

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Balance, lower limb muscle strength and sports performance

#### 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

#### 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 Province, 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

##### City

Rasht

##### Province

Guilan

##### Postal code

4193743138

##### Phone

+98 13 3332 4505

##### Email

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

#### City

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#### Province

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#### Postal code

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#### Phone

+98 13 3332 8845

#### Email

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

##### Street address

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

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##### Phone

009842532837

##### Email

masoomehek2000@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

The University of Guilan

**Full name of responsible person**

Masoomeh Evazkhah

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

The University of Guilan

**Full name of responsible person**

Masoomeh Evazkhah

**Position**

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4199613776

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**Email**

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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**