

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Impact of empowerment program on participation and attachment of parents with premature infants admitted to neonatal intensive care unit of Sayyad Shirazi Hospital in Gorgan in 1397

Protocol summary

Study aim

Impact of Breast Immunization Program on Premature Infant

Design

The experimental group was a premature infant, admitted in the intensive care unit of Sayyad Shirazi Hospital. The nurses are randomly selected and the intervention and control groups are divided by coin throwing. The total number is 50. The trial is a type of clinical trial.

Settings and conduct

The place of intervention of the intensive care unit of Sayyad Shirazi Hospital in Gorgan is done by clinical trial. The samples are divided into test and control groups. First, pre test intervention is taken. On the fourth day of admission to the intervention group, the first stage of self-remittance is implemented. Four days later, the implementation of the first stage, the second stage of implementation, is taken in the field of participation in the pre-test. Two days prior to discharge, the test pre-test is also done for attachment.

Participants/Inclusion and exclusion criteria

Reading and writing literacy and aged 18+. It is directly responsible for the care of the patient. Parents do not have physical and mental disabilities. Premature infants with a baby's age have no problem and no malformations. 26 to 34 weeks and birth weight less than 2500 grams. If they do not want to continue their collaboration, they will be excluded from the study. Two absentee sessions eliminate parents from studying.

Intervention groups

The intervention is carried out in an empowering program and providing information on premature infants in order to increase participation and attachment and increase compliance with the critical situation in the intervention and control group.

Main outcome variables

Parental compatibility with existing conditions
Parent company in baby care
An attachment to the premature baby was born
Take advantage of your potential abilities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170512033932N6**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

Registration date

2019-01-06, 1397/10/16

Registrant information

Name

Hosein Motahariniya

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3222 4908

Email address

h_hojjati@aliabadiu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-02, 1397/07/10

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of empowerment program on participation and attachment of parents with premature infants admitted to neonatal intensive care unit of Sayyad Shirazi Hospital in Gorgan in 1397

Public title

An Empowerment Program on Parents with Preterm Infants

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Get informed consent from the company in this study.. Reading and writing materials are over 18 years old . It is the direct responsibility of caring for the patient. Waldin is not physically and mentally handicapped Premature infants admitted at age 26 to 34 weeks and birth weight less than 2500 grams.

Exclusion criteria:

If they do not want to continue their collaboration, they will be excluded from the study Two absentee sessions eliminate parents from studying

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization is done with sealed envelope tools in such a way that the envelopes are written in letters A and B, and the mothers are asked to select an envelope that the group A of the intervention group and the B group will be tested.

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 Golestan University of Medical Sciences

Street address

Gorgan, Golshahr Square, Golshahr 32, Gorgan

City

Gorgon

Province

Golestan

Postal code

1234

Approval date

2018-08-27, 1397/06/05

Ethics committee reference number

IR.GOUMS.REC.1397.092

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

In this study, the effect of parents empowerment on their participation in care and their attachment level is studied

ICD-10 code

ICD-10 Cha

ICD-10 code description

عوامل مؤثر بر سلامت و تماس با خدمات بهداشتی و درمانی

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

Parents have premature infants

Timepoint

Before intervention, 4.8 days after intervention and 2 days before discharge

Method of measurement

Avant Attachment Questionnaire and Participation Questionnaire for Parents with Premature Infants

Secondary outcomes

empty

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

ntervention group: Includes 25 parents with premature infants. After receiving the pre-test, the demographic characteristics, attachment and participation of the parents in the 2-4 days after the admission and 4-4 days after the first stage receive the necessary training for the newborns, and 2 days before the post-discharge post-attachment test And participate.

Category

Behavior

2

Description

Control group: Twenty-five parents with premature infants admitted to the neonatal intensive care unit, on the second day of admission, pre-test, demographic characteristics, attachment and participation were taken without intervention. Two days before the discharge, the post-test was also taken

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Hospital

Full name of responsible person

Hanieh Sajadi

Street address

Golshahr Square, Golshahr Street 32

City

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Province

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Postal code

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Phone

+98 17 3322 3131

Email

H_hojjati@aliabadiu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Rouhollah Samii

Street address

Azad University Street, Azad University of Aliabad

City

Ali Abad

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Golestan

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Email

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Grant name

2000000

Grant code / Reference number

1234

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

Yes

Title of funding source

Islamic Azad University

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**

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University of Ali Abad Katoul

Full name of responsible person

Hanieh Sajadi

Position

Nures

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hanieh Sajadi

Position

Nures

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Islamic Azad University

Full name of responsible person

Golbahar Akhondzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Results and results of the study will be shared

When the data will become available and for how long

Post-print information will be publicly available

To whom data/document is available

All students and researchers can apply for information.

Under which criteria data/document could be used

Use of questionnaires and titles for further studies and studies is allowed.

From where data/document is obtainable

Email haniehsajadi74@gmail.com Message to be sent.

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

Email request or contact

Comments