Uma Revisão Sistemática da Literatura

MASTERS DISSERTATION  
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## ACRONYMS AND ABBREVIATIONS

- ACTH – Adrenocorticotropin hormone
- AVP – Arginine Vasopressin
- CBA – Controlled Before and After
- CRH – Corticopressin Releasing Hormone
- DeCS – Descritores de Ciências da Saúde
- EBNP – Evidence-Based Nursing Practice
- EBP – Evidence Based Practice
- ESEP – Escola Superior de Enfermagem do Porto
- GOR – Gastro-Oesophageal Reflux
- HPA - Hypothalamus-pituitary-adrenocortical
- ICN – International Council of Nursing
- JBI® – Joanna Briggs Institute®
- LC/NE – *Locus Caeruleas*/Norepinephrine
- MeSH – Medical Subject Heading
- PNS – Parasympathetic Nervous System
- PPIs - Proton Pump Inhibitors
- RCT – Randomized Controlled Trial
- RSL – Revisão Sistemática da Literatura
- SNS - Sympathetic Nervous System

SRL – Systematic Review of the Literature

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## ABSTRACT

**INTRODUCTION:** Infantile colic is a common problem that affects around 20% of babies in the first months of life. However, it is often poorly understood by parents and caregivers. Its aetiology is not yet known and an effective treatment remains unidentified although studies suggests there are many techniques to reduce colic (Savino and Tarasco, 2010). Infant massage has been advised by paediatricians and nurses as one of these methods that could be more effective.

**OBJECTIVES:** To understand the effectiveness of massage in the infant's colic relief.

**METHODS:** The Systematic Review of the Literature was performed based on the Joanna Briggs Institute® model. After delineating the scientific question based on the "PICO" model – "The effectiveness of massage in relieving colic in infants" – with the keywords infant, newborn, neonate, baby, massage, colic and their synonyms in Portuguese and English and the databases Scopus®, Web of Science® and EbscoHost® were used to identify the articles. Only articles written in Portuguese or English were included. A total of 123 articles were found. The references of these articles were analyzed and the other articles, that could eventually help to answer the scientific question, were also included in the investigation. Once the duplicates were removed, a total of 56 studies were submitted to analyses. After their submission to the inclusion and exclusion criteria, 52 were eliminated and 4 were submitted to a methodological quality assessment, performed with resources available in the Joanna Briggs Institute®. The process was conducted by two independent researchers. The disagreements from the revision process were discussed with a third investigator.

**RESULTS:** Four studies were included: a quasi-experimental study and three randomized controlled trials. The findings do not point for the existence of consistency about the benefits of massage in infants' colic relief. Massage can be effective when compared with rocking the

baby and when associated with aromatherapy using lavender oil. The technique reveals itself equally efficient compared to a crib vibrator, but less efficient than sucrose solution, herbal tea and hydrolysed formula.

CONCLUSIONS: The analyses of the selected articles suggests that the findings support the use of massage to relief colic symptoms. However, further investigations about the best technique to use, how and when should be performed.

KEY-WORDS: infant, newborn, neonate, baby, massage, colic

## RESUMO

**INTRODUÇÃO:** A cólica na infância é um problema comum que afeta cerca de 20% de crianças nos seus primeiros meses de vida. Contudo, é frequentemente mal compreendida por pais e cuidadores. A sua etiologia ainda não é conhecida e um tratamento eficaz continua por identificar apesar dos estudos apontarem para diversas técnicas para a redução da cólica (Savino and Tarasco, 2010). A massagem infantil tem sido recomendada por pediatras e enfermeiras como um dos métodos que poderão ser mais efetivos.

**OBJETIVO:** compreender a efetividade da massagem no alívio da cólica da criança.

**MÉTODOS:** Foi efetuada uma Revisão Sistemática da Literatura de acordo com o modelo preconizado pelo Instituto Joanna Briggs®. Após definida a questão científica baseada no modelo “PICO” – “O efeito da massagem no alívio das cólicas do lactente” – com os descritores criança, recém-nascido, neonato, bebé, massagem e cólica e seus sinónimos mais frequentemente utilizados em inglês e português, foram consultadas as bases de dados Scopus®, Web of Science® e EbscoHost® para identificação dos artigos. Apenas artigos nos idiomas de português e inglês foram incluídos. Foram encontrados no total 123 artigos. As referências destes artigos foram analisadas e outros artigos, que poderiam eventualmente auxiliar a responder à questão de partida, foram também incluídos para investigação. Assim que os duplicados foram removidos, um total de 56 estudos foi sujeito a análise. Depois da sua submissão aos critérios de inclusão e exclusão, 52 foram eliminados e 4 foram submetidos a uma avaliação de qualidade metodológica, efetuada com recurso aos instrumentos disponibilizados pelo Instituto Joanna Briggs®. O processo foi conduzido por dois investigadores independentes. Foram discutidos com um terceiro investigador os diferendos que ocorreram no processo de revisão.

**RESULTADOS:** Quatro estudos foram incluídos: um estudo quasi-experimental e três estudos randomizados. Os resultados não apontam para a existência de consistência acerca dos benefícios da massagem no alívio da cólica da criança. A massagem poderá ser efetiva quando comparada com o balanço do bebê e quando associada à aromaterapia com óleo de lavanda. A técnica revela-se igualmente eficiente comparada com um vibrador de berço, mas menos eficaz do que a solução de sacarose, chá de ervas e fórmula hidrolisada.

**CONCLUSÕES:** A análise dos artigos selecionados sugere que os resultados suportam o uso da massagem no alívio dos sintomas de cólica. Contudo, investigação adicional deverá ser feita no sentido de compreender qual a melhor técnica, como e quando a utilizar.

**PALAVRAS-CHAVE:** criança, recém-nascido, neonato, bebê, massagem, cólica



## INTRODUCTION

Infantile colic is a common problem between infants in their early age. Even though it affects around 20% of babies in the first months of life, it is often a poorly understood matter for parents and caregivers leading to anxious visits to the paediatricians and community nurses (Savino and Tarasco, 2010; Bahrami, Kiani and Noras, 2016).

Despite all the research, its aetiology is not yet understood and an effective treatment remains unknown (Savino and Tarasco, 2010). The uncertainty about the matter and the feeling of helplessness towards the child suffering is often a reason for increased stress and sleep deprivation in parents and caregivers (Waddell, 2013).

The sleepless nights and the powerlessness has been associated with a stressful relationship between carers and the child, besides an increased feeling of rejection in mothers when compared with mothers of infants who do not show signs of colic (Kheir, 2012).

Research suggests there are many techniques to reduce colic. Infant massage has been advised by paediatricians and nurses as one of these methods that could be effective.

Around the world, infant massage has been increasingly used as a traditional practice for centuries. Although the used techniques vary around the world, the nourishing nature of the touch and the gestural communication between a baby and its caregiver are the base of this practice.

Throughout the years, massage has been associated with the improvement of mental and physical development in healthy infants as well as in infants in Neonatal Intensive Care units (NICUs) where the baby is submitted to a stressful environment and the stimulation can be poor (Bennet, Underdown and Barlow, 2013).

Although some studies suggest the use of alternative medicines like teas, glucose or massage therapy there is not a consistent and helpful document that gathers all the evidence about the matter. It is from the lack of an evidence-based clinical decision that this Systematic Review of the Literature emerges.

Traditional reviews are usually articles based on opinions, which is not a safe or scientific base for knowledge. In this style of review, the author frequently presents the information he is going to reveal and uses sources that reinforce his point of view disregarding any other sources that may lead to a different path (Bernardo, Nobre and Janete, 2004).

On the other hand, a systematic review that uses a methodology that can be reproduced by other researchers, has plausible criteria and scientific-based conclusions represents a strong and solid base of knowledge (Bernardo, Nobre and Janete, 2004).

Nurses are involved every day in the development of new practices and in the evolution of nursing, which makes them the most suitable people in the process of caring, which is one of the main focuses of health professionals. It is essential that nurses remain focused in improving quality care, which from a paediatric point of view also means evolving in a way that patient and family needs come together for better health outcomes.

Nursing is indeed a new science that seeks answers to its clinical questions. The lookout for the most recent evidence-based practice (EBP) allows nursing to ensure a high-quality patient care and above all: an evidence-based healthcare.

To develop a good systematic review, a focused, objective and specific clinical question has to be constructed. In this case, the question emerged from the fact that, as previously said, many health professionals currently advise the use of massage to alleviate colic symptoms since the technique has been proved to be effective in different developmental areas of the infant.

The present review was made to contribute to the Master's Degree in Child's Health and Paediatric Nursing in Oporto's Superior School of Nursing (Escola Superior de Enfermagem do Porto). This project was developed based on the Joanna Briggs Institute® Systematic Review of the Literature model.

The main goal of the present SRL is to collect scientific evidence in order to understand the effectiveness of massage in the infant's colic relief. In order to fulfil it specific goals were underlined: i) to delineate the key concepts of the Systematic review; ii) to develop a Systematic Review of the Literature Protocol; iii) to identify the action mechanism of the massage in the infants' colic relief; iv) to identify the studies found about the subject; v) to

analyse the available studies about the topic; vi) to evaluate the methodological quality of the studies used on this Systematic Review; vii) to analyse the scientific evidence found; and viii) to synthesize the evidence regarding the theme.



## 1. THEORETICAL FRAMEWORK

The touch constitutes one of the most basic needs of any human being. Infant massage has been performed around the world for many years. Several studies have already been accomplished and the conclusions are unanimous: massaging babies is proven to be effective in the stimulation of their development.

*“Infant massage is a common child care practice in many parts of the world, most especially Africa and Asia. For example, infants are massaged for several months of their life in Nigeria, Uganda, India, Bali, Fiji, New Guinea, New Zealand (the Maori), Venezuela and the Soviet Union” (Auckett, 1981 in Field, 1993).*

Besides the effectiveness on development and growth, it is believed that massage can also contribute to the treatment of colicky babies.

### 1.1. Infantile Colic

Infantile colic is a worldwide paediatric concern that affects approximately 20% of infants, this means that, in the first three months of life, one in every five infants develop colic (Bahrami, Kiani and Noras, 2016). With nearly 90% of incidence in the first month, colic can start early in infancy and last until 4 to 5 months of age (Hodge and Murphy, 2014; Cohen-Silver and Ratnaplan, 2009), although some studies refer that it can last up to 6 months. Its peak appears to be between one month and six weeks of age and tends to decrease between 3 and 4 months of age in regularity and intensity (Hodge and Murphy, 2014).

Infants with colic are characterized by a loud, continuously and *“paroxysmal crying”*, as the author Kheir (2012) refers. Although, the definition of colic is more complex than that. Colic is defined by many authors by the rule of three originated in 1954: *“crying for more than three hours per day, for more than three days per week, and for longer than three weeks”* (Roberts, Ostapchuk and O’Brien, 2004, p. 735). The crying due to colic can sometimes also be associated with redness of the face, bending the legs, releasing gas, irritability and even reflux (Cohen-Silver and Ratnaplan, 2009; Hodge and Murphy, 2014). This definition is applied to babies considered healthy and that are being well-fed (Roberts, Ostapchuk and O’Brien, 2004).

Kheir (2012, p. 1) refers that *“(…) colic is one of the major challenges of parenthood”*, being one of the most common reasons why parents look for medical guidance. Naturally, *“infantile colic can be distressing to parents whose infant is inconsolable during crying episodes”* (Roberts, Ostapchuk and O’Brien, 2004, p. 735). Colic episodes often trigger feelings like stress, exhaustion and helplessness in parents (Hodge and Murphy, 2014). Even though this is a stressful situation for the carer, paediatricians consider it as a benign condition (Bahrami, Kiani and Noras, 2016). Kheir (2012) suggests that parents should be encouraged to jot down this episodes in order to make it easier on the physician to understand the situation and diagnose correctly.

### *1.1.1. Aetiology of Colic*

Its etiology is many times unclear, but several authors defend that this is a multi-factorial condition possibly related to the immaturity of the gut, its altered motility, painful abdominal contractions, deficient development of the digestive system, lactose intolerance, food sensitivity, gut inflammation, over feeding, altered intestinal flora, gas or even a misfit relationship between mother and child, increasing the baby’s anxiety and temperament (Hodge and Murphy, 2014; Bahrami, Kiani and Noras, 2016).

Although some may think that bottle-fed infants have less chance of developing colic, it is proven that *“(… the incidence of colic in breastfed and bottle-fed infants is similar, mothers who are breastfeeding should be encouraged to continue”* (Roberts, Ostapchuk and O’Brien,

2004, p. 737). Roberts, Ostapchuk and O’Brien (2004) state that ceasing breastfeed would deprive the baby from receiving all the benefits from it and would not improve his colic symptoms.

### 1.1.2. Colic Management

Infantile colic is very common, although there is no consensus about the most effective treatment. According to Bahrami, Kiani and Noras (2016) and Cohen-Silver and Ratnaplan (2009) treatment based on the following factors have been used: dietary, pharmacological, behavioural modifications and alternative therapies (table 1).

Table 1 – Colic treatments

Conventional Treatment	Complementary and Alternative Therapies
→ Pharmacological treatments	→ Nutrition and supplements
→ Anti-cholinergic drugs	→ Probiotics
→ Antispasmodic drugs	→ Herbal medicine
→ Eliminating foods that cause gas, allergy	→ Homeopathy
→ Dietary advices (type of nutrition)	→ Chiropractic
→ Breast-fed infants	→ Acupuncture
→ Bottle-fed infants	→ Behavioural interventions
	→ Playing soft music
	→ Warm baths
	→ Aromatherapy

Adapted from: Bahrami, Kiani and Noras, 2016, p. 1954

Many of these treatments have been performed and advised throughout the years some showing good results, but others have been proven to be ineffective and even unsafe (Bahrami, Kiani and Noras, 2016).

## *Pharmacological Treatment*

There are many pharmacological treatments described in numerous studies. Some authors believe that these medications are often prescribed in response to the parent's anxiety and frustration towards the situation rather than the actual diagnostic of the infant, which leads to a tremendous debate about the matter (Hassal, 2012; Hudson et al, 2012 in Hodge and Murphy, 2014).

Reports about the use of anticholinergic medications like dicyclomine hydrochloride and dicycloverine showed to be effective in reducing an increased gut peristaltic activity. However, loose bowel movements as an adverse effect were reported, as well as apnoea, breathing difficulty, seizures and syncope (Kheir, 2012; Cohen-Silver and Ratnaplan, 2009). Besides, its misuse led to overdose which left the infants *"(...) dopey, wide-eyed, and excessively sleepy"* (Cohen-Silver and Ratnaplan, 2009, p. 15). Studies reporting to other anticholinergics also showed increased sleepiness in the infants (Cohen-Silver and Ratnaplan, 2009).

*"Various reports indicate that increasing numbers of newborns are being prescribed strong antacid drugs (example, Prilosec), histamine antagonists (example, ranitidine) and proton pump inhibitors (PPIs; example, omeprazole) for symptoms associated with GOR and colic"* (Hassal, 2012; Hudson et al, 2012 in Hodge and Murphy, 2014).

According to a study performed in New Zealand, between the years of 2006 and 2010 the number of medication dispensed for newborns increased exponentially from 4650 to 8231, in which 111% are associated to babies between zero to three months and 80% ages between four to six months (Hodge and Murphy, 2014).

Investigators affirm that there is no evidence that supports the prescription of omeprazole to treat these symptoms. They believe that this increase is due to the fact that the term *acid reflux* was being used incorrectly, giving the idea that PPIs (Proton Pumps Inhibitors) would be the solution. On the opposite, the use of this medication was associated with a high incidence of gastroenteritis, pneumonia and respiratory tract infections (Hassal, 2012; Hudson et al, 2012 in Hodge and Murphy, 2014).

Simethicone is a pharmacological method considered safe, cheap and easily available, which aims to decrease the wind. However, numerous randomized studies were performed to test its performance and all concluded that it does no better than a placebo (Waddell, 2013; Savino and Tarasco, 2010; Kheir, 2012; Cohen-Silver and Ratnaplan, 2009).



### *Diet Change*

Several groups that believe colic is a gastrointestinal pathology support a change in the diet, mainly to hydrolysed whey or milk based on the fact that the normal milk was leading to a poor gut digestion causing excessive gas. In fact, many studies show a decreased crying time in babies which were submitted to this change, which works as an incentive to many physicians to recommend it (Cohen-Silver and Ratnaplan, 2009). However, it is important to remember that this strategy is not proven to be effective in all cases of colic (Hodge and Murphy, 2014).

There are also studies that show decreased crying periods when mothers have a hypoallergenic diet free of milk, egg, wheat and nuts. Some believe that hypoallergenic formulas should be reserved for babies that are truly allergic to cow's milk protein (Cohen-Silver and Ratnaplan, 2009).

*“Infantile colic may be one of the first symptoms of food allergy (...). If there are concerns/suspicions that the baby may have a food allergy (...) then a two to four week trial of a hypoallergenic formula in bottle-fed babies, or cow-milk free diet in breastfeeding mothers would be warranted alongside appropriate dietetic advice to ensure nutritional adequacy, including provision of sufficient calcium and vitamin D from other sources)”* (Waddel, 2014, p. 18, 20).

For babies that are not believed do have an allergy to lactose, it's important to consider the possibility of a lactase deficiency, not allowing the infant to produce enough lactase to match the amount of lactose received. In this case, mothers should make sure that one breast is completely empty before offering the second breast. This because the first milk has more lactose than the milk in the end of the feed (Waddel, 2014).

### *Probiotics*

Recent perspectives are using different alternative therapies as probiotics to understand if this could be the path to follow in reducing colic. Probiotics are *“(...) live microorganisms that when administered in adequate amounts confer a health benefit on the host (...)”* (Council for Agricultural Science and Technology, 2007, p. 1). Microbes colonize humans and animals being part of the body's ecosystem. These microbes play an extremely important role *“(...) in*

*the development of intestinal cells and participate in the maturation and function of the innate immune system”* (Council for Agricultural Science and Technology, 2007, p. 3).

Although there’s still a lot to learn about this microbes, it’s known that each person has its own singular microbe population that colonize different parts of the body, one of these parts is the intestinal tract. These are usually stable, though some conditions may affect this population as antibiotics, immunosuppression, and diarrhoea, between many others, returning to normal without any intervention after having been disturbed (Council for Agricultural Science and Technology, 2007).

The probiotic submitted to more tests to assess its effectiveness in colicky babies is the *Lactobacillus* group. Results showed an amazing decrease in daily median crying time (159min to 51min) when compared, for example with simethicone (177min to 145min), according to this study, there were no adverse effects (Cohen-Silver and Ratnaplan, 2009).

### *Alternative Therapies*

Measures like oral hypertonic glucose have also showed that 30% of the infants had a reduction of the crying time when compared with the placebo sterile water (Cohen-Silver and Ratnaplan, 2009; Kheir, 2012).

Also some infusions of herbal teas containing chamomile, vervain, licorice, fennel and lemon balm essence showed positive results when used till three times a day, giving a maximum of 150ml. Although, since there is no standard of dose, strength of the products associated with the possibility of interfering with the feeds, these measures should be used very cautiously (Kheir, 2012).

### *Chiropractic*

The evidence about chiropractic measures, specifically spinal manipulation shows very inconclusive results (Kheir, 2012; Cohen-Silver and Ratnaplan, 2009). According to Cohen-Silver and Ratnaplan (2009) physicians should discouraged this practice.

### *Behaviour Modification*

The 5Ss technique when done correctly is proven to be effective in reducing infant crying and stimulate the baby to sleep. This technique includes:

1. *Swaddling*, using a big and loose blanket, allowing the baby to move the hips if desired and it's very important to avoid overheating and head covering;
2. *Side or stomach* by holding the baby on his side or positioning in prone to calm him down;
3. *Shhh* by making this noise close to the baby's ear;
4. *Swinging*, jiggling the baby with gentle movements supporting his neck and head;
5. *Sucking*, allowing the baby to suck on a clean finger or pacifier (Kheir, 2012).

