

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of multi component neuromuscular exercises on balance and sport performance of futsal players with down syndrome

Protocol summary

Study aim

Evaluation of the effect of multi-component neuromuscular training on balance, strength, and sports performance of futsal players with Down syndrome

Design

A randomized, single-blind, controlled phase II clinical trial with a parallel group design of 30 participants, randomized using the RAND function in Microsoft Excel.

Settings and conduct

Tests are administered before and after the intervention, with participants results recorded. An eight-week multi-component neuromuscular training program is conducted, three sessions weekly (24 total). Each session lasts 40–45 minutes: 10 warm-up, 30 training, 5 cool-down. Group sessions take place at Behzisti and Pas sports halls in Rasht.

Participants/Inclusion and exclusion criteria

Inclusion Criteria of Participants: Gender: male; Age range: 20–30 years; Diagnosis of Down syndrome; IQ between 50 and 70, or being trainable; Minimum of 3 years of sports experience; Regular training (at least three sessions per week); No history of lower limb injury in the past six months that could cause functional or structural limitations; no history of lower limb surgery that could alter the natural alignment of the body; No evident orthopedic, perceptual, or musculoskeletal disorders; No use of specific medications that could affect balance. Exclusion Criteria of Participants: Failure to cooperate in performing the pre-test or post-test; Incomplete participation in the training program for any reason; Absence from more than three training sessions or two consecutive sessions; Experiencing pain or injury during training; unwillingness to continue participation.

Intervention groups

Intervention group: Participants perform multi-component neuromuscular training. Control group: Participants receive no intervention and only engage in their daily activities.

Main outcome variables

Balance, lower limb muscle strength and sports performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251126068122N1**

Registration date: **2025-12-13, 1404/09/22**

Registration timing: **prospective**

Last update: **2025-12-13, 1404/09/22**

Update count: **0**

Registration date

2025-12-13, 1404/09/22

Registrant information

Name

Masoomeh Evazkhah

Name of organization / entity

University of Guilan

Country

Iran (Islamic Republic of)

Phone

+98 13 4253 2837

Email address

masoomehek2000@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-03-01, 1404/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of multi component neuromuscular exercises on balance and sport performance of futsal players with down syndrome

Public title
The Effect of Exercise Training on the Sports Performance of Futsal Players with Down Syndrome

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Gender: Male Age range: 20 to 30 years Diagnosis of Down syndrome IQ between 50 and 70, or being trainable Minimum of 3 years of sports experience Regular training (at least three sessions per week) No history of lower limb injury in the past six months that could cause functional or structural limitations, and no history of lower limb surgery that could alter the natural alignment of the body No evident orthopedic, perceptual, or musculoskeletal disorders No use of specific medications that could affect balance
Exclusion criteria:
Failure to cooperate in performing the pre-test or post-test Incomplete participation in the training program for any reason Absence from more than three training sessions or two consecutive sessions Experiencing pain or injury during training, or unwillingness to continue participation

Age
From **20 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are randomly assigned to one of the two study groups using a random number table, and they receive the corresponding intervention.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants will not be informed about their allocation to the study groups and will be kept blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in biomedical research of guilan university

Street address

5th Kilometer of Persian Gulf Highway, Rasht, Guilan Provience, Iran

City

Rasht

Province

Guilan

Postal code

4199613776

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.GUILAN.REC.1404.002

Health conditions studied

1

Description of health condition studied

Individual with Down syndrome

ICD-10 code

Q90

ICD-10 code description

Down syndrome

Primary outcomes

1

Description

Balance

Timepoint

The balance tests were assessed at baseline and after the eight week intervention.

Method of measurement

Stork Test and Y Balance Test

2

Description

Lower limb muscle strength

Timepoint

The Lower limb muscle strength tests were assessed at baseline and after the eight week intervention.

Method of measurement

30-Second Chair Stand Test

3

Description

Sports performance

Timepoint
Sport performance tests were assessed at baseline and after the eight week intervention.

Method of measurement
The assessments were selected from the futsal sports skill test battery for individuals with intellectual disabilities.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Multi-component neuromuscular exercises for eight weeks, three days per week, lasting 40 to 45 minutes.

Category
Rehabilitation

2

Description
Control group: During the eight week period, the control group performed their regular futsal training three days per week.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Behzisti Sports Club, Rasht and Pas Sports Club, Rasht

Full name of responsible person
Hamed Atashafrouz

Street address
Behzisti Sports Club, Parastar Street, Farhang Square, Rasht, Guilan Province, Iran

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atashafrouzh1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Guilan

Full name of responsible person
Dr.Ali Bani

Street address
5th Kilometer of Persian Gulf Highway, Rasht, Guilan Province, Iran

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bani@guilan.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
The University of Guilan

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
The University of Guilan

Full name of responsible person
Masoomah Evazkhah

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Adapted Physical Education and Sport for People with Disabilities

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5th Kilometer of Persian Gulf Highway, Rasht, Guilan Province, Iran

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data from the measured variables will be shareable once individuals have been de-identified.

When the data will become available and for how long

The access period will begin in 1405 (2026).

To whom data/document is available

Only for researchers employed at academic and scientific institutions.

Under which criteria data/document could be used

The scientific use of the data for improvement and comparison with other research is allowed.

From where data/document is obtainable

Correspondence with researchers for obtaining necessary information can be directed to:
masoomehek2000@gmail.com

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

Requesters are required to submit the justification for using the documents to the following email address. The researcher will review the request and provide a response at the earliest opportunity:
masoomehek2000@gmail.com

Comments