

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Survey of effect exercise on fatigue and sleep quality mothers in postpartum

Protocol summary

Summary

The postpartum period is transition to critical stage and the rapid changes that are experienced postpartum therefore mother being exposed to unpleasant experiences of fatigue and changes in sleep pattern. exercise training are effective methods in postpartum period lead to accelerate recovery and achieve higher level of health in mothers. The purpose of this study is to determine the effect exercise training on fatigue and sleep quality of mothers in the postpartum period. The study is randomize clinical trial; mothers randomly assigned to two groups(40 exercise and 40 control); pilates exercise perform five sessions per week for eight weeks in mothers intervention group, starting exercise is rather 36 hours after delivery and until first week after birth;control group will not received intervention.fatigue and sleep quality measurement in the beginning of study (37 weeks of pregnancy), 24 hours after delivery and first four weeks and two four weeks postpartum

General information

Acronym

Exercise

IRCT registration information

IRCT registration number: **IRCT201102275912N2**

Registration date: **2011-12-30, 1390/10/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-30, 1390/10/09

Registrant information

Name

Mandana Mir Mohammad Ali Ei

Name of organization / entity

Tehran University of Medical Scinces

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

Email address

mirmohammad@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-09-21, 1389/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of effect exercise on fatigue and sleep quality mothers in postpartum

Public title

Effect of exercise on fatigue and sleep quality mothers in postpartum

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Inclusion criteria: Iranian born, Age Range 18-35, At least the end of primary education, Primiparous, Absence of any disease, acute and chronic physical and mental, Healthy Infant ,Exclusive Breast feeding, Access to computer or VCD device for watch video, Exclusion criteria : postpartum depression, forget consecutive three sessions or withdrawal five sessions of

exercise, Appearing any medical or obstetric that inconsistent with the exercise, Life shift or migrate to other cities during the study, Infant Hospitalization any reason, Diagnosis of postpartum anemia

Age

From **18 years** old to **35 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

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

Tehran University of Medical Sciences and Health Services

Street address

Keshavarz BLD, Ghods street, Central building of Tehran University of Medical Sciences, 6th floor

City

Tehran

Postal code

Approval date

2011-03-01, 1389/12/10

Ethics committee reference number

1949/130/89/ص

Health conditions studied

1

Description of health condition studied

Fatigue and Sleep Quality

ICD-10 code

094,099

ICD-10 code description

Other Obstetric Conditions, Not elsewhere classified

Primary outcomes

1

Description

Fatigue (General Fatigue, Physical Fatigue, Mental Fatigue, Reduce Activity, Reduce Motivation)

Timepoint

24 hour after delivery, four weeks postpartum, eight weeks postpartum

Method of measurement

Multidimensional Fatigue Inventory

2

Description

Sleep quality(subjective Sleep quality, Sleep latency, Sleep duration, Sleep efficiency, Sleep disturbance, Sleep medication)

Timepoint

24 hour after delivery, four weeks postpartum, eight weeks postpartum

Method of measurement

Pittsburgh Sleep Quality

Secondary outcomes

empty

Intervention groups

1

Description

Control group except usual activities of daily do'nt perform intervention and throughout the study will be supervised.

Category

Treatment - Drugs

2

Description

Intervention group will be perform pilates exercise preferably consecutive 5 sessions per week to time 30 min for eight weeks

Category

Treatment - Drugs

3

Description

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

One urban Health center

Full name of responsible person
farzaneh ashrafinia, postgraduate student
Street address
Emam Street, Rafsanjan
City
Rafsanjan

2

Recruitment center
Name of recruitment center
Two urban Health center
Full name of responsible person
farzaneh ashrafinia, post graduate student
Street address
15 Khordad street, Rafsanjan
City
Rafsanjan

3

Recruitment center
Name of recruitment center
Three urban Health center
Full name of responsible person
farzaneh ashrafinia postgraduate student
Street address
Mirafzali street
City
Rafsanjan

4

Recruitment center
Name of recruitment center
Four urban Health center
Full name of responsible person
farzaneh ashrafinia post graduate student
Street address
West Amirkabir street
City
Rafsanjan

5

Recruitment center
Name of recruitment center
Five urban Health center
Full name of responsible person
Farzaneh ashrafinia , post graduate student
Street address
Kargar street, Rafsanjan
City
Rafsanjan

6

Recruitment center
Name of recruitment center
Six urban Health center
Full name of responsible person
farzaneh ashrafinia, postgraduate student
Street address

Amir kabir street, Rafsanjan
City
Rafsanjan

7

Recruitment center
Name of recruitment center
Seven urban Health center
Full name of responsible person
farzaneh ashrafinia, postgraduate student
Street address
West Amir kabir, Rafsanjan
City
Rafsanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Tehran University of Medical Sciences
Full name of responsible person
Abbas Hoshmand Behabadi
Street address
Faculty of Nursing and Midwifery, Nosrat ST, Tohid SQ
City
TEhran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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 Scinces
Full name of responsible person
Mandana Mir Mohammad Ali Ei
Position
Scientific Instructor
Other areas of specialty/work
Street address
Tehran
City
Faculty of Nursing and Midwifery, Nosrat ST, Tohid Sq

Postal code

00989123906609

Phone

+98 21 6692 7171

Fax

+98 21 6690 4252

Email

mirmohammad@tums.ac.ir

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

Faculty of physical Education of Teacher training University

Full name of responsible person

Hamid Rajabi

Position

Associate Professor

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

Faculty of physical Education of Teacher training University, Mirdamad St

City

Tehran

Postal code**Phone**

+98 21 2226 9545

Fax**Email**

hrajabi@hotmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Farzaneh Ashrafi Nia

Position

Graduate Student

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

Faculty of Nursing and Midwifery, Nosrat St, Tohid Sq

City

Tehran

Postal code**Phone****Fax****Email**

ashrafifarzaneh60@yahoo.com

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*