It's also very important to remind parents to exhaust all the possibilities that may be making the baby uncomfortable, like hunger, wet nappy, too hot or cold. Only after excluding all these factors, then try to relax the baby (Kheir, 2012).

## **1.2. Infant Massage**

Traditionally, mothers all over the world make use of the soft touch and the appliance of small pressure in the abdomen in the attempt to control their children's pain and bloating abdomens (Bahrami, Kiani and Noras, 2016).

*"Massage is an effective method of relaxation and therapy, and one of the most popular methods of alternative medicine in the world. Massage consists of a series of hand gestures and skills on a regular basis and certain body tissues to influence the nervous system, muscle, skin, joints and blood circulation (...)"* (Bahrami, Kiani and Noras, 2016, p. 1956).

This happens because during the massage various sensorial stimulations are reaching the baby, which calms him down. However, over stimulation may have the opposite effect, making the baby more and more irritable (Huhtala et al, 2000).

It is believed that the massage mechanism stimulates the secretion of melatonin in the pituitary gland, which is the hormone responsible for the feelings of calmness and sleepiness, enabling rest-activity rhythms to be developed. By relaxing the gastrointestinal tract and

allowing a good digestion, it is possible to calm the infant and reduce its gas, allowing him to sleep (Neto and Castro, 2008; Bahrami, Kiani and Noras, 2016).

It appears that the massage has similar effects to the parasympathetic nervous system (PNS), which is the system responsible for allowing the body to respond to calm situations characterized by low activity and bodily restoration. The PNS regulates a wide number of body functions like blood circulation, temperature, respiration and digestion (Richter and Wright, 2013).

This calm feeling improves the hypothalamus-pituitary-adrenocortical (HPA) axis function which may improve organ function (Bahrami, Kiani and Noras, 2016). The structures involved in this axis are the endocrine glands: the hypothalamus, the pituitary gland and the adrenal glands. The interactions between the three of them controls reactions to stress, mood and emotions (Guilliams and Edwards, 2010).

The HPA axis is commonly called “*the stress response system*” and many studies have been conducted in order to comprehend the cascade of events that happen when the brain perceives a stressor. The key to understand this mechanism lays in the understanding of the HPA axis and the Sympathetic Nervous System (SNS).

*“When the hypothalamus is triggered by a stressor, corticotropin-releasing hormone (CRH) (...) and arginine vasopressin (AVP) are secreted, eliciting both the production of adrenocorticotropin hormone (ACTH) from the posterior pituitary and the activation of the noradrenergic neurons of the locus caeruleas/norepinephrine (LC/NE) system in the brain. The LC/NE system is primarily responsible for the immediate “fight or flight” response driven by epinephrine and norepinephrine, while ACTH drives the production of cortisol from the adrenal cortex”* (Guilliams and Edwards, 2010, p. 1, 2).

In a normal situation, high levels of cortisol in the blood inhibit the secretion of CRH and ACTH by a negative feedback mechanism (figure 1).

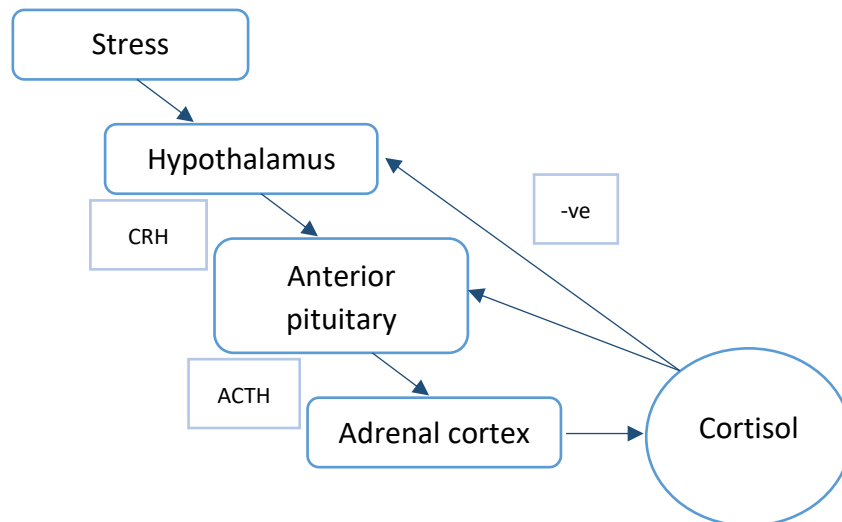


Figure 1 – The Stress Response System (CRH: *Corticotropin Releasing Hormone*; ACTH: *Adrenocorticotropin Hormone*; -ve: *negative feedback*)

Adapted from: Phillips et al, 2006, p. 726

Based on the image, it is possible to understand that the negative feedback of the cortisol is designed in order to prevent a long-term exposure of the tissues to the two previous substances. It is known that the chronic and repeated exposure of the brain to stressors can lead to a dysregulation of the HPA axis and posteriorly the adequate secretion of cortisol, which may affect organ function (Guilliams and Edwards, 2010).

### 1.2.1. *Massage Techniques*

Massage is for some considered a way of communication between caregiver and baby. This is one of the reasons why a slow and relaxed touch should be used to transmit calmness. During the massage, the baby will communicate what he likes and dislikes. It is important to remember that, like adults, not always babies are open to receive a massage.

There are different ways to understand if the baby is feeling pleasure from the massage, like making eye contact, smiling and relaxed. However, if the baby is crying, looking very stressed

and tense, turning his head away or even trying to walk away from the touch, these are general signs that the baby is not enjoying the moment (Hopkinson, 2010).

In this chapter, one of the many massage techniques will be presented and basic strokes will be shown based in the author Hopkinson (2010). Each movement should be performed five times, unless the baby shows signs that he is not appreciating.

To massage the abdomen (Hopkinson, 2010):

- Downwards open hand strokes on the baby's abdomen, one hand after the other (*Full Water Wheel*);
- Place the thumbs above the umbilicus and slide them out to the sides all the way to the back (*Thumb Open Book*);
- By visualising a clock on the baby's abdomen, start with one hand on 9 o'clock sliding it until the 3 o'clock making a circular movement. Repeat with the other hand from 3 o'clock to 9 (*Sun and Moon*).

According to Hopkinson (2010), a routine that aims for the relief of colic includes the following:

- Start by resting the hands on the baby's tummy;
- Repeat *Full Water Wheel* technique six times;
- Pull the knees up and hold for 30 seconds before bringing them down;
- Position the hands on the baby's abdomen and hold for a moment;
- Perform *Sun and Moon* technique;
- Pull the knees back up and hold for 30 seconds before bringing them down;
- Again place the hands in the baby's abdomen and hold.

The author states that by repeating the sequence three times and using the technique two times a day for four weeks, there will be a relief in the baby's colic.

For constipation, the author suggests the *I Love U* technique (Hopkinson, 2010):

- Placing the right hand on the baby's top left side of the abdomen, draw an "I" downwards;
- Draw an "L" upside down, starting from right to left across the abdomen and then slide down until the groin;
- Finally, draw a clockwise upside down "U".

In the end of the massage, the excess of oil should be cleaned and the baby wrapped in a clean towel or blanket.





## 2. METHODOLOGY REFERENTIAL

The acknowledgement of the importance of Evidence-Based Practice (EBP) is a step of major importance in nursing practice. Its application allows the nursing community to develop and improve their care according to the most recent evidence available. It is our responsibility as a science to keep searching for new and better knowledge. Research and EBP are a necessity to the growth of nursing.

As the ICN states *“the availability of information and the growth of science have led to significant improvements in health outcomes throughout the world”* (ICN, 2012 p. 3). It is our duty to gather our efforts and *“close the gap between evidence and action”* (ICN, 2012, p. 3). The more we close this gap, a better *“environment conducive to evidence-informed decision making and practice”* will be built (International Council of Nurses, 2012, p. 3).

Furthermore, nursing practice when based on evidence leads to a higher quality of care, an improvement in the outcomes, reduction in the costs and increases nurses satisfaction when compared to traditional care approaches (Melnyk et al, 2010).

### 2.1. Evidence Based Practice

Nursing is a very recent science, which means that there are a lot of subjects that haven't been investigated, studied and defined. To take care of the patient according to the best that is possible, nurses have the obligation to continue their studies and in this way deliver care

in the most correct means available. Spector (sd, p. 30) defines Evidence-based Health care as the “*umbrella*” under which the health care professionals should be regulated.

*“To many students, it seems much more exciting and important to be with patients in various settings. It is often hard for beginning practitioners to appreciate the value of learning the research process and the importance of evidence in providing patient care. To appreciate the importance of evidence”* (Schimt and Brown, 2015, p.3).

In a daily basis people require nursing care. If we imagine any of the situations that we’ve been through in practice, what would be more desirable: a care grounded on evidence or one established by tradition? When the situation is described like this is quite easy to acknowledge the importance of Evidence Based Practice (EBP) (Schimt and Brown, 2015).

According to Burns and Grove (2011, p.4):

*“(…) the ultimate goal of research is the development of an empirical body of knowledge for a discipline or profession, such as nursing (...). The ultimate goal of nursing is an evidence-based practice that promotes quality, cost-effective outcomes for patients, families, healthcare providers, and the healthcare system”.*

Evidence Based Practice is the responsible for the fusion of both concepts.

Whilst analysing the literature about EBP it’s possible to find various conceptions about the subject. Based on Schimt and Brown (2015, p. 4) EBP is a process which involves *“the examination and application of research findings or other reliable evidence that has been integrated with scientific theories”.*

According to Sacket et al. (1996 cit in Beyea and Slattery, 2006, p. 1) EBP is defined as *“the conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients”.*

Nurses have the responsibility towards the patients, their needs and principles.

*“The patients need(s) might focus on health promotion, illness prevention, acute or chronic illness management or rehabilitation. In addition, patients bring values or unique preferences, expectations, concerns, and cultural beliefs to the clinical encounter”* (Burns and Grove, 2011, p.5).

This way, the evidence-based practice encourages patients and their families to play an active role in the management of their health and sickness process.

*“It is the unique combination of the best research evidence being implemented by an expert nurse clinician in providing quality, cost-effective care to a patient with specific health need and values that results in evidence-based practice”* (Brown, 2009; Craig and Smyth, 2007; Sacket et al., 2000 cit in Burns and Grove, 2011, p.5).

*“Nurses’ unique perspective on patient care obliges nurses to build their own body of evidence through scientific research”* (Schimt and Brown, 2015, p.4).

The literature gives us many descriptions of EBP but they are all built over three pillars: empirical studies, available clinical expertise and resources and patients preferences (figure 2). A recent concept from 2005 defines it in a very concrete and simple way as a *“problem solving”* method that uses updated, present and trustworthy evidence to answer clinical questions combining one’s professional experiences and expertise and patient’s needs, values and beliefs (Melnyk and Fineout-Overholt, 2005 cit in Keele, 2011, p. 75).



Figure 2 – Elements of evidence based practice

Source: International Council of Nursing, 2012, p. 7

Actually, EBP has its foundations in medicine, which is the reason why the term used was *“evidence based medicine”*. With the years, this term suffered some changes and nowadays we refer to it as *“evidence-based practice”* because other areas besides medicine recognized its importance (Beyea and Slattery., 2006, p. 1).

The concept was coined by a British epidemiologist Archie Cochrane (1909-1988) who reprimanded medical practice due to the lack of critical points of view concerning the

examination of evidence. He believed that patients only had the obligation to pay for the care that was implemented based on scientific facts. Furthermore, he also believed that those facts should preferably be based on randomized clinical trials (Schimt and Brown, 2015, p.4).

Cochrane even proposed that systematic reviews of the literature about various disciplines should be done in order to build a solid and trustworthy resource center. As a result of this, the Cochrane Center has been producing systematic reviews about healthcare procedures for 20 years (Schimt and Brown, 2015, p.4; The Cochrane Collaboration, consult. in November 2016).

This allows all the healthcare professionals to base their practice in a group of the best available evidence instead of only using a single study as a backup knowledge. Besides, many health interrogations cannot be answered by only one study. It's a human impossibility to control all the factors that influence health and sickness. Furthermore, it would be unmanageable for the investigators to study all of them at once.

Over time, with more research being completed, the public access to any kind of evidence got bigger and easier (Schimt and Brow., 2015). With this good aspect also came the risk of more erroneous information. To avoid that, The Cochrane Collaboration is aiming to

*"(...) anyone who is interested in using high-quality information to make health decisions. Whether you are a doctor or nurse, patient or carer, researcher or funder, Cochrane evidence provides a powerful tool to enhance your healthcare knowledge and decision making"* (The Cochrane Collaboration, consult. in November 2016).

Some authors argue that due to the uniqueness of the nursing knowledge, the proper term to be used should be even more specific and is now referred to as *"Evidence-based nursing practice"* (EBNP) (Keele, 2011).

Over the years, several different conceptual models have been created in order to provide guidelines to implement EBP till now. Three of the most common models and the ones that have been used to develop the recent ones are the Stetler model, the Iowa model and the ACE Star Model (Keele, 2011).

Stetler (2001 cit in Keele, 2011, p. 75 & 76) who refers that this process has to cross 5 stages:

1. *"Preparation"*: which evolves the identification of the problem and its further validation according to evidence.

2. *“Validation”*: in this phase is included the critiques and the synthesis of the found documents (eg. systematic reviews of the literature, scientific evidence, empirical and non-empirical studies, etc.) plus the evaluation and qualification of each item according to a *“table of evidence”*. The point is to discard sources that are not credible and also stop the process if the evidence is insufficient.
3. *“Comparative evaluation/Decision making”*: at this stage the goal is to synthesize the findings, decide about what can and cannot be used. The author may even start a study on her own if she finds the information useless.
4. *“Translation/Application”*: developing a proposal of changes is the pillar of this phase. Deciding where, how and when they can be applied; if they should be putted into practice with an individual, a group or an organization; the strategies to apply the planed interventions, etc. The author of this model even suggests that a pilot project can be conducted.
5. *“Evaluation”*: can be made in two ways: formal or informal. The costs should be considered and the evaluation of the outcomes should be made.

According to the Iowa model (figure 3), a study has to start with a *“trigger/problem. These triggers may be knowledge focused or problem focused”* (Keele, 2011, p. 76). This author defends that a team composed by *“key stakeholders, clinicians, staff nurses, and other champions of evidence-based practice”* should be formed if the problem is a priority for the institution (Keele, 2011, p. 76).

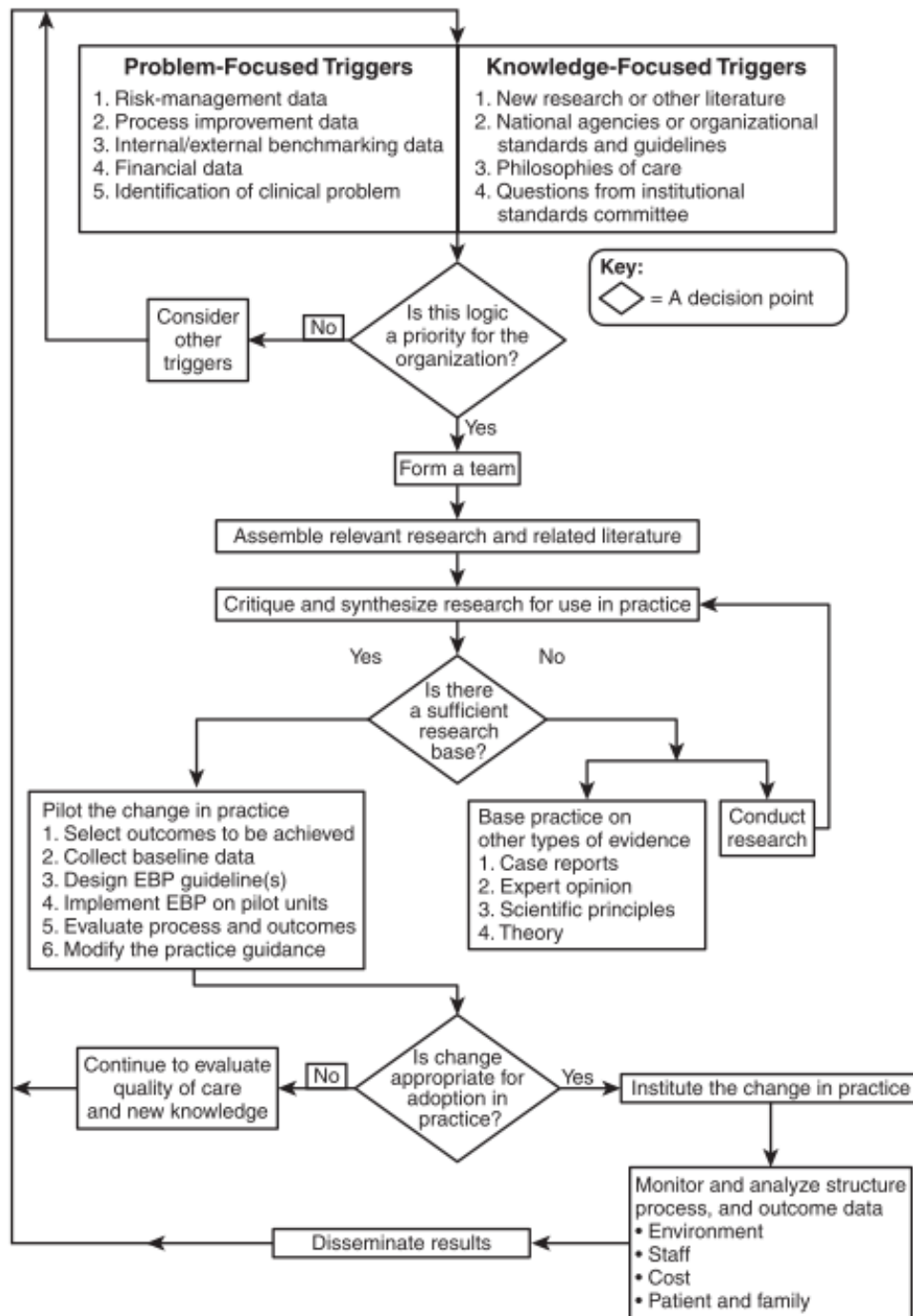


Figure 3 – Iowa Model

Source: Keele, 2011, p. 77

After the team is trained, the next thing to do is gather the evidence and synthesize it. In the authors opinion “a pilot of the practice change occurs if there is sufficient evidence to support the change” (Keele, 2011, p. 76). Later, an evaluation of the results and outcomes should be done and further publication.

From the analysis of the figure, it's interesting to acknowledge how clearly all the stages are specified and how the author clearly drives the investigator through all the phases indicating what to do in each one of them.

The uniqueness of nursing knowledge is the base for all the models that were presented so far. The same happens with the model shown below. What they all have in common and at the same time what makes them exceptional is the highlight they all give to the communication with the target of the care and the fact that they adapt the planned interventions to the actual individual, population or organization.

At last, but not the least, the ACE (Academic Centre for Evidence-Based Practice) Star Model is represented in the figure 4. This model describes the *“relationship between various stages of knowledge transformation”*. According to this model, this concept is defined as *“the conversation of research findings from primary research results, through a series of stages and forms, to impact on health outcomes by way of evidence-based care”* (Stevens, 2004 cit in Keele, 2011, p. 79).

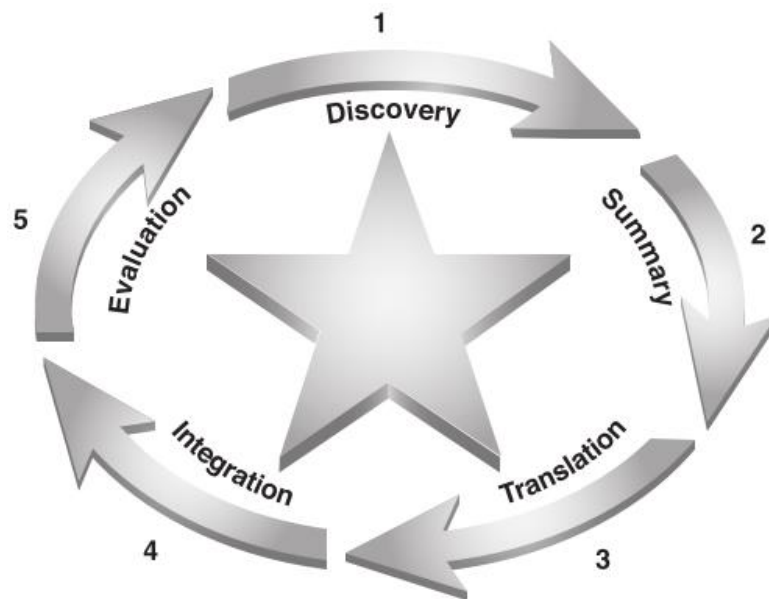


Figure 4 – ACE Star Model

Source: Keele, 2011, p. 78

What this model proposes is a diagram that can be applied to evidence to continuously put the process of EBP in action. Every point of the star has its own meaning and they all intend to represent each phase that knowledge has to go through (Keele, 2011, p. 79).

1. *“Knowledge discovery”*: gathering of all the new knowledge either qualitative or quantitative;

2. *“Evidence summary”*: synthesize all the information regarding the issue, including the findings from systematic reviews and meta-analyses;
3. *“Translation into practice recommendations”*: cross the evidence gathered with evidence collected based on clinical expertise; the aim of this stage is to translate the findings and the practical strategies for a specific population regarding a specific issue;
4. *“Integration into practice”*: apply the practical strategies through the previously defined methods, always respecting the individual and the institution that might change from one to another and also might affect its implementation;
5. *“Evaluation”*: the evaluation and validation of the applied changes based on the patient health outcomes and client satisfaction.

It also explains the *“very nature of the knowledge necessary to transform practice”*. According to the K. R. Stevens *“understanding the concepts in the ACE Star Model is fundamental to moving knowledge into clinical decision making”* (K. R. Stevens, personal communication, April 20, 2010 cit in Keele, 2011, p. 79).

This model clearly represents the cycle through which all the knowledge should be subjected to. Also, from what is possible to assess by the presented models it's easy to see how much and in what way they helped and were pillars to the contemporaneous models, like the one from Joanna Briggs Institute® in which this SRL will be based on.

The process to use EBP in nursing always includes the identification of the problem, a planning phase, implementation and further evaluation. This is what the previous models contain and also what they have in common with the one from Joanna Briggs Institute® that is presented in the next paragraph.

## **2.2. Joanna Briggs® Model**

The Joanna Briggs Institute® (JBI®) is an international research and development organisation. It is one of the biggest agencies for evidence-based health care. The fact that they are non-profit allows every person to have access to their publications. It is based in the



Faculty of Health Sciences at the University of Adelaide in South Australia (International Council of Nurses, 2012). Its aim is to facilitate the EBP worldwide and give meaning to health care knowledge making it feasible, appropriate, meaningful and effective. Its actions are undertaken by:

- *“developing methods to appraise and synthesis evidence, conducting systematic reviews and analyses of the research literature (evidence synthesis)*
- *globally disseminating information in diverse formats to inform health systems, health professionals and consumers (evidence transfer)*
- *facilitating the effective implementation of evidence and the evaluation of its impact on healthcare practice and health outcomes (evidence utilization)”*  
(The Joanna Briggs Institute®, consult. 25 May 2016, p. 11).

Every year this organisation publishes a *Reviewers’ Manual* in order to provide the support needed for those who are conducting systematic reviews and intend to use this methodology and method as a pillar (The Joanna Briggs Institute®, 2015).

*“The Institute collaborates internationally with over 70 entities across the world. The Institute and its collaborating entities promote and support the synthesis, transfer and utilization of evidence through identifying feasible, appropriate, meaningful and effective health care practices to assist in the improvement of health care outcomes globally”* (International Council of Nurses, 2012, p. 9).

These four concepts of *feasibility, appropriateness, meaningfulness* and *effectiveness* are the base of true meaning of knowledge.

According to Pearson and colleagues (p. 201, 2005 cit in Jordan et al, 2016, p. 5) evidence is *“the basis of belief; the substantiation or confirmation that is needed in order to believe that something is true”*. The meaning of this is based on the fact that for nurses to be able to determine the value of a range of interventions and procedures an extensive review of the existent evidence is needed. *“While evidence of effectiveness is acknowledge as being of value, other types of evidence are considered equally important as they are designed to answer different clinical questions”* (Jordan et al., 2016, p. 5).

The articulation between evidence and its actual capacity to be applied in practice is assessed by the FAME (**F**easibility, **A**ppropriateness, **M**eaningfulness, and **E**ffectiveness) scale which refers to the four main concepts above stated. This scale makes every decision making

process a reasonable process which seeks to conduct research in the right direction (Jordan et al., 2016).

According to the JBI®, **feasibility** is defined as “the extent to which an activity or intervention is practical or viable in a particular context or situation”; the concept of **appropriateness** is described as “the extent to which an intervention or activity fits with a particular context or situation”; **meaningfulness** is seen as being “the extent to which an intervention or activity is positively experienced by an individual or group” and finally, “the extent to which an intervention achieves the intended result or outcome” is denominated by **effectiveness** (Jordan et al., 2016, p. 5). All of these concepts are represented in the model suggested by The Joanna Briggs Institute®.

The Evidence Based Healthcare Model first proposed by the JBI® was published in 2005 (figure 5) and without a doubt, it became a marker that represents the Institute exclusive and singular way to conceptualise evidence based healthcare and its operationalisation.

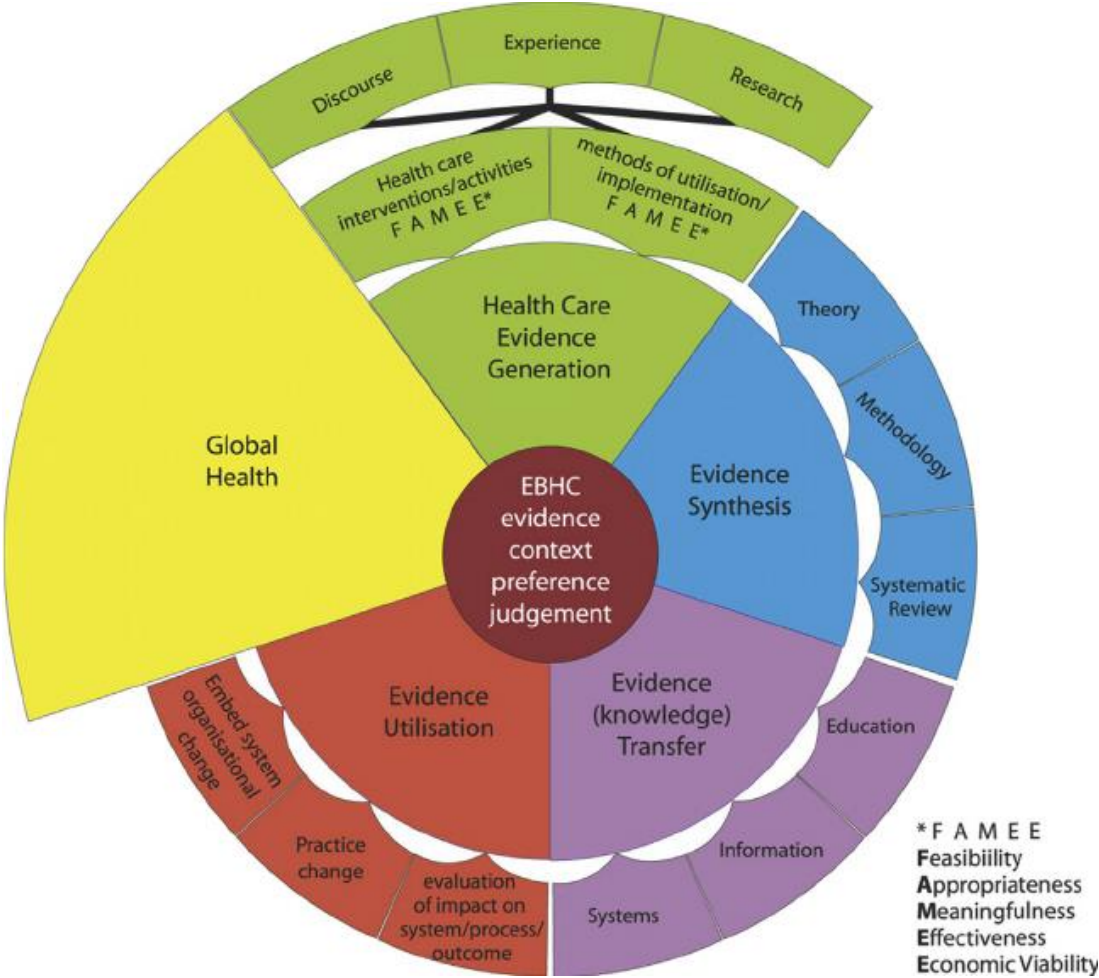


Figure 5 – 2005 Evidence Based Healthcare Model by JBI®

Source: JBI® (2016) in

[https://www.researchgate.net/profile/Craig\\_Lockwood/publication/268692800/figure/fig1/AS:295492463415302@1447462301859/fig-1-The-Joanna-Briggs-Institute-conceptual-model-for-evidence-based-health-care.png](https://www.researchgate.net/profile/Craig_Lockwood/publication/268692800/figure/fig1/AS:295492463415302@1447462301859/fig-1-The-Joanna-Briggs-Institute-conceptual-model-for-evidence-based-health-care.png)

It was based on the concept that defined EBP as a *“clinical decision-making that considers the best available evidence; the context in which the care is delivered; client preference; and the professional judgement of the health professional”* (Pearson et al, 2005, p. 209 cit in Jordan et al., 2016, p. 2).

This model aims to represent the four major components of the Evidence-Based Nursing Practice as the Health Care Evidence Generation, the Evidence Synthesis, the Evidence Transfer and finally the Evidence Utilisation and obviously each of its components.

Since this model is now more than a decade old, it has been highly applied and used as base for several works, the decision to improve and empower it was clear. This way and because the model is now a role model to follow, some changes were made in its structure and design, but always keeping the same pillars (figure 6).

Some of the changes made were related with the colours and to improve the visuals of the model. For this, a better harmony between the colours took place and now they respect the visible colour spectrum in its accurate sequence. Besides that, the sections that were out of the main circle (3 sections for each wedge) are now a paler version of the adopted colours for each one of the major sections in order to outline the importance of the last ones (Jordan et al., 2016).



Figure 6 – The new Evidence Based Healthcare JBI® model

Source: JBI® (2016) in <[http://joannabriggs.org/assets/img/Model\\_2016.jpg](http://joannabriggs.org/assets/img/Model_2016.jpg)>

The inner circle remains mainly the same not only from a design perspective but also from the colours. The decision to maintain this was specially to keep the main concept of the Model. The central colour is still red and according to the authors it might always remain like that in order to represent the strength of the concept (Jordan et al., 2016).

The wedges that were exterior in the 2005 model were also articulated with the centre providing an easier reading and a better harmony in its use (Jordan et al., 2016). Furthermore, this allows a fluent understanding of which steps belong to *Global Health* (sustainable impact, engagement, knowledge need), *Evidence Generation* (research, expertise, discourse), *Evidence Synthesis* (systematic review, evidence summary, guidelines), *Evidence Transfer* (education, systems integration, active dissemination) and finally *Evidence Implementation* (context analysis, facilitation of change, evaluation process & outcomes).

One of the biggest changes in terms of significance is related to the flow between the central concepts. If we look carefully, we can see that in the 2005 model, it was not clearly represented. In the current model, the concept is represented through a diagram with large arrows which explains the continuous cycle between each section. However, the model also highlights that the cycle is not necessarily one linear process, but is interchangeable within the teaching process by using smaller arrows (Jordan et al., 2016).

According to the Joanna Briggs Institute® (Jordan et al., 2016, p. 4) *"(...) the rationale for this decision was to ensure that there was directional clarity. Making the arrows the same size would imply there was some confusion regarding the preferred direction"*.

Furthermore, due to the major significance of the four concepts explained above (feasibility, appropriateness, meaningfulness and effectiveness) they were moved to the central pebble of the Model. According to the JBI® (consult in 27 May, 2016, p. 5),

*"(...) the FAME scale is not only a reflection of the different types of research that are undertaken by health researched but it also drives the conduct of different types of reviews, the generation of derivative products and resources and their implementation in practice"*.

There is no doubt that this model represents a significant amount, not only for JBI® in what concerns the development of the organization but also because of the scientific improvement that it stands for. Clearly this model has a major significance for those who intend to produce scientific contents and especially for everything that Evidence Based Healthcare means for the enhancement of knowledge and for those who seek to practice their profession based on reason and research.

### **2.3. Systematic Review of the Literature**

The fundamentals of EBP can be achieved by using the Systematic Review of the Literature (SRL) (De-La-Torre-Ugarte-Guanilo, Takahashi and Bertolozzi, 2011) which *"(...) seeks to identify all the available evidence with respect to a given theme"* (Torgerson, 2003, p. 6).

A Systematic Review is a secondary research because it comprises a various number of strategies and techniques to organize the outcomes achieved by all the primary research. Its history goes back centuries, even though educational researchers are amongst the more recent users. The claim of first group using this method is made by astronomers, although there is evidence of its practice in: “(...) *medicine (i.e. treatments for scurvy in the eighteenth century), agriculture (also the eighteen century), astronomy, and the ‘psychology of time’ (nineteenth century)*” (Torgerson, 2003, p. 9).

Despite the fact that this concept of “*research synthesis*” has been in practice for centuries, the term “*systematic review*” is recent and was primarily applied related to health care research (Torgerson, 2003).

*“Systematic reviews have become increasingly popular across the allied health, education, and disability and rehabilitation fields. Unlike traditional narrative reviews, systematic reviews aim to minimize bias in locating, selecting, coding, and aggregating individual studies. This rigor in minimizing bias is what makes these reviews systematic”* (Schlosser, 2007, p. 1).

In a systematic review all its methods are plainly showed allowing the reader to analyse the process and subject it to scrutiny. They “*have the advantage of including all the studies in a field (sometimes positive and negative studies), so the reader can judge using the totality of evidence whether the evidence supports or refutes a given hypothesis*” (Torgerson, 2003, p. 6).

As Torgerson stated in one of her many works, due to the fact that all the evidence related to the topic in study is included in the SRL and even the excluded documents are compiled, as well as the reasons for its rejection is explained, the findings are inevitably less likely to be selected. All this factors contribute to less chance of biases and therefore more rigorous (Torgerson, 2003).

*“Conventionally, systematic reviews are needed to establish clinical and cost-effectiveness of an intervention or drug. Increasingly, however, they are required to establish if an intervention or activity is feasible, if it is appropriate (ethnically or culturally) or if it relates to evidence of experiences, values, thoughts or beliefs or clients and their relatives ... However, systematic reviews are most needed whenever there is a substantive question, several primary studies – perhaps with disparate findings – and substantial uncertainty”* (Hemingway and Brereton, 2009, p. 3).

The aims of a Systematic Review have been documented throughout the years, and now gathered they are presented by Torgerson (2003, p. 7, 8):

- “(i) to address a specific (well focused, relevant) question;*
- (ii) to search for, locate and collate the results of the research in a systematic way;*
- (iii) to reduce bias at all stages of the review (publication, selection and other forms of bias);*
- (iv) to appraise the quality of the research in the light of the research question;*
- (v) to synthesize the results of the review in an explicit way;*
- (vi) to make the knowledge base more accessible;*
- (vii) to identify gaps; to place new proposals in the context of existing knowledge;*
- (viii) to propose a future research agenda; to make recommendations;*
- (ix) to present all stages of the review in the final report to enable critical appraisal and replication”.*

### 2.3.1. *The stages of a Systematic Review*

In order to advance with a systematic review, a developmental process is required to achieve rigorous and reliable content. As Torgerson (2003, p. 8) states, it is indispensable *“the application of strategies that limit bias in the assembly, critical appraisal, and synthesis of all relevant studies on a specific topic”*.

According to The Joanna Briggs Institute® this process comprises the following stages (Table 2):

Table 2 – Stages of a Systematic Review of the Literature according to The Joanna Briggs Institute®

Stage 1	Developing the review protocol
Stage 2	Developing the review question
Stage 3	Identifying inclusion and exclusion criteria
Stage 4	Detailing the search strategy
Stage 5	Critical appraisal - quantitative evidence Critical appraisal - qualitative evidence
Stage 6	Data extraction - quantitative evidence Data extraction - qualitative evidence
Stage 7	Data synthesys - quantitative evidence Data synthesys - qualitative evidence
Stage 8	Final report

Adapted from: Queen’s Joanna Briggs Collaboration<sup>a</sup>, 2015, p. 6-25

### 2.3.1.1. Stage 1: Developing the Review Protocol

The development of a protocol assures that the content maintains its scientific rigor and that the risk of bias are minimized as previously referred. A *protocol* is constructed to define the concepts and the theoretical background needed to advance with the review (Torgerson, 2003).

*“The background section should communicate the key contextual factors and conceptual issues relevant to the review question. It should explain why the review is required and provide the rationale underpinning the inclusion criteria and the focus of the review question, for example justifying the choice of interventions to be considered in the review”* (Centre for Reviews and Dissemination, 2009, p. 6).

The protocol is a tool and it works as a guide along the process and it should contain:



- “The review question
- The criteria that will be used to select the literature
- Databases you plan to search
- How the quality of the studies will be assessed
- What details will be extracted from the studies
- Strategies for synthesis” (Queen’s Joanna Briggs Collaboration<sup>®</sup>, 2015, p. 6).

Is important not to forget though that as a process of research and findings, all the stages will have to be adapted alongside with new discoveries. Therefore, we can consider it an “(...) interactive process (...)”, where the investigator may have to review and adjust his protocol in order to achieve its goals (Figure 7) (Queen’s Joanna Briggs Collaboration<sup>®</sup>, 2015).

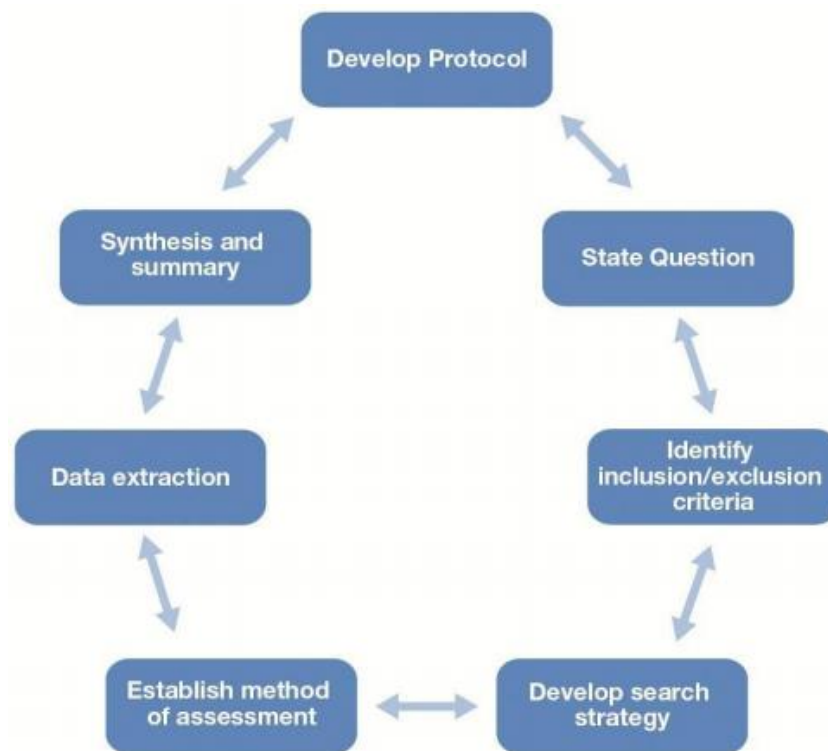


Figure 7 – Developing a Protocol

Source: Queen’s Joanna Briggs Collaboration<sup>®</sup>, 2015, p. 5

### 2.3.1.2. Stage 2: Developing the Review Question

The next step of is to define the review question. This one must be clear in order to offer any reader a comprehension of the content in the document (Centre for Reviews and Dissemination, 2009). According to Hemingway the organization of the research is done

based on the question that needs to state clearly “(...) *the objectives of the review, intervention or phenomena of interest, relevant patient groups and subpopulations (...), the types of evidence or studies that will help answer the question, as well as appropriate outcomes*” (Hemingway and Brereton., 2009, p. 4).

