

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of education on lifestyle enhancing health in mothers with premature infants admitted to neonatal intensive care unit

Protocol summary

Study aim

Comparison of health promotion lifestyle in mothers with premature infants admitted to infants in intensive care unit in two groups

Design

Clinical practice with a control and eye control group, randomized

Settings and conduct

A quasi-experimental study with the control group and the control group on the effect of education on the health promoting lifestyle of mothers with infants admitted to the Neonatal Intensive Care Unit in the Mazandaran Univeristy of Medical Sciences Hospital without blindness with a questionnaire. First, before the intervention, a pre-test, then a post-test and a three-month follow-up. Questions will be completed during these steps. Samples will be divided into two groups. Sampling will be done sequentially according to the entry criteria.

Participants/Inclusion and exclusion criteria

1.No addiction 2.At least the reading and writing skills 3.Not having a history of known physical and mental illnesses (depression, schizophrenia, obsession, etc.) 4.No stress other than hospitalization (Death or diagnosis of a malignant disease) 5.Not having a particular problem during pregnancy 6.Be primogenic 7.Gestational age 36-28 weeks 8.of anomalies and congenital anomalies 9.Infant admission for at least 2 weeks in Neonatal Intensive Care Unit

Intervention groups

Investigating the effect of education on the health promoting life style of mothers with hospitalized newborns using a questionnaire which was first performed in the control and control groups before and after the post-test and follow-up period

Main outcome variables

The Effect of Education on Increasing the Lifestyle Improvement of Maternal Mothers with Newborns Attended in Neonatal Intensive Care Units

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181105041556N2**

Registration date: **2019-01-29, 1397/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-29, 1397/11/09**

Update count: **0**

Registration date

2019-01-29, 1397/11/09

Registrant information

Name

Raziyeh Mazroei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3266 4468

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-11, 1397/10/21

Expected recruitment end date

2019-04-10, 1398/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education on lifestyle enhancing health in mothers with premature infants admitted to neonatal intensive care unit

Public title

Education on Health Promoting Lifestyle

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Lack of drug addiction at least literacy reading and writing not having a history of known physical and mental illnesses (depression, schizophrenia, obsession, etc) lack of stress other than hospitalization (death or diagnosis of a disease Malignant) having no specific problem during pregnancy Be primogenic Gestational age 36-28 weeks Absence of anomalies and congenital anomalies Infant admission for at least 2 weeks in Neonatal Intensive Care Unit

Exclusion criteria:

The mother is not comfortable with the instruction given

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 78

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Valiasr Ave., Rashid Yasemi St., Faculty of Nursing, Iran

City

Tehran

Province

Tehran

Postal code

9357131131

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.718

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

The effect of education on health promotion in mothers with hospitalized neonates

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

Mother's Lifestyle Score in Walker Questionnaire

Timepoint

The effect of health education on improving the quality of life of mothers with hospitalized newborns was done as a case group and control group using a questionnaire. Pre-test, post-test and follow-up trials were performed before intervention

Method of measurement

Walker questionnaire

Secondary outcomes

empty

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

Intervention group: In the intervention group before the intervention, pre-test, then post-test and follow-up quarterly. The educational program is taught in the form of a booklet on lifestyle health promotion programs for two weeks each week.

Category

N/A

2**Description**

Control group: There was no intervention for the "control group".

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amol Imam Ali Hospital

Full name of responsible person

zahra litkouhi

Street address

Imam Ali Hospital , Noor Street

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amol

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Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Kazem Malekoti

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Tehran, Hemat Highway next to Milad Tower

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Web page address

<https://www.drsaina.com/cn-hs-008cb2c9022f42af9d1eb317601e039c>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Zahra Litkouhi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable