

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

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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.

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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

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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)

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University Blvd., University of Sistan and Baluchestan

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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

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

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Other areas of specialty/work

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Person responsible for updating data

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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