

Designing Study Protocol: The Effects of Rhythmic Maternal Movements on Motor Performance of Preterm Infants Hospitalized in a Neonatal Intensive Care Unit: A Randomized Controlled Clinical Trial

Aida Ravarian¹, Farin Soleimani², Nahid Rahmani³, Firoozeh Sajedi⁴, Moslem Shaabani⁵, Mehdi Noroozi⁶, Mohammad A Mohseni-Bandpei^{3*}

1. Pediatric Neurorehabilitation Research Center, Department of Occupational Therapy, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

2. Pediatric Neurorehabilitation Research Center, University of Social Welfare and Rehabilitation Sciences (USWR), Tehran, Iran

3. Department of Physical Therapy, Pediatric Neurorehabilitation Research Center, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

4. Pediatric Neurorehabilitation Research Center, Clinical Sciences Department, University of Social Welfare and Rehabilitation Sciences (USWR), Tehran, Iran

5. Audiology Department, University of Social Welfare and Rehabilitation Sciences (USWR), Tehran, Iran

6. Department of Psychiatry, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

ABSTRACT

Background: The fetus receives various vestibular stimuli as a result of its mother's walking and other activities, while premature infants are deprived of these typical stimuli due to hospitalization in a neonatal intensive care unit (NICU).

Methods: A single blinded randomized controlled clinical trial was designed to evaluate the effect of rhythmic maternal movements (RMM) on motor performance of infants born preterm with gestational age under 34 weeks. The aim of this plan is to stimulate the vestibular system in infants after preterm birth in hopes of improving motor performance. Seventy preterm infants will be randomized to experimental and control groups. The infants in the experimental group will be given RMM to improve motor development, heart rate and saO_2 . A neonatal occupational therapist trains mothers to do the RMM with a doll and explains the protocol. RMM is performed twice a day for a week. The Test of Infant Motor Performance (TIMP) is carried out at baseline and after a week of intervention by a blinded assessor.

Discussion: This paper designed to study the effects of rhythmic maternal movements on motor performance, heart rate and saO_2 of preterm infants hospitalized in a Neonatal Intensive Care Unit.

Keywords: Motor performance, Preterm infants, Rhythmic maternal movements, Vestibular stimulation

Introduction

Infants born preterm are at greater risk of various developmental disorders than those born at full term (1). In addition to exhibiting lower muscle tone, they exhibit fewer movements. As a consequence, their development of postural

control, which is required for stability, orientation, and spatial organization, is compromised (2). Such motor problems can contribute to learning difficulties and cognitive problems (3). In addition, infants born preterm

* Corresponding author: Mohammad A Mohseni-Bandpei, Department of Physical Therapy, Pediatric Neurorehabilitation Research Center, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran. Email: Mohseni_Bandpei@yahoo.com

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are more likely to experience minor developmental delays, such as speech and motor delays, than term infants (4, 5).

Studies investigating the difference in sensory processing between infants born preterm and term infants report that premature infants tend to have lower sensory scores on response to deep touch and vestibular stimulation (6, 7).

Infants in the neonatal intensive care unit (NICU), as opposed to full term infants in utero, are continually exposed to excessive visual and auditory stimuli, such as lights and loud sounds, while being deprived of the vestibular stimulation typical of the natural environment of the uterus (8-11). The NICU often fails to address such sensory needs of infants born preterm, with potentially adverse effects on the infant's sensory processing patterns and neuromotor development (12, 13).

Modulation, connection specificity, and functional characteristics of neural connections are critically dependent on sensory inputs. The unborn child's neurodevelopment is thus influenced by environmental factors (14). Several studies demonstrated that maternal exercises during pregnancy have positive effects on newborn, infant, and child neural development, behavior, and motor skills (15, 16). As a result of maternal movements, neural growth, vestibular nerve myelination, and motor development may be positively affected. As compared to infants whose mothers were inactive during pregnancy, infants of active mothers demonstrated better motor skills (16). Thus, it may be possible to use appropriate movements and vestibular stimulation as an effective therapy in early intervention with preterm infants in NICUs (17).