This question can be formed using the model PICO (Queen’s Joanna Briggs Collaboration®, 2015):

**P** = Problem / Patient / Population

**I** = Intervention

**C** = Comparison / Control / Context

**O** = Outcome

The population should be chosen based on its relevance to the population to which the review conclusions will be applied and also:

*“(...) explicit inclusion criteria should be defined in terms of the disease or condition of interest. Any specific restrictions should be clinically justifiable and relevant. Eligibility must usually be applied to the whole study and consideration of how to deal with studies that include a mixed population, some of whom are relevant to the review and some of whom are not, is required. If the inclusion criteria are broad, it may be informative to investigate effectiveness across subgroups and participants”* (Centre for Reviews and Dissemination, 2009, p. 8).

The interventions investigated can be formulated in two different ways: either use general terminology or more specific one. When the intention is to frame a specific intervention, the authors can define the nature of the intervention, the individual (or group) performing that intervention make explicit the situation in which that same intervention is performed (Centre for Reviews and Dissemination, 2009).

Furthermore,

*“Where comparative studies are to be included, the protocol should also specify which comparators are eligible. (...) The protocol should also specify whether any co-interventions carried out at the same time affect eligibility for inclusion; this applies to both the intervention(s) and the comparator(s)”* (Centre for Reviews and Dissemination, 2009, p. 8).

The 'C' standing for "Comparison" can be omitted if there is no comparison. It can also be substituted for "Control", which is more suitable for when the study refers to a Randomized Controlled Trial (RCTs), or when applied to studies where there is a control group and an experimental one, which are designated Controlled Before and After (CBA) (Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015). The 'C' may also stand for "Context" "(...) if your review focuses on a particular circumstance" (Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015, p. 7).

Additionally, in a systematic review a set of pertinent outcomes should be objectively defined and it's vital to explain the reason for the inclusion of each outcome. "Although the review may aim to consider a series of outcomes, it is rare that inclusion would be restricted to only those studies that report all the outcomes of interest" (Centre for Reviews and Dissemination, 2009, p. 9).

It is also at this stage that the researcher should detail and define topics of interest (JBI<sup>®</sup>, 2015). This section needs to explicitly communicate the conceptual meaning that the author of the SRL is giving to the terms he is using (Centre for Reviews and Dissemination, 2009).

In order to help with this process, it is useful to consult the US National Library of Medicine that developed the Medical Subject Headings<sup>®</sup> (MeSH<sup>®</sup>) terms for online terminology (Welsh and Anagnostelis, 2001). This platform can be used to "...provide specific subject headings" (Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015, p. 8) since it allows the researcher to access links to different terms for the same concept (Welsh and Anagnostelis, 2001).

Based on this database, the DeCS<sup>®</sup> (Descritores em Ciências da Saúde<sup>®</sup>) was created by the BIREME (Biblioteca Regional de Medicina). The DeCS<sup>®</sup> provides structured vocabulary in Portuguese, Spanish and English, with the aim to provide one single path to access information in the three languages independently of the idiom of the researched word (DeCS<sup>®</sup>, 2017).

After gathering the group of keywords that represent each component of the research, it is necessary to organize them. In order to give a logical meaning to the terms and to the research, the Boolean terms can and should be used (Lopes, 2002). NOT, OR and AND are the Boolean terms used in research and they determine how the keywords are connected (EBSCO<sup>®</sup>, 2017):

- NOT excludes all the research results the include the terms that follow;
- AND combines the research results that include all the terms that follow; and
- OR gathers the research results that include at least one of the terms that follow (EBSCO<sup>®</sup>, 2017).

#### 2.3.1.3. Stage 3: Identifying Inclusion and Exclusion Criteria

Besides the fact that the question works as a guide throughout the elaboration of the review, its clarity represents one step closer to achieve the inclusion and exclusion criteria. These must be specific since they will play a determinant part in the selection of the studies for the review.

According to the Joanna Briggs Institute®, the extent of information that an investigator is going to include in his research depends on the inclusion and exclusion criteria. The investigator should give himself “(...) *enough to investigate but not so much so that you drown in the literature*” (Queen’s Joanna Briggs Collaboration®, 2015, p. 7).

The inclusion criteria should be detailed in order to capture all the studies of interest. The Centre for Reviews and Dissemination (2009) states that the criteria should not be too narrow but neither too broad, since in the first case there is the risk of missing relevant studies that won’t allow the generalization. On the opposite, if the criteria are too wide, there will be too much information making it difficult for the researcher to analyse and synthesise.

As suggested above, this criteria should aim to the participants, the interventions and the outcomes. It’s also in this context that the type of studies to be included in the review should be specified like, for example: clinical trials, randomized controlled trials, etc. (Queen’s Joanna Briggs Collaboration®, 2015).

A review should always be conducted based on the best quality and most recent evidence. This way, after primary selection, “*the quality of the included studies should be formally assessed as this will impact on the reliability of the results and therefore on the conclusions drawn*” (Centre for Reviews and Dissemination, 2009).

According to Berwinger et al (2007), criteria related to the methodological quality of the included studies should not be a factor in the inclusion or exclusion criteria since this aspect will be submitted to analyses later on.

#### 2.3.1.4. Stage 4: Detailing the Search Strategy

The next step is to detail the search strategy, which involves the recording of all the steps taken during the systematic search of the literature (Table 3).

Table 3 – Detailing the search strategy

<b>Step 1: finding keywords</b>	Thinking about relevant words for the theme.
<b>Step 2: initial search</b>	Carry out a preliminary search using those keywords; From the findings, select those that suit the subject; Select keywords used in their title, abstract and index.
<b>Step 3: second search</b>	Make a secondary search in databases using those keywords; Limit the research if necessary by applying criteria like date, language, etc.
<b>Step 4: hand search</b>	Hand search the reference lists of the retrieved papers to select any other that might relate to the subject.
<b>Step 5: selecting studies</b>	Analyse the articles relevance by their title and abstract. If the study seems to answer the criteria, then the full article should be retrieved.
<b>Step 6: maintaining a record</b>	Record all the steps of the research: <ul style="list-style-type: none"> <li>• Databases;</li> <li>• Any specified limitation;</li> <li>• Keywords;</li> <li>• Total number of articles found with each search method</li> <li>• Number of articles that answer the criteria and were selected for the review.</li> </ul>

Adapted from: Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015

In the end of this process, the articles obtained still have to go through some filters to make sure that the information that they have corresponds to the information the researcher seeks.

In a preliminary phase, the selection of the studies is based on a screening of titles and abstracts, confronting them with the inclusion criteria. Afterwards, the full article is screened to decide to include it or not in the review (Centre for Reviews and Dissemination, 2009).

The Joanna Briggs Institute® suggests a tree to present clearly all the decisions made along the process of excluding articles (Figure 8).

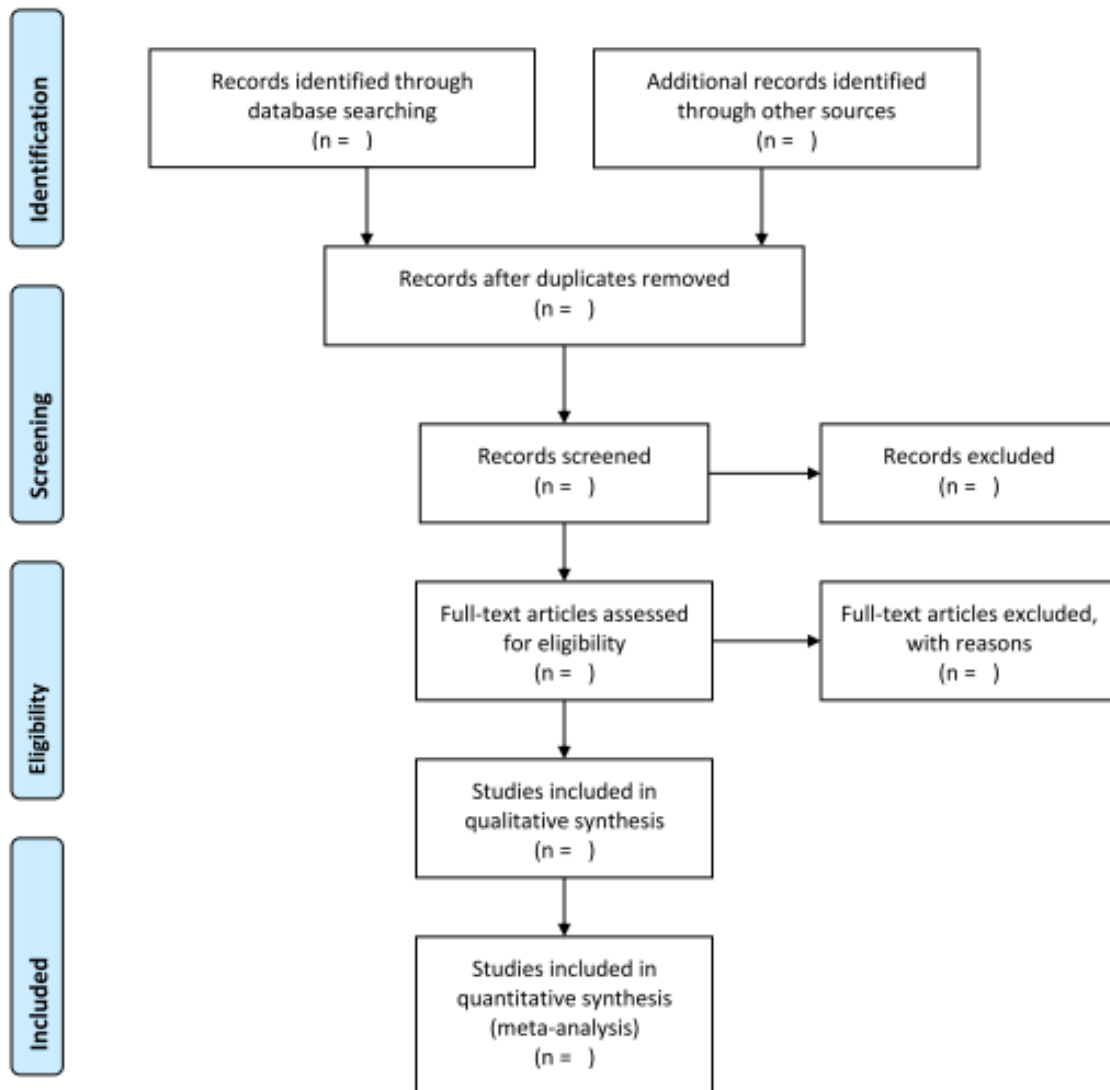


Figure 8 – Decision tree

Source: Queen’s Joanna Briggs Collaboration®, 2015, p. 10

### 2.3.1.5. Stage 5: Critical appraisal

According to Berwanger et al. (2007) to ensure that the SRL is valid and applicable the document needs to be submitted to a methodological quality test.

*“The quality of each article needs to be assessed in order to establish and maintain a consistent and high standard of methodological rigor. Furthermore, it is important to assess the quality of the research to minimize the risk of an inclusive review resulting*

*from excessive variation in the quality of the studies” (Queen’s Joanna Briggs Collaboration<sup>®</sup>, 2015, p. 11).*

Berwanger et al. (2007) states the principles to evaluate a SRL:

- To assess the internal validity:
  - Is the PICO question structured and focused PICO?
  - Was a wide research performed?
  - Was there a prior definition of the inclusion and exclusion criteria?
  - Was there an assessment of the quality of the included studies?
  - Was data extraction based on standard methods avoiding bias?
- To assess the importance of the findings:
  - Was a metaanalysis performed? If so, were the results of the group of studies? Were the results clear and precise?
  - Was there consistency between results? If not, did the authors explore the possible causes?
- To assess the appliance of the results to the practice:
  - Is the sample comparable to my population?
  - Can the intervention be performed in my population?
  - Would the intervention be accepted by my population?

The process of the critical appraisal must always be conducted by two reviewers either in qualitative or quantitative studies.

In quantitative studies the appraisal is composed by two steps:

*“(1) Selection – An initial assessment that occurs following the search and addresses the question “should the paper be retrieved?”*

*(2) Critical Appraisal – Occurs when paper has been retrieved and addresses the question ‘should the study be included in the review?’ ” (Queen’s Joanna Briggs Collaboration<sup>®</sup>, 2015, p. 11).*

When it comes to a quantitative study, the methodological precision of an investigation depends on its design, which means that the type of investigation used determines if the results are going to be more or less rigorous (Queen’s Joanna Briggs Collaboration<sup>®</sup>, 2015). Below is presented a figure (Figure 9) showing the study designs hierarchy from the one more rigorous to the least according to the Joanna Briggs Institute<sup>®</sup>.

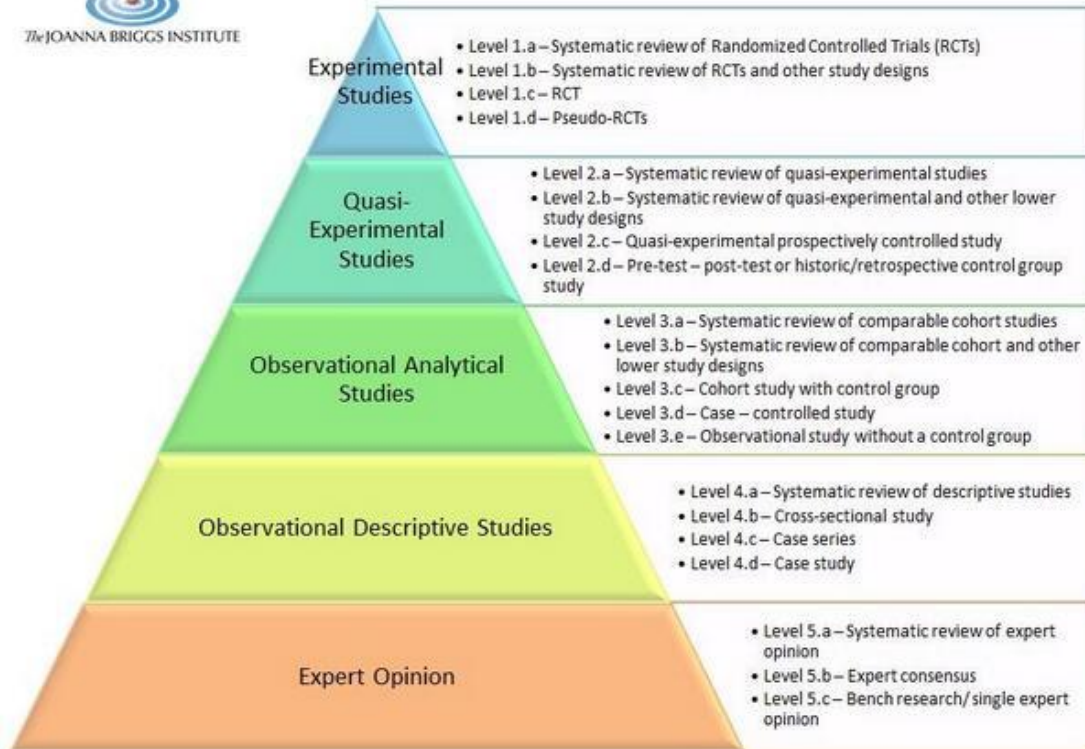


Figure 9 – Hierarchy of study designs to assess the effects of interventions

Source: JBI® 2016 in <[https://pbs.twimg.com/media/Bmc\\_V3fCMAA9SNa.jpg](https://pbs.twimg.com/media/Bmc_V3fCMAA9SNa.jpg)>

The Joanna Briggs Institute® includes also in this division in last place the studies characterized by *expert opinion based in bench research or consensus* (Queen’s Joanna Briggs Collaboration®, 2015).

When referring to qualitative evidence:

*“The focus of critical appraisal for qualitative evidence is on the rigor of the research design and quality of reporting. Qualitative approaches are located in diverse understandings of knowledge; they do not distance the researcher from the researched; and the data analysis is legitimately influenced by the researcher when they interpret the data”* (Queen’s Joanna Briggs Collaboration<sup>a</sup>, 2015, p. 15).

The critical appraisal of qualitative studies are based on the consistency along its execution, meaning the *“(…) study methodology, study methods, representation of the data and the interpretation of the results”* (Queen’s Joanna Briggs Collaboration<sup>a</sup>, 2015, p. 15). Besides this factor, the critical appraisal also contemplates the level of explanation that the researches does of the biases. The last aspect is related with the association between what



is stated that the participants said and the achieved conclusions (Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015).

In this type of study the participants' point of view has to be presented. The evaluation of this qualitative data is subjected to the investigator's understanding of its meaning. The results proposed by the researcher are analysed and classified according to three degrees of **plausibility**:

- (1) Unequivocal – when the data is undeniably evidence of the conclusion, there is no doubt about the information reported or observed and so this is not open to discussion;
- (2) Plausible – refers to findings that, even though they might be open to different interpretations, it is reasonable to believe that the data collected can be interpreted the way the investigator did. These findings are open to challenge and discussion;
- (3) Unsupported – refers to conclusions that are not at all sustained by the collected data (Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015).

#### 2.3.1.6. Stage 6: Data Extraction

Quantitative and qualitative data are extracted from the information collected using standardised data extraction tools. At this stage all the specific information related to the interventions, populations, methods, methodologies and meaningful outcomes for the scientific question and objectives will be extracted and organized for further analysis (Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015).

- The **methodology** concerns all the theoretical background that supports the research;
- The **method** refers to the technique used to collect the data (e.g. interview, observation, survey, questionnaire, etc.);
- The **intervention** is the planned interference performed in a specific situation as part of the research process;
- The **participants** are the ones determined by the inclusion and exclusion criteria.

Is it advised to build a form in which all this information is described, as JBI<sup>®</sup> states:

*“The extraction form should be developed to provide you with the necessary details and evidence to answer your review question. It is often necessary to adapt the data*

*extraction form so that you are retrieving data that is specific to your research question” (Queen’s Joanna Briggs Collaboration<sup>®</sup>, 2015, p. 13).*

#### *2.3.1.7. Stage 7: Data Synthesis*

Once the process of extracting the data is finished is time to perform the synthesis of the data. This process is essential in both qualitative and quantitative data due to the fact that these results are going to be used to base recommendations for practice (De-La-Torre-Ugarte-Guanilo, Takahashi and Bertolozzi, 2011).

In quantitative systematic reviews the synthesis of data can be performed using meta-analysis. This is *“a statistical combination of data from similar studies; used to give an overview of the included studies”* (Joanna Briggs Institute<sup>®</sup>, 2014, p. 171). A systematic review can have as many meta-analyses as the number of identified outcomes in the data collected.

On the other hand, in qualitative systematic reviews there is a diversity of methods available to synthesise the results. Even though each methodologies has its own particularities, when used together they complement each other. *“Some methodologies prioritize the construction or explanation of theories and some aim at describing a specific phenomenon”* (De-La-Torre-Ugarte-Guanilo, Takahashi and Bertolozzi, 2011, p. 1259).

