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**EFFECTIVENESS OF THE APPLICATION OF MASSAGE THERAPY AND  
KINESITHERAPY BY PARENTS ON PREMATURE NEONATES: A RESEARCH  
PROTOCOL**

**RUNNING HEAD: Massage in preterm neonates: Research Protocol**

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### **CONFLICT OF INTEREST**

No conflict of interest has been declared by the authors.

### **AUTHOR CONTRIBUTIONS**

| <b>Criteria</b>   | <b>Author Initials</b>       |
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| Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;  | MJAA, DFG, MDRG              |
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| Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. | BO, JGS, SM, MJAA, DFG, MDRG |

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## **ABSTRACT**

**Aim:** The study aims to analyze the efficacy of massage therapy and kinesitherapy applied by parents of premature infants admitted to hospital.

**Background:** Premature newborns suffer early somatic deprivation that has adverse effects on their growth and development and that also has a negative impact on the emotional state of their parents. Massage therapy and kinesitherapy is beneficial in alleviating somatic deficit and facilitates the bond between parents and newborns.

**Design:** A quasi-experimental community intervention trial will be conducted in a neonatology unit.

**Methods:** This study will compare the benefits of a 15-minute massage protocol applied by parents with the usual medical and nursing care provided by neonatal units for premature babies. The evaluation of neuromotor development will take place through the Spanish Premie-Neuro scale. The determination of weight, size and head circumference will be based on the unit's usual procedures.

**Discussion:** If the implementation of a massage therapy and kinesitherapy protocol is effective in promoting the growth and development of hospitalized premature infants, the results of this study could provide an impetus for the inclusion of somatic stimulation in the usual nursing care provided for preterm infants.

**Impact:**

Prematurity and its associated morbidity pose a major global public health problem. Somatic and kinesthetic stimulation has beneficial effects on anthropometric and neuromotor development in preterm infants. The results will have a positive impact on premature neonates and their families, both during the hospitalization, as well as a positive socio-economic effect throughout their lives (education, work, disability)

**Trial registration:** NCT03704012

**Keywords:** massage, premature, preterm, newborn, neonate, kinesitherapy, parents, nursing, nurse, education.

## INTRODUCTION

Prematurity is one of the world's most important health problems. Today, it is the second-leading cause of death in children under 5 years of age and it stands out as the single most important cause of death during the critical period of the first month of life (Liu *et al.* 2012, Blencowe *et al.* 2012). Being born premature, with a very low weight, increases the risk of complications such as respiratory distress, retinopathy of prematurity, patent ductus arteriosus, bronchopulmonary dysplasia, late onset sepsis and necrotizing enterocolitis (Stoll *et al.*, 2010). According to a report from the World Health Organization (WHO) (March of Dimes *et al.* 2013), one in ten newborns around the world are premature and one million of them die from complications each year. The prematurity rate varies widely by country. In most European countries, preterm birth rates have risen. However, the extent of these increases is varied among the different countries and regarding the type of pregnancy (Zeitlin *et al.* 2013).

The main challenges that neonatal nurses face in neonatal intensive care units (NICUs) do not only imply ensuring survival, but also contributing to the optimal growth and development of preterm infants and performing actions aimed at supporting this achievement, adapting this approach to the children's degree of neurological maturity. Consequently, an urgent need for early interventions towards improving preterm infants' growth and development is evidenced (Fucile & Gisel 2010) Neonatal nurses are the main caregivers in the NICU. Therefore, they have a key role in influencing the developing neonates' environment, as well as the therapeutic interventions aimed at ensuring their optimal development (Altimier *et al.* 2015).

It is also very important to involve families, since there is evidence regarding the important role of parents in the proper development of preterm newborns (Davis *et al.* 2003). As a result of their work in direct contact with families, nurses have an opportunity to promote positive interactions between preterm neonates and their parents (Evans *et al.* 2006).

## BACKGROUND

### **Somatic stimulation of the hospitalized preterm newborn**

In addition to suffering the immaturity inherent in prematurity, preterm newborns are deprived, at an early stage, of the somatic stimulation provided by the contact between their skin and the amniotic fluid and uterine walls that takes place during the child's development in the womb. This contact has proven to influence the child's proper growth and neurodevelopment (Mathai *et al.* 2001; Im & Kim 2009).