In a systematic review, the effects of vestibular stimulation on vital signs, growth and neurodevelopment of preterm infants in NICU were described (18). It is reported to have an effect on reducing apnea, improving respiratory function, and improving quiet sleep (17, 19-23). Rocking is also effective in reducing infant crying and/or irritability. Thus, infants are able to pay more attention to external events and respond accordingly (24). Various types of vestibular stimulation were evaluated for effects on passive muscle tone, posture, neuromuscular maturity, and neuromotor development in preterm infants such as; hammock, sinusoidal oscillation, waterbed and rocking. It was reported that vestibular stimulation may enhance the motor

development of infants born preterm who are at risk of developmental delay (25-27). Effects of vestibular stimulation provided by parents has not been reported.

Thus, the purpose of this research will be to investigate the motor performance, heart rate and saO_2 of premature infants following post birth rhythmic maternal movements (RMM) that stimulate all parts of the vestibular system.

Methods

A Randomized Controlled Clinical Trial (RCT) will be conducted to test the following hypotheses:

- Early maternal rhythmic movements may improve the motor performance of preterm infants.
 - Early maternal rhythmic movements may improve heart rate and SaO_2 of preterm infants.
- The following specific aims will be addressed:
- To investigate whether RMM are suitable for use in an enriched and early intervention setting in the NICU.
 - To evaluate whether RMM are useful in promoting motor performance in low-risk preterm infants when compared to standard care.
 - Given a successful outcome, to propose the RMM package as a new intervention for infants born preterm.

Study design

A parallel group, assessor-blinded, RCT will be conducted in order to compare the effects of RMM on preterm infants with the standard of care. Eligible patients from Rasoul Akram Hospital in Tehran, Iran, will participate in the study. A baseline assessment will be performed (for both the experimental and control groups) and a reassessment will be conducted one week after the completion of the RMM protocol.

Study sample

The study population will be recruited from infants born preterm admitted to the NICU at the Rasoul Akram Hospital, Tehran, Iran. The neonatology team will determine which infants are eligible based on pre-determined inclusion and exclusion criteria. Parents will be informed about the aims of the study and, if interested, will give written informed consent for their infant to participate.

A preterm infant who meets the following criteria will be included in this study:

Inclusion Criteria:

- Gestational age (GA) at birth ≤ 34 weeks.
- Can tolerate handling at postmenstrual age (PMA) 34 weeks
- Parents able to read and understand the Persian language.

Exclusion criteria:

- Preterm infants that need surgery during NICU hospitalization, hydrocephaly, Intraventricular hemorrhage (grade III or IV) and Periventricular Leukomalacia (PVL), retinopathy of prematurity grade III or more, dermatologic problem of skin, severe respiratory distress, congenital anomaly, repeated tachycardia or bradycardia, unstable infants.
- Mothers with positive HIV test or with physical or mental disorders.

Sample size calculations

A difference in motor performance on the Test of Infant Motor Performance (TIMP) between the experimental and the control groups of 0.5 SD is considered as clinically significant. The Confidence interval is 95% and the statistical power is 80%, and the probability of two ranges ($\alpha=0.05$) is estimated. The sample size was determined using previous similar studies (28). With a power of 80% and a significance level of 0.05, a sample of 28 infants in each group was required to detect a clinically applicable change of 5 in the TIMP raw score. Considering possible dropouts, 35 infants born preterm are calculated in each group.

The randomization processes

Simple consecutive random method will be used for assigning subjects. Randomization is performed by a web-based randomization system and a secretary not connected with the study will be responsible for the allocation sequence for concealment. These random sets will be sealed in numbered envelopes so that infants will be placed into one of two groups; an experimental group receiving Rhythmic Maternal Movements (RMM) in addition to routine interventions and a control group receiving only routine interventions.

Considering the nature of the intervention, twins will be randomly assigned to the same group. In order to prevent bias by knowing the group assignment, randomization will occur after the assessment of baseline motor performance (Figure 1).

The Blinding process

Families, therapists, and nurses will not be

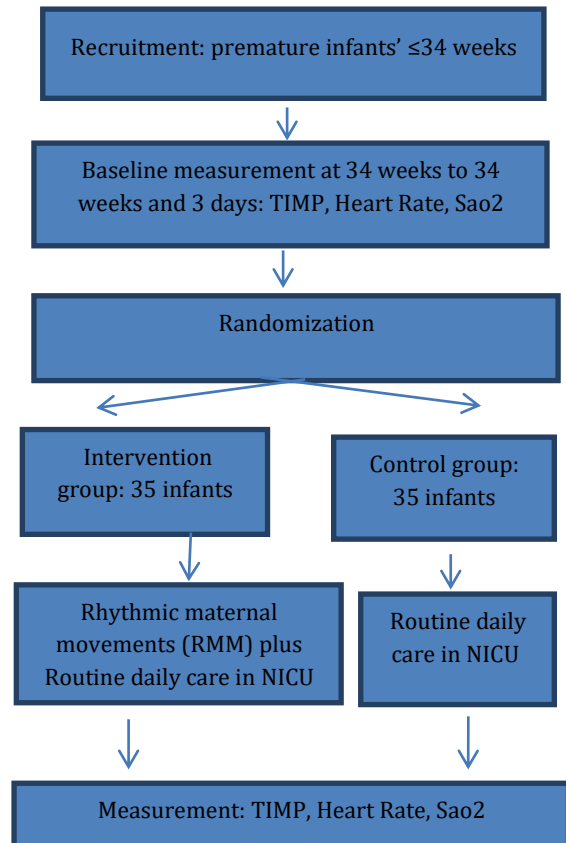


Figure 1. Flowchart of RCT

blinded to the allocation group during the course of the trial. Outcome measures will be administered, videotaped and scored by an assessor blinded to the group allocation.

Content of intervention

Rhythmic Maternal Movements (RMM)

Stimulation of the vestibular system of preterm infants by their mothers during hospitalization in the NICU is the main intervention to be studied. A neonatal occupational therapist with more than ten years' experience will train mothers in conducting the RMM package through theoretical and practical sessions. The Rhythmic Maternal Movements protocol is presented in Table.1. This protocol was piloted with 5 stable preterm infants and their mothers in the NICU. Mothers were eager to be involved in their infants' treatment and welcomed learning and performing the RMM protocol with their infants. All 5 infants became very calm and relaxed during and after the exercises and fell into a stable state. None showed signs of instability while performing or after the RMM.

Table 1. Rhythmic Maternal Movements

Type of movement	Times × Duration	Time	Each Distance	Speed	Rate
Left to Right (Rest)	10×6s 30s	60s	60cm	10cm/s	5 cycle/min
Anterior to posterior (Rest)	10×6s 30s	60s	60cm	10cm/s	5 cycle/min
Up- Down (Rest)	10×6s 30s	60s	30cm	5cm/s	5 cycle/min
Rotation Clockwise Counter clockwise (Rest)	6s (0-180° right) 6s (0-180° left) 30s	12s	180° 180°	30°/s	5 cycle/min
Rotation Clockwise Counter clockwise (Rest)	6s (0-180° right) 6s (0-180° left) 30s	12s	180° 180°	30°/s	5 cycle/min
Rotation Clockwise Counter clockwise (Rest)	6s (0-180° right) 6s (0-180° left) 30s	12s	180° 180°	30°/s	5 cycle/min

Therapy protocol

The duration of the intervention will be about 10 minutes done twice a day for a week (at most 14 times and at least 10). The intervention will be conducted between 20 and 30 minutes following a meal, when the infant is still awake.

It is important for the infant to remain stable during intervention. From 1 minute before to 1 minute after the intervention, the infants' heart rate, Sao₂ and states of arousal will be monitored and recorded by a neonatal occupational therapist with more than 10 years' experience. Whenever the infant exhibits any of the following signs of stress or discomfort, the intervention is to be terminated: facial grimaces, skin color changes, irregular respiration, changes in muscle tone, uncontrolled movements, continuous changes in arousal level or drop in heart rate and Sao₂.

A medical and nursing intervention as a routine program will be provided to both the experimental group and the control group while they are hospitalized, and the experimental group will be additionally receiving the RMM. The nurses and neonatologists will not be blinded to the group assignment, as it will be impossible to prevent them from observing the mothers providing the intervention protocol. Prior to initiating the study, the issue of refraining from applying the intervention to other babies in the NICU will be discussed.

Routine care in NICU

The term routine care refers to the current

treatment and care that are performed in NICUs in Iran according to a protocol outlined by the Iran Ministry of Health and Medical Education. Kangaroo Mother Care (KMC) is considered routine care in Iran and all eligible infants in both the experimental and the control groups will receive KMC once a day for 20 minutes.

Outcome measures

In addition to demographic data, information about the current medical status will be obtained from patient records and through interviews with parents.