According to JBI<sup>®</sup> (2016) there are two main approaches to synthesise qualitative data: meta-aggregation and meta-ethnography. The meta-aggregation *“(…) seeks to move beyond an outcome of implicit suggestions in order to produce directive statements that guide practitioners and policy makers”* (Joanna Briggs Institute<sup>®</sup>, 2014, p. 171) and the meta-ethnography *“(…) aims to produce new theoretical understandings”* (Joanna Briggs Institute<sup>®</sup>, 2014, p. 171).

The figure 10 sums up the method to be used to synthesise evidence based on its methodology.

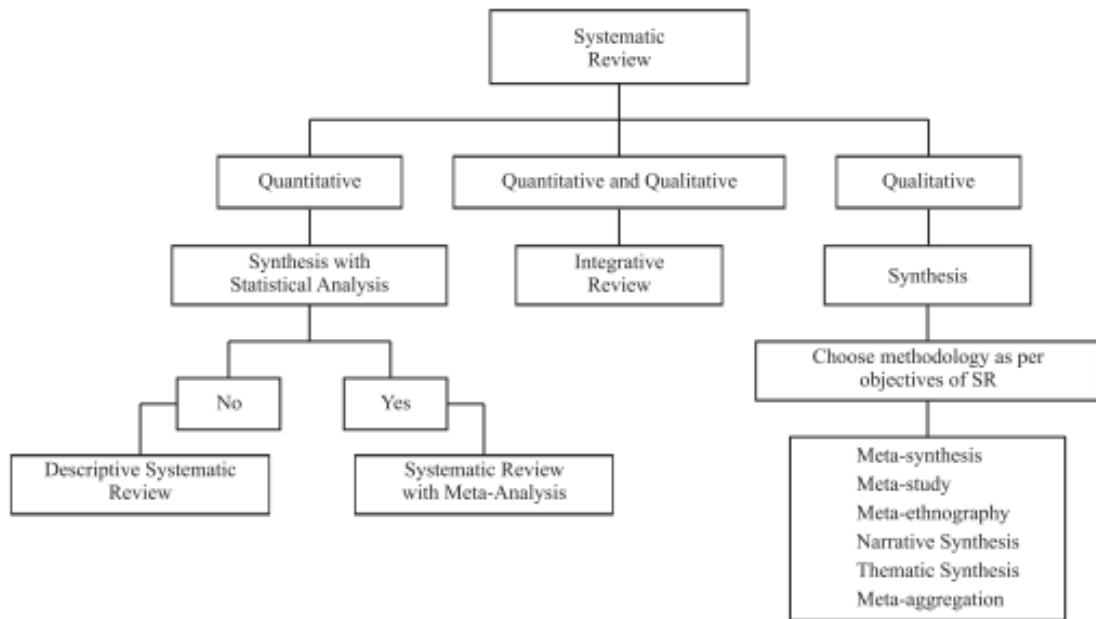


Figure 10 – Methodologies for synthesise scientific evidence

Source: De-La-Torre-Ugarte-Guanilo, Takahashi and Bertolozzi, 2011, p. 1259

In both qualitative and quantitative data, a detailed extraction and synthesis of the information are key points in the elaboration of a Systematic Review. Their findings will result in recommendations of the practice (Joanna Briggs Institute®, 2014).

### 2.3.1.8. Stage 8: Final Report

The final report is as important as the rest of the review itself. This “(...) should describe the review methods clearly and in sufficient detail that others could, if they wished, repeat them” (Centre for Reviews and Dissemination, 2008, p. 77).

There are various suggested structures of systematic reviews reports, but the main goal is to do it the more specifically as possible.

According to the Centre for Reviews and Dissemination (2008) there are evidence stating that the readers’ understanding and interpretation of the final conclusions can be affected by the way the final report is written.



### **3. EMPIRICAL STUDY**

This chapter is about all the steps taken in the development of the present Systematic Review of the Literature including research process, definition of inclusion and exclusion criteria, as well as its goals.

The present work is based on the Joana Briggs Institute® since this institution presents very clear guidelines on the development of a work such as the present one, allowing it to have a structure and follow a line of thinking. This institution also provides tables to be used to organize the methods.

#### **3.1. Aims of the Systematic Review of the Literature**

The initial definition of goals allows the author to follow a path in the direction of its final intentions. Therefore, the main aim established for the present work consists in: understanding the effectiveness of the colic massage in the infant's colic relief.

The specific goals are:

- To operationalize the key concepts of this Systematic Review;
- To develop a Systematic Review of the Literature Protocol;
- To identify the action mechanism of the massage in the infant's colic relief;

- To evaluate the methodological quality of the studies used on this Systematic Review;
- To analyse the scientific evidence found;
- To identify the studies found about the subject;
- To analyse the available studies about the topic;
- To synthesize the evidence regarding the theme;

## **3.2. Developing the Review Protocol**

As previously mentioned, the review protocol establishes a predetermined project to guarantee the accuracy of the work as well as the diminishment of the chance of the author to be subjected to bias. This is also essential to the writer not to lose his focus (Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015).

A synthesis of the protocol of the present review, also based in the JBI<sup>®</sup> model, can be found attached in the end of the document (Appendix I). The extended protocol is going to be presented hereafter.

### *3.2.1. Developing the Review Question*

As referred above in the document *"applying these concepts to your question will help provide clarity about the focus of your review and the issues you will explore"* (Queen's Joanna Briggs Collaboration<sup>®</sup>, 2015, p.6). The development of the review question is based on the PICO template as showing below (Table 4).

Table 4 – PICO template for the Systematic Review

<b>P</b> <b>Population</b>	<b>I</b> <b>Intervention</b>	<b>C</b> <b>Comparison</b>	<b>O</b> <b>Outcomes</b>
Infants	Massage	-----	Colic relief

Based on this, the question for the Systematic Review of the Literature emerged:

**Is massage effective in infant’s colic relief?**

The definition of these key-words is essential to clarify their concepts:

- An infant is understood to be any child with age between 2 weeks and 6 months.
- To massage consists in applying pressure and/or rubbing a certain part of the body (International Council of Nurses®, 2010, p. 98).
- Colic is defined as “(...) *paroxysms of excessive crying in an otherwise healthy baby lasting more than 3 hours per day, occurring > 3 days in any week for 3 weeks (...)*” (Wessel et al. cit in Kheir, 2014, p.1).

### 3.2.2. Identifying inclusion and exclusion criteria

Is true that the review question guides the author, although it’s important to define the inclusion (Table 5) and exclusion criteria (Table 6) so that the review subject remains delimited and focused: “*Use the inclusion and exclusion criteria to vary the breadth of your topic, giving yourself enough to investigate but not so much that you drown in the literature*” (Queen’s Joanna Briggs Collaboration®, 2015, p.7) According to the JBI®, this criteria should be based on four factors: the participants, the intervention, the outcomes and research methodologies of the findings.

Table 5 – Inclusion Criteria

Participants	<b>Studies referring to healthy infants</b>	The concept of colic applies to infants considered healthy.
	<b>Studies referring to infants between two weeks and six months of age</b>	90% of the colic incidence is reported early in infancy (Hodge and Murphy, 2014). Studies about the matter report that its incidence tends to decrease close to the 5/6 months of age.
Intervention	<b>Studies that investigate the effectiveness of the massage in colicky infants</b>	Studies that explore the use of massage in the relief of infant colic are the aim of this review.
Outcomes	<b>Studies reporting outcomes on the effectiveness of massage in infantile colic</b>	Studies that report results about the effectiveness of massage in colicky babies will be considered in the review.
	<b>Studies reporting outcomes on the effectiveness of massage associated with other factors/methods in infantile colic</b>	Studies reporting the intervention in study associated with other interventions will be considered.
Research methodologies	<b>Primary studies</b>	Primary studies are “(...) often based on principals of the scientific method (...) Although the application of the scientific method varies from field to field, the general principles of the scientific method allow researchers to learn more about the world and observable phenomena” (Driscoll, 2011, p.154).
	<b>Experimental studies, Quasi-experimental studies and Observational studies</b>	A review should be grounded in good quality studies (Schlosser, 2007).
	<b>Studies published until February of 2017</b>	The review aims to acknowledge all the literature about the matter.



<b>Full text</b>	<b>Available full text articles</b>	All the articles which full text is available will be considered in the SRL
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Each one of the found articles has to be assessed for their eligibility against the defined criteria. Only this way the researcher can assure that the included articles are relevant and applicable in the matter.

Table 6 – Exclusion Criteria

Participants	<b>Studies referring to sick, hospitalized infants and/or with any kind of disability</b>	Studies related to non-healthy infants will be excluded.
	<b>Studies referring to infants over six months of age</b>	Studies investigating infants with age superior to 6 months of age will not be considered.
Intervention	<b>Studies that do not investigate the effectiveness of the massage in colicky infants</b>	Studies investigating methods not related to massage will be disqualified.
	<b>Studies investigating the effectiveness of the massage compared to other methods</b>	Studies related with the effectiveness of the technique compared to other used methods will not qualify to the investigation, since the aim is to understand the effectiveness of the massage and not compare it with other techniques.
Outcomes	<b>Studies reporting outcomes not associated with massage</b>	Studies not investigating the massage intervention will be excluded.
Research methodologies	<b>Secondary studies</b>	The systematic review of the literature is a secondary study itself; the use of secondary studies may affect the judgement of the reviewer regarding the primary investigation.

	<b>Opinion studies or studies based on consensus</b>	Studies based on expert opinions or <i>consensus</i> are considered to have low levels of evidence.
<b>Full text</b>	<b>Full text unavailable</b>	The articles which full text is not available will not be considered in the SRL

### 3.2.3. Finding the keywords

Once the development of the inclusion and exclusion criteria is complete, it is essential that the researcher explores the topic and lists relevant words that could be used in the process of describing and directing to the subject in matter. To assist in this, the MeSH Browser<sup>®</sup> and the DeCS Server<sup>®</sup> were used (Table 7).

Table 7 – MeSH Browser<sup>®</sup> and DeCS Server<sup>®</sup> terms

Population	Intervention	Comparison	Outcome
<b>Infants</b>	Massage	No comparison	Colic relief
MeSH Browser <sup>®</sup>			
<b>Neonate</b> <b>Newborn</b> <b>Baby</b>	Massage	_____	Colic
DeCS Server <sup>®</sup>			
<b>Newborn</b> <b>Neonate</b>	Massage	_____	colic

In order to understand if the identified keywords were the more commonly used, an abstract research about the subject was performed, concluding that there was no need to add other descriptors.

The studies included in the present research will be in Portuguese or English idiom and the present SRL should include all the articles that answer the inclusion and exclusion criteria presented above.

As said before, it is essential for the assessment of the quality and validity of a SRL that any other researcher is able to follow the same steps described and reach the same results.

### 3.2.4. The database research

Before any research in a database the researcher should take some time to get to know its specificities since *“The terminology is different for each database. Each database will have a different set of subject headings”* (Queen’s Joanna Briggs Collaboration®, 2015, p.8). This way, at this stage a recognition of the databases and their indexation system was completed with the assistance of an expert. In the table 8 is possible to observe a simple description of each database is presented, as well as the strategy used (Table 8).

Table 8 – Advanced research methodology

Database	Research strategy
<b>Scopus®</b> was produced by the editor Elsevier® in 2004. Since, it has been the lead database with the largest number of abstracts and citations of literature from various areas: science, technology, medicine, social sciences, arts and humanities (Elsevier®, 2017; Elsevier®, 2014).	TITLE-ABS-KEY((infant OR newborn OR neonate OR baby) AND massage AND colic) AND ( LIMIT-TO(LANGUAGE,“English” ) OR LIMIT-TO(LANGUAGE,“Portuguese” ) )  Filters: Portuguese and English idiom
<b>Web of Science®</b> produced by Clarivate Analytics®, which counts already with 1.75 million journal publications and over 200.000 clinical trials in numerous areas (Clarivate, 2017). It is a multidisciplinary database that gathers references and citations from main journals from the areas	TS=((infant OR newborn OR neonate OR baby) AND massage AND colic) OR TI=((infant OR newborn OR neonate OR baby) AND massage AND colic) OR AI=((infant OR newborn OR neonate OR baby) AND massage AND colic)

of sciences, social sciences, arts and humanities (De-la-Torre-Ugarte-Guanilo, 2011).	Filters: Portuguese and English idiom
<b>Ebsco Host</b> <sup>®</sup> can be used by new researchers, providing a basic search option, but also by experienced researchers since there's also available an advanced search option (EBSCO <sup>®</sup> , 2017). For more than 70 years, has provided access to several areas like business, education, technology, science, medicine, psychology and sports (EBSCO <sup>®</sup> , 2017).	TI ( (neonate OR newborn OR infant OR baby) AND massage AND colic ) OR SU ( (neonate OR newborn OR infant OR baby) AND massage AND colic ) OR AB ( (neonate OR newborn OR infant OR baby) AND massage AND colic )  Filters: Portuguese and English idiom

### 3.2.5. The databases' results

The search strategy for a SRL should be clear and comprehensible in order to allow it to be reproducible. Each step taken in the review should be obviously stated at this stage of the protocol (Joanna Briggs Institute<sup>®</sup>, 2015).

The research of the articles for the present SRL conducted on the 17 of March of 2017. All the articles previous to this date were included in the analyses of the review. The same research strategy was applied by two independent researchers (see Appendix II).

In a primary research 123 articles were found by both researchers. After the removal of the duplicates, both researchers got to a total of 54 studies. Finally, whilst analysing the reference list of the identified articles, two more studies were added to the investigation, reaching a final number of 56 articles (Table 9).

Table 9 – Database Results

Database	Results
Scopus®	43
Web of Science®	14
Ebsco Host®	66
<b>Total</b>	123
<b>After removal of duplicates</b>	54
<b>Number of results after identifying records through the articles references</b>	<b>56</b>

### 3.2.6. Selection of the studies

After the removal of the duplicates and addition of the articles identified through the articles references, 56 studies were selected (see Appendix III). *“Once all possible studies have been identified, they should be assessed (...)”* (Hemingway and Brereton, 2009, p. 4). This assessment implies that the studies need to be submitted to an eligibility test against inclusion and exclusion criteria (Hemingway and Brereton, 2009).

In order to facilitate this process, a table was created with simple “yes” or “no” questions regarding the inclusion criteria. This aims to select all the studies of interest for this SRL. This test consists in submitting the articles to eligibility questions (Appendix IV) and if any of them presents at least one negative answer, it should be excluded.

The application of this instrument in the 56 articles is presented in the Appendix V. Each of the articles was given a number as shown in the attached document. The understanding of the process that led to the decision made on the articles included is explained with the filling of the table.

This selection was performed independently by 2 investigators and as a final result 4 articles (highlighted in the appendix). will be submitted to a critical appraisal: (2) The effectiveness of massage therapy in the treatment of infantile colic symptoms: A randomized controlled trial; (9) The effectiveness of aromatherapy massage using lavender oil as a treatment for

infantile colic; (17) Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic; (30) Infant massage compared with crib vibrator in the treatment of colicky infants.

### 3.2.7. Critical appraisal

Posterior to the initial submission of the studies to the inclusion/exclusion criteria, they should be submitted to a critical appraisal. This ensures that the high standards of rigor are maintained along the present review. Also the “... aim in critically appraising (...) data is to limit bias and thus establish the validity of the study” (The Joanna Briggs Institute®, consult.2016, p. 71).

All the studies were submitted to a critical appraisal based in the Joanna Briggs Institute® criteria (Appendix VI). Hereafter is presented a table with the number attributed to the articles, respective country of origin, level of evidence based in the Joanna Briggs® criteria and also their methodological quality score (Table 10).

Table 10 – Level of evidence and methodological quality based on the JBI®

Study number	Name of the article	Country	JBI® Level of evidence	JBI® Methodological Quality score
2	<i>The effectiveness of massage therapy in the treatment of infantile colic symptoms: A randomized controlled trial</i>	Iran	I	7 points High quality
9	<i>The effectiveness of aromatherapy massage using lavender oil as a treatment for infantile colic</i>	Turkey	II	5 points Moderate quality
17	<i>Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic</i>	Turkey	I	6 points Moderate quality

30	<i>Infant massage compared with crib vibrator in the treatment of colicky infants</i>	Finland	I	6 points Moderate quality
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The following flowchart aims to exhibit the mental organization of the present work, since the first stage of research until the scrutiny of the selected articles (Figure 11).

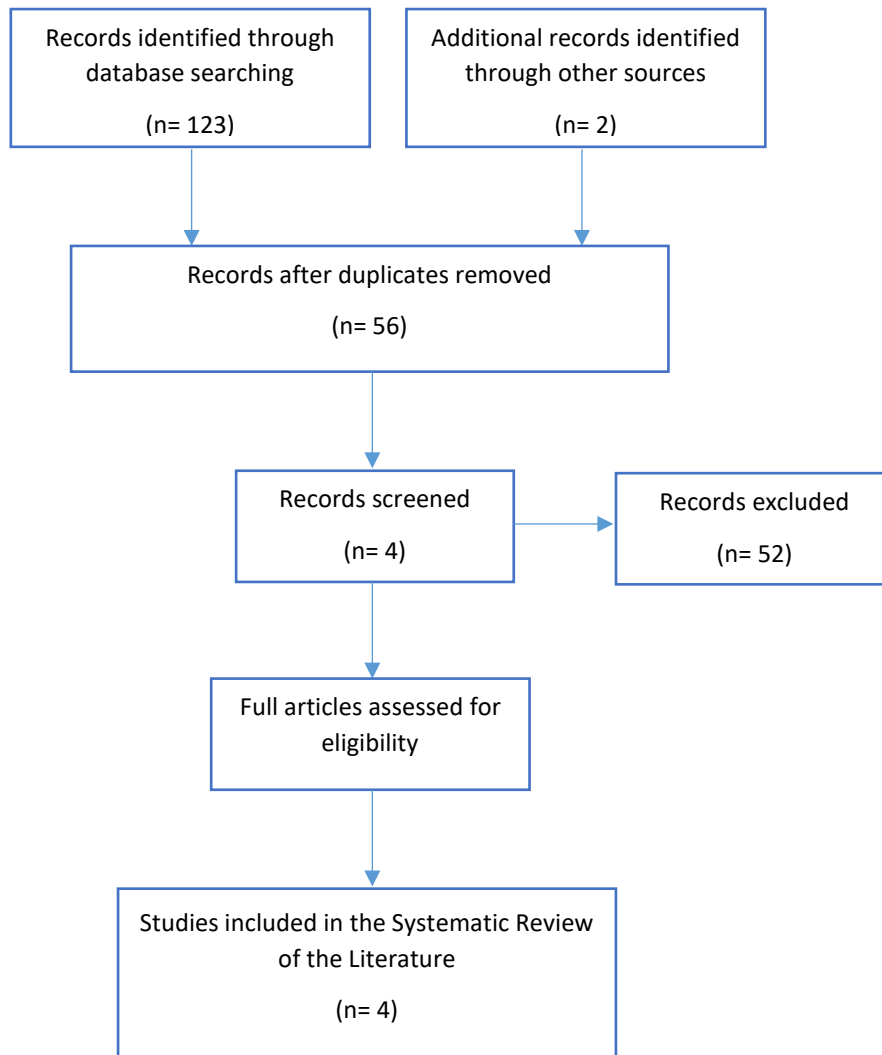


Figure 11 – Systematic Review Flow Diagram

### 3.2.8. *Data extraction*

The process of gathering and synthesising the relevant information of a study is denominated by data extraction (Queen's Joanna Briggs Collaboration®, 2015). According to the JBI® it is important to develop a standard data extraction tool in order to collect the same type of data from all the studies included in the review (The Joanna Briggs Institute®, 2014). Also, this stage allows the reader to have an organized, logical and descriptive summary of the information gathered from each article, allowing him to comprehend the decisions made at the point of the conclusions (The Joanna Briggs Institute®, 2015).

