Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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
2019-09-07, 1398/06/16

Registrant information
Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan 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
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

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Person responsible for scientific inquiries

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Reproductive Health Specialist

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

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