

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The Effect of Ultrasound on Delayed Onset Soreness After Aerobic Exercise in Middle Aged Diabetic Women's

#### Protocol summary

##### Study aim

The effect of ultrasound on delayed onset muscle soreness of middle-aged diabetic women after 8 weeks of aerobic exercise

##### Design

The clinical trial includes a sample size of 30 middle-aged women (15 in the experimental group and 15 in the control group), parallel and random groups.

##### Settings and conduct

Imam Ali (AS) Health Center, which is the place where diabetics are referred in Zabol city, was selected and after issuing the necessary introduction letters and permits, sampling was done during the completion period of 30 volunteers according to the study protocol. Meanwhile, the participants of the project (patients and medical staff of the center) have become blind to the study.

##### Participants/Inclusion and exclusion criteria

Middle-aged women (41-49 years old) with diabetes and without history of delayed onset quadriceps muscle soreness. Provide medical license to participate in sports

##### Intervention groups

Both study groups have the same exercise program (aerobic exercise for 8 weeks and 3 sessions of 45 minutes each week with an ergonomic bike with an intensity of 60 to 70% Vo2max) in which the Borg scale is used to vary their fatigue. In the experimental group, after training by a specialist, the ultrasound lever treats the quadriceps muscle for 7 minutes at a frequency of 3 MHz.

##### Main outcome variables

Delayed Onset Muscle Soreness (DOMS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211201053244N1**

Registration date: **2022-06-21, 1401/03/31**

Registration timing: **retrospective**

Last update: **2022-06-21, 1401/03/31**

Update count: **0**

##### Registration date

2022-06-21, 1401/03/31

##### Registrant information

###### Name

Mohammadreza Rezaeipour

###### Name of organization / entity

University of Sistan and Baluchestan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3113 2241

###### Email address

rezaeipour@ped.usb.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-22, 1401/03/01

##### Expected recruitment end date

2022-06-20, 1401/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Ultrasound on Delayed Onset Soreness After Aerobic Exercise in Middle Aged Diabetic Women's

##### Public title

Delayed Onset Muscle Soreness (DOMS)

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

diabet middle-age women No movement restrictions

### Exclusion criteria:

Failure to provide a permission participation in sports activities.

## Age

From **41 years** old to **49 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

A simple randomization model with confidential registration of the intervention and control group on paper and drawing it by the participants will be used. In this method, the type of treatment assigned to the two groups is completely unpredictable.

## 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 Committees of University of Sistan and Balouchestan

##### Street address

University of sistan and baluchestan, University Blv.

##### City

zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816745639

#### Approval date

2022-03-13, 1400/12/22

#### Ethics committee reference number

IR.USB.REC.1400.110

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes

#### ICD-10 code

E08

#### ICD-10 code description

Diabetes mellitus due to underlying condition

## Primary outcomes

### 1

#### Description

Delayed Onset Muscle Soreness

#### Timepoint

The experimental group will complete the pain questionnaire one hour after the implementation of the training protocol and the use of ultrasound and 24 hours after that. The control group will complete the pain questionnaire one hour after the exercises and 24 hours later.

#### Method of measurement

Pain Questionnaire (based on Van Korf)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Experimental group Intervention: Aerobic training at 8 weeks and 3 sessions of 45 minutes per week on a 60-70% Vo2max ergometer bike plus ultrasound for 7 minutes at a frequency of 3 MHz on the quadriceps muscle in each session.

#### Category

Rehabilitation

### 2

#### Description

Control group: Aerobic training at 8 weeks and 3 sessions of 45 minutes per week on a 60-70% Vo2max ergometer bike.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Ali Health Center

##### Full name of responsible person

Tahere bameri

**Street address**

Imam Hossein Square, 3rd Modares Blv.

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**Position**

Assoc.Prof.Dr

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of Sistan and Baluchestan

**Full name of responsible person**

Dr. kourd (Research director)

**Street address**

University Blvd., University of Sistan and Baluchestan

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**Province**

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info@usb.ac.ir

**Web page address**

<https://www.usb.ac.ir/>

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

Yes

**Title of funding source**

University of Sistan and Baluchestan

**Proportion provided by this source**

20

**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**

University of Sistan and Baluchestan

**Full name of responsible person**

Mohammadreza Rezaeipor

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

University of Sistan and Baluchestan

**Full name of responsible person**

Rezaeipour Mohammadreza

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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**Person responsible for updating data****Contact****Name of organization / entity**

University of Sistan and Baluchestan

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Rezaeipour Mohammadreza

**Position**

Associate professor

**Latest degree**

Ph.D.

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

It is necessary to check and obtain the necessary permissions, including from patients.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available