

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Oct 2023

The effect of supportive counseling on the mothers' mental health of premature newborns: a randomised controlled trial

Protocol summary

Study aim

To determine the effect of supportive counseling on mental health in premature infants' mothers.

Design

Randomized controlled trial with two parallel arms.

Settings and conduct

This study will be conducted on 66 mothers with premature infants who have been admitted to the infant's intensive care unit of Al-Zahra hospital. The researcher will refer to hospital and will select women who have been given birth between the week 28 to 33 weeks and 6 days, and they will be invited to participate in the study. Then the Mental Health Questionnaire (MHQ) will be completed by mothers. Individuals who have received a score of less than 24 according to MHQ will be included in the study and written consent will be obtained. Then, the other questionnaires including the socio-demographic information and the postpartum bonding questionnaire will be completed. The researcher will record the weight, height and head circumference of the infant into the anthropometric indices checklist.

Participants will be randomly assigned into two groups of counseling and control. Participants will be followed up 8 weeks after childbirth and MHQ will be completed.

Participants/Inclusion and exclusion criteria

Participants will be women who have been given birth between the week 28 and 33 weeks and 6 days and their babies have been admitted to the NICU.

Intervention groups

The intervention group will receive supportive counseling and control group will receive routine care.

Main outcome variables

The main outcome variable is mental health who will be measured by MHQ in the first 72 hours and at 8 weeks postpartum.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N46**
Registration date: **2018-10-29, 1397/08/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-29, 1397/08/07**

Update count: **0**

Registration date

2018-10-29, 1397/08/07

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-26, 1397/08/04

Expected recruitment end date

2019-03-25, 1398/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive counseling on the mothers' mental health of premature newborns: a randomised

controlled trial

Public title

The effect of supportive counseling on the mothers' mental health of premature newborns

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least secondary education Babies who borned between 28 to 33 weeks and 6 days and hospitalized in NICU Having a phone number to follow-up Resident of Tabriz city Nulliparous mothers Mothers who delivered less than 72 hours

Exclusion criteria:

Uncertainty about being able to attend all consultation sessions. Use of psychoactive drugs and antidepressants, history of pre-pregnancy psychiatric problems based on the participant's statement. Existence of any congenital anomaly in the baby Mothers who will be hospitalized for more than 72 hours.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 66

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be conducted using the website www.random.org and through blocking with block sizes of four and six (Stratification based on the gestational age of 28-30 weeks and 6 days and 31 to 33 weeks and 6 days) and an allocation ratio of 1: 1 to the two groups of counseling and control.

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2018-10-15, 1397/07/23

Ethics committee reference number

IR.TBZMED.REC.1397.593

Health conditions studied

1

Description of health condition studied

Mental health

ICD-10 code

Z00.4

ICD-10 code description

General psychiatric examination, not elsewhere classified

Primary outcomes

1

Description

Mental health of mothers

Timepoint

Preintervention in the first 72 hours after delivery, Postintervention in 8 weeks after childbirth

Method of measurement

Mental Health Questionnaire

Secondary outcomes

1

Description

Postpartum bonding

Timepoint

Preintervention in the first 72 hours after delivery, postintervention in 8 weeks after childbirth

Method of measurement

Postpartum Bonding Questionnaire

2

Description

Anthropometric indices of infants

Timepoint

Preintervention in the first 72 hours after delivery, postintervention in 8 weeks after childbirth

Method of measurement

Preintervention based on the infants file, postintervention measured by the researcher

Intervention groups

1

Description

Intervention group: For the intervention group, supportive counseling will be provided during six 45-60 minutes sessions.

Category

Prevention

2

Description

Control group: The control group will be received routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital of Tabriz

Full name of responsible person

Leila Seiedi Biarag

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Baghshomal Crossroad, Southern Artesh Street, Tabrizs ,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Goltasht Street, Azadi Avenue, Tabriz

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iro@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Leila Seiedi Biarag

Position

MSc student of conseling in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data of participants are privacy.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The results of clinical study will be published as article.

When the data will become available and for how long

Immediately after publishing the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article.

From where data/document is obtainable

Email: mirghafourvandm@tbzmed.ac.ir

What processes are involved for a request to access data/document

Maximum one week after the communication by email.

Comments