In addition and as a factor associated with this early sensory deprivation, the need for preterm infants to stay in the NICU or in an incubator prevents them from the necessary continued contact with their parents. This has proven to negatively affect both the psycho-biological development of the child and the emotional status of the parents (Brett *et al.* 2011, Ionio *et al.* 2016; Pace *et al.* 2016).

Our understanding of all these factors has meant that, over recent years, many hospitalization units for premature infants have begun to carry out a series of care procedures focused on cutaneous, kinesthetic and sensory stimulation, with the aim of promoting an enrichment of the hospital environment and facilitating a suitable psychomotor development of premature infants (Field *et al.* 2006, 2010, Pallás & Arriaga 2008)

These interventions are consistent with care focused on development, as they make it possible to create a similar environment to the intrauterine one and adapt the stimuli that preterm infants receive to their degree of brain maturation. Furthermore, it has been shown that if parents are encouraged to apply this stimulation, there are beneficial improvements in the well-being of parents and improvements in the bonds between mother and child (Damato 2004, Muller-Nix *et al.* 2004; Stefana, Padovani, Biban & Lavelli, 2018)

One of the interventions most frequently deployed to provide somatic stimulation to newly hospitalized premature infants is massage therapy. Many physical therapy programs applied to preterm infants combine stimulation through movement with somatic stimulation, giving rise to massage therapy and kinesitherapy protocols specifically designed for this population (Field *et al.* 1986, 2008, Diego *et al.* 2005; Ho *et al.* 2010; Asadollahi *et al.* 2016)

### **Benefits of massage therapy and kinesitherapy protocols in hospitalized premature infants**

Most research on somatic and kinesthetic stimulation for hospitalized preterm neonates agrees in its pointing out a benefit in relation to factors linked to the growth of preterm infants (Diego *et al.* 2007; Field *et al.* 2008; González *et al.* 2009; Massaro *et al.* 2009, Kumar *et al.* 2011, Saeadi *et al.* 2015, Jabraeile *et al.* 2016, Niemi 2017).

In some cases, a weight increase has been found by the end of the implementation of the massage protocol and/or at the time of discharge (Diego *et al.* 2007, Massaro *et al.* 2009, Guzzeta *et al.* 2009, Jabraeile *et al.* 2016) and in other cases benefits have been found at 1 or 2 months of age (Arora *et al.* 2005; Akhavan *et al.* 2013; Fallah *et al.* 2013).

When applied to premature infants, massage therapy has shown verified benefits for a better neurodevelopment of the child. A study conducted by Ferreira and Bergamasco (2010) observed this effect in children receiving tactile and kinesthetic stimulation, as the study preterms showed an improvement in motor skills and in behavioral and weight outcomes, as well as a tendency towards shorter hospital stays. In addition, Fucile and Gisel (2010) as well as Ho *et al.* (2010) found superior motor development in preterm infants who had received somatic and kinesthetic stimulation. In 2010, Procianoy *et al.* published a study where these benefits were observed at 24 months (corrected age). In 2016, the results of an investigation

which also showed that massage had beneficial effects on development, both at the time of discharge and when the babies were assessed at corrected ages of 12 and 24 months, were published (Lai *et al.* 2016).

The influence of massage therapy on the brain development of the preterm newborn is demonstrated in two studies led by Andrea Guzzeta (Guzzeta *et al.* 2009, 2011). When a somatic stimulation protocol is applied, extrauterine brain maturation in low-risk premature infants is similar to the process of brain maturation that they would have had if they had continued their development in the mother's uterus.

Other benefits of massage applied to hospitalized newborn infants are a decreased risk of neonatal sepsis (Mendes & Procianoy 2008), the lowest number of days of hospitalization (Mendes & Procianoy 2008, Ho *et al.* 2010) and reduced stress levels in the newborn (Smith *et al.* 2003a, 2003b).

## **THE STUDY**

### **Aims**

The study will aim to analyze the efficacy of massage therapy and kinesitherapy applied by parents of premature infants admitted to hospital to improve biological status, neuro-motor activity and other associated factors. Our specific objectives will be as follows: (a) Assess the reduction of days of hospitalization due to massage and kinesitherapy procedures applied by parents; (b) determine the effects of massage and kinesitherapy procedures on neuro-motor development in premature infants; (c) examine the effects of intervention on physiological and anthropometric variables; and (d) identify the influence of intervention on care and feeding in premature infants during hospitalization.



