Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 commitee 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 perfomance

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

City

Rasht

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Postal code

4193743138

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+98 13 3332 4505

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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 Provience، 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

Masoomeh 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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Person responsible for scientific inquiries

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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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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