

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 apgar 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

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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

Mashhad University of Medical Sciences

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

Other areas of specialty/work

Nursery

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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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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