

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

THE EFFECT OF YOGA ON ANXIETY AND FUNCTIONAL STATUS OF NULLIPAROUS WOMEN IN THE POSTPARTUM PERIOD

Protocol summary

Study aim

Practical purposes: If the effectiveness of yoga exercises in the postpartum period on functional status or reducing anxiety in nulliparous women in the postpartum period can be confirmed: 1- In order to improve the functional situation 2- Reduction of postpartum anxiety To be used by midwives and relevant experts in intravenous and postpartum care.

Design

Randomized controlled clinical trial without blinding with control and intervention groups

Settings and conduct

This interventional study is a randomized controlled clinical trial in the postpartum period on nulliparous women referred to 2 Qazvin Health Centers affiliated to Qazvin University of Medical Sciences, with the aim of the effect of yoga exercises on functional status and anxiety. Will be done after delivery. The research environment in this study will be health centers in Qazvin. The research community will consist of primiparous women referring to health centers in Qazvin.

Participants/Inclusion and exclusion criteria

Inclusion criteria Primiparous women Age 18 to 40 years Women with uncomplicated natural childbirth No known mental illness and use of psychiatric drugs Has a live baby and no abnormalities Having physical health according to the mother On the 10th to the 30th day of the mother's postpartum period Not participating in other sports classes at the same time Having and being able to use mobile phones and virtual networks to participate in virtual classes Exclusion criteria Up to two sessions of non-participation in yoga Reluctance to continue cooperation in research

Intervention groups

Yoga exercises are taught regularly according to the protocol to the intervention group during 8 to 10 sessions and the control group receives routine care and after the study, they are given brochures and educational videos.

Main outcome variables

Yoga exercises can affect maternal and fetal outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210907052403N1**

Registration date: **2022-03-05, 1400/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-05, 1400/12/14**

Update count: **0**

Registration date

2022-03-05, 1400/12/14

Registrant information

Name

Samira Romina

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-25, 1401/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

THE EFFECT OF YOGA ON ANXIETY AND FUNCTIONAL STATUS OF NULLIPAROUS WOMEN IN THE POSTPARTUM PERIOD

Public title

The effect of yoga on anxiety and performance of women in the postpartum period

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Primiparous women
Age 18 to 40 years
Women with uncomplicated natural childbirth
No known mental illness and use of psychiatric drugs
Has a live baby and no abnormalities
Having physical health according to the mother
On the 10th to the 30th day of the mother's postpartum period
Not participating in other sports classes at the same time
Having and being able to use mobile phones and virtual networks to participate in virtual classes

Exclusion criteria:

Up to two sessions of non-participation in yoga
Reluctance to continue cooperation in research

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking will be used to balance the number of samples assigned to each of the study groups. The samples are divided into two groups of intervention and control by blocking randomization method and from each center, an equal number of people will be randomly divided into individual units in two groups A and B. The size of all blocks is equal and 36 people in the intervention group and 36 people in the control group will be randomly assigned to the random number table. In the randomization table, the samples are coded and the researcher randomly starts from a table point in the direction of the row or column to select the sample people from the table. The selection of the point can be done by closing the eyes and placing a finger or the tip of a pen on the table. Selects the same number of digits in the row or column direction and then controls the path numbers. The researcher will inevitably encounter two types of numbers, one of which is smaller than the number of the study population and the other is larger than the population. Which only considers and selects smaller numbers. The selected number is in fact the individual code of the community that is selected as a

sample. This goes on until a small number can be selected based on the number of sample people. After completing the sample size, the sampling work is completed. Also, blinding is not used.

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**

Management of Research and Technology of the University of Tehran

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No. 1, Tehran University of Medical Sciences
Headquarters Building, 6th Floor, Room 605,
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Province

Tehran

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1417653761

Approval date

2022-02-01, 1400/11/12

Ethics committee reference number

IR.TUMS.FNM.REC.1400.189

Health conditions studied**1****Description of health condition studied**

Anxiety and functional status by doing postpartum yoga movements

ICD-10 code

Y93.42

ICD-10 code description

Activity, yoga

Primary outcomes**1****Description**

Functional status after delivery

Timepoint

Before and 14 days after the intervention

Method of measurement

Functional Status Questionnaire

2

Description

Anxiety

Timepoint

Before and 14 days after the intervention

Method of measurement

Beck Anxiety questionnaire

Secondary outcomes

1

Description

Social Support

Timepoint

Before and 14 days after the intervention

Method of measurement

Perceived Social Support Questionnaire

2

Description

Breastfeeding

Timepoint

Before and 14 days after the intervention

Method of measurement

Breastfeeding self-efficacy questionnaire

Intervention groups

1

Description

Intervention group: 36 people are in the Intervention group. In this study, yoga exercises to strengthen the minds and bodies of participants virtually in the postpartum period for 10 sessions, each session for 30 minutes for 5 weeks and 2 sessions per week by the researcher. In connection with the intervention group of yoga exercises in the form of online training by the researcher who has passed the postpartum yoga training course, will be uploaded on the site at the appointed time and the site link will be provided to the members of the intervention group. These tutorials can be applied online and offline for users. Skype software will be used to check the correct movement and the researcher will perform the movements visually for the mothers. After making sure that the movements are performed by the mother, the next movement will be uploaded at a specific time and the mother will be asked to Perform the movements calmly and accurately at the appointed time, then the researcher will call the mother to make sure that she performs those movements. Yoga exercises will be performed according to the protocol of Jayashari et al. The process of execution and the type of movements in each session are as follows: 1. Move the bridge 2. Move the knee towards the chest 3. Exercise one leg forward for the transverse abdominal muscles 4- Exercise in hugging (working on the muscles of the upper back) 5.

Lateral extension exercise (longitudinal stretching of the spine muscles) 6- Lying down (to strengthen the muscles of the back and shoulders) 7. Strength recovery exercises in the legs and lower abdomen 8- Exercise the abdominal and pelvic muscles while sitting on a chair 9-Exercise the muscles of the upper back while lying down 10-Exercise the abdominal and pelvic muscles while sitting on a chair 11-Exercise lateral extension of longitudinal stretch of spinal muscles 12-Simple screw drill 13. Rotation and twisting in the hand 14-Sitting deep screw 15. Bend forward on the chair The movements that will be done in each class are such that the beginning of each class is with a breathing meditation and relaxation, then the above exercises are performed, one repetition from each exercise in the first session and 2 repetitions in the second session, 3 repetitions in the third session. The fourth will be 4 repetitions and in sessions 5 to 10 of each movement will be 5 repetitions. At the end of the exercises, relaxation exercises will be performed. The order of these movements is the same in all sessions and the time spent in that movement (the amount of pause in each movement increases the difficulty of movement) gradually increases during the sessions.

Category

Lifestyle

2

Description

Control group: 36 people are in the control group. In the control group, except for routine actions, no intervention will be performed. Also, if you wish, postpartum yoga exercises will be provided to the control group after the intervention.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bolandian Health Center in Qazvin

Full name of responsible person

Dr. Alireza Mehr Alian

Street address

above the canal, Shahid Babaei Street, Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Afsane Safaii

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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

Zohre Khakbazan

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable