Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The evaluation of the effect of emotional intelligence promotion education on the stress of mothers with premature newborns admitted to neonatal intensive care units

Protocol summary

Study aim
Determination of the effectiveness of emotional intelligence promotion training on the stress of mothers with premature newborns admitted to neonatal intensive care units

Design
In this study, 80 mothers with preterm newborns were selected and assigned randomly into control and intervention groups (40 in each group).

Settings and conduct
This study was performed in neonatal intensive care units of hospitals affiliated to Shiraz University of Medical Sciences. This study was not blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Fluency in Persian language, reading and writing skills, no previous history of an infant admitted to the neonatal intensive care unit, consent form for the participation in the project, no absence in group sessions. Exclusion criteria: discharge or transfer of the newborn to another health care center before completing the parental stress index after maternal training and the lack of cooperation of the mother during the training period.

Intervention groups
The emotional intelligence training program was held in six group sessions, each group includes a maximum of 10, and each session was held twice a week for 90 minutes. During each session, rest time was considered for each of the mothers, if necessary. The training was given by a clinical psychologist. The control group received no intervention.

Main outcome variables
The level of stress in mothers with preterm newborns

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180215038743N1**
Registration date: **2018-09-16, 1397/06/25**
Registration timing: **retrospective**

Last update: **2018-09-16, 1397/06/25**
Update count: **0**

Registration date
2018-09-16, 1397/06/25

Registrant information
Name
Malihe Arianfar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 5331 7547
Email address
m.arianfar@kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-21, 1396/02/01

Expected recruitment end date
2017-05-22, 1396/03/01

Actual recruitment start date
2016-12-21, 1395/10/01

Actual recruitment end date
2017-08-23, 1396/06/01

Trial completion date
empty

Scientific title
The evaluation of the effect of emotional intelligence

promotion education on the stress of mothers with premature newborns admitted to neonatal intensive care units

Public title
The evaluation of the effect of emotional intelligence promotion education on the stress of mothers with premature newborns admitted to neonatal intensive care units
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Fluency in Persian At least the reading and writing skills No past history of having an infant admitted to the neonatal intensive care unit Filling out the consent form for the participation in the project No absence in group sessions
Exclusion criteria:
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling was done by convenience sampling method. 80 mothers with premature infants were selected and divided into intervention and control groups in a simple randomized sampling by drawing (40 in each 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
Deputy of Research and Technology of Kerman University of Medical Sciences
Street address
Deputy of Research and Technology of Kerman University of Medical Sciences, Ebnesina st, Somayeh Crossroads, Kerman
City
kerman
Province
Kerman
Postal code
7616913555
Approval date
2016-09-22, 1395/07/01
Ethics committee reference number
IR.KMU.REC.1395.576

Health conditions studied

1

Description of health condition studied
STRESS
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
stress
Timepoint
Before the intervention and 1 month after the intervention
Method of measurement
Miles and Funk parental stressor scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The emotional intelligence training program was held in six group sessions, with 10 persons in each group, twice a week, and each session was 90 minutes. During each session, a rest time was considered for mothers, if necessary. The training was given by a clinical M.A psychologist.
Category
Rehabilitation

2

Description
Control group: Control group: no action
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Zeynabie hospital
Full name of responsible person
Farokh Abazari
Street address
Defense Qods -Shiraz
City
Shiraz
Province
Fars
Postal code
7153813311
Phone
+98 71 3726 6812
Email
f_abazari@kmu.ac.ir

2

Recruitment center
Name of recruitment center
Hafezie hospital
Full name of responsible person
Farokh Abazari
Street address
Chamran Blvd, Shiraz
City
Shiraz
Province
Kerman
Postal code
7194634786
Phone
+98 71 3628 4366
Email
f_abazari@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Farokh Abazari
Street address
Deputy of Research and Technology of Kerman University of Medical Sciences, Ebnesina st, Somayeh Crossroads, Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5219
Email
f_abazari@kmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Farokh Abazari
Position
Nursing Ph.D
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Haft Bagh High Way, Nursing and Midwifery School, Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34331325119
Email
f_abazari@kmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Farokh Abazari
Position
Nursing Ph.D
Latest degree
Ph.D.
Other areas of specialty/work
Health Promotion
Street address
Haft Bagh High Way, Nursing and Midwifery School,

Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34331325119

Email

f_abazari@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Farokh Abazari

Position

Nursing Ph.D., faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Nursing and Midwifery School, Haft Bagh High Way, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34331325119

Email

f_abazari@kmu.ac.ir

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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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