Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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