

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### study of The effect of physical activity in water on musculoskeletal pain in pregnant women

#### Protocol summary

##### Study aim

To examine the effect of physical activity in water on the amount of musculoskeletal pain in pregnant women referring to Qazvin health centers

##### Design

Clinical trial with intervention and control group (each group of 30), community based and pragmatic, with parallel, randomized block

##### Settings and conduct

60 pregnant women who has the conditions to enter the study is available and after completing the checklist for demographic and pregnancy information and Nordic musculoskeletal pain questionnaire, Roland Morris's back pain and visual analogue and Confirmation of Musculoskeletal pain will be entered into the study with written consent, then the samples will be randomly divided into intervention and control groups. In the intervention group, receiving usual care during pregnancy, physical activity in water 3 times per week and 60 minutes each time for 8 The week will be performed by a trained researcher at the pool and in the control group just the usual care with You will receive.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: The desire to participate in the study  
Having musculoskeletal pain Not having chronic illness  
Gestational age is 20-23 weeks Exclusion criteria:  
Exercise contraindication in pregnancy Having a mental illness Fear of water

##### Intervention groups

Intervention group: In the intervention groups, in addition to the usual prenatal cares, Participate in the water physical activity program, 3 times a week for 8 weeks. The sessions were composed of three phases: warming up exercises; the main phase (divided into aerobic exercise and force and resistance exercise) and a phase of stretching and relaxation. Control group: They were received the usual prenatal care.

##### Main outcome variables

Musculoskeletal pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190130042565N1**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

##### Registration date

2019-08-26, 1398/06/04

##### Registrant information

##### Name

Masomeh Rezai niaraki

##### Name of organization / entity

The Collage of Nursing and Midwifery Qazvin

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3377 4522

##### Email address

m.rezainiaraki@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-06, 1397/12/15

##### Expected recruitment end date

2019-10-07, 1398/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

study of The effect of physical activity in water on musculoskeletal pain in pregnant women

**Public title**

Effect of water activity on musculoskeletal pain in pregnancy

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Having musculoskeletal pain Not having chronic diseases (blood pressure, diabetes, cardiovascular disease, etc.) Not having known musculoskeletal disorders based on mother's statement Gestational age 23-20 weeks

**Exclusion criteria:**

Having a contraindication for exercise during pregnancy Having mental illness Fear of water

**Age**

No age limit

**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**

60 low risk pregnant women selected by a convenience sampling method. They were selected and by the block randomization technique assigned into intervention and control groups (two groups n=30).

**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**

Qazvin University of Medical Sciences, Bahonar Blvd.

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34197-59811

**Approval date**

2019-01-08, 1397/10/18

**Ethics committee reference number**

IR.QUMS.REC.1397.284

**Health conditions studied****1****Description of health condition studied**

Musculoskeletal pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

**Primary outcomes****1****Description**

Musculoskeletal pain in pregnant women

**Timepoint**

Before and after intervention

**Method of measurement**

Nordic musculoskeletal pain inventory, Roland Maurice Low Back Pussy Questionnaire, Visual Analogue

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In the intervention groups, in addition to the usual prenatal cares, Participate in the water physical activity program, 3 times a week for 8 weeks. The sessions were composed of three phases: warming up exercises; the main phase (divided into aerobic exercise and force and resistance exercise) and a phase of stretching and relaxation.

**Category**

N/A

**2****Description**

Control group: They were received the usual prenatal care.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Health centers of Qazvin city

**Full name of responsible person**

Fatemeh Ranjkesh

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Qazvin university of medical sciences, Bahonar Blvd.,  
Qazvin city

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franjkes@qums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fatemeh Ranjkesh

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Vice-Chancellor's Office for Research and Technology  
Affairs, Qazvin University of Medical Sciences, Shahid  
Beheshti Avenue

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research.dpt@qums.ac.ir

**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**

Fatemeh Ranjkesh

**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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**Contact**

**Name of organization / entity**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fatemeh Ranjkesh

**Position**

Lecturer

**Latest degree**

Master

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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

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

Not applicable

### Title and more details about the data/document

All the data have code to identify.

### When the data will become available and for how long

2019

### To whom data/document is available

Qazvin University of Medical Sciences

### Under which criteria data/document could be used

By confirmation of Qazvin University of Medical Sciences

### From where data/document is obtainable

Qazvin University of Medical Sciences

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

Refer to Qazvin University of Medical Sciences or sending email to franjkesh@qums.ac.ir

### Comments