Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of Training Based on Continuous Care Model on Quality of Life and Quality of Sleep in the Postpartum Period

Protocol summary

Summary

Objectives: The Postpartum period is a critical time for a woman, as well as for her newborn and family. Women in this period need help and support. This study will be undertaken to determine whether the education based on continuous care model affect on quality of life and sleep? Design: This interventional study, conducted on 86 mothers who admitted in Tehran Baharloo hospital. Women are divided in two groups of 43 as the intervention group and the control group. To avoid data transfer, sampling will be done for the control or intervention group within every other day. Participants: 86 Iranian mothers with vaginal delivery; without complications after delivery; willingness to breast feeding. Exclusion criteria including the mothers unwillingness to continue participation in the trial; maternal and infant hospitalization during the study; neonatal or infant death during the study; lack of breast feeding. Intervention: In the experimental group, intervention is applying based on continuous care model. The continuous care was performed in four stages: orientation; sensitization; control; evaluation. The intervention group will be received 30-60 minutes face to face education and one educational researcher made booklet at the time of discharge and will receive telephone follow up or home visit for the next 3 months. The control group will receive usual care after giving birth. Main outcome variables: Quality of life and Quality of Sleep. The day before discharge, will be completed Edinburgh Postnatal Depression questionnaire, Pittsburgh Sleep Quality Index (PSQI) and Specific Postnatal quality of Life questionnaire will be completed. After the end of intervention, Pittsburgh Sleep Quality Index and Specific Postnatal quality of Life questionnaire will be re-completed in both intervention group and the control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403152324N14**
Registration date: **2014-07-20, 1393/04/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-07-20, 1393/04/29

Registrant information

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Maryam Keshavarz
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2014-04-13, 1393/01/24

Expected recruitment end date

2014-08-21, 1393/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Training Based on Continuous Care Model on Quality of Life and Quality of Sleep in the Postpartum Period

Public title
Quality of Life in Postpartum

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Live, healthy and term infant; No history of Physical and mental illness in the mother; Lack of postpartum complication such as postpartum hemorrhage, preeclampsia, infection; No incidence of adverse events, including death and ... in the last 3 months; Willingness to breast feeding; Demands of pregnancy; Ability to read and write Exclusion criteria: Mother or infant hospitalization during the study; Baby and infant deaths during the study; Psychological problems after childbirth; The incidence of adverse events during the study, including the death of relatives; Lack of exclusive breastfeeding

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
No

Secondary trial Id
No

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical commitment of Tehran University of Medical Sciences

Street address
Sixth floor, Central office, Ghods St, Keshavarz Blvd- Tehran, Iran

City
Tehran

Postal code

Approval date
2014-02-17, 1392/11/28

Ethics committee reference number
2716/ 130/ 92 /د

Health conditions studied

1

Description of health condition studied
Quality of Life after childbirth

ICD-10 code
Z39.2

ICD-10 code description
Routine postpartum follow up

2

Description of health condition studied
Quality of Sleep after Childbirth

ICD-10 code
O94,O99

ICD-10 code description
Other Obstetric Conditions, Not elsewhere classified

Primary outcomes

1

Description
Quality of Life

Timepoint
Before the intervention, and 3 months after intervention

Method of measurement
Specific Postnatal Quality of Life

2

Description
Quality of sleep

Timepoint
Before the intervention, and 3 months after intervention

Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description
No

Timepoint
No

Method of measurement

No

Intervention groups

1

Description
In addition to routine care, continuous care model program has been running for 3 months . Before hospital discharge, demographic questionnaire, postpartum depression, postpartum QOL questionnaire and the Pittsburgh Sleep Quality Index has been aggregated and then a meeting for 30 to 60 minutes training manual for mothers has been explained and it is given to mothers, then follow-up (weekly phone calls and in person at home if necessary) will be conducted in the first 12 weeks postpartum. The average of phone calls will be 20 minutes and based on client needs it may be changed. There is possibility for maternal subjects to have 24 hour calls with the researcher. 12 weeks later the same questionnaire to be completed.

Category
Lifestyle

2

Description
Control group:The control group will receive usual care after giving birth

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Baharloo hospital

Full name of responsible person
Maryam keshavarz

Street address
Behdari St, Rah Ahan Sq, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person
Dr. Akbar Fotohi

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Sixth floor, Central office, Ghods St, Keshavarz Blvd,Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research, Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Science

Full name of responsible person
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Position
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty