

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

the effect of early interventions with telemedicine on the development of premature babies and the self-efficacy of their parents in the corona pandemic

Protocol summary

Study aim

Determining the impact of timely interventions through distance education on the development process of premature babies and their parents' self-efficacy
Community Verified icon

Design

The clinical trial has two control and intervention groups, double-blind, randomized and is conducted on 32 patients.

Settings and conduct

Available samples from newborns admitted to the NICU department of Imam Hossein and Mahdiah Hospital in Tehran

Participants/Inclusion and exclusion criteria

Birth at 30 to 36 weeks of pregnancy 2- Baby weighing more than 1500 gr 3- Parents' ability to read and write and master Persian language 4- Having a smart mobile phone and relative familiarity with virtual systems and social networks
Community Verified icon

Intervention groups

30 to 37 weeks premature babies hospitalized in the nicu department of Imam Hossein and Mahdiah Hospital in Tehran

Main outcome variables

Parental self-efficacy, newborn development, questionnaire for measuring knowledge-attitude-performance of mothers of premature babies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220725055554N1**
Registration date: **2022-12-27, 1401/10/06**
Registration timing: **prospective**

Last update: **2022-12-27, 1401/10/06**

Update count: **0**

Registration date

2022-12-27, 1401/10/06

Registrant information

Name

zahra amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8824 3160

Email address

zahra.mini75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-06, 1401/10/16

Expected recruitment end date

2023-04-18, 1402/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of early interventions with telemedicine on the development of premature babies and the self-efficacy of their parents in the corona pandemic

Public title

tele-education on premature's parents

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

1-birthday 30 to 36 weeks of pregnancy 2- Baby weighing more than 1500 gr 3- Parents' ability to read and write and master Persian language 4-Having a smart mobile phone and relative familiarity with virtual systems and social networks

Exclusion criteria:

-Severe brain damage or congenital anomalies according to the medical record 2- Baby feet 3- Hospitalization in NICU for less than a week or more than a month 4-Apgar score lower than 7 5- IVH grade 3 or 4 6- Babies without a guardian or a single parent 7-Severe malaise of mother and baby 8-Addicted or alcoholic parents

Age

From **210 days** old to **259 days** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation to two intervention and control groups is done in a simple random manner and in the form of alternating stratified blocks. That is, 4 samples with similar demographic information written in English letters and all possible permutations for placement Community Verified icon In the intervention or control group, it is written on separate pieces of paper, then a permutation is selected from among the papers randomly and by lottery. The first 2 samples will be in the intervention group and the next two samples will be in the control group. According to the week of birth, the samples are matched in two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Bailey's face-to-face test will be conducted by a foreign trainer without knowledge of the treatment groups. The participants were unaware of the purpose of the study and allocation to the groups. The data analyst will be a statistical consultant.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice President of Research and Technology Shahid Beheshti University of Medical Sciences

Street address

gisha

City

tehran

Province

Tehran

Postal code

1651139969

Approval date

2022-12-03, 1401/09/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.569

Health conditions studied

1

Description of health condition studied

prematurity

ICD-10 code

I49.4

ICD-10 code description

Other and unspecified premature depolarization

Primary outcomes

1

Description

Parental self-efficacy

Timepoint

At the beginning of the study and 3 months after that

Method of measurement

PMPSE (perceived maternal parenting self-efficacy)

2

Description

Baby development

Timepoint

At the beginning of the study and 3 months after that

Method of measurement

bayley and ASQ (age and stages questionnaire)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 3 months of free distance Includes videos, photos, videos and educational images prepared based on the MITP (mother infant

transaction) program and hug care training.education on how to care for and develop premature babies.3 months and 6 training sessions will be held every other week.

Category

Rehabilitation

2

Description

Control group: The control group is a group that does not receive training during 3 months and only benefits from the routine interventions of the hospital. It only completes the primary and secondary questionnaires.Community Verified icon

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Zahra Amini

Street address

Madani

City

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Province

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1617763141

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Email

info@ehmc.ir

2

Recruitment center

Name of recruitment center

Mahdijeh Hospital

Full name of responsible person

Zahra Amini

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Shisheh Gar

City

Tehran

Province

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Postal code

1185817311

Phone

+98 21 5506 2628

Email

mahdijeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Sadigheh Naiemi

Street address

Gisha

City

Tehran

Province

Tehran

Postal code

1651139969

Phone

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Fax

Email

zahra.mini75@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

1

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Amini

Position

Occupational Therapist

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Amini

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

It is published at the discretion of the respective professors

When the data will become available and for how long

6 months later

To whom data/document is available

Students

Under which criteria data/document could be used

From where data/document is obtainable

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

Comments