According to the JBI® (2015), the reviewer should extract from the included articles information that allows a more organized understanding of the study: author(s), year of publication, country, aims, sample or population size, methodologies used, the intervention in study and its duration as well as the outcomes of the investigation.

The developed tables and data extraction of the studies included in this SRL were based in the instruments provided by the JBI® and can be found attached to this document (see Appendix VII).



## **4. FINAL REPORT**

Following the data extraction JBI® suggests that the findings from the data extraction should be discussed and placed into a context (Hemingway and Brereton, 2009).

A systematic review requires meticulous execution and all the details must be analysed and taken into account. In order to do so, this chapter will contain an analysis and discussion of the articles included in the present SRL.

### **4.1. Assessment of the studies included in the SRL**

As shown in the previous chapter, all the steps taken to reach the studies that will be included in the present SRL were based on the process sat by the JBI®. The data extraction presented was also fulfilled based on the table instruments provided by the Institute.

The selected articles shall now be submitted to an analysis based on their characteristics rather than in their content as it happened previously. Only this way is possible to ensure that the present review earns the badge of “systematic” (Hemingway and Brereton, 2009).

The following tables will summarize the included articles showing their main characteristics.

Table 11 – Articles' summary based on the sample, statistics, main results and conclusions

Author(s)	Sample	Statistics	Main results	Conclusions
Sheidaei et al. (2016)	N=100	Pearson's Chi-square Independent t-test	Massage group shows improvement of colic symptoms. Severity of colic improved only in the rocking group.	Colic symptoms were relieved in colicky infants in both massage and rocking.
Çetinkaya and Basbakkal. (2012)	N=40	Homogeneity test Independent t-test	There was a statistically significant difference in the mean weekly crying times in the aromatherapy massage group. There was no statistically significant difference in the control group.	Aromatherapy massage with lavender oil could reduce infantile colic.
Arikan et al. (2008)	N=175	Variance analysis Chi-squared test Paired samples t-test Dunnet's t-multiple comparison test Duncan's multiple comparison test	Mean crying time decreased in the massage, sucrose solution, herbal tea and hydrolysed formula groups but not in the control group.	Hydrolysed formula should be the first choice in the treatment of infantile colic.
Huhtala et al. (2000)	N=58	Variance analysis two-sample t-test Homogeneity test	Over the 4 weeks the amount of total daily crying decreased similarly in both the intervention with massage and the control group with crib vibration.	Infant massage cannot be recommended for treatment of infantile colic.

As shown in the table 11, the included articles are quite recent since they were published between the years of 2000 and 2016.

Table 12 – Studies’ demographic and geographic characteristics

Study number	Study title	Country & Year	Periodic	Institution
2	<i>The effectiveness of the massage therapy in the treatment of infantile colic symptoms: A randomized controlled trial</i>	Iran, 2016	Medical Journal of the Islamic Republic of Iran	Amirkabir Hospital of Arak
9	<i>The effectiveness of aromatherapy massage using lavender oil as a treatment for infantile colic</i>	Turkey, 2012	International Journal of Nursing Practice	Denizli Health Department
17	<i>Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic</i>	Turkey, 2008	Journal of Clinical Nursing	Department of Pediatrics of the Yakutiye Research Hospital
30	<i>Infant massage compared with crib vibrator in the treatment of colicky infants</i>	Finland, 2000	Pediatrics	Turku University Hospital

The articles were all published in English by different journals: Medical Journal of Islamic Republic of Iran, International Journal of Nursing Practice, Journal of Clinical Nursing and Pediatrics. Analysing the table 12, it’s perceptible that two of the articles are originally from Turkey (S9, S17), one is from Iran (S2), and one is from Finland (S30).

Table 13 – Articles’ design characteristics

Study number	Study type	Study design	Mean to obtain data
2	Quantitative study	Randomized clinical trial	Diary
9	Quantitative study	Quasi-experimental trial	Diary
17	Quantitative study	Randomised-controlled study	Face-to-face interview Questionnaire Diary
30	Quantitative study	Randomized controlled trial	Diary

The previous table shows that all the studies are quantitative and experimental, they all include control and intervention groups. Between them, there are three randomized controlled trials (S2, S17 and S30) and one quasi-experimental trial (S9). In the four studies, the investigators resorted to a diary as a method to collect data. One of the studies also used the face-to-face interview and a questionnaire (S17).

As stated previously, all the articles were submitted to a thorough data extraction which is attached to the presented document. The main information extracted from those, will be presented afterwards to analyse and to contextualize the evidence.

Table 14 – Main results and conclusions of the included articles

Study number	Interventions	Results	Main conclusions regarding the intervention in study
2	<p>In the intervention group mothers were taught to execute the massage correctly by an expert and asked to massage their infants for 15-20 minutes, once during the day and once during the night before sleeping, for a week;</p> <p>In the control group mothers rocked their infant gently for 5-25 minutes when the colic symptoms appeared;</p> <p>Both groups recorded daily the duration, severity and number of colic cries for a week as well as the amount of hours of sleep.</p> <p>Similar diaries were completed one and two days before the beginning of the interventions as a baseline.</p>	<p>The number of colic cries in the massage group was reduced from 8.34/day to 4.26/day.</p> <p>The severity of colic was reduced from 5.13 to 2.71 in the massage group.</p> <p>The average sleep duration increased 2.9h/day for the infants in the massage group.</p>	<p>Massage therapy could be more effective than rocking for treatment of infantile colic.</p>
9	<p>Before the experiment, infants from both group were examined and the diagnostic of colic was confirmed by pediatricians.</p> <p>After the primary observation, five other contacts with one week apart were carried out. Intervention and control group mothers recorded for a week any episode of cry that lasted longer than 15 minutes.</p>	<p>The results show that there was a statistically significant difference in the mean weekly crying times in the treatment group (13.28hours/week</p>	<p>Aromatherapy massage using lavender oil could be effective for the reduction of infantile colic.</p>

	<p>Once the preliminary data was collected, mothers in the treatment group received aromatherapy massage training and were given a booklet with the information transmitted in the training.</p>	<p>to 6.27hours/week). There was no statistically significant difference in the control group (13.35hours/week to 13.37hours/week).</p>	
17	<p>Initially parents were given a questionnaire about the infant's behaviour, temperament, sleeping and eating patterns and precedent of colic.</p> <p>Parents recorded crying times as well as durations and after were trained to perform the assigned regime depending on the group the baby was in.</p> <p>Massage: parents administered massage twice a day for 25 minutes during the symptoms of colic;</p> <p>Sucrose: parents administered a dose of 2ml of 12% solution twice daily at 5 and 8pm;</p> <p>Herbal tea: a dose of 35ml of fennel tea was given three times a day;</p> <p>Formula: only infants fed with standard formula were included in this group, where the regular formula was replaced by a hydrolysed one;</p> <p>Control: no intervention was administered to this group.</p> <p>All the parents were visited by a paediatrician and nurse and trained in the scoring method.</p>	<p>The mean crying time (hours per day) decreased significantly in the massage group (5.34hours/day to 4.37hours/day), sucrose solution group (5.71hours/day to 3.94hours/day), herbal tea group (5.11hours/day to 3.20hours/day) and hydrolysed formula group (4.91hours/day to 2.69hours/day). However, there were no significant statistical differences in the control group (4.60hours/day to 4.51hours/day).</p>	<p>Infant massage was shown to be the least effective method in the treatment of infantile colic in comparison with the other methods.</p>
30	<p>Parents recorded in provided diaries the crying, sleeping and feedings of the infant for a week (baseline). After that they started a 3 week intervention record.</p> <p>Massage group: a trained nurse taught the massage technique and</p>	<p>Over the 4 weeks the amount of total daily crying decreased similarly in both the intervention (massage) and the</p>	<p>Infant massage cannot be recommended for treatment of infantile colic.</p>

<p>gave them a brochure with instructions. The baby received 3 daily massages (2 whole body massages for 20-30 minutes and 1 belly massage for 15 minutes). Crib vibrator group received the device along with the instructions in the beginning of the intervention. The device was installed at the bottom of the infant's crib. Parents should use it 3 times a day for 25 minutes.</p> <p>Parents of both groups were interviewed at the end of the 1<sup>st</sup> and 3<sup>rd</sup> week about the perceived effectiveness of the intervention on the colic symptoms. The amount of colic symptoms were rated as 1) decreased, 2) not changed and 3) increased; the intervention was rated as 1) colic decreasing, 2) no effect, 3) colic increasing and 4) cannot say.</p>	<p>control (crib vibrator) group. The massage group had a decrease of 48% in the mean of total daily crying and the crib had a decrease of 47%. In terms of mean daily colicky cry, the massage group had a decrease of 64%, while the crib group had a decrease of 52%.</p>	
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## 4.2. Analyses of the Evidence Found in the Studies

During a careful analyses of the four selected studies is possible to reach some conclusions regarding benefits of the use of massage in infants.

In the study number 2, there were no statistically significant differences between the groups in terms of the sample characteristics. In this investigation, since the factors evaluated were the number of colic cry per day, the duration of cry per day, the duration of sleep per day and the severity of colic per day, the baselines of this ones were also measured one and two days before the start of the interventions.

The number of colic cry per day had a statistically equivalent baseline in both groups (one day before the intervention: 6.12 in the massage group and 6.92 in the rocking group; two

days before the intervention: 5.74 in the massage group and 6.52 in the rocking group). Although, there were noticed statistically significant differences between the baselines of the other factors.

The duration of cry per day was 4.96h in the massage group and 3h in the rocking group one day before the intervention, and 4.58h in the massage group against 2.86h in the rocking group two days before, which shows that the duration of cry per day was higher in the massage group at baseline.

Also, significant differences were found in the duration of sleep per day which was 9.22h in the massage group and 12.24h in the rocking group, showing that the length of the sleep was higher in the rocking group at baseline.

Furthermore, the severity of the colic per day showed a statistical difference between the groups (massage: 68% medium and 32% severe; control: 22% moderate, 44% medium and 34% severe), which shows that the severity of colic was higher in the massage group.

All these statistically significant differences measured were taken into account by the investigators while analysing the data.

The authors presented graphics illustrating their results (Figure 12).

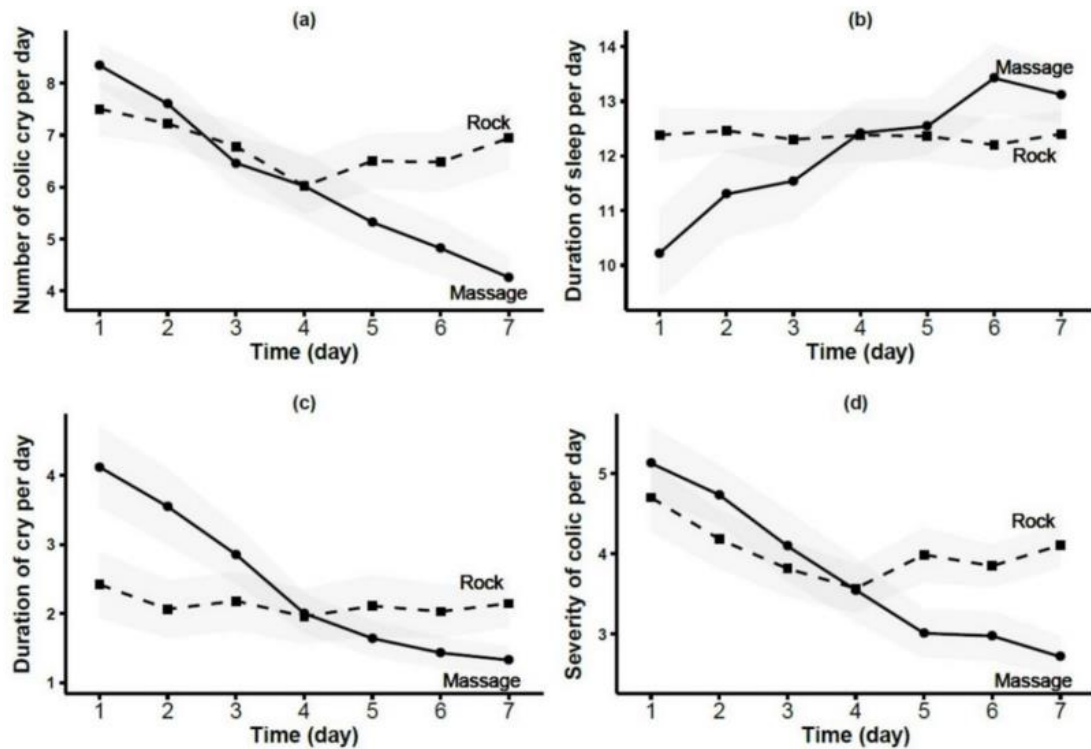


Figure 12 – Outcomes of the Study number 2

Source: Sheidaei et al, 2016, p. 5

From the graphic, it is possible to understand that in the massage group there was improvement in all the four categories investigated.

The number of colic cry per day decreased from 8.34 to 4.26 whilst in the rocking group there were not noticed significant differences. The duration of sleep increased 2.9 hours in the massage group and in comparison there are no differences in the control group. Same happens in the duration of the crying time where it is noticeable a big decrease against no differences in the rocking group.

In fact there are previous studies confirming the benefits of massage in sleeping and crying. In a systematic review about massage in the promotion of mental and physical health in infants under six months carried out by Underdown et al (2009), it was concluded that massage is an effective method for the improvement of this aspects.

Although there is a slight improvement of the severity of colic until day 4 in the rocking group alongside the massage group, if we consider the values of the beginning of the intervention and the end of it, there are no statistically significant differences in the parameter for the rocking group. On the other hand, it is evident the decrease of the severity of colic per day from 5.13 to 2.71 in the massage group, showing a statistically significant improvement in this factor.

In summary, based in this study, the results are in favour of the massage group suggesting that this can be a viable method to decrease colic symptoms in infants when compared to rocking the child.

Analysing the Study number 9, also data like age, birth order, weight, weekly crying time, type of feed, and sex of the infant were collected in order to equally distribute the groups. Also in this study the investigators collected baseline data on the mean weekly crying times of babies for both intervention (aromatherapy massage) and control group (no intervention).

In the baseline observation there were no statistically significant differences between mean weekly crying times in the groups: 13.28h in the aromatherapy massage group and 13.35h in the control group.

After the beginning of the intervention, there were statistically significant differences in the intervention group during the evaluation period: observation 1 – 11.27h; observation 2 – 9.5h; observation 3 – 7.56h and final observation – 6.27h. No changes were noticed in the control group.



Table 15 – Outcomes of the Study number 9: mean weekly crying time (hours/week)

Observation	Treatment group	Control group
	N=20	N=20
Preliminary observation	13.28	13.35
Observation 1	11.27	13.25
Observation 2	9.54	13.21
Observation 3	7.56	13.14
Final observation	6.27	13.37

Adapted from: Çetinkaya and Masbakkal, 2012, p. 167

Actually, according to England (1999) essential oils can influence a child's behaviour and emotional wellbeing since they are very sensitive to smell. The author suggests that chamomile, lavender and camomile oil, between others, are the best to perform aromatherapy colic massage.

Based on this study that united two methods, it is possible to conclude that aromatherapy massage using lavender oil mixed with almond oil could be a viable technique to for the reduction of infantile colic.

In analyses of the study number 17, it is possible to observe that also characteristics like age of the baby, sex, birth and current weight, feeding type, delivery type, mother and father's education, mother and father's age and gestational age of the baby were also collected.

This study has 5 groups of infants under research and there are also baseline measures for the mean crying time from each group. Analysing the demographic data and the baselines, the authors did not find statistically significant differences between groups.

When analysing the collected data, it is possible to observe that all the groups had some benefit from the intervention, apart from the control group who had no intervention.

Table 16 – Outcomes of the Study number 17: crying time (hours/day)

Groups	n	Mean of crying time before intervention	Mean of crying time after intervention
Massage	35	5.34	4.37
Sucrose	35	5.71	3.94

<b>Herbal tea</b>	35	5.11	3.20
<b>Hydrolysed formula</b>	35	4.91	2.69
<b>Control</b>	35	4.60	4.51
<b>Total</b>	175	5.14	3.74

Adapted from: Arikan et al, 2008, p. 1759

As it is perceptible from the Table 16, all the groups show a statistically significant decrease in the mean crying time except the control group. The differences are most obvious in the hydrolysed formula group. After that, the herbal tea was the intervention that showed biggest decrease in the mean crying time. The methods that showed a smaller difference were the sucrose and the massage group.

Based on this study it is possible to assume that massage therapy can be an effective method to decrease colic symptoms, although there are other methods with better results such as hydrolysed formula, when children are fed with formula, herbal tea or sucrose.

In the study number 30, like the previous articles, preliminary data was collected showing that there were no statistically significant differences between groups. Although, after comparing the baselines of crying time, the groups differed statistically: 2.1 in the massage group against 2.9 in the crib vibrator group, so the infants in the last group had more colic cries than the massage group.

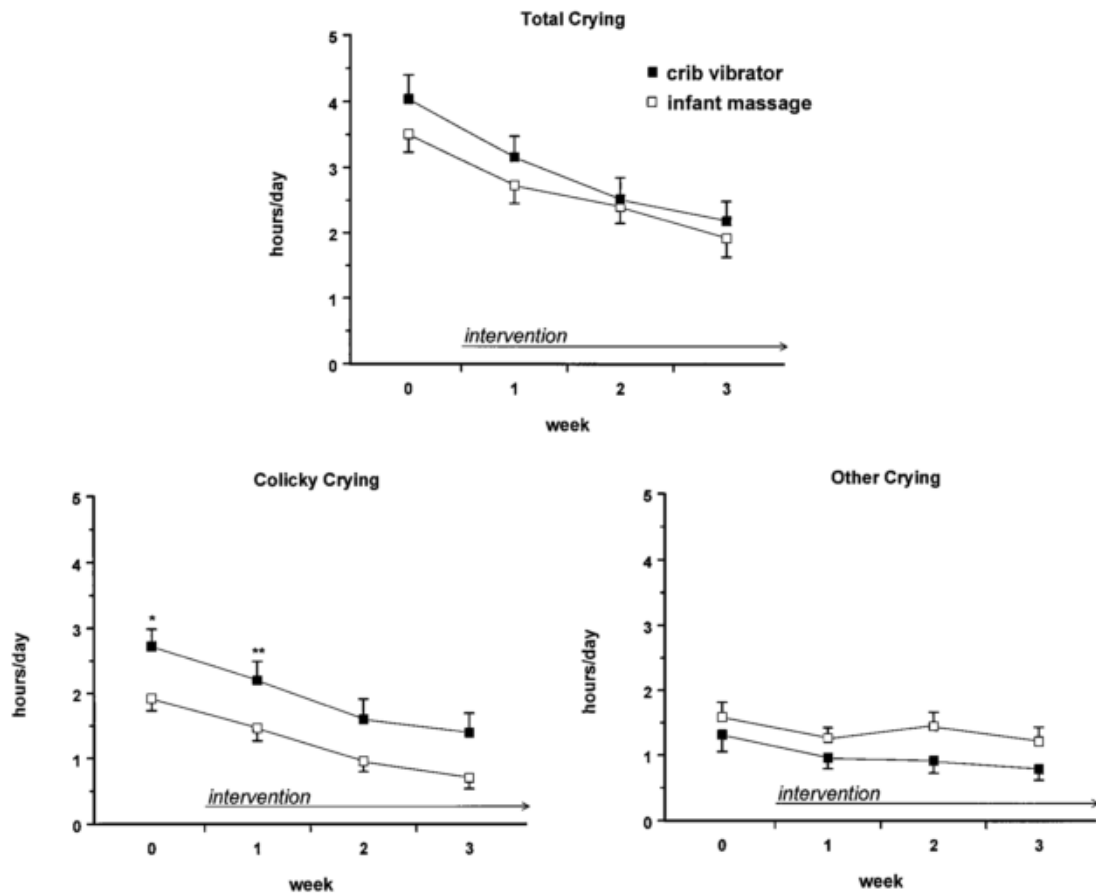


Figure 13 – Outcomes of the Study number 30

Source: Huhtala et al, 2000, p. 4

Over the 3 weeks intervention the mean of the total crying time decreased in both groups. When looking closely to the results and the graphics provided by the researchers, it is possible to conclude that this decrease is due to the reduction of the mean colicky cry: 64% drop in the massage group and 52% in the crib vibrator group. On the other hand, the mean of the other crying suffers barely any difference with a decrease of 17% in the massage group and 15% in the vibrator group.

