

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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)

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+98 71 5331 7547

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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

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2

Recruitment center

Name of recruitment center

Hafezie hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

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