

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Yoga on weight gain and maternal anxiety in women with excessive gestational weight gain

Protocol summary

Study aim

To determine the effect of Prenatal Yoga on weight gain and maternal anxiety of pregnant women with excessive gestational weight gain that referred to Comprehensive health centers in Qom

Design

Sampling is Convenience but assigning individuals to the control and intervention groups is random

Settings and conduct

Participants will be accessed through Comprehensive health centers in Qom which are centers for pregnancy, new born and early parenting .After specifying the groups, we will have a weekly weight check. And our intervention, which was a yoga class, will be done in groups

Participants/Inclusion and exclusion criteria

Inclusion criteria :Primiparous women 18-46 years of age/ Diagnosed with (EGWG)/being at 24-30 weeks of gestation / healthy Singleton pregnancy/ Wiling to participate in the study / ability to attend at least one yoga per week for majority of intervention (i.e., at least 70% of sessions)/ do not already have a specific disease before pregnancy/No special complications in pregnancy/ have not participated in similar yoga or exercise courses
Exclusion:the patients will be excluding if they skip the yoga trainings for more than once during the intervention also in case of the occurrence of any conditions that turn the pregnancy into a high-risk condition.

Intervention groups

we have two groups :the control and intervention group .In addition to receiving routine care, the participants in the intervention group will contracted to perform Prenatal yoga group exercises for 6 weeks

Main outcome variables

Decrease Weight gain-Decrease anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110621006854N5**

Registration date: **2022-06-17, 1401/03/27**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-17, 1401/03/27**

Update count: **0**

Registration date

2022-06-17, 1401/03/27

Registrant information

Name

Elham Ebrahimi

Name of organization / entity

Azad University

Country

Iran (Islamic Republic of)

Phone

+98 22 1522 3903

Email address

ebrahimi_308@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Yoga on weight gain and maternal anxiety in women with excessive gestational weight gain

Public title

Yoga and maternal weight gain and anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous women 18-46 years of age Diagnosed with (EGWG) being at 24-30 weeks of gestation healthy Singleton pregnancy Willing to participate in the study ability to attend at least one yoga per week for majority of intervention do not already have a specific disease before pregnancy and No special complications in pregnancy have not participated in similar yoga or exercise courses

Exclusion criteria:

if they skip the yoga trainings for more than once during the intervention in case of the occurrence of any conditions that turn the pregnancy into a high-risk condition.

Age

From **18 years** old to **46 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

Participants randomly using the site www.random.org and through Stratification quota random blocking with 4 and 6 block sizes and with ratio 1: 1 allocation to control and intervention groups (yoga receiving group and control group) (routine care) Were allocated. Blocking was performed by a person not involved in sampling and data analysis. Direction Hide allocation, type of intervention written on a piece of paper and inside opaque envelopes Was numbered. These random envelopes after signing a written consent in The presence of the mother was opened and the type of group was specified and the mother was informed.

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 the School of Nursing and Midwifery, Tehran University of Medical Sciences

Street address

Tehran School of Nursing and Midwifery, East Nosrat Street ,Tohid Square,Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2022-05-21, 1401/02/31

Ethics committee reference number

IR.TUMS.FNM.REC.1401.023

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

2

Description of health condition studied

Overweight

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Overweight

Timepoint

6 weeks

Method of measurement

a research grade scale (Tanita WB-800S digital weight scale)

2

Description

Anxiety

Timepoint

6 weeks

Method of measurement

The State Trait Anxiety Inventory (STAI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: yoga exercises twice a week for 6 weeks (includes yoga exercises with breathing exercises and relaxation). The names of each of these weeks are as follows: 1) opening greeting/intention setting, 2) pranayama (i.e., breathing exercises), 3) warm-up/sun salutations (i.e., flowing sequence), 4) prenatal yoga sequence (e.g., combination of sun salutations, vinyasa (i.e., movement between poses), and standing, seated, and/or balancing poses), 5) cool-down 6) Savasana (i.e., final resting pose)

Category

Treatment - Other

2

Description

Control group: not doing yoga exercises (Routine pregnancy care with weekly weight check)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health center of Qom province

Full name of responsible person

Dr. Bahareh Zare

Street address

Qom Health Center, facing Alley 6, 20 meters from Beheshti Street, Imam Khomeini Street, Qom

City

Qom

Province

Ghoum

Postal code

3719714953

Phone

+98 25 3660 0017

Email

toghajalal@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tuqa Jalal Jumaah

Street address

first unit/tasnim apartment/Shahid taqi khosrobigi street/15khordad blv

City

Qom

Province

Ghoum

Postal code

3714861813

Phone

+98 25 3355 4721

Email

toghajalal@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Elham Ebrahimi

Position

Professor and Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

The first door of a rural house, Haj Amini Alley, Farhang Street, Faramesh Square, Damavand, Tehran

City

Qom

Province

Tehran

Postal code

۳۹۷۱۷۱۳۹۶۷

Phone

0253354721

Email

ebrahim_i_308@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Elham Ebrahimi

Position

Professor and Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

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Email

ebrahimi_308@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Tuqa Jalal Jumaah

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

first unit/tasnim apartment/Shahid taqi khosrobigi

street/15khordad blv

City

Qom

Province

Ghorm

Postal code

3714861813

Phone

+98 25 3355 4721

Email

toghajalal@yahoo.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants information is protected and their names are not required.

When the data will become available and for how long

1401

To whom data/document is available

Reputable journals

Under which criteria data/document could be used

niversities of Medical Sciences

From where data/document is obtainable

Try not to use the documents personally

What processes are involved for a request to access data/document

Provide complete information and pay

Comments