Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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

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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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Postal code
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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

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Sponsors / Funding sources

1

Sponsor
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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
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University of Sistan and Baluchestan
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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