

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of face to face training and E-learning on the fatigue and maternal and baby's quality of sleep in the postpartum period

Protocol summary

Summary

Objective: Determining and comparing the impact of face to face training and E- learning on the fatigue and sleep quality of the mother and baby in the postpartum period
Design: sampling method is convenience and the samples were randomly placed in groups. Method: Providing training in the intervention group about sleeping of mother and her baby, health, nutrition, rest, relaxation techniques. Filling out the questionnaire without providing any training in the control group. The population: mothers and infants from the tenth to the sixtieth day after birth. Inclusion criteria: not having postpartum depression and underlying disease in the mother. Exclusion criteria: postpartum depression. The sample size: 120 subjects. Intervention: Training in the field of sleep disorders in the mother and her infant during postpartum by face-to-face and E- learning methods like providing CD and sending Bluetooth on the phone. The intervention time: 10 days after delivery. The outcome: reduced fatigue and sleep disorders in the mother and infant in the postpartum period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062722939N1**
Registration date: **2015-08-31, 1394/06/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-31, 1394/06/09

Registrant information

Name

Zahra Gholami

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan university of medical science

Expected recruitment start date

2015-07-11, 1394/04/20

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of face to face training and E-learning on the fatigue and maternal and baby's quality of sleep in the postpartum period

Public title

The impact of education on the fatigue and sleep disorders in the mother and infant in the postpartum period

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: People giving birth to live, singleton

healthy, people who are breastfeeding (exclusive breastfeeding or with milk), No risk of bleeding during and after delivery (with the question of the mother), After delivery of the highest hospitalization was 3 days, having an underlying medical condition (asthma, kidney disease, congestive heart failure, gastroesophageal reflux disease, rheumatic disorders, joint pain and other musculoskeletal, diabetes) who are sleep disorders, Lack of depression during the study period (with the use of the Edinburgh Postnatal Depression Scale short-be determined (according to the Edinburgh questionnaire, people who score less than 13 get-out, depressed and those with scores equal to or greater than 13 acquire, they will be considered depressed), Married Women and Iranian nationality, no drug addiction and no Hypnotic drugs addiction (for example benzodiazepines), no repeated spontaneous abortions, no neonatal death, Non-working mother";" Exclusion criteria: Unwillingness to continue cooperation during the study, not completing the questionnaire completely and correctly, people who suffer from postpartum depression during the study (diagnosed with the information given to mothers at the beginning of the study), providing any disease or disorder that it effects on the sleep of the mother and infant during the study such as long-term cold (more than three days), infectious diseases that cause fever, prolonged fever, hospitalization of the mother and infant, factors such as postpartum bleeding after the sampling.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
For randomization, among all cases in health centers, 10 cases of postpartum mothers on the basis of inclusion criteria will be selected randomly. Random selection of cases will be on the basis of weekdays. Meaning that Saturday and Tuesday will be assigned to face-to-face training group, Sunday and Wednesday will be assigned to E-learning group, Monday and Thursday will be dedicated to the control group. Then every day, with convenient sampling method, qualified individuals are selected for inclusion.

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comitte of Isfahan university of Medical Sciences

Street address

Hezar jarib street, Isfahan university of medical science, Isfahan.

City

Isfahan

Postal code

8174673461

Approval date

2015-07-07, 1394/04/16

Ethics committee reference number

IR.MUI.REC.1394.3.301

Health conditions studied

1

Description of health condition studied

Fatigue and sleep disorder

ICD-10 code

F53

ICD-10 code description

Other mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

The mother fatigue

Timepoint

Before and one and two months after the intervention

Method of measurement

Intensity of fatigue Questionnaire

2

Description

The sleep quality of the mother

Timepoint

Before and one and two months after the intervention

Method of measurement

3**Description**

The sleep quality of infant

Timepoint

Before and one and two months after the intervention

Method of measurement

The record form of mean duration of infant's sleep

Secondary outcomes1**Description**

Timepoint

Method of measurement

Intervention groups1**Description**

Intervention group 1: Face to face training on the tenth day after birth for 45-30 minutes and then send the hygienic SMS until the sixtieth day after birth

Category

Behavior

2**Description**

Intervention group 2: Giving an educational CD on the tenth day after birth and then sending the hygienic SMSs until the sixtieth day after birth.

Category

Behavior

3**Description**

Control group: No intervention Just fill out the questionnaire.

Category

N/A

Recruitment centers1**Recruitment center****Name of recruitment center**

Amir Hamzeh Health Center

Full name of responsible person

zahra gholami

Street address

Amir Hamzeh Health Center, Ghaemie, Isfahan.

City2**Recruitment center****Name of recruitment center**

Nawab Safavi Health Centre

Full name of responsible person

zahra gholami

Street address

Ahmadabad square, Isfahan

City

Isfahan

3**Recruitment center****Name of recruitment center**

Ibn Sina Health Center

Full name of responsible person

zahra gholami

Street address

Ibn Sina street, Shohada square, Isfahan

City

Isfahan

4**Recruitment center****Name of recruitment center**

25-dastgerd Health center

Full name of responsible person

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Ghaemie, 25dastgerd Health Center, Isfahan.

City

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for research, Isfahan university of medical science

Full name of responsible person

Mehdi Nemat bakhsh

Street address

Vice chancellor for research, Isfahan university of medical science, Faculty of Nursing and Midwifery

City

Isfahan

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, Isfahan university of medical science

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**

Isfahan University of Medical Sciences

Full name of responsible person

zahra gholami

Position

Masters student

Other areas of specialty/work**Street address**

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Position

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Web page address**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*