

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of cognitive-behavioral counseling on the mental health of mothers who have premature infants hospitalized in neonatal intensive care unit of Hazrat Zeinab Shiraz city 2016. Hospital in

Protocol summary

Study aim

Determining the effect of cognitive-behavioral counseling on mental health of mothers with premature infants admitted to Neonatal intensive care unit of Zainab Hospital in Shiraz

Design

The research method was quasi-experimental, consisting two control and trial groups. The population consisted of 50 (25 in the intervention and 25 in the control group) mothers with premature infants who had inclusion criteria who were randomly selected. inclusion criteria include mothers whose infants have been hospitalized due to premature for at least 3 weeks, and the mother doesn't suffer any mental and physical disorders, didn't receive counseling services before and had no history of preterm infant births.

Settings and conduct

After a pretest, cognitive behavioral group counseling sessions were held in six sessions of 45 minutes, two sessions a weeks for the mothers in the intervention group who scored 23 and more in the Goldberg & Hiller Mental Health Questionnaire; and a posttest was held after the completion of the counseling. The control group with cited criteria have passed the pre-test and post-test in a three-week interval without any intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria include mothers whose infants have been admitted in NICU due to prematurity for least three weeks, and the mother doesn't suffer any mental and physical disorders, didn't receive counseling services before and had no history of preterm infant births. Exclusion criteria are the baby's discharge, death died or transfer to another hospital

Intervention groups

Intervention as cognitive-behavioral group counseling for 6 sessions, each session 45 minutes, twice a week

Main outcome variables

The counseling has had a positive impact, although the exact results are not yet clear and the data is in the analysis phase.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170611034452N2**

Registration date: **2017-12-03, 1396/09/12**

Registration timing: **retrospective**

Last update: **2017-12-03, 1396/09/12**

Update count: **0**

Registration date

2017-12-03, 1396/09/12

Registrant information

Name

Atefeh Ahmadi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5205

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Kerman University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of cognitive-behavioral counseling on the mental health of mothers who have premature infants hospitalized in neonatal intensive care unit of Hazrat Zeinab Shiraz city 2016. Hospital in

Public title
The effect of cognitive-behavioral counseling on the mental health of mothers who have premature infants

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Mothers of premature infants hospitalized at neonatal intensive care unit for at least 3weeks, without any physical or psychological problems, without premature infant born, receiving no consulting service
Exclusion criteria:
 the infant has entered to NICU from another hospital or be died/discharge before the end of the study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
50 individuals were selected using simple random sampling and divided into control and intervention group, each with 25 individuals. the analysis results would be analyzed using SPSS.

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
 Kerman University of Medical Sciences & Health Services
Street address
 Kerman-first of the Haft Bagh Allavi - Pardis of Kerman Un
City
 Kerman
Province
 Kerman
Postal code
 76169-13555
Approval date
 2017-03-13, 1395/12/23
Ethics committee reference number
 IR.KMU.REC.1395.970

Health conditions studied

1

Description of health condition studied
Mental Health

ICD-10 code
F90- F98

ICD-10 code description
Behavioural and emotional disorders with onset usually occurring in childhood and adolescence

Primary outcomes

1

Description
Cognitive behavioral counseling

Timepoint
Six sessions of 45 minutes in three weeks

Method of measurement
Goldberg & Hiller Questionnaire

Secondary outcomes

1

Description
Mental health

Timepoint
Before and after cognitive behavioral counseling in the intervention group and without intervention intervention in the control group

Method of measurement
Goldberg & Hiller Questionnaire

Intervention groups

1

Description
Intervention in the form of cognitive-behavioral group

counseling was conducted in mothers with a mental health score of 23 and above twice a week for 45 minutes during the three weeks in the intervention group. In the control group, without consulting, w

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrat Zeynab Hospital in Shiraz

Full name of responsible person

Elaheh samani

Street address

Shiraz, Defaee Moghadas Square, Hazrat Zeynab Training Center City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research of Kerman University of Medical Sciences

Full name of responsible person

Atefeh ahmadi

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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

Deputy of Research of 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

Atefeh Ahmadi

Position

proffessor asistant

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Psychology

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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

No - There is not a plan to make this available