At baseline, the motor performance of the infant will be assessed using the Test of Infant Motor Performance (TIMP), and performance will be reassessed after one week of intervention. The heart rate and Sao₂ of infants in the experimental group will be monitored and recorded before and after each intervention session, and in the control group, they will be recorded on the first and last day.

Primary outcome measure

The TIMP is used to identify age-appropriate or delayed motor development in infants as well as changes in motor development over time. The TIMP is designed to examine the infant's head control, postural control, stability, and alignment of parts of the body, as well as the infant's movement responses to visual and auditory stimuli. The TIMP is valid from the 34th week of PMA to the fifth month of CA (corrected age), and is comprised of 13 items for observation of

spontaneous movement and 29 items elicited by standardized positioning and handling(29). Previous studies have demonstrated that the TIMP is responsive to intervention in preterm and term infants through four months CA (30-32). Translation, cross cultural adaptation, and evaluation of reliability and validity of the Persian TIMP were performed by the research team (33).

Analysis

An intention-to-treat (ITT) analysis will be applied for data analysis and an IBM SPSS statistical 26 packages will be used. The comparability of the intervention and control groups will be evaluated at baseline. Prior to the data analysis, the pattern of missing data will be assessed. The results of all measures will be controlled for outliers and checked for normality. Throughout all analyses, the level of significance will be set at $p < 0.05$.

As appropriate, quantitative variables are denoted with a mean and standard deviation if they have a normal distribution or with a median and range if they do not. In qualitative data, variables will be presented as percentages and frequencies. A Paired t-test or Wilcoxon test will be used to evaluate inter group changes, and analysis of covariance (ANCOVA) will be used for between groups comparisons and in the case of qualitative variables, the Pearson chi square or Fisher exact test will be used.

Ethical approval

The study is approved by the clinical trial of IRAN: IRCT20200809048338N1 and has been given ethical approval by the Ethic Committee of University of Social Welfare and Rehabilitation sciences (USWR): IR.USWR.REC.1399.084.

Discussion

A disruption in pregnancy or even prolonged bed rest without RMM and pleasant vestibular stimulation may contribute to the high prevalence of impaired vestibular processing, motor delay, and neurodevelopmental delays in premature infants. In response, the purpose of this study is to assess the effects of the RMM protocol for preterm infants before they leave the NICU in order to enhance their motor development.

As a result of natural developmental processes, the vestibular system is the first sensory system to mature in humans. By the 21st week of pregnancy, development is complete and at the 25th week, the system can respond to intrauterine accelerations (34). In addition, the vestibular

nerve is the first cranial nerve to mature, and it is myelinated between the eighth and ninth months of pregnancy (35). Due to the fetus' floating position in the amniotic fluid, the vestibular system is continuously stimulated throughout the pregnancy (17). Each component of the vestibular system is most sensitive to a particular movement (linear or rotational) and stimulating each part of the system can facilitate the development of that component as well as the development of the system as a whole.

As a result of mothers' movements, full-term newborns have had stimulation of this system during their fetal period (19, 21). Preterm infants, on the other hand, are kept relatively motionless in an incubator with no suitable vestibular stimulation.

The aim of this study is to present the background and the design for a randomized controlled clinical trial to compare a new intervention, the rhythmic maternal movements (based on suitable vestibular stimulation), with the routine care for preterm infants at risk of neurodevelopmental disorders.

Various forms of vestibular stimulation have been used with preterm infants. These include; hammock, sinusoidal oscillation, waterbed, vertical or horizontal swinging, and rocking. These movements can be delivered manually or by using specialized devices. In contrast, the RMM protocol involves all components of the vestibular system as a package and doesn't involve any equipment or other staff time once the training is done.

Using the rigorous scientific design set by CONSORT guidelines, we will study the effects of RMM on motor development in a group of lower risk infants born preterm.

It is the goal of this research to evaluate the feasibility of the RMM protocol and determine its effect on the motor performance and vital signs of a group of infants without serious medical complications. Upon successful implementation, the RMM system may be adapted and applied in further studies involving infants who are at a higher risk for neurodevelopmental disorders. In the field of infant early intervention, the RMM program presents an innovative approach. We anticipate that the trial will allow clinicians to expand infant access to early intervention.

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Conflicts of interest

The authors declare that they have no competing interests.

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