According to the researches, 92% of the infants in the massage group and 93% in the vibrator group showed less total crying time by the end of the intervention when compared to the baseline.

The authors did not find statistically significant differences inter-groups, proving that the massage might be as effective as a crib vibrator. Regardless, the massage was effective in the intervention group, since the study shows a statistically significant difference between the baseline analysis and the final.

Also, in this study parents were asked to record their perception about the effects of the given intervention on the symptoms, rating it as 1) decreased, 2) not changed, 3) increased and 4) cannot say. Parents from both groups rated the interventions effects similarly since 93% of those affirmed a decrease on colic symptoms over the 3 weeks.

During this period of time, 61% of families in the massage group and 63% of families in the control group affirm to have perceived a decrease in the colic symptoms. Also, 21% of these families in the massage group and 30% in the crib group affirm that they did not perceive any effect on colic symptoms. Moreover, none of the families reported a perception of increase in the symptoms.

This data suggests that infant massage does not have different results when compared to crib vibrator in the relief of colic cry. Although this results show no difference between both methods, colic cry was in fact decreased which leads to believe that massage is an effective method to relief colic.

### **4.3. Discussion of the Evidence Found in the Studies**

As previously referred, a Systematic Review always needs to be cautiously planned in order to provide evidence and base to the actions health professionals take. Evidence based decisions are the goal of every researcher.

Analysing the findings of the four selected articles, it is possible to perceive that all the implemented interventions have a positive result in the relief of colic symptoms in infants.

In the study number 2 the control group had as intervention gently rocking the baby when the symptoms of colic appeared. Rocking the baby is quite an instinctive action for mothers and other caregivers to soothe the infants, which might be the reason why there's no changes in the duration or number of colic cry per day in this control group since all the mothers in both groups and on the other studies could have been doing the same since the babies' birth.

In the study number 9 and 17, the control groups had no intervention and the baselines of this had no statistically significant differences by the end of the study. On the other hand, in

the study number 30 the massage was compared to a crib vibrator and both interventions had similar results.

This results suggests that any of these interventions (massage associated or not with aromatherapy, crib vibrator, sucrose solution, herbal tea and hydrolysed formula) will provide a relief to the baby colic symptoms. Besides, if an intervention is effective at the end of one, two or three weeks, the continuity of its execution might relief the babies until their gastrointestinal system is mature enough not to show any signs of colic.

This studies show that safe and minor pain relief methods that can easily be executed by the carers could be the answer for an effective relief of colic pain.

This positive findings might also be related with the psychological side of mothers or caregivers, since in all the groups where they were actually performing an intervention different of what they were used to, the groups had positive results.

Regardless, in response to the question of the present Systematic Review, massage is an effective method to relief colic in infants.

#### **4.4. Limitations of the Systematic Review**

As any other research, also the present Systematic Review has some limitations which are mainly related to the strength of the articles included. This factor is perceived whilst the analyses of the critical appraisals of each study.

The generalization of the results might also be not possible due to the reduced number of studies included in the present review.

Another restriction of this review comes from the fact that the intervention in study was not described in detail in any of the studies. This means that in the 4 articles it is only referred that the massage was taught to the parents by health professionals, the researchers or experts, but in none of them is described the technique used. This is a big limitation of the review since it is not possible to understand how this intervention could be more viable.

Moreover, the studies written in other languages besides Portuguese and English were not included and neither were not published investigations.

#### **4.5. Implications for the Practice**

As previously mentioned, colic symptoms are one of the biggest causes of stress for caregivers and also one of the main reasons why they consult their health professionals. This is one of the focal motives why nurses are in a good position to keep parents informed about effective methods to help relieving it.

The massage is definitely a good method to relief colic as concluded from the analysed studies. This way, it should be advised by health professionals.

It is a technique that can be used during the episode of colic to relief its symptoms or to prevent them. One of the articles suggests that the massage should be performed with a gentle stroke along the different parts of the body.

Also, parents should not massage the areas where the baby does not appreciate touch, since. According to the evidence, babies should be massaged at least two to three times a day for 15 to 30 minutes each time.

Unfortunately, it is not possible to define the best massage technique based on the studies included in the present review, since the procedures were not specified by the authors.

## CONCLUSION

The Systematic Review of the Literature is one of the most important methods of research in a way that it allows the investigators to reunite evidence about a specific matter, making the review a resourceful source of information for the evidence based practice and decision making in any area.

Earlier in the history of research, the proposals for upgrading the interventions were based merely in primary studies. However, with the increase of numerous research papers, it was mandatory the development of a method in which these articles were analysed and synthesized in order to produce evidence and to propose alterations in care centred on Evidence-Based Practice.

*“In an ideal world, nurses could keep up to date by reading all of the published literature in their relevant area. In reality, with approximately a thousand new publications each year relevant just to surgical nursing, for example, this is clearly an impossible task”* (Courtney and McCutcheon, 2010, p. 5).

Nowadays with so much information, not always truthful, it is imperative that the development and improvement of health care practice reflects the results of scientific productions.

The aim of this SRL was to investigate the effectiveness of massage as a possible mean to relief infantile colic in healthy infants. When going through the present paper it is possible to affirm that all the goals initially delineated were accomplished whilst the elaboration of the Systematic Review.

It is undeniable the importance of the theme since, as previous data showed, so many infants suffer from colic and so many parents and caregivers look for an ideal solution. Furthermore,

as a health professional, it is always best practice to seek the most recent and accurate source of information to provide my clients the most viable information possible.

After an analyses of the selected studies it is possible to conclude that the findings support the use of massage to relief colic symptoms. Massage should be encouraged by health professionals and should be performed by parents and caregivers since the investigations shows evidence of its benefits in sleep and crying patterns, modern-child bond and in the decrease of hormones that influence the stress of the child.

Further investigations about the best technique to use, how and when must be carried out. In addition, it would be important to investigate the association of different methods as a better answer for the issue.

The elaboration of this paper was extremely important for my development as a paediatric specialist nurse, not only because it allowed me to deepen my knowledge about the theme but also because it provided me with the understanding needed to achieve new data and how to analyse, synthetize and interpret it.

Writing my masters dissertation has made me face many challenges, but being able to overcome these has helped me not only to develop as a nurse, but to grow as an individual. Undertaking a systematic review has broadened my own horizons about clinical studies, and taught me to approach my work by questioning new methods, challenging current practice and embracing change.



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## **APPENDIXES**



## **APPENDIX I**

### **Systematic Review of the Literature Research Protocol**



## Systematic Review of the Literature Research Protocol

A Systematic Review of the Literature is an extremely rigorous process followed in order to “(...) *identify the studies on one specific theme, applying explicit and systematized search methods; evaluate the quality and validity of those studies, as well as the applicability in the context where changes will be made, so as to select the studies to provide SE (scientific evidence) and provide their synthesis, with a view to facilitate implementation in EBP (Evidence Based Practice)*” (De-La-Torre-Ugarte-Guanilo, Takahashi and Bertolozzi, 2011, p. 1256). According to these, to do so it is essential to define a SR (Systematic Review) protocol in which all the different parts of the process are planned, described and organized in order to reduce the risk of bias and reassure the quality and liability of the investigation. Unfortunately, as Schlosser (2007) refers, the definition of a protocol is one of the aspects that is frequently neglected. “*A protocol is developed a priori, and it is advisable that the authors of the systematic review adhere as closely as possible to the protocol*” (Schlosser, 2007, p.2) as if it was a “*road map*” which provides the guidance that the investigator needs. The registration of these moments is also essential so that it is possible for the SR to “*be reproduced and verified by other researches*” (De-La-Torre-Ugarte-Guanilo, Takahashi and Bertolozzi, 2011, p. 1256).

### Systematic Review of the Literature Protocol Protocolo da Revisão Sistemática da Literatura

### Observations/reasons Observações/Justificações

<p><b>Start question</b> Pergunta de partida</p>	<p>PICO question</p> <table border="1" data-bbox="660 798 1332 949"> <thead> <tr> <th>Population</th> <th>Intervention</th> <th>Comparison</th> <th>Results</th> </tr> </thead> <tbody> <tr> <td>Infants</td> <td>Massage</td> <td>—————</td> <td>Colic relief</td> </tr> </tbody> </table> <p><b>The effectiveness of massage in relieving colic in infants: A Systematic Review of the Literature</b></p> <p>O efeito da massagem no alívio das cólicas do lactente: Uma Revisão Sistemática da Literatura</p> <p><b>Key concepts:</b></p> <ul style="list-style-type: none"> <li>→ Infant: any child with age between 2 weeks and 6 months.</li> <li>→ Massage: applying pressure and/or rubbing a certain part of the body (International Council of Nurses®, 2010, p. 98).</li> </ul>	Population	Intervention	Comparison	Results	Infants	Massage	—————	Colic relief	<p>“<i>An SR should be carefully planned to guarantee the validity of the results, as it improves the foundations of the proposed changes</i>” (De-La-Torre-Ugarte-Guanilo, Takahashi and Bertolozzi, 2011, p.1256). According to the same authors, a Systematic Review of the Literature is meant to answer a very specific and objective question, which leads the investigator to formulate one.</p>
Population	Intervention	Comparison	Results							
Infants	Massage	—————	Colic relief							

	<p>→ Colic: colic was defined by a paediatrician Morris Wessel in 1954 by the “rule of three”: “(...) <i>paroxysms of excessive crying in an otherwise healthy baby lasting more than 3 hours per day, occurring &gt; 3 days in any week for 3 weeks (...)</i>” (Wessel et al. cit in Kheir, 2014, p.1).</p>		
<p><b>Main goal</b> Objetivo principal</p> <p><b>Specific goals</b> Objetivos específicos</p>	<p><b>To understand the effectiveness of massage in the infant’s colic relief.</b></p> <ul style="list-style-type: none"> <li>→ To operationalize the key concepts of this Systematic Review;</li> <li>→ To develop a Systematic Review of the Literature Protocol;</li> <li>→ To identify the action mechanism of the massage in the infant’s colic relief;</li> <li>→ To evaluate the methodological quality of the studies used on this Systematic Review;</li> <li>→ To analyse the scientific evidence found;</li> <li>→ To identify the studies found about the subject;</li> <li>→ To analyse the available studies about the topic;</li> <li>→ To synthesize the evidence regarding the theme;</li> </ul>		
<b>Background</b>	<p>The performance of infant massage has been increasing in our society, not only by the health professionals, but also by the baby’s parents or caregivers. This is considered to be a facilitating method to eliminate gas bubbles that remain in the baby’s intestine. <i>“Infantile colic is a common but poorly understood and often frustrating problem for parents and caregivers and it is frequently a reason for consultations with paediatricians and community nurses”</i> (Savino and Tarasco, 2010, p. 791). Health professionals commonly suggest and support the parents to apply the massage technic in order to help the baby relieving colic symptoms. An infant may begin to experience colic around two weeks of age and fortunately it doesn’t last forever since it stops around four to six months of age. Infantile colic is a worldwide paediatric concern that affects approximately 20% of infants, this means that, in the first three months of life, one in every five infants develop colic (Bahrami, Kiani and Noras, 2016). The term “infantile colic” has been used basically to describe excessive crying. However, colic goes a lot beyond that and its diagnosis is clinical. The massage is commonly used not only because it is a non-pharmacological method, but also because of its easy usage. Despite all this, the effectiveness of the massage use has been a study subject for a long time.</p>		
<p><b>Inclusion Criteria</b> Critérios de inclusão</p>	<p><b>Participants</b></p>	<p><b>Studies referring to healthy infants</b></p> <p><b>Studies referring to infants between two weeks and six months of age</b></p>	<p>The concept of colic applies to infants considered healthy.</p> <p>90% of the colic incidence is reported early in infancy (Hodge and Murphy, 2014). Studies about the matter report that its incidence tends to decrease close to the 5/6 months of age.</p>
	<p><b>Intervention</b></p>	<p><b>Studies that investigate the effectiveness of the massage in colicky infants</b></p>	<p>Studies that explore the use of massage in the relief of infant colic are the aim of this review.</p>

	<b>Outcomes</b>	<b>Studies reporting outcomes on the effectiveness of massage in infantile colic</b>	Studies that report results about the effectiveness of massage in colicky babies will be considered in the review.
		<b>Studies reporting outcomes on the effectiveness of massage associated with other factors/methods in infantile colic</b>	Studies reporting the intervention in study associated with other interventions will be considered.
	<b>Research Methodologies</b>	<b>Primary studies</b>	Primary studies are “(...) often based on principals of the scientific method (...) Although the application of the scientific method varies from field to field, the general principles of the scientific method allow researchers to learn more about the world and observable phenomena” (Driscoll, 2011, p.154).
		<b>Experimental studies, Quasi-experimental studies and Observational studies</b>	A review should be grounded in good quality studies.
		<b>Studies published until February of 2017</b>	The review aims to acknowledge all the literature about the matter.
<b>Full text</b>	<b>Available full text articles</b>	All the articles which full text is available will be considered in the SRL	
<b>Exclusion criteria</b> Critérios de exclusão	<b>Participants</b>	<b>Studies referring to sick, hospitalized infants and/or with any kind of disability</b>	Studies related to non-healthy infants will be excluded.
		<b>Studies referring to infants over six months of age</b>	Studies investigating infants with age superior to 6 months of age will not be considered.
	<b>Intervention</b>	<b>Studies that do not investigate the effectiveness of the massage in colicky infants</b>	Studies investigating methods not related to massage will be disqualified.
		<b>Studies investigating the effectiveness of the massage compared to other methods</b>	Studies related with the effectiveness of the technique compared to other used methods will not qualify to the investigation, since the aim is to understand the effectiveness of the massage and not compare it with other techniques.
	<b>Outcomes</b>	<b>Studies reporting outcomes not associated with massage</b>	Studies not investigating the massage intervention will be excluded.

	<b>Research methodologies</b>	<b>Secondary studies</b>	The systematic review of the literature is a secondary study itself; the use of secondary studies may affect the judgement of the reviewer regarding the primary investigation.
		<b>Opinion studies or studies based on <i>consensus</i></b>	Studies based on expert opinions or <i>consensus</i> are considered to have low levels of evidence.
	<b>Full text</b>	<b>Full text unavailable</b>	The articles which full text is not available will not be considered in the SRL
<b>Methods to identify the scientific evidence</b> Método de identificação de evidências científicas	<b>Electronical</b> Eletrónico	Ebsco Host <sup>®</sup> (through ESEP) Web of Science <sup>®</sup> (through ESEP) Scopus <sup>®</sup> (through ESEP)	
	MESH <sup>®</sup> TERMS: (infant OR neonate OR newborn OR baby) AND massage AND colic		
	DECS <sup>®</sup> : (newborn OR neonate) AND massage AND colic		
	Others: baby.		
<b>Method to select the studies</b> Método de seleção de estudos	→ The studies will be submitted to the inclusion and exclusion criteria. → The studies will be submitted to a critical appraisal and methodological quality assessment based in the Queen's Joanna Briggs Collaboration <sup>®</sup> .		<i>"Once all possible studies have been identified, they should be assessed (...)"</i> (Hemingway and Brereton, 2009, p. 4). This assessment implies that the studies need to be submitted to an eligibility test against inclusion and exclusion criteria (Hemingway and Brereton, 2009).
<b>Solution process to assess discrepancies between revisers on the selection of the articles</b> Processo de solução para discordâncias entre revisores na seleção de artigos	Discrepancies between researchers will be discussed with a third investigator.		According to JBI <sup>®</sup> (Consult. 2016, p. 88) <i>"any disagreement over the assessment status of a study between the primary and secondary reviewers should be resolved through discussion with a third reviewer"</i> .
<b>Methodological quality evaluation</b> Avaliação da qualidade metodológica	Performed based on the JBI <sup>®</sup> Critical Appraisal tools.		It is mandatory that each identified study is submitted to an assessment to ensure that a high standard of methodological quality is maintained (Queen's Joanna Briggs Collaboration <sup>®</sup> , 2015).



<b>Data extraction method</b> Método de extração dos dados	Performed based on the JBI® Data Extraction tools.	This is important to develop a standard data extraction tool in order to collect the same type of data from all the studies included in the review (The Joanna Briggs Institute®, 2014).
<b>Abstract/ publication of the data</b> Síntese/Disseminação dos dados	Article	The increase of scientific productions enhances the need to produce SRL by incorporating the various evidences and producing health policies (De-La-Torre-Ugarte-Guanilo, Takahashi and Bertolozzi, 2011).

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**APPENDIX II**  
**Research Strategy**



# Research Strategy

**Date:** 17/ 03/2017

**Investigator:** Bárbara Lemos

**Boolean Sentence:**

(neonate OR newborn OR infant OR baby) AND massage AND colic)

**Data bases:**

- **Scopus (through ESEP)**  
Activated filters: Portuguese and English idiom
- **Web of Science (through ESEP)**  
Activated filters: Portuguese and English idiom
- **Ebsco Host (through ESEP)**  
Activated filters: Portuguese and English idiom

Database	Results
Scopus®	43
Web of Science®	14
Ebsco Host®	66
<b>Total</b>	<b>123</b>
<b>After removal of duplicates</b>	<b>54</b>
<b>Number of results after identifying records through the articles references</b>	<b>56</b>

## Research Strategy

**Date:** 17/ 03/2017

**Investigator:** Ana Paula Prata

**Boolean Sentence:**

(neonate OR newborn OR infant OR baby) AND massage AND colic)

**Data bases:**

- **Scopus (through ESEP)**  
Activated filters: Portuguese and English idiom
- **Web of Science (through ESEP)**  
Activated filters: Portuguese and English idiom
- **Ebsco Host (through ESEP)**  
Activated filters: Portuguese and English idiom

Database	Results
Scopus®	43
Web of Science®	14
Ebsco Host®	66
<b>Total</b>	<b>123</b>
<b>After removal of duplicates</b>	<b>54</b>
<b>Number of results after identifying records through the articles references</b>	<b>56</b>

**APPENDIX III**  
**Research Results**





## Research Results

Study nr	Study name
<b>1</b>	Somatic Research: Massage for infantile colic
<b>2</b>	The effectiveness of massage therapy in the treatment of infantile colic symptoms: A randomized controlled trial
<b>3</b>	Effects of infant massage on jaundiced neonates undergoing phototherapy
<b>4</b>	Infantile Colic: Recognition and Treatment
<b>5</b>	O uso da massagem para alívio de cólicas e gases em recém-nascidos (The use of massage to relieve colic and gases in newborns)
<b>6</b>	Massage for promoting mental and physical health in typically developing infants under the age of six months (Review)
<b>7</b>	What midwives need to know about baby massage
<b>8</b>	Infantile colic, facts and fiction
<b>9</b>	The effectiveness of aromatherapy massage using lavender oil as a treatment for infantile colic
<b>10</b>	The effect of infant massage in comparison with rocking on the duration and frequency of crying time in patients with infantile colic
<b>11</b>	Pediatric Tuina: Ancient Chinese massage for Children
<b>12</b>	Nutritional Supplements and Other Complementary Medicines for Infantile Colic: A Systematic Review
<b>13</b>	Colic in infants
<b>14</b>	Effectiveness of manual therapies: the UK evidence report
<b>15</b>	Commentary on Arikian D et al. (2008) Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic. Journal of Clinical Nursing 17, 1754-1761
<b>16</b>	Treatment options for infant colic
<b>17</b>	Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic
<b>18</b>	Ask our experts
<b>19</b>	Primary care from infancy to adolescence
<b>20</b>	Methods used to eliminate colic in infants in the eastern parts of Turkey
<b>21</b>	Effectiveness of chiropractic treatment for infantile colic
<b>22</b>	Infantile Colic
<b>23</b>	The gripe: an integrative approach to infant colic
<b>24</b>	Massage intervention for promoting mental and physical health in infants aged under six months
<b>25</b>	Newborn care practices in low socioeconomic settlements of Karachi, Pakistan
<b>26</b>	Activities that...Promote Learning Through Touch
<b>27</b>	Infant colic: what works -- what doesn't?
<b>28</b>	As they grow. 0-12 months: the magic touch: the power to help your baby relax, sleep better, and even grow faster is right at your fingertips
<b>29</b>	All the right moves: baby massage can do everything from relieve colic to boost baby's immune system. Learn the power of your touch

