Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of fatigue caused by functional training with different levels of movement complexity on cortico-muscular coherence in specific scales of effort perception in active women

Protocol summary

Study aim

The aim of the present study was to investigate the effect of fatigue induced by functional training with different levels of movement complexity (functional training based on simple or complex movements) compared to non-functional training during specific self-reported measures of perceived exertion (RPE=Rate of Perceived Exertion) on cortical-muscular coherence in active women.

Design

A 3-group, double-blind, crossover clinical trial with simple, phaseless randomization on 15 subjects.

Settings and conduct

A scientific-research and fundamental study in the field of sports neurophysiology will be conducted in the sports physiology laboratory, with participants and laboratory experts blinded to this research.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the present study included age range of 18 to 28 years, being active (150 to 300 minutes of moderate intensity or 75 to 150 minutes of vigorous intensity per week) (43), and normal body mass index (18 to 25 kg/m2). Other inclusion criteria for the present study included not having cardiovascular and neuromuscular diseases and musculoskeletal injuries. Also, not taking medications, supplements, tobacco, and alcohol were essential prerequisites for study entry. Regular menstrual cycles were required to control hormonal factors. Exclusion criteria for the present study included unwillingness to participate in any of the phases of the study, occurrence of any injury or discomfort during the exercise protocol, and inability to perform the exercises due to severe fatigue or other conditions that potentially affect exercise performance.

Intervention groups

Protocol Group 1 Protocol Group 2 Protocol Group 3

Main outcome variables

Fatigue from functional training with different levels of movement complexity , effort perception scale, corticospinal coherence

General information

Reason for update

Acronym

NPHE

IRCT registration information

IRCT registration number: **IRCT20260806070547N1**
Registration date: **2026-08-12, 1405/05/21**
Registration timing: **prospective**

Last update: **2026-08-12, 1405/05/21**
Update count: **0**

Registration date

2026-08-12, 1405/05/21

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-14, 1405/05/23

Expected recruitment end date

2026-11-20, 1405/08/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of fatigue caused by functional training with different levels of movement complexity on cortico-muscular coherence in specific scales of effort perception in active women

Public title
The effect of fatigue caused by functional training with different levels of movement complexity on cortico-muscular coherence in specific scales of effort perception in active women
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Being active (150 to 300 minutes of moderate intensity or 75 to 150 minutes of vigorous intensity per week) Normal body mass index (18 to 25 kg/m2) Absence of cardiovascular and neuromuscular diseases and musculoskeletal injuries Avoiding drugs, supplements, tobacco, and alcohol Regular menstrual cycle
Exclusion criteria:
Unwillingness to participate in any stage of the research Any injury or discomfort during the exercise protocol and inability to perform the exercises due to extreme fatigue or other conditions that potentially affect the execution of the exercises
Age
From **18 years** old to **28 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with an individual and accessible unit will be performed from the statistical population, namely young active women living in Tehran, based on the SPSS statistical software. In this way, after collecting the samples using an accessible method and confirming the eligibility of each individual, a list of names or initial codes of all participants is entered into the SPSS environment. Then, a random number with a uniform distribution between zero and one is generated for each individual. Before generating these numbers, an initial Seed (for example, equivalent to the start date of the study) is set in the Random Number Generators section so that the randomization process is completely reproducible (repeatable). After sorting the generated numbers, by setting a cut point of 0.5, people whose random number is less than 0.50 are assigned to the intervention group and the rest (number greater than or equal to 0.50) are assigned to the control/proof group. This method is the simplest random assignment model in which each participant has a completely equal chance (50-50) of being placed in each group, and the assignment of individuals is completely independent of individual characteristics (such as age and physical activity history) and also independent of the researcher's judgment. Finally, to ensure the success of randomization, the balance of the distribution of background variables (such as mean age and body mass index) between the two groups is examined using t-tests or chi-square tests, and the results will be presented in the report
Blinding (investigator's opinion)
Double blinded
Blinding description
To blind the study according to the requirements of the ethics committee, participants were only informed of the general objectives of the study and remained unaware of the details of the interventions, grouping, and main hypotheses. In the laboratory section, all samples and raw data were labeled with multilayer random codes (including letters and numbers without a meaningful sequence) by an independent person (other than the operator and analyst) before being delivered to the experts, so that the experts were not aware of the allocation of samples to the intervention or control groups. The decryption key for these codes is kept in separate sealed envelopes with the data manager (who had no role in the initial collection and analysis process) and is not accessible until the database is finalized and the accuracy of the data entry is confirmed by the ethics committee, in order to ensure both observer bias and complete confidentiality of the data until the final locking (Data Lock).
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alzahra University
Street address
Vanak, Sheikh Bahai Square, Avesta Street, Deh Vanak Street, Al-Zahra University, Faculty of Sport Sciences
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Tehran

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Approval date
2025-12-09, 1404/09/18
Ethics committee reference number
R.ALZAHRA.REC.1404.084

Health conditions studied

1

Description of health condition studied
Fatigue from functional training with varying levels of movement complexity on specific scales of perceived effort.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fatigue induced by functional training with varying levels of movement complexity on specific scales of effort perception on corticospinal coherence.
Timepoint
There will be 72 hours between testing sessions.
Method of measurement
To calculate the effect of fatigue caused by functional training with different levels of complexity on specific scales of perceived effort on cortical-muscular coherence, two electroencephalography and electromyography devices will be used, and for the perceived effort scale, a 10-item RPE questionnaire will be used.

Secondary outcomes

1

Description
corticomascular coherence
Timepoint
72 hours between testing sessions
Method of measurement
Electroencephalography and electromyography have been used to examine cortico-muscular coherence.

Intervention groups

1

Description
Intervention group: Protocol 1: Functional squat training on the ground Intervention group: Protocol 2: Functional squat training on the Bosuball Exercise group: Protocol 3: Functional squat training on the Bosuball with upper limb movements
Category
Other

Recruitment centers

1

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Sponsors / Funding sources

1

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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
Alzahra universuty
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

Alzahra university

Full name of responsible person

Leila ghazaleh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sports biomechanics

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

EEG, neuromuscular, output data for statistical steps. Only 3 minutes of resting EEG data can be shared with participants.

When the data will become available and for how long

Access period starts 1 year after results are published.

To whom data/document is available

The data will be available to the supervisors-advisors and the student to complete the remaining stages of the thesis.

Under which criteria data/document could be used

Only 3 minutes of resting EEG data can be made available to participants one year after printing.

From where data/document is obtainable

Dr. Leila Ghazaleh with contact number +989125458969

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

If the legal authority for the research deems it appropriate, it will take about a week for the data to be made available to the participant after the data request process.

Comments