### **Design and methodology**

A quasi-experimental community intervention trial will be conducted in the Neonatology Unit at University Hospital of León (Spain). The hospital is part of Spain's national health system.

### ***Research hypothesis***

The high incidence of premature birth and the associated morbidity through these patients' lives are an important public health problem in Spain.

Until now, premature infants hospitalized in the Neonatology Unit at León University Hospital did not receive any type of intervention based on physical methods (for example, massage or mobilization).

We hypothesize that the application by parents of massage therapy and kinesitherapy on premature infants during the infants' hospital stay will facilitate biological, anthropometric and neurological development in the newborns and will reduce the number of days that they spend in hospital. In addition, such measures will allow significant financial savings.

### ***Study Setting***

The study will be conducted at the Neonatology Unit of a public hospital, in Spain.

### *Participants*

The target population will comprise all the premature infants admitted to the Neonatology whose hospitalization meet the inclusion criteria: (a) 48 hours of life; (b) informed consent given by parents; (c) weight between 1,250 and 2,249 grams; (d) intact skin; (e) stable physiological parameters; (f) absence of congenital and genetic abnormalities; (h) absence of central nervous system abnormalities; and (i) hemodynamic stability. The exclusion criteria include: (a) the family's refusal to participate in the study; (b) high-frequency mechanical ventilation; (c) fraction of inspired oxygen greater than 70%; (d) inotropic support; (e) septic shock; (f) persistent tachycardia or bradycardia and (g) gastrointestinal disorders.

### *Allocation process*

Premature infants who meet the inclusion criteria will be assigned to an intervention group or to a control group. The control group will consist of premature infants from the first to the sixth month and those from the nineteenth month to the twenty-fourth month. Meanwhile, the intervention group will comprise premature infants between the sixth and eighteenth months.

The research team will decide not to randomize the assignment of the premature infants because they share parents-children space in the control and intervention groups, so will consider it more appropriate to allocate groups according to different periods. Thus, the first half will correspond to the control group and the second to the intervention group during the first year, with the opposite correspondence during the second (Figure 1).

### *Intervention*

Parents who give their informed consent to participate in the project will receive learning and teaching processes during the first 48 hours of the premature infant's life. They will receive these over two 45-minute sessions (one per day). In the sessions, they will have to demonstrate ability and proficiency in the application of massage and kinesitherapy in accordance with what we present below.

The moderate pressure massage therapy will consist of the 15-minute preterm infant massage therapy protocol used by Field et al. (1986). Treatment will be provided for two 15-minute periods per day, during the morning and late shifts.

Prior to the start of the session, the father/mother responsible for the application of the protocol will wear a gown and remove accessories (for example, rings, watches or bracelets) from their hands. After that, parents will wash their hands properly and according to the hospital's protocol. The hand-washing process will be supervised by staff at the neonatal unit involved in the project.

Each treatment session will be divided into three phases of 5 minutes each. During the first and third phases (massage therapy phases), the premature neonates will be massaged for five minutes, spending one minute in each part of the body by following the sequence: 1) from the top of the head to the neck; 2) from the neck across the shoulders; 3) from the upper back to the waist; 4) from the thigh to the foot, on both legs; and 5) from the shoulder to the hand, on both arms. During the kinesitherapy phase (second phase), the preterm infant will be placed in a supine position and each arm, each leg and finally both legs together, will be flexed and extended for one minute in each segment.

### ***Study measures***

The data collection questionnaire will consist of two parts. In the first part, the research group members will initially collect socio-demographic data such as age of parents, marital status, educational level, ethnicity and toxic habits such as cigarette consumption. After that, they will obtain information about the infant's date of birth, gestational week, prematurity cause, type of delivery and gender.

The second part of the questionnaire will consist of data collected during the first contact with the premature infant (at 48 hours of life): anthropometric measurements (birth weight and height and head circumference) and neurological assessment according to the Spanish Premie-Neuro Scale (Fernández *et al.* 2015). These same variables shall also be collected at discharge (final evaluation). In the final assessment, the research group will also collect other variables such as need for mechanical ventilation, non-mechanical ventilation or supplementary oxygen, or if the premature infant has undergone major medical procedures (lumbar puncture or central catheterization). We will also obtain the days of hospitalization.

All these variables will be recorded by researchers working at the hospital. They will be responsible for data collection and will use an online database. The nursing staff will be responsible for conducting assessments in relation to unknown parameters to be taken into consideration as study variables (hospital days, anthropometric measurements, neurological assessment, etc.).