<b>30</b>	Infant massage compared with crib vibrator in the treatment of colicky infants
<b>31</b>	Home remedies
<b>32</b>	Infants' colic and belly massage
<b>33</b>	The physician and a commonsense approach to breast-feeding
<b>34</b>	Management of musculoskeletal dysfunction in infants
<b>35</b>	The excessively crying infant: Etiology and treatment
<b>36</b>	Management of infantile colic
<b>37</b>	Complementary and alternative medicine in children: An analysis of the recent literature
<b>38</b>	Managing infants who cry excessively in the first few months of life
<b>39</b>	The evidence-base for complementary medicine in children: A critical overview of systematic reviews
<b>40</b>	Infantile colic: Is a pain syndrome
<b>41</b>	New treatments for infant colic
<b>42</b>	Chiropractic diagnosis and management of non-musculoskeletal conditions in children and adolescents
<b>43</b>	Effectiveness of a Modified Mother-Infant Transaction Program on Outcomes for Preterm Infants from 3 to 24 months of age
<b>44</b>	Perinatal depression: Treatment options and dilemmas
<b>45</b>	Safety and efficacy of acupuncture in children: A review of the evidence
<b>46</b>	Complementary, holistic, and integrative medicine: Colic (Review)
<b>47</b>	Traditional infant rearing practices in India: Myths and reality
<b>48</b>	Randomised controlled trial of swaddling versus massage in the management of excessive crying in infants with cerebral injuries
<b>49</b>	Complementary medicine in pediatrics: A review of acupuncture, homeopathy, massage, and chiropractic therapies (Review)
<b>50</b>	Management of infantile colic (Review)
<b>51</b>	Infants' colic and belly massage
<b>52</b>	The obstetrician's approach to the breast and breastfeeding (Article)
<b>53</b>	Massage for Infantile Colic: Review and Literature
<b>54</b>	Infant massage does not reduce colic symptoms
<b>55</b>	Effectiveness of treatments for infantile colic: systematic review
<b>56</b>	Manipulative therapies for infantile colic (Review)

## **APPENDIX IV**

**Eligibility test based on inclusion and exclusion criteria**



## Eligibility test based on inclusion and exclusion criteria

Article:		Yes	No
<b>Participants</b>	<b>Question 1)</b> Does the study refer to healthy infants?		
	<b>Question 2)</b> Does the study refer to infants between 2 weeks and 6 months?		
<b>Intervention</b>	<b>Question 3)</b> Does the article investigate effectiveness of the massage?		
<b>Outcomes</b>	<b>Question 4)</b> Does the article report outcomes on the effectiveness of massage in infantile colic?		
<b>Research methodologies</b>	<b>Question 5)</b> Does the article refer to a primary study?		
	<b>Question 6)</b> Does the article refer to an experimental, Quasi-experimental or observational study?		
	<b>Question 7)</b> Was the study published until February of 2017?		
<b>Full text</b>	<b>Question 8)</b> Is the article's full text available?		
<b>Idiom</b>	<b>Question 9)</b> Is the full text in English or Portuguese?		



## **APPENDIX V**

**Results of the eligibility test based on inclusion and exclusion criteria**







24	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x
25	N/A	N/A	N/A	N/A		x		x	x		x		x		x		x		x
26	N/A	N/A	N/A	N/A		x		x		x		x		x		x			x
27																x			x
28	N/A	N/A	N/A	N/A		x		x		x		x		x		x			x
29																x			x
30	x		x		x		x		x		x		x		x		x		x
31																x			x
32																x			x
33																x			x
34	N/A	N/A	N/A	N/A		x		x		x		x	x		x		x		x
35	N/A	N/A	N/A	N/A		x		x		x		x	x		x		x		x
36	N/A	N/A	N/A	N/A		x		x		x		x	x		x		x		x
37	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x
38	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x
39	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x
40	N/A	N/A	N/A	N/A		x		x		x		x	x		x		x		x
41	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x
42	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x
43		x	x			x		x	x		x		x		x		x		x
44		x		x		x		x		x		x	x		x		x		x
45		x		x		x		x		x		x	x		x		x		x
46																x			x
47																x			x
48		x		x	x			x	x		x		x		x		x		x
49	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x
50	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x
51																x			x
52																x			x

<b>53</b>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x	
<b>54</b>																x				x
<b>55</b>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x	
<b>56</b>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		x		x	x		x		x		x	



## **APPENDIX VI**

### **Critical appraisals of the included studies**



## Critical appraisal of the experimental study

### *“The effectiveness of the massage therapy in the treatment of infantile colic symptoms: A randomized controlled trial” (S2)*

Reviewer: Bárbara Lemos

Date: 02/05/2017

Author: Ali Sheidaei, Alireza Abadi, Farid Zayeri, Fatemeh Nahidi, Nafiseh Gazerani, Anita Mansouri      Year: 2016      RecordNumber: IRCT201106054317N5

	Yes	No	Unclear
1. Was the assignment to treatment groups truly random?			x
2. Were the participants blinded to treatment allocation?		x	
3. Was allocation to treatment groups concealed from the allocator?			x
4. Were the outcomes of people who withdrew described and included in the analysis?	x		
5. Were those assessing the outcomes blind to the treatment allocation?	x		
6. Were control and treatment groups comparable at entry?	x		
7. Were groups treated identically other than for the named interventions?	x		
8. Were outcomes measured in the same way for all groups?	x		
9. Were outcomes measured in a reliable way?	x		
10. Was appropriate statistical analysis used?	x		

Score	Quality level
0-3	Low
4-6	Moderate
7-9	High

Overall appraisal:

**Include** [ x ]

**Exclude** [ ]

**Seek further info** [ ]

## Critical appraisal of the experimental study

### *“The effectiveness of aromatherapy massage using lavender oil as a treatment for infantile colic” (S9)*

Reviewer: Bárbara Lemos

Date: 02/05/2017

Author: Bengu Çetinkaya, Zumrut Basbakkal

Year: 2011

Record Number:

	Yes	No	Unclear
1. Was the assignment to treatment groups truly random?		x	
2. Were the participants blinded to treatment allocation?		x	
3. Was allocation to treatment groups concealed from the allocator?			x
4. Were the outcomes of people who withdrew described and included in the analysis?			x
5. Were those assessing the outcomes blind to the treatment allocation?		x	
6. Were control and treatment groups comparable at entry?	x		
7. Were groups treated identically other than for the named interventions?	x		
8. Were outcomes measured in the same way for all groups?	x		
9. Were outcomes measured in a reliable way?	x		
10. Was appropriate statistical analysis used?	x		

Score	Quality level
0-3	Low
4-6	Moderate
7-9	High

Overall appraisal:

Include [ x ]

Exclude [ ]

Seek further info [ ]



### Critical appraisal of the experimental study

***“Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic” (S17)***

Reviewer: Bárbara Lemos

Date: 02/05/2017

Author: Duygu Arikan, Handan Alp, Sebahat Gozum, Zerrin Orbak, Esra Karaca Çifçi

Year: 2007

Record Number:

	Yes	No	Unclear
<b>11. Was the assignment to treatment groups truly random?</b>			x
<b>12. Were the participants blinded to treatment allocation?</b>		x	
<b>13. Was allocation to treatment groups concealed from the allocator?</b>		x	
<b>14. Were the outcomes of people who withdrew described and included in the analysis?</b>	x		
<b>15. Were those assessing the outcomes blind to the treatment allocation?</b>		x	
<b>16. Were control and treatment groups comparable at entry?</b>	x		
<b>17. Were groups treated identically other than for the named interventions?</b>	x		
<b>18. Were outcomes measured in the same way for all groups?</b>	x		
<b>19. Were outcomes measured in a reliable way?</b>	x		
<b>20. Was appropriate statistical analysis used?</b>	x		

Score	Quality level
0-3	Low
4-6	Moderate
7-9	High

Overall appraisal:

**Include [ x ]**

**Exclude [ ]**

**Seek further info [ ]**

## Critical appraisal of the experimental study

***“Infant massage compared with crib vibrator in the treatment of colicky infants”***

**(S30)**

Reviewer: Bárbara Lemos

Date: 02/05/2017

Author: Virpi Huhtala, Liisa Lehtonen, Riitta Heinonen, Heikki Korvenranta

Year: 2000

Record Number:

	Yes	No	Unclear
<b>21. Was the assignment to treatment groups truly random?</b>	x		
<b>22. Were the participants blinded to treatment allocation?</b>		x	
<b>23. Was allocation to treatment groups concealed from the allocator?</b>		x	
<b>24. Were the outcomes of people who withdrew described and included in the analysis?</b>	x		
<b>25. Were those assessing the outcomes blind to the treatment allocation?</b>		x	
<b>26. Were control and treatment groups comparable at entry?</b>		x	
<b>27. Were groups treated identically other than for the named interventions?</b>	x		
<b>28. Were outcomes measured in the same way for all groups?</b>	x		
<b>29. Were outcomes measured in a reliable way?</b>	x		
<b>30. Was appropriate statistical analysis used?</b>	x		

Score	Quality level
0-3	Low
4-6	Moderate
7-9	High

Overall appraisal:

**Include [ x ]**

**Exclude [ ]**

**Seek further info [ ]**

## **APPENDIX VII**

### **Data extraction of the included articles**



## Data extraction form for the experimental study

### *“The effectiveness of the massage therapy in the treatment of infantile colic symptoms: A randomized controlled trial” (S2)*

<b>Reviewer</b>	<b>Bárbara Lemos</b>
<b>Extraction date</b>	10/05/2017
<b>Title</b>	<i>The effectiveness of the massage therapy in the treatment of infantile colic symptoms: A randomized controlled trial</i>
<b>Author(s)</b>	Ali Sheidaei Alireza Abadi Farid Zayeri Fatemeh Nahidi Nafiseh Gazerani Anite Mansouri
<b>Local / Date</b>	Iran, 2016
<b>Journal</b>	Medical Journal of the Islamic Republic of Iran
<b>Study method</b>	Randomized clinical trial
<b>Aim of the study</b>	Explore the efficacy of massage therapy compared to rocking in reducing infantile colic symptoms (duration and number of cries, sleep duration and severity of infantile colic)
<b>Participants</b>	N=100 (50 infants included in the massage group and 50 in the rocking/control group)
<b>Intervention</b>	In the intervention group: <ul style="list-style-type: none"> <li>→ Mothers were taught to execute the massage correctly by an expert;</li> <li>→ Mothers were asked to massage their infants for 15-20 minutes, once during the day and once during the night before sleeping, for a week;</li> </ul> In the control group: <ul style="list-style-type: none"> <li>→ Mothers rocked their infant gently for 5-25 minutes when the colic symptoms appeared;</li> </ul> Both intervention and control group recorded daily the duration (minutes), severity (Visual Analog Scale) and number of colic cries for a week as well as the amount of hours of sleep. Similar diaries were completed one and two days before the beginning of the interventions as a baseline.
<b>Study results</b>	The massage group shows improvement of all the colic symptoms. Only the severity of colic improved in the rocking group.
<b>Author’s conclusions</b>	Colic symptoms were relieved in infants who received a massage over a one-week intervention, while rocking only affected positively the severity of colic which leads to believe that massage therapy can be more effective than rocking in the relief of colic symptoms.
<b>Reviewer’s comments</b>	When it comes to demographic variables, both groups were comparable at entry. Although, there are statistically significant differences in the

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baseline measurements of the duration of cry per day as well as in the baselines of sleep and colic severity. According to the data provided, the four factors were measures one and two days before the start of the study which is a good way to understand the start point of each group.

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## Data extraction form for the experimental study

### *“The effectiveness of aromatherapy massage using lavender oil as a treatment for infantile colic” (S9)*

<b>Reviewer</b>	<b>Bárbara Lemos</b>
<b>Extraction date</b>	10/05/2017
<b>Title</b>	<i>The effectiveness of aromatherapy massage using lavender oil as a treatment for infantile colic</i>
<b>Author(s)</b>	Bengu Çetinkaya Zumrut Basbakkal
<b>Local / Date</b>	Turkey, 2012
<b>Journal</b>	International Journal of Nursing Practice
<b>Study method</b>	Quasi-experimental trial
<b>Aim of the study</b>	Investigate the effect of aromatherapy massage using lavender oil in infantile colic
<b>Participants</b>	N=40 (20 infants included in the control group and 20 in the treatment group)
<b>Intervention</b>	<p>Before the experiment, both infants in the intervention and control group were examined and the diagnostic of colic was confirmed by pediatricians. After the primary observation, 5 others with 1 week apart were carried out to monitor the infants.</p> <p>The mothers recorded for a week any episode of cry that lasted longer than 15 minutes.</p> <p>Once the preliminary data was collected, the mothers in the treatment group received aromatherapy massage training at home. A solution of 1 drop of lavender oil with 20 ml of almond oil, prepared by the research team, should be used to perform the abdominal massage within 1-2 minutes of the start of the colic attack. The massage was to last between 5-15 minutes.</p> <p>The mothers were taught the massage technique and practiced on a dummy. They were also given a booklet with all the information transmitted in the training.</p> <p>Once the research was complete the mothers in the control group were also taught the massage technique and were given booklets despite the fact that their babies did not receive any kind of intervention.</p>
<b>Study results</b>	<p>The results show that there was a statistically significant difference in the mean weekly crying times in the treatment group (13.28hours/week to 6.27hours/week).</p> <p>On the other hand, there was no statistically significant difference in the control group (13.35hours/week to 13.37hours/week).</p>
<b>Author’s conclusions</b>	The aromatherapy massage using lavender oil could be effective for the reduction of infantile colic.
<b>Reviewer’s comments</b>	Both treatment and control group were comparable at entry not only in terms of demography but also in the total crying time per week before the start of the study.

## Data extraction form for the experimental study

### *“Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic” (S17)*

<b>Reviewer</b>	<b>Bárbara Lemos</b>
<b>Extraction date</b>	10/05/2017
<b>Title</b>	<i>Effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic</i>
<b>Author(s)</b>	Duygu Arikan Handan Alp Sebahat Gozum Zerrin Orbak Esra Karaca Çifçi
<b>Local / Date</b>	Turkey, 2008
<b>Journal</b>	Journal of Clinical Nursing
<b>Study method</b>	Prospective and randomised-controlled study
<b>Aim of the study</b>	Individually evaluate the effectiveness of massage, sucrose solution, herbal tea or hydrolysed formula in the treatment of infantile colic.
<b>Participants</b>	N=175 (35 in the massage group, 35 in the sucrose group, 35 in the herbal tea group, 35 in the formula group and 35 in the control group)
<b>Intervention</b>	Initially parents were given a questionnaire about the infant’s behaviour, temperament, sleeping and eating patterns and precedent of colic. Parents recorded crying times as well as durations and after were trained to perform the assigned regime depending on the group the baby was in. <ul style="list-style-type: none"> <li>→ Massage: parents administered massage twice a day for 25 minutes during the symptoms of colic;</li> <li>→ Sucrose: parents administered a dose of 2ml of 12% solution twice daily at 5 and 8pm;</li> <li>→ Herbal tea: a dose of 35ml of fennel tea was given three times a day;</li> <li>→ Formula: only infants fed with standard formula were included in this group, where the regular formula was replaced by a hydrolysed one;</li> <li>→ Control: no intervention was administered to this group.</li> </ul> All parents were visited by a paediatrician and nurse and trained in the scoring method.
<b>Study results</b>	The mean crying time (hours per day) decreased significantly in the massage group (5.34hours/day to 4.37hours/day), sucrose solution group (5.71hours/day to 3.94hours/day), herbal tea group (5.11hours/day to 3.20hours/day) and hydrolysed formula group (4.91hours/day to 2.69hours/day). However, there were no significant statistical differences in the control group (4.60hours/day to 4.51hours/day).
<b>Author’s conclusions</b>	Hydrolysed formula should be the first choice in the treatment of infantile colic.
<b>Reviewer’s comments</b>	The randomization of the groups was not total since the hydrolysed formula intervention was only applied to bottle fed babies and the control group had only breast fed infants. Since one of the possible reasons for the



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	colic is related to the feeding method, the intervention in study should be compared with a group control in which the infants were bottle fed with a non-hydrolysed formula.
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## Data extraction form for the experimental study

***“Infant massage compared with crib vibrator in the treatment of colicky infants”***

**(S30)**

<b>Reviewer</b>	<b>Bárbara Lemos</b>
<b>Extraction date</b>	10/05/2017
<b>Title</b>	<i>Infant massage compared with crib vibrator in the treatment of colicky infants</i>
<b>Author(s)</b>	Virpi Huhtala Liisa Lehtonen Riitta Heinonen Heikki Korvenranta
<b>Local / Date</b>	Finland, 2000
<b>Journal</b>	Pediatrics
<b>Study method</b>	Randomized controlled trial
<b>Aim of the study</b>	Evaluate the effectiveness of infant massage compared with that of a crib vibrator in the treatment of infantile colic
<b>Participants</b>	N=58 (28 in the massage group and 30 in the crib vibrator group)
<b>Intervention</b>	<p>Parents recorded in provided diaries the crying, sleeping and feedings of the infant for a week (baseline). After the 1 week baseline recording, mothers started a 3 week intervention record.</p> <p>In the massage group, a trained nurse taught the massage technique and gave them a brochure with instructions. The baby received 3 daily massages (2 whole body massages for 20-30 minutes and 1 belly massage for 15 minutes).</p> <p>The crib vibrator group received the device along with the instructions in the beginning of the intervention. The device was installed at the bottom of the infant’s crib. Parents should use it 3 times a day for 25 minutes.</p> <p>Parents of both groups were interviewed at the end of the 1<sup>st</sup> and 3<sup>rd</sup> week about the perceived effectiveness of the intervention on the colic symptoms. The amount of colic symptoms were rated as 1) decreased, 2) not changed and 3) increased; the intervention was rated as 1) colic decreasing, 2) no effect, 3) colic increasing and 4) cannot say.</p>
<b>Study results</b>	Over the 4 weeks the amount of total daily crying decreased similarly in both the intervention (massage) and the control (crib vibrator) group.
<b>Author’s conclusions</b>	<p>Over the 4 weeks the amount of total daily crying decreased similarly in both the intervention (massage) and the control (crib vibrator) group.</p> <p>The massage group had a decrease of 48% in the mean of total daily crying and the crib had a decrease of 47%.</p> <p>In terms of mean daily colicky cry, the massage group had a decrease of 64%, while the crib group had a decrease of 52%.</p>
<b>Reviewer’s comments</b>	<p>According to the data provided, the number of interventions (periods/day) in the massage group and in the crib vibrator group are quite similar:</p> <ul style="list-style-type: none"> <li>→ First week 2.2 in massage and 2.5 in crib</li> <li>→ Second week 2.2 in massage and 2.1 in crib</li> <li>→ Third week 2.0 in massage and 1.9 in crib</li> </ul>

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Although, the duration of the intervention (hours/day) is not:

- First week 0.9 in massage and 1.3 in crib
- Second week 0.9 in massage and 1.2 in crib
- Third week 0.8 in massage and 1.0 in crib

This discrepancy should be analysed.

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