

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### “Designing a Neurodevelopmental care Interventional package of Preterm infants in NICU (from birth to 1 month corrected age) for parents and determining its effectiveness on developmental outcomes in infancy”

#### Protocol summary

##### Study aim

Prematurity is one of the major causes of developmental delay, and parent education and intervention can be effective in reducing the developmental delay of these infants at a time. This study aimed to design a neuro-evolving interventional package for the preterm infants for parents in Iran. Design And its effectiveness in assessing the evolutionary outcomes of the childhood period. This study is a randomized cluster randomized clinical trial, initially based on the review of available resources, the content of the intervention packet will be based on evidence. Finally, the strategies for implementation and implementation of the package will be identified with the views of the experts and the parents. In the second stage, the effectiveness of the "interventional package of neuro-neurological-neonatal care for the parents of the premature newborns will be investigated on evolutionary implications in infancy. Entry into a study in which their babies are admitted to the NICU. Subsequently, interventional interventions for the parents of the intervention group during the hospitalization period will be implemented in the hospital, and will be closed to the same observation group with the same number of pages with the design It will be similar to the original package that includes the routine tutorial package After that, at the end of one month of modulation, using the Bailey (III) test, then the modified results will be evaluated with the age and procedure questionnaire (ASQ)

##### Design

Community-based

##### Settings and conduct

Millad Hospital Rasol Akram Hospital Ali Askhar Hospital

##### Participants/Inclusion and exclusion criteria

Preterm infants in NICU

##### Intervention groups

Preterm infants in NICU

##### Main outcome variables

Designing a Neurodevelopmental care Interventional package for Preterm infants Short-term outcomes after extreme preterm birth Developmental Outcome of Premature Infants

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180125038502N1**  
Registration date: **2018-01-30, 1396/11/10**  
Registration timing: **prospective**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

##### Registration date

2018-01-30, 1396/11/10

##### Registrant information

##### Name

Fatemeh Fallah Rostami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 0099

##### Email address

fat.rostami@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-06, 1396/12/15

##### Expected recruitment end date

2018-08-06, 1397/05/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

“Designing a Neurodevelopmental care Interventional package of Preterm infants in NICU (from birth to 1 month corrected age) for parents and determining its effectiveness on developmental outcomes in infancy”

**Public title**

“Designing a Neurodevelopmental care Interventional package of Preterm infants in NICU (from birth to 1 month corrected age) for parents and determining its effectiveness on developmental outcomes in infancy”

**Purpose**

Supportive

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

Preterm infants in NICU

**Exclusion criteria:****Age**

From **196 days** old to **238 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **32**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Mothers and evaluators of the outcomes and analysis of data about the grouping of samples will be blind . To avoid contamination of information, time and space blocks are used.

**Placebo**

Used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of University of Social Welfare and Rehabilitation Sciences

**Street address**

University of Social Welfare and Rehabilitation Sciences.Kodakyar St.Velenjak Blvd.Tehran.Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۵۷۱۳۸۳۴

**Approval date**

2017-11-06, 1396/08/15

**Ethics committee reference number**

IR.USWR.REC.1396.252

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

Designing a Neurodevelopmental care Interventional package

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Designing a Neurodevelopmental care Interventional package of Preterm infants

**Timepoint**

Before the intervention begins

**Method of measurement**

Content validity ratio and content validity index

**2****Description**

Developmental Outcome of Premature Infants

**Timepoint**

in the 4 month and 6 month

**Method of measurement**

Ages and stages questionnaire

**Secondary outcomes**

empty

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

Intervention group: The status of newborns at the beginning of the study was determined by using

variables: gender, type of delivery, type of pregnancy, occupation and parental education, place of residence, history of failure in the family, number of variables, head circumference, height of the baby during birth, breast size at birth, The Apgar score of minutes 1 and 5, gestational age, and maternal age will be assessed. For pre-test, Ballard's new test is used in two groups. Then, an intervention pack will be implemented for the intervention group's parents during the hospitalization periods phone number for contacting a researcher will also be provided to parents to contact you if needed. Supervising the implementation of the evolutionary care package will be done by the researcher and guidance in the neonatal intensive care unit. Afterwards, in 4 and 6 months, the consequences will be evaluated with the ASQ tool.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Milad Hospital

##### Full name of responsible person

Fatemeh fallah rostami

##### Street address

Millad tower,Haki, highway,Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614531

##### Phone

+98 21 84090

##### Email

fallah.rostami@yahoo.com

##### Web page address

<http://www.miladhospital.com>

### 2

#### Recruitment center

##### Name of recruitment center

Rasoul Akram Hospital

##### Full name of responsible person

Fatemeh Fallah Rostami

##### Street address

Tehran,Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6655 8811

##### Email

fallah.rostami@yahoo.com

### 3

#### Recruitment center

##### Name of recruitment center

Ali Asghar Children's Hospital

##### Full name of responsible person

Fatemeh Fallah Rostami

##### Street address

Zafar St,Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۵۶۱۳۶۴۳۱۹۷

##### Phone

+98 21 2222 2041

##### Email

fallah.rostami@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of social welfare and rehabilitation sciences

##### Full name of responsible person

Fatemeh Fallah Rostami

##### Street address

University of Social Welfare and Rehabilitation Sciences.Kodakyar St.Velenjak Blvd.Tehran.Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713834

##### Phone

+98 21 2218 0099

##### Email

fallah.rostami@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Fatemeh Fallah Rostami

**Position**

Candidate PHD student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

**Street address**

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Fatemeh Fallah Rostami

**Position**

Candidate PhD Student

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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## Person responsible for updating data

### Contact

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University of social welfare and rehabilitation sciences

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Fatemeh Fallah Rostami

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**Latest degree**

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**Email**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Yes

**When the data will become available and for how long**

Yes

**To whom data/document is available**

Yes

**Under which criteria data/document could be used**

Yes

**From where data/document is obtainable**

Yes

**What processes are involved for a request to access data/document**

Yes

**Comments**

Yes