### ***Procedure and data collection***

The study will last for two years, or four semesters. In the first and the last semesters, we will collect the first data for the control group. In the second and third semesters, the research group will collect the data for the intervention group.

### *Data analysis*

A database will be created using Stata 14.0 software and the data obtained from the questionnaire will be entered into the database so that it could subsequently be analyzed statistically.

For the descriptive analysis, we will calculate mean, median, standard deviation and total interquartile ranges for each of the continuous variables, as well as the relative frequencies with confidence intervals of 95% for different values of the qualitative variables. We will also calculate differences between the initial, intermediate and end situations by calculating the impact of change.

For the analysis of the relationships between variables, correlation values will be calculated by linear regression when both variables were continuous. The odds ratio and the chi-square will be calculated when comparing dichotomous variables. The Student t-test will be used to compare differences in continuous variables between the 2 groups and the Mann-Whitney U-test (Kruskal-Wallis test for 2 samples) will be applied to compare the differences between the 2 groups in the non-parametric variables. The relative risk (RR) also associated with the intervention will be calculated as the incidence ratio of change in the intervention group and the incidence of change in the control group. A p-value of  $< 0.05$  will be considered statistically significant.

### **Ethical considerations**

The principles of written informed consent and confidentiality will be observed during data collection. The study was approved by the hospital's Ethics Committee on November 23, 2010.

## **Validity, reliability and rigor**

The study's scientific rigor will be ensured through a solid foundation of safety, credibility and reliability. The massage therapy and kinesitherapy protocol was designed by Field et al. (Field *et al.* 1986) for a population of newly hospitalized premature infants and was subsequently employed in another five studies on the same population. All nurses participating in the project will receive specific training in the intervention protocol and in evaluating neuromotor development using the Spanish Premie-Neuro scale. The principal investigator of the project will periodically analyze a percentage of the data collected to ensure their consistency and quality. The participating hospital is a tertiary-level one and has the appropriate human and material resources to carry out this project.

## **DISCUSSION**

There is sufficient scientific evidence to support the application of somatic stimulation in preterm infants during hospitalization (Diego et al. 2007; Massaro, Hammad, Jazzo & Aly, 2009; Guzzeta et al., 2009; Fallah et al., 2013; Jabraeile et al., 2016), owing to its benefits on multiple aspects associated with prematurity: Increase in weight and size (Diego *et al.* 2007, Field *et al.* 2008, Massaro *et al.* 2009, Kumar *et al.* 2011, Jabraeile *et al.* 2016; Niemi 2017) and facilitation of psychomotor development and brain maturation (Fucile & Gisel 2010, Ho *et al.* 2010, Procianoy *et al.* 2010, Guzzetta *et al.* 2011, Lai *et al.* 2016, Stefana *et al.* 2018) However, there are many hospitals that have not incorporated somatic stimulation in the care provided to preterm infants.

Our hypothesis in the present study protocol is that preterm infants whose parents apply a massage therapy and kinesitherapy protocol on them during their hospitalization will have better anthropometric, neuromotor and biological development than the control group. No

adverse effects are expected from the implementation of the protocol and it is also expected that benefits will be obtained in terms of the emotional state of the parents and of a better establishment and maintenance of the mother-infant bond.

If this hypothesis is confirmed, the results could help to generalize the implementation of protocols for somatic stimulation in neonatal premature and intensive care units as an effective and low cost measure to facilitate growth and development of hospitalized preterm neonates.

### **Limitations**

Parental consent to participate in the study is unknown, although it would be expected that there would be few refusals to participate, as the intervention and procedures for collecting the variables are of a non-invasive nature. Moreover, the intervention carried out by parents included in the protocol will be developed to for it to be applied by them and so the massage therapy and kinesitherapy will be simplified. On the project web page, parents will be able to find information about the research and a video explaining the protocol of the intervention.

### **CONCLUSION**

The results of this research will identify the effects of a massage therapy and kinesitherapy protocol applied by parents to their hospitalized preterm infants in terms of neuromotor and anthropometric development and of other associated factors.

The results of our study could modestly help to involve families in the care of preterm infants and promote intervention that is focused on infants' development and adapted to their level of neurological maturity.

