

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effect of respiratory muscle fatigue on the gait pattern of active and inactive older adults

Protocol summary

Study aim

Comparing the effect of respiratory muscle fatigue on the gait pattern of active and inactive older adults

Design

This study is a quasi-experimental investigation with a pre-test-post-test design and parallel groups. Participants will be allocated non-randomly into two groups (active and inactive older adults) based on their physical activity level. The sample size will consist of 30 participants.

Settings and conduct

After obtaining informed consent and assessing the inclusion criteria, eligible participants were enrolled at the Sports Science Research Institute and allocated into two groups (active and inactive older adults) based on their physical activity level. Gait pattern assessment was first performed under pre-test conditions in the gait laboratory. Subsequently, respiratory muscle fatigue was induced, and the post-test gait assessment was immediately repeated under the same conditions. All procedures were conducted in a single session under controlled laboratory conditions. The study was conducted without blinding.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Being aged between 65 and 70 years, being able to perform activities of daily living and participate in assessments, completing the Physical Activity Questionnaire and having the individual's physical activity level determined, and having a normal Body Mass Index.

Intervention groups

Intervention Group 1 (active elderly): induction of respiratory muscle fatigue using the Zebris respiratory training device at 60% of maximal inspiratory pressure during a laboratory session. Intervention Group 2 (inactive elderly): induction of respiratory muscle fatigue using the Zebris respiratory training device at 60% of maximal inspiratory pressure during a laboratory session.

Main outcome variables

Step length, Step width, Double support phase, Right and left single support phase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260526069540N1**

Registration date: **2026-07-20, 1405/04/29**

Registration timing: **prospective**

Last update: **2026-07-20, 1405/04/29**

Update count: **0**

Registration date

2026-07-20, 1405/04/29

Registrant information

Name

Reza Norouzi

Name of organization / entity

Allameh Tabataba'i University

Country

Iran (Islamic Republic of)

Phone

+98 916 927 3651

Email address

reznrz148@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of respiratory muscle fatigue on the gait pattern of active and inactive older adults

Public title

Investigation of the Effect of Respiratory Fatigue on Gait Pattern

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being in the 65–70 age range Living in the city of Tehran Having the ability to carry out daily activities and participate in assessments Completing the Physical activity questionnaire to determine the individual's level of physical activity Having a body mass index (BMI) within the normal range

Exclusion criteria:**Age**

From **65 years** old to **70 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Allameh Tabataba'i University

Street address

Central Campus, Allameh Tabataba'i University, Olympic Village, Olympic Village Square, Tehran.

City

tehran

Province

Tehran

Postal code

۱۴۸۹۶۸۳۹۹۱

Approval date

2026-04-27, 1405/02/07

Ethics committee reference number

IR.ATU.REC.1405.025

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

Aging

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

step length

Timepoint

Before the intervention, immediately after the intervention

Method of measurement

ZEBRIS gait analysis system

2**Description**

step width

Timepoint

Before the intervention, immediately after the intervention

Method of measurement

ZEBRIS gait analysis system

3**Description**

double support phase

Timepoint

Before the intervention, immediately after the intervention

Method of measurement

ZEBRIS gait analysis system

4**Description**

single support phase of the right and left legs

Timepoint

Before the intervention, immediately after the intervention

Method of measurement

ZEBRIS gait analysis system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1 (Active Older Adults): The intervention in this study consists of the acute induction of respiratory muscle fatigue through inspiratory muscle resistance training using the PowerBreathe inspiratory muscle trainer. This device is an adjustable mechanical instrument that provides resistance during inspiration, allowing the training intensity to be individualized based on each participant's maximal inspiratory pressure (P_Imax). Prior to the intervention, each participant's maximal inspiratory pressure (P_Imax) is measured using a handheld mouth pressure manometer. Participants perform three maximal inspiratory efforts with one-minute rest intervals between attempts, and the highest recorded value is considered the baseline P_Imax. Following the determination of P_Imax, the resistance of the inspiratory muscle trainer is set at 60% of the participant's baseline P_Imax. Participants perform repeated forceful inspiratory breaths through the device while seated in a standardized upright position. The intervention is conducted as a single acute laboratory session and consists of one bout of inspiratory muscle resistance exercise performed until the criterion for respiratory muscle fatigue is reached. The protocol continues until the participant is unable to generate at least 90% of the baseline P_Imax in three consecutive maximal inspiratory efforts. This criterion is considered indicative of functional respiratory muscle fatigue. Once fatigue is confirmed, the participant immediately proceeds to the post-intervention walking assessment, during which spatiotemporal gait parameters are reassessed. The intervention is performed only once and is designed solely to induce acute, transient respiratory muscle fatigue. Therefore, it does not involve a multi-session training program or any form of long-term respiratory muscle training.

