Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of Stretching exercises on back pain and quality of sleep among pregnant women

Protocol summary

Study aim
the effect of Stretching exercises on Low Back Pain and Sleep Quality in Pregnant Women Referred to Kowsar Teaching Hospital

Design
A randomized controlled clinical trial with a single group (Yoga Hata) randomly assigned without placement

Settings and conduct
Intervention in this study involves performing a type of pregnancy yoga program that is referred to the Kosar Hospital clinic after being selected by the researchers as a study and the yoga program by a trained yoga instructor with an international degree and an undergraduate degree. A midwife with a 7-year experience teaching yoga to pregnant mothers runs a specialized yoga club. For the intervention group, the yoga program includes Hata Yoga style and includes physical movements (50 minutes), meditation (15 minutes), and breathing and relaxation exercises (10 minutes).

Participants/Inclusion and exclusion criteria
log in: 1. Having informed consent to participate in the study. 2. Age group 18 to 35 years. 3. Having a normal pregnancy according to the written diagnosis of a specialist gynecologist (not having ivf for pregnancy, no underlying illness in the family, having normal weight). 4. First pregnancy and single pregnancy. 5. Ability to read and write. 6. Having a normal BMI (between 19/8 and 25). 7. Pregnancy age 24 to 28 weeks. Not logged in: 1. History of orthopedic surgery. 2. History of lumbar disc according to medical records. 3. Having experience in yoga class or regular exercise (Pilates, Tai Chi). 4. During Yoga Exercises If the fetus becomes difficult, the delivery of choice is by caesarean section or by more than 2 sessions of yoga class absent.

Intervention groups
Pregnant women in this group will start their first yoga session of pregnancy from 26 to 28 weeks of gestation and up to 37 minutes of gestation twice a week for 75 minutes.

Main outcome variables
Low back pain and sleep quality and pregnancy anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190919044819N1**
Registration date: **2019-12-27, 1398/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-27, 1398/10/06**
Update count: **0**

Registration date
2019-12-27, 1398/10/06

Registrant information

Name
narges hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7768 4704

Email address
nargeshossini123@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-01-30, 1398/11/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Stretching exercises on back pain and quality of sleep among pregnant women

Public title

Investigating the effect of Stretching exercises on back pain and quality of sleep among pregnant women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to participate in the study Age group 18 to 35 years First pregnancy and single pregnancy Having a normal BMI Pregnancy age 24 to 28 weeks Have a normal pregnancy according to the written diagnosis of a specialist gynecologist

Exclusion criteria:

History of Orthopedic Surgery. History of lumbar discs according to medical records. Having experience in yoga class or regular exercise (Pilates, Tai Chi)

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

They will be selected by random allocation without assigning people. In this way, every pregnant mother who is eligible to study will be placed in a binary blue orb (hatha yoga) of 33, a red (control) of 33, and the pregnant mother will remove one orb and enter the orb. Hatha will be yoga or control.

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

Ethics Committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Boulevard, Qazvin University of Medical Sciences

City

gazvin

Province

Qazvin

Postal code

34417431874

Approval date

2019-12-21, 1398/09/30

Ethics committee reference number

IR.QUMS.REC.1398.246

Health conditions studied

1

Description of health condition studied

back pain-Sleep quality disorder

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

back pain

Timepoint

At the beginning of the study (before the intervention) and And one month after the intervention

Method of measurement

Visual scale for measuring pain

2

Description

sleep quality

Timepoint

At the beginning of the study (before the intervention) and And one month after the intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention in this study involves performing a kind of yoga program during pregnancy. Pregnant women referred to the Kowsar Hospital Clinic are selected by the researchers after

being eligible for the study. The yoga program is run by a trained yoga instructor with an international degree in yoga and a bachelor's degree in midwifery with a 7-year experience of teaching pregnant mothers about yoga. For the intervention group, the yoga program will include Hata Yoga style and the yoga program will include physical movements (50 minutes), meditation (15 minutes) and breathing and relaxation exercises (10 minutes), based on several studies of this type of yoga. Participants will also begin their first pregnancy yoga session from week 26 to 28 of gestation and will complete two yoga sessions for the next 75 minutes during the 37th week of pregnancy.

Category

Rehabilitation

2

Description

Control group: The pregnant mother should not receive any intervention.The usual prenatal care that all pregnant women receive will be provided.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Leila Dehghankar

Street address

Qazvin, Khon Bahonar University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Leili Yekefallah

Position

Assistant Professor of Qazvin Nursing School

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information on the effect of Stretching exercises on back pain and quality of sleep among pregnant women
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
Qazvin University of Medical Sciences Pregnancy Yoga Health Centers
Under which criteria data/document could be used
Through a valid university site
From where data/document is obtainable
Qazvin- Qazvin University of Medical Sciences- School of Nursing and Midwifery
What processes are involved for a request to access data/document
Send authors email
Comments