

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of one period of tactile kinetic stimulations of preterm neonates on state anxiety of their mothers

Protocol summary

Summary

Objectives: Mothers of preterm neonates in comparison with mothers of neonates born at term, faced with further stress and anxiety. The aim of this study was to investigate the effect of 10 days tactile kinetic stimulations by mothers of preterm neonates on maternal state anxiety. Design: For this purpose, among neonates of Amiralmomenin hospital neonatal unit of Semnan city, 40 mother and their preterm neonates selected purposefully and randomly divided into two experimental and control groups. Setting and conduct: mothers of experimental group conducted tactile kinetic stimulations on neonates while the control group neonates received only usual care. Spielberger Inventory was used to measure maternal anxiety. Before intervention and after 10 days of intervention, questionnaire was completed by mothers and then obtained data were compared together. Participants: neonates with gestational age 32-37 weeks and Apgar score above 7 were selected. Intervention: mothers of experimental group were trained to conducted tactile kinetic stimulations on neonates for 10 days, three times a day and each time for 20 minutes. main outcome measures: tactile kinetic stimulation reduced the anxiety of mothers with infants preterm.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012918945N3**

Registration date: **2016-02-24, 1394/12/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-24, 1394/12/05

Registrant information

Name

Mansoureh Mokaberian

Name of organization / entity

Shahrood University of Technology

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Semnan University of Medical Sciences

Expected recruitment start date

2014-12-01, 1393/09/10

Expected recruitment end date

2014-12-31, 1393/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of one period of tactile kinetic stimulations of preterm neonates on state anxiety of their mothers

Public title

The effect of massage of preterm neonates on anxiety of mothers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a Persian race; not admitted to

neonatal intensive care unit during the investigation; the mother with the baby in the neonatal ward; there was no history of genetic disease; psychiatric and addiction in the mother; aged between 20 and 35 years of mother; gestational age 32- 37 weeks and Apgar score in first and fifth minutes later than 7 children. Exclusion criteria: the need for medical interventions on children; the incidence of symptoms of skin disease and infectious disease in neonates; unstable and irregular heartbeat; do not touch techniques work for at least two consecutive times and unwillingness to continue cooperation

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization was done by simple random sampling

Secondary Ids

1

Registry name

Amiralmomenin Hospital of Semnan

Secondary trial Id

2889

Registration date

1393-09-11, 773/01/-190

2

Registry name

Amiralmomenin Hospital of Semnan

Secondary trial Id

2889

Registration date

1393-09-11, 773/01/-190

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical

Sciences

Street address

Semnan, Basij Blvd

City

Semnan

Postal code

Approval date

2014-12-02, 1393/09/11

Ethics committee reference number

2889

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

state anxiety

Timepoint

. Before intervention and after 10 days of intervention

Method of measurement

Spielberger Inventory

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

intervention group: phase 1& 3: Tactile stimulation phase 2: kinetic stimulation

Category

Treatment - Other

2

Description

Control group: Receiving usual care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital of Semnan

Full name of responsible person

Mansoureh Mokaberian

Street address

Semnan, MostafaKhomeini Blvd

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Semnan University of
Medical Sciences

Full name of responsible person

dr. Rashidipoor

Street address

Semnan.Basij Blvd

City

Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Semnan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Tehran University

Full name of responsible person

Mansoureh Mokaberian

Position

phd of physical education

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty