

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of counseling with empowerment approach on stress and self-esteem of mothers with premature neonates: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of counseling with empowerment approach on stress and self-esteem of mothers with premature neonates

Design

This is a randomized clinical trial, in which 80 eligible mothers will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible mothers with premature neonates referring to the Fatemieh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 40 years, Stability of the hemodynamic status of the neonate, Singleton, First pregnancy, Wanted pregnancy, Low self-esteem (score less than 30 using the Rosenberg scale), Having stress (score above 46 using the Parental Stress Scale), Living together with her husband, Literate, Persian language, A resident of Hamadan city, Exclusion criteria: Mental disorder

Intervention groups

Intervention group: Routine treatment and care for neonates plus counseling with empowerment approach to the mother in 4 sessions, 2 sessions per week, face to face, including how to care for the baby, the baby's needs, the continuous positive communication between mother and baby, the baby's moods and behaviors, emotional communication with the baby, stress reduction methods between mother and baby, and age-appropriate games Control group: Routine treatment and care for neonates

Main outcome variables

Stress, self-esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N369**

Registration date: **2020-09-28, 1399/07/07**

Registration timing: **prospective**

Last update: **2020-09-28, 1399/07/07**

Update count: **0**

Registration date

2020-09-28, 1399/07/07

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of counseling with empowerment approach on stress and self-esteem of mothers with premature neonates: a randomized clinical trial

Public title

Effect of counseling with empowerment approach on stress and self-esteem of mothers with premature neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 40 years, Stability of the hemodynamic status of the neonate, Singleton, First pregnancy, Wanted pregnancy, Low self-esteem (score less than 30 using the Rosenberg scale), Having stress (score above 46 using the Parental Stress Scale), Living together with her husband, Literate, Persian language, Resident of Hamadan city,

Exclusion criteria:

Mental disorder

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-08-22, 1399/06/01

Ethics committee reference number

IR.UMSHA.REC.1399.475

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

Primary outcomes

1

Description

Stress

Timepoint

Before the intervention and 2 weeks later

Method of measurement

Using the Parental Stress Scale (PSS)

2

Description

Self-esteem

Timepoint

Before the intervention and 2 weeks later

Method of measurement

Using the Rosenberg self-esteem questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment and care for

neonates plus counseling with empowerment approach to the mother in 4 sessions, 2 sessions per week, face to face, including how to care for the baby, the baby's needs, the continuous positive communication between mother and baby, the baby's moods and behaviors, emotional communication with the baby, stress reduction methods between mother and baby, and age-appropriate games

Category

Treatment - Other

2**Description**

Control group: Routine treatment and care for neonates

Category

Other

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

Fatemieh Hospital in Hamadan city

Full name of responsible person

Marzieh Karimi

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

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Hamadan

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6517838695

Phone

+98 81 3828 3939

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Marzieh Karimi

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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