Category

Rehabilitation

2

Description

Intervention Group 2 (Inactive Older Adults): The intervention in this study consists of the acute induction of respiratory muscle fatigue through inspiratory muscle resistance training using the PowerBreathe inspiratory muscle trainer. This device is an adjustable mechanical instrument that provides resistance during inspiration, allowing the training intensity to be individualized based on each participant's maximal inspiratory pressure (P_Imax). Prior to the intervention, each participant's maximal inspiratory pressure (P_Imax) is measured using a handheld mouth pressure manometer. Participants perform three maximal inspiratory efforts with one-minute rest intervals between attempts, and the highest recorded value is considered the baseline P_Imax. Following the determination of P_Imax, the resistance of the inspiratory muscle trainer is set at 60%

of the participant's baseline P_Imax. Participants perform repeated forceful inspiratory breaths through the device while seated in a standardized upright position. The intervention is conducted as a single acute laboratory session and consists of one bout of inspiratory muscle resistance exercise performed until the criterion for respiratory muscle fatigue is reached. The protocol continues until the participant is unable to generate at least 90% of the baseline P_Imax in three consecutive maximal inspiratory efforts. This criterion is considered indicative of functional respiratory muscle fatigue. Once fatigue is confirmed, the participant immediately proceeds to the post-intervention walking assessment, during which spatiotemporal gait parameters are reassessed. The intervention is performed only once and is designed solely to induce acute, transient respiratory muscle fatigue. Therefore, it does not involve a multi-session training program or any form of long-term respiratory muscle training.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports Science Research Institute

Full name of responsible person

Reza Norouzi

Street address

No. 3, 5th Alley, Mir Emad Street, Motahari Avenue, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1587958711

Phone

+98 21 8874 7836

Email

info@ssrc.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Allameh Tabataba'i University

Full name of responsible person

Mandana Tishehyar

Street address

Research, Technology and Innovation Office, Central Campus of Allameh Tabataba'i University, Dehkadeh Square, Olympic Village, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code
1485643449
Phone
+98 21 4473 7561
Fax
Email
tishehyar@atu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Allameh Tabataba'i University
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
Allameh Tabataba'i University
Full name of responsible person
Reza Norouzi
Position
Master Student
Latest degree
Bachelor
Other areas of specialty/work
Sport Injuries and Corrective Exercises
Street address
No. 14, Ahmad Abbasi Alley, Moftazi Street, Navab Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1331684969
Phone
+98 916 927 3651
Email
reznrz148@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Allameh Tabataba'i University
Full name of responsible person
Reza Norouzi
Position

Master student
Latest degree
Bachelor
Other areas of specialty/work
Sport injuries and Corrective exercises
Street address
No 81, Acadia Medical Equipment Passage Navab Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1331684969
Phone
+98 916 927 3651
Fax
Email
reznrz148@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Allameh Tabataba'i University
Full name of responsible person
Reza Norouzi
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Sport injuries and Corrective exercises
Street address
No 81, Acadia Medical Equipment Passage Navab Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1331684969
Phone
+98 916 927 3651
Fax
Email
reznrz148@gmail.com

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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is 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

Title and more details about the data/document

Data related to gait pattern parameters and maximal inspiratory pressure (PImax). All individual data will be de-identified through coding and removal of identifying information, and thus can be shared in anonymized form. Sharing of data related to the primary outcomes of the study is possible.

When the data will become available and for how long

The data access period will begin 6 months after the publication of the final study results.

To whom data/document is available

Researchers and investigators affiliated with universities and academic or research institutions.

Under which criteria data/document could be used

Submission of a brief research proposal including the study objectives and analytical methods; use of the data solely for scientific and research purposes; no attempt to identify participant identities; prohibition of data transfer to third parties without prior authorization; and mandatory citation of the original study as the data source.

From where data/document is obtainable

Correspondence via email includes sending formal requests such as a letter of introduction, research objectives, and a description of the intended analyses to the corresponding researcher at reznrz148@gmail.com; in cases where scientific approval or further coordination is required, applicants may also contact the supervising professor, Dr. Hashem Piri, at hpiry63@gmail.com; required documents include an official letter of introduction from a university or research center, a description of the research objectives and type of intended analysis, as well as a written commitment to comply with research ethics principles and data confidentiality; requests will be reviewed by the corresponding researcher and, if necessary, in coordination with the supervising professor, and will be approved and granted access after evaluation.

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

Submission of a data access request accompanied by a description of the research purpose. The request will be reviewed and approved by the principal investigator, and upon approval, de-identified coded data will be provided to the applicant. The processing and data delivery time is approximately 2 to 4 weeks after receipt of a complete request.

Comments