The expected beneficial effects will relate to growth and development of the preterm newborn and will entail a reduction in the socio-medical costs associated with preterm births.

#### **CONFLICT OF INTEREST**

No conflict of interest has been declared by the authors.

#### **AUTHOR CONTRIBUTIONS**

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (<http://www.icmje.org/recommendations/>)]:

- Substantial contributions to conception and design, acquisition of data or analysis and interpretation of data.
- Drafting the article or critically revising significant intellectual content of it.

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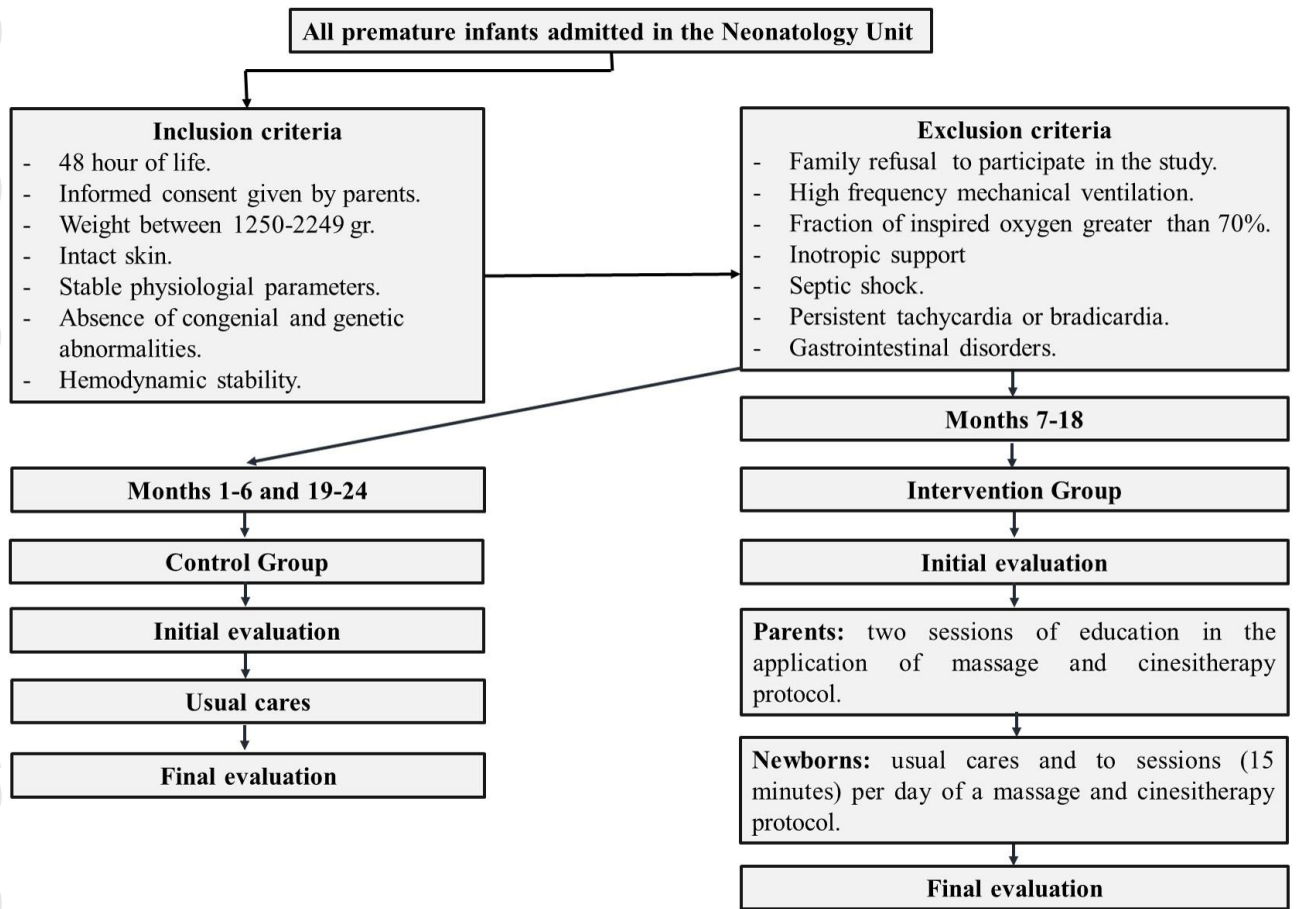


Figure 1. Summary of the research protocol.