

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Designing a Vestibular Stimulation Package for preterm infants admitted at Neonatal Intensive Care Unit (NICU) and the effects of its implementation on motor performance and behavior of premature infants admitted at the NICU: A Single Blind Randomized Clinical Trial (RCT).

Protocol summary

Study aim

The effect of Vestibular Stimulations on motor performance and behavior of premature infants

Design

A clinical trial with a control group, one-sided blind, randomized, on 70 premature infants that using a simple consecutive random method by opening the sealed envelopes.

Settings and conduct

This research will be performed in Hazrate Rasool Akram Hospital. After filling in the demographic information questionnaire and reviewing the inclusion and exclusion criteria, the infants who meet the inclusion criteria will be selected and the informed consent form will be filled in by the infant's parents. Infants who enter the study are evaluated by an blind assessor and then they are randomly assigned to the intervention or control group. After the intervention period, the secondary evaluation will be performed again by the same evaluator.

Participants/Inclusion and exclusion criteria

Infants with a gestational age of 34 weeks or less who are in the normal range at birth and at 34 weeks of gestation age are stable in vital and physiological symptoms and have no specific underlying diseases can be included in the study.

Intervention groups

The control group benefits from routine services of the neonatal ward. The intervention group, in addition to having routine interventions in the neonatal ward, uses a designed package of vestibular stimuli. This package has been written by a group of experts in this field and is applicable and approved for premature infants.

Main outcome variables

Behavior and Motor Performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200809048338N1**

Registration date: **2021-08-15, 1400/05/24**

Registration timing: **prospective**

Last update: **2021-08-15, 1400/05/24**

Update count: **0**

Registration date

2021-08-15, 1400/05/24

Registrant information

Name

Aida Ravarian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	intervene in the intervention and control groups will be done.
Scientific title	Placebo
Designing a Vestibular Stimulation Package for preterm infants admitted at Neonatal Intensive Care Unit (NICU) and the effects of its implementation on motor performance and behavior of premature infants admitted at the NICU: A Single Blind Randomized Clinical Trial (RCT).	Not used
Public title	Assignment
Effect of Vestibular Stimulation on motor performance and behavior of premature infants admitted at the Neonatal Intensive Care Unit.	Parallel
Purpose	Other design features
Supportive	
Inclusion/Exclusion criteria	Secondary Ids
Inclusion criteria:	empty
Parents' desire for their infants to participate in the study. Fetal age is 34 weeks of gestation or less. Living in Tehran province.	Ethics committees
Exclusion criteria:	1
Neonates who need surgery during hospitalization. Neonates with hydrocephalus. Neonates with moderate to severe brain damage, such as grade III to IV interventricular hemorrhage. Neonates with grade III or higher premature retinopathy. Neonates with untouchable skin. Neonates with severe respiratory problems (require FiO2 above 75%). Neonates with severe congenital anomalies. Neonates with tachycardia (rapid heartbeat) and bradycardia (slow heartbeat). Neonates who look unstable. Multiple pregnancy. Existence of physical and psychological illness of the mother that has created a disability for the mother. Mother with a history of HIV. Existence of symptoms of infant syndrome.	Ethics committee
Age	Name of ethics committee
From 3 days old	Ethics committee of University of Social Welfare and Rehabilitation Sciences
Gender	Street address
Both	Kodakyar Ave., Daneshjo Blvd., Evin
Phase	City
N/A	Tehran
Groups that have been masked	Province
• Outcome assessor	Tehran
Sample size	Postal code
Target sample size: 70	1985713834
Randomization (investigator's opinion)	Approval date
Randomized	2020-10-25, 1399/08/04
Randomization description	Ethics committee reference number
Simple consecutive random method will be used for sampling. The allocation sequence for concealment will be done by a non-research person (secretary) so that using a sealed envelope, infants will be placed in two groups receiving vestibular stimuli in addition to routine interventions and a group of routine interventions.	IR.USWR.REC.1399.084
Blinding (investigator's opinion)	Health conditions studied
Single blinded	1
Blinding description	Description of health condition studied
In this study, the initial evaluation of motor performance and behavior of the infant as well as the final evaluation by the evaluator unaware of the process and how to	preterm infants
	ICD-10 code
	ICD-10 code description
	Primary outcomes
	1
	Description
	Motor performance
	Timepoint
	At the beginning of the study (before the start of the study) and one week after the start of the intervention.
	Method of measurement
	How to measure motor performance is the Test of Infant Motor performance.
	2
	Description
	Behavior
	Timepoint
	At the beginning of the study (before the start of the study) and one week after the start of the intervention.

Method of measurement

How to measure the neonate's behavior will be through the Nidcap test.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Stimulations of the vestibular system in the form of Lateral movements, Anterior_Posterior movements, Up_Down movements and Rotational motions. Lateral movements (at a distance equivalent to one step of the mother to the sides about 30-35 cm) are right_left and left_right movements with a speed of 12-14 cycles / minute and then 30 seconds rest.

Anterior_posterior movements (at a distance equal to one step forward about 30-35 cm) and with a speed of 12-14 cycles / minute then 30 seconds rest. Up-down movements (distance equal to 10-15 cm) and at a speed of 12-14 cycles / minute and then 30 seconds rest.

Rotational motions are 2 clockwise and counterclockwise movements up to 180 degree in a row for 30 seconds (this step is repeated up to 3 times in a row) at a speed of 10 cycles / minute, i.e. 6 movements in 1 minute and Twice they will rest for 30 seconds between interventions.

Category

Rehabilitation

2

Description

Control group: Routine interventions in the Neonatal Intensive Care Unit.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasool Akram Medical Hospital

Full name of responsible person

Aida Ravarian

Street address

Hazrate Rasool Akram Hospital, Niayesh St.,
Satarkhan Av., Tehran, 1449614535, IRAN.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr. Fariba Yadeghari

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Web page address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Aida Ravarian

Position

Phd Student

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

For further researches

From where data/document is obtainable

call 00989122633687

What processes are involved for a request to access data/document

about one week.

Comments