

# 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

+98 28 3289 7461

##### Email address

s.romina314@gmail.com

##### 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

**Street address**

No. 1, Tehran University of Medical Sciences  
Headquarters Building, 6th Floor, Room 605,  
University Research and Technology Management,  
Keshavarz Blvd Intersection and Ghods St., Tehran.

**City**

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**Province**

Tehran

**Postal code**

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

#### **City**

Qazvin

#### **Province**

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#### **Postal code**

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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

**Street address**

School of Nursing and Midwifery, Tohid Square, Dr. Mirkhani St., (Eastern Nosrat ), Tehran.

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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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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Samira Romina

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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### Person responsible for updating data

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**Other areas of specialty/work**

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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