

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of family-centered and individual-centered empowerment program on sleep quality and mental health of primiparous women in postpartum period

Protocol summary

Study aim

The effect of family-centered empowerment program on sleep quality and mental health of primiparous women in postpartum period

Design

The non-blinded Randomized Clinical Trial (RCT) with controls, parallel groups and sample size of 90 participants will be conducted. Allocation of samples in control and intervention groups will be done randomly and using a card in at the packets with dark inner covers being selected by participating women. Then, the research samples will select each packet voluntarily.

Settings and conduct

The place of the study will be two out of three health centers located in the Astara city, Gilan province, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous women; mother's willingness to participate in the study; singleton pregnancy; direct infant responsibility with mother. Non-inclusion criteria: Educated in one of the disciplines of medical science; Any acute or chronic maternal illness; Cigarette and alcohol use; Medical prohibition to breastfeed (based on the case's document); Congenital infant disease requiring hospitalization; Maternal or infant hospitalization due to underlying illness

Intervention groups

In intervention group 4 sessions are held in which the caregiver, husband and infant are present. The family-based empowering model will be implemented step by step in 4 sessions (2 hours per session and once in a week). At the same time the control group only receive routine care. The final evaluation in both groups will be done one month after the treatment.

Main outcome variables

Sleep quality, Mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110425006284N16**

Registration date: **2019-10-22, 1398/07/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-22, 1398/07/30**

Update count: **0**

Registration date

2019-10-22, 1398/07/30

Registrant information

Name

Maryam Modarres

Name of organization / entity

Tehran university of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of family-centered and individual-centered empowerment program on sleep quality and mental health of primiparous women in postpartum period

Public title
Comparison of family-centered and individual-centered empowerment program on sleep quality and mental health

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous women Mother's willingness to attend study
Single pregnancy Direct infant responsibility with mother
Exclusion criteria:
educated in one of the fields of medical science Any acute or chronic maternal illness Smoking and alcohol Medical prohibition for breastfeeding mother (based on case's document) Congenital infant disease requiring hospitalization Maternal or infant hospitalization due to underlying illness

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of samples in control and intervention groups will be carried out randomly and using cards in packets with dark inner cover being selected by participating women. Then the research samples will select each packet voluntarily. Those participants who select the intervention packets will be the intervention group and others who selected the control cards will be the controls. This process will be continued until the end of sampling.

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 Tehran University of Medical Sciences
Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Mirkhani St., Tohid Square, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2019-08-21, 1398/05/30
Ethics committee reference number
IR.TUMS.FNM.REC.1398.099

Health conditions studied

1

Description of health condition studied
Quality of sleep
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Mental health
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep quality score in the Petersburg questionnaire
Timepoint
At baseline (before intervention), immediately after intervention (duration of intervention is 4 weeks), 1 month after intervention
Method of measurement
Petersburg sleep quality questionnaire

2

Description
Mental health score in Goldberg General Health Questionnaire
Timepoint
At baseline (before intervention), immediately after intervention (duration of intervention is 4 weeks), 1 month after intervention
Method of measurement
Goldberg General Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: is comprised of 45 participants being treated with Dr. Alhani's 4-steps Family-based empowering model (perceived threat from the outcomes, self-efficacy through problem solving, self-esteem through educational participation, and evaluation) in 4 sessions for two hours once in a week and accompanied by their husbands and infants.

Category

Behavior

2

Description

Control group: Includes 45 people who receive routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadzadeh Health Center

Full name of responsible person

Farahnaz Azizi

Street address

Shahid Mohammadzadeh Health Center, Eastern
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mommadali Sahraiyan

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Vice Chancellor for Research and Technology, Sixth
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Modarres

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

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Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Midwifery

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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data is potentially shareable after people are unrecognizable

When the data will become available and for how long
Since 2020

To whom data/document is available
For academic and scientific staff

Under which criteria data/document could be used
To evaluate the variables of this study

From where data/document is obtainable
Farahnaz Azizi f.azizi@iau-astara.ac.ir 09113816613

What processes are involved for a request to access data/document
After receiving the email of the applicant, the data will be made available to them.

Comments