

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Assessment of the Effect of Educational Intervention with a Smart Phone Mobile Application on the Neurodevelopmental Status of Infants admitted in NICU of Vali-E-Asr Hospital

Protocol summary

Study aim

Determining the effect of an educational intervention with a mobile phone application on the neurodevelopmental status of infants with a history of hospitalization in the NICU

Design

A randomized controlled trial, parallel design, not blinded with, 140 people (two groups of 70 people), divided by random numbers table. Phasing is not applicable.

Settings and conduct

Infants born in Vali-E-Asr Hospital with a history of hospitalization in the NICU are randomly divided into two groups, and the parents/caregivers of one of them will receive an educational intervention with the upcoming mobile application, in addition to routine training. Comparison of 2 groups in terms of developmental status will be done with ASQ test and Baley tool in the first 6 months of life.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All vulnerable children with a history of NICU hospitalization and outpatient admission at the Development Clinic Exclusion criteria: unwillingness of parents/caregivers to cooperate

Intervention groups

Children with a history of hospitalization in the NICU were randomly divided into two groups, and educational intervention with a mobile phone application was given to the parents/caregivers of one of the two groups, in addition to the routine trainings of the Evolution Clinic, from before the end of the neonatal period (28 days) until the end of 6 months. Routine training includes massaging the infant and targeted games with him, which is based on the UNICEF protocol (Care for Child Development), and is taught to the caregivers by a growth and development specialist. Educational intervention also includes sensory-motor, social-emotional and cognitive games appropriate to the child's

age and periodic evaluation of these skills.

Main outcome variables

Children's neurodevelopmental disorder; The level of satisfaction of parents

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190416043290N3**

Registration date: **2023-08-04, 1402/05/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-04, 1402/05/13**

Update count: **0**

Registration date

2023-08-04, 1402/05/13

Registrant information

Name

Raheleh Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6659 1316

Email address

raheleh.moradi1987@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the Effect of Educational Intervention with a Smart Phone Mobile Application on the Neurodevelopmental Status of Infants admitted in NICU of Vali-E-Asr Hospital

Public title
The effect of educational program of mobile phone on infant development

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
All vulnerable infants= <2 months old with a history of NICU admission and outpatient admission at the development clinic
Exclusion criteria:
Infants diagnosed with late neurodevelopmental disorders.

Age
To **2 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the order of first visit/admission in developmental clinic, the participants include in random chain and simple randomization is carried out by using a table of random numbers - a large collection of numbers that are generated completely randomly without a specific pattern or order. First, we determine the direction of reading the numbers in the table (for example, up, down, left or right); Then even numbers are assigned to the intervention group and odd numbers to the control group.

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 Tehran University of Medical Sciences

Street address

Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2023-06-20, 1402/03/30

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.112

Health conditions studied

1

Description of health condition studied

childhood neurodevelopmental status

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The child's neurodevelopment score in language, cognitive, motor, communication and problem solving areas

Timepoint

0 (before intervention), 4, and 6 months

Method of measurement

by ASQ questionnaire and Baley test

Secondary outcomes

1

Description

child's neurodevelopmental disorder

Timepoint

0 (before intervention), 4, and 6 months

Method of measurement

Prescribing early occupational therapy (before 6 months) and the result of an abnormal Baley test

Intervention groups

1

Description

Intervention group: educational intervention with a

mobile phone application (Ati) in parents/caregivers, in addition to the routine training of the evolution clinic, will take place from before the end of the newborn period (28 days) until the end of 6 months. The educational intervention includes sensory-motor, social-emotional and cognitive games appropriate to the child's age.

Category

Behavior

2

Description

Control group: Routine training includes infant massage and targeted games, which are based on the UNICEF (Care for Child Development) protocol and the publications of the Department of Infant Health, and are taught to caregivers by a growth and development specialist.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Raheleh Moradi

Street address

Imam Khomeini Hospital Complex, Gharib Ave.,
Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6659 1316

Email

raheleh.moradi1987@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Central Organization of the University, Quds St.,
Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3698

Email

raheleh.moradi1987@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Raheleh Moradi

Position

Midwife-Rsearcher

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

Imam Khomeini Hospital Complex, Keshavarz
Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6659 1316

Email

raheleh.moradi1987@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mamak Shariat

Position

Full Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pediatrics

Street address

Imam Khomeini Hospital Complex, Gharib Ave.,
Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6659 1316

Email

raheleh.moradi1987@gmail.com

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

Tehran University of Medical Sciences

Full name of responsible person

Raheleh Moradi

Position

Midwife-Researcher

Latest degree

Master

Other areas of specialty/work

Reproductive Health

Street address

Imam Khomeini Hospital Complex, Gharib Ave.,

Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

0098 66591316

Email

raheleh.moradi1987@gmail.com

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available