

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

Name

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Name of organization / entity

Iran University of Medical Sciences

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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 /s

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

O94,099

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

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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

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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

Masome Asghari

Position

MA

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