

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of yoga in pregnancy on anxiety and child birth self-efficacy of nulliparous pregnant women

Protocol summary

Study aim

General Purpose: determining the effect of yoga on anxiety and self-efficacy in labour of primipar women referred to health centers in Zahedan in 2017
Special Purpose: Determination and Comparison of mean changes in anxiety score of primipar women in two groups of intervention (yoga) and control
Determination and comparison of mean changes in self-efficacy score in labour of primipara women in two groups of intervention (yoga) and control

Design

Studied population included primipar women referred to health centers. sampling and randomization method is as follows, first the list of all eligible women is prepared from the selected health centers, then after receiving permission of participated eligible women, individuals with randomization block will be divided into two groups: intervention and control. Each participant in the intervention and control group is assigned a code. Both of intervention and control group included 30 individuals

Settings and conduct

. Intervention is conducted in the hall where Yoga instructor by a trained researcher are present. This is a clinical trial study. Since the nature of the study is sport, it is not possible to blind people. Only the statistics specialist will be unaware of this matter that, which person belongs to which group (intervention or control).

Participants/Inclusion and exclusion criteria

The criteria for entering the study are: gestational age of 18-40 , singleton, gestational age of 27-26 weeks, Iranian, having reading and writing skills, non-use of psychosocial drugs, non-attendance at yoga classes and similar sports, lack of physical illness (performing yoga exercises can endanger the health of one's or his fetus) such as injury or spinal cord surgery, no recurrent abortions, lack of addiction, lack of physical and mental illness, lack of obstetric problems such as cerclage, high fever, rupture of membranes, Placentaprevia and polyhydramnios. Exclusion criteria: internal problems and

Surgery, hypertension in pregnancy , Diagnosing Placenta Previa , threat of premature labor - unwillingness to cooperate and participate in aerobics and Pilates classes , Lack of regular attendance in meetings.

Intervention groups

Intervention Two questionnaires namely, anxiety Inventory and self-efficacy with a demographic information form are completed at the same time on 26th week in intervention and control group. Yoga intervention is conducted from week 27 to 31 for 5 weeks every three days. The post-test is repeated at week 34 from both group.

Main outcome variables

Limitations Non-attendance at yoga classes that is followed up by phone. If there is a problem during the exercise, a visit of gynecologist will be taken.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160704028794N2**

Registration date: **2018-01-01, 1396/10/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-01, 1396/10/11**

Update count: **0**

Registration date

2018-01-01, 1396/10/11

Registrant information

Name

farnoosh khojasteh

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 33442481

Email address

khojasteh@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-11, 1396/09/20

Expected recruitment end date

2018-04-23, 1397/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of yoga in pregnancy on anxiety and child birth self -efficacy of nulliparous pregnant women

Public title

The effect of yoga in pregnancy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Nulliparous pregnant women Pregnancy single parenthood Pregnancy Age English 26-32 weeks Literacy reading and writing

Exclusion criteria:

Lack of physical and mental illness Absence of midwifery problems (of Cerebral palsy) Repetitive abortion Cerclage Preterm rupture of membrane

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocks

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a clinical trial study Since the nature of the study is sport, it is not possible to blind people. Only the statistics specialist will be unaware of this matter that, which person belongs to which group (intervention or control).

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

SquareHesabi; Daneshgah Ave

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

IR.ZAUMS.REC.1396.152

Health conditions studied

1

Description of health condition studied

بارداری

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score that a person receives from standardized pregnancy anxiety questionnaires.The score that a person earns from self-efficacy questionnaires.First, the pregnancy anxiety questionnaire and Childbirth Self Efficacy Inventory in the 27-26 weeks for both groups, then after five weeks of intervention, two weeks after the last intervention in both groups

Timepoint

First, the pregnancy anxiety questionnaire and childbirth self efficacy inventory in the 27-26 weeks for both groups, then after five weeks of intervention, two weeks after the last intervention in both groups

Method of measurement

Standardized pregnancy anxiety questionnaires childbirth self efficacy inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, individuals in 27th week of gestation for 5 weeks each week will receive a 45-60 minute session of yoga exercises, including position-selecting, controlled respiratory exercises, and Releasing and relaxation exercises in the gym where yoga instructors and researcher are present.

Category

Lifestyle

2

Description

Control group: The control group will receive the usual care of the pregnancy.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Health Center

Full name of responsible person

Farnoosh Khojasteh

Street address

Zahedan Hearmand Street

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Sistan-va-Balouchestan

Postal code

9815733169

Phone

+98 54 3344 2481

Fax

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Email

khajasteh@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Noor Mohammad Bakhshani

Street address

Dr Hasabi's Square, Daneshgah Blvd

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taheri@zaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Khojasteh. Farnoosh

Position

science committee

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Blvd Behdasht

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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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

Not applicable