Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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+98 23 3345 5399

Email address

mokaberian@ut.ac.ir

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
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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