

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Investigating the effect of rocking the newborn horizontally on the attachment behaviors of mothers with premature newborn hospitalized in the neonatal intensive care unit (NICU)

#### Protocol summary

##### Study aim

The effect of rocking the newborn horizontally on the attachment behaviors of mothers with premature newborn hospitalized in the NICU .

##### Design

A non-randomized clinical trial with control and intervention groups on 72 mothers with premature newborn

##### Settings and conduct

Location : the NICU of Shiraz Hafez Hospital ,The questionnaire related to the demographic information of mother and baby is completed by the researcher as well as the Avant attachment checklist . The intervention is done after the second day of the baby's birth. The intervention consists of rocking a calm and alert baby horizontally, half an hour before feeding, for 12 minutes a day (four times and three minutes each time) and five times a week. The correct method of intervention is taught to the mother by the researcher in a practical way. The babies of mothers in control group only receive routine care including: cardio-respiratory monitoring, oxygen therapy, infant feeding, infant positioning, fluid therapy , phototherapy .After two weeks, the mothers of both groups complete the questionnaires again and are compared with before the intervention

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Mothers with a baby with a fetal age of 33-36 weeks, no need for mechanical ventilation , no chronic maternal disease and possession of the ability for skin, eye or voice contact with the baby : Exclusion criteria : baby care by family members other than the mother

##### Intervention groups

In order to prevent the exchange of information, at first all mothers who meet the entry criteria will be selected as the control group. After the discharge of the control group, sampling of the intervention group will begin. The

control group receives only routine care. The intervention group performs horizontal rocking of the baby , In addition to routine care

##### Main outcome variables

Attachment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230312057699N1**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

##### Registration date

2023-05-13, 1402/02/23

##### Registrant information

##### Name

Zahra Nikbakhti

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3832 2868

##### Email address

z.nikbakhti@stu.ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-15, 1402/02/25

##### Expected recruitment end date

2023-10-12, 1402/07/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of rocking the newborn horizontally on the attachment behaviors of mothers with premature newborn hospitalized in the neonatal intensive care unit (NICU)

**Public title**

Investigating the effect of rocking the newborn on the attachment behaviors of mothers with premature newborn

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Mothers with babies with a fetal age of 33-36 weeks  
Hemodynamic stability No need for mechanical ventilation Absence of congenital malformations Not having a chronic illness of the mother and having skin, eye or voice contact with the newborn

**Exclusion criteria:**

Taking care of the baby by other family members other than the mother

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 72

**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 Yazd University of Medical

Sciences

**Street address**

Islamic Azad university Complex ,Shohadaye Gornam Blvd , Alem Square , Safaeiye

**City**

Yazd

**Province**

Yazd

**Postal code**

8915813135

**Approval date**

2023-04-19, 1402/01/30

**Ethics committee reference number**

IR.SSU.REC.1402.002

**Health conditions studied****1****Description of health condition studied**

Caring for a premature baby

**ICD-10 code**

Z76.3

**ICD-10 code description**

Healthy person accompanying sick person

**Primary outcomes****1****Description**

Attachment

**Timepoint**

Measurement of attachment before the start of the intervention (first stage) and after two weeks have passed since the start of the intervention

**Method of measurement**

Avant Attachment Checklist

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The intervention consists of rocking a calm and alert baby horizontally, half an hour before feeding, for 12 minutes a day (four times and three minutes each time) and five times a week for two weeks. The baby is hugged by the mother and gently rocked horizontally. During the non-stop horizontal rocking, every 10 seconds the baby is checked for signs of stress and if even one of the signs of stress is observed, the intervention is stopped for 15 seconds and after that, the intervention starts again. In case of repeated stress symptoms three times in a row, the intervention will be stopped in that period of time

**Category**

Other

## 2

### Description

Control group: Babies receive only routine care

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hafez Hospital

##### Full name of responsible person

Zahra Nikbakhti

##### Street address

Chamran Ave

##### City

Shiraz

##### Province

Fars

##### Postal code

71946-34786

##### Phone

+98 71 3647 9531

##### Email

nikbakht5253@gmail.com

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Amin Salehi Abarghuei

##### Street address

Shahid Doctor Bahonar Square

##### City

Yazd

##### Province

Yazd

##### Postal code

8916978477

##### Phone

+98 35 3724 0171

##### Email

samat@ssu.ac.ir

##### Grant name

##### Grant code / Reference number

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

No

##### Title of funding source

Yazd 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

Yazd University of Medical Sciences

##### Full name of responsible person

Zahra Nikbakhti

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Anesthesiology

##### Street address

No.172 , Building Radvin., 16 Alley., North Safir Blvd., Shiraz Town

##### City

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##### Province

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7176613622

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Zahra Pourmovahed

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

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12 Ave., Jihad Blvd., Safaeiye

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Zahra Nikbakhti

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

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**Province**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be 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