Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
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
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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 (PImax).Prior to the intervention, each participant's maximal inspiratory pressure (PImax) 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 PImax.Following the determination of PImax, the resistance of the inspiratory muscle trainer is set at 60% of the participant's baseline PImax. 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 PImax 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 (PImax).Prior to the intervention, each participant's maximal inspiratory pressure (PImax) 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 PImax.Following the determination of PImax, the resistance of the inspiratory muscle trainer is set at 60% of the participant's baseline PImax. 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 PImax 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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
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

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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