

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of squat sport training versus no training on fatigue and quality of life in pregnant women: a randomized clinical trial

Protocol summary

2019-09-07, 1398/06/16

Study aim

To assess the effect of squat sport training versus no training on fatigue and quality of life in pregnant women

Design

This is a randomized clinical trial, in which 100 eligible pregnant women will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible pregnant women with fatigue who will refer to Comprehensive Health Centers in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the cluster randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years Second trimester Singleton Literate Normal body mass index Exclusion criteria: Any pregnancy complications Any background disease Mental disorders Musculoskeletal diseases

Intervention groups

Intervention group: Routine pregnancy care plus squat sport training for 30 to 45 minutes daily for 8 days
Control group: Just routine pregnancy care

Main outcome variables

Primary outcome: Assessing the severity of fatigue
Secondary outcome: Assessing the quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N292**
Registration date: **2019-09-07, 1398/06/16**
Registration timing: **prospective**

Last update: **2019-09-07, 1398/06/16**

Update count: **0**

Registration date

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of squat sport training versus no training on fatigue and quality of life in pregnant women: a randomized clinical trial

Public title

Effect of squat sport training versus no training on fatigue and quality of life in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 35 years Second trimester Singleton Literate
Normal body mass index
Exclusion criteria:
Any pregnancy complications Any background disease
Mental disorders Musculoskeletal diseases

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the pregnant women to the intervention and control groups by cluster randomization of the health centers. To do this, we will write the names of the Comprehensive Health Centers on the paper sheets and then assign each health center to one of the "intervention" or "control" groups through drawing a lot. Then, depending on to which center every pregnant woman refer, she will be assigned to the intervention or control groups.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-08-13, 1398/05/22

Ethics committee reference number

IR.UMSHA.REC.1398.423

Health conditions studied

1

Description of health condition studied

Fatigue

ICD-10 code

O26.812

ICD-10 code description

Pregnancy related exhaustion and fatigue, second trimester

Primary outcomes

1

Description

Assessing the severity of fatigue

Timepoint

Before the intervention and 8 days after that

Method of measurement

Using multidimensional Fatigue Index (MFI)

Secondary outcomes

1

Description

Assessing the quality of life

Timepoint

Before the intervention and 8 days after that

Method of measurement

Using standard SF-36 questionnaire

Intervention groups

1

Description

Intervention group: Routine pregnancy care plus squat sport training for 30 to 45 minutes daily for 8 days, including shoulder width squats, open leg squats, closed leg squats, staggered squats, single leg squats, side buttock squats, full squats, sitting squats, and ball squats. At the beginning of each session for 10 minutes are devoted to warming up and at the end of sessions 10 minutes are devoted and cooling down. The workouts will start with low numbers and sets, and then in the next sessions and better physical fitness, the intensity and number of workouts will be increased.

Category

Treatment - Other

2

Description

Control group: Just routine pregnancy care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan City

Full name of responsible person

Maryam Malmir

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

maryam.malmir69@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Malmir

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

maryam.malmir69@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Seyedh Zahra Masoomi

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

zahramid2001@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

poorolajal@umsha.ac.ir

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

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