Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of performing multisensory intervention (ATVV) by mother on self-esteem and mental health of mothers of preterm infants

Protocol summary

Study aim
the effect of multisensory intervention (ATVV) on self-esteem and mental health of mothers of preterm infants.

Design
Study of a clinical trial, non-random allocation with two intervention and control groups, on 60 premature infants

Settings and conduct
In Imam Reza (AS) and Ghaem Mashhad hospitals, in the control group of routine care and in the intervention group, multisensory stimulation was performed and evaluation of maternal mental health and self-esteem in mothers with demographic information questionnaire and Rosenberg self-esteem scale and Glanderberg general health. From the beginning of the intervention, after the intervention, one month later in both intervention and test groups.

Participants/Inclusion and exclusion criteria
Infant admission: 28-32 weeks of age with Apgar score above 7 and no need for resuscitation and no major congenital anomalies and intracerebral hemorrhage and with stable clinical condition Maternal admission: Satisfaction with the study, no mental disorders and drug age Has a history of serious family disputes and is able to be present with the baby.

Intervention groups
In the ATVV (auditory-tactile-visual-vestibular) multisensory intervention group includes: auditory, tactile, visual and atrial stimulation, which is tactile stimulation by the mother after preparing the baby and warming her hands on five areas of the baby's body for 5 minutes. Minutes and to stimulate vision from the mother's direct gaze to the baby and to stimulate hearing the mother's voice is used as a lullaby or the mother speaks directly to the baby

Main outcome variables
Evaluation of mental health and self-esteem in mothers of premature infants

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210127050152N1**
Registration date: **2021-02-15, 1399/11/27**
Registration timing: **prospective**

Last update: **2021-02-15, 1399/11/27**
Update count: **0**

Registration date
2021-02-15, 1399/11/27

Registrant information

Name
Azam Neyestani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 58 3232 1049

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neyestania911@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of performing multisensory intervention (ATVV) by mother on self-esteem and mental health of mothers of preterm infants

Public title
The effect of multisensory intervention (ATVV) on self-esteem and mental health of mothers of preterm infants

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
1- The age of the baby should be in the range of 28-32 weeks based on the gestational age. 2 - Infants do not have congenital malformations (congenital heart disease, gastrointestinal and neurological defects, etc.) 3. Infants do not need invasive mechanical ventilation (except receiving oxygen with a cannula). 4. No intracerebroventricular hemorrhage (grade 3 and 4) Stable clinical condition (pink baby color, body temperature 37-36 degrees, oxygen saturation above 90%) No need for advanced resuscitation during hospitalization 7. Infants with a fifth minute apkard above 7 The mother has the consent to participate in the study. The mother does not have known mental disorders such as bipolar disorder and severe depression. According to the mother herself, she should not use drugs. According to the mother, there should be no serious differences in the family. The mother should be able to be with the baby.

Exclusion criteria:
Congenital heart disease, gastrointestinal and neurological defects in the infant The baby needs mechanical ventilation and resuscitation Existence of cerebral hemorrhage in the infant Unstable clinical condition Maternal dissatisfaction with participation in the study Existence of addiction and history of mental disorders in the mother

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Ethics Committee of Mashhad University of Medical Sciences , fakori blvd , mashhad town

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2021-01-26, 1399/11/07

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.082

Health conditions studied

1

Description of health condition studied
Conditions arising in the perinatal period|birth|premature (infant)

ICD-10 code
P07.39

ICD-10 code description
Preterm newborn, gestational age 36 completed weeks

Primary outcomes

1

Description
Self-esteem of mothers with premature babies

Timepoint
Before and after the intervention and one month later

Method of measurement
Self-esteem by Rosenberg Self-Esteem Questionnaire

Secondary outcomes

1

Description
Mental health of mothers with premature babies

Timepoint
Before and after the intervention and one month later

Method of measurement
Glanderberg General Health Questionnaire

Intervention groups

1

Description

Intervention group:During the training courses, the researcher learns multisensory stimulation in order to be able to give the necessary training to the mother. The accuracy of the mother's multisensory stimulation in one session is confirmed by the researcher. Multisensory stimulation is performed by the mother for 30 minutes before feeding and twice daily for 5 days. After that, it is recommended to repeat it for up to a month. A weekly follow-up is done to continue the intervention.

Category

Treatment - Other

2

Description

Control group: Routine care (hug care) is performed

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital Mashhad

Full name of responsible person

Hamid Reza Behnam Vashani

Street address

Mashhad, Koohsangi St., Ghaem Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Behnam Vashani

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Khorasan Razavi, Mashhad, University Street - next to Hoveyzeh Cinema - Ghorashi Building - Research Deputy and

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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

Vice Chancellor for Research, Mashhad University of Medical 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

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Behnam Vashani

Position

Faculty of Nursing, Mashhad University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Instructor and faculty member of the School of Nursing, Mashhad University of Medical Sciences

Latest degree
Master
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available