

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Effect of whole body vibration training (Vibration Therapy) and Quinoa intake on physical performance and muscles electromyography characteristics involved at the Gait initiation in multiple sclerosis patients

#### Protocol summary

##### Study aim

To examine the effects of combined WBV and quinoa supplement on physical performance and electromyographic features of lower limb muscles during walking in MS.

##### Design

The study was conducted at the University of Birjand, Faculty of Physical Education and Sport Sciences (Behavioral Sciences Campus). Participants were recruited from clinics in Birjand. The whole-body vibration therapy intervention was performed in faculty laboratories (such as the Exercise Physiology Laboratory), and electromyographic and functional assessments were also performed at the same location.

##### Settings and conduct

The study was conducted at the University of Birjand, Faculty of Physical Education and Sport Sciences (Behavioral Sciences Campus). Participants were recruited from clinics in Birjand. The whole-body vibration therapy intervention was performed in faculty laboratories (such as the Exercise Physiology Laboratory), and electromyographic and functional assessments were also performed at the same location.

##### Participants/Inclusion and exclusion criteria

Participants: ۳۴ patients with relapsing-remitting multiple sclerosis (RRMS) with Expanded Disability Status Scale (EDSS) scores from ۱ to ۶ (mean age  $۴۱.۹ \pm ۸.۹$  years, ۷۹.۴% female) recruited from clinics in Birjand.

##### Intervention groups

Whole body vibration plus quinoa supplement (n=۱۰)  
Whole body vibration (n=۸) Quinoa supplement (n=۹)  
Placebo (n=۷)

##### Main outcome variables

The main outcome variables included the Timed Up and Go (TUG) test to assess dynamic balance and coordination of movement, the 7.5-meter walk test to measure walking speed, and muscle synergy

characteristics based on the NMF index in electromyography (EMG) of the lower limb muscles (tibialis anterior, soleus, rectus/biceps femoris, gluteus medius) at the beginning of walking. Sleep quality and wakefulness were also assessed through a questionnaire!

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250309065000N1**

Registration date: **2026-03-10, 1404/12/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2026-03-10, 1404/12/19**

Update count: **0**

##### Registration date

2026-03-10, 1404/12/19

##### Registrant information

##### Name

seyyed mojtaba hosseini

##### Name of organization / entity

University of Birjand

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3102 7995

##### Email address

rahbordi2012@gmail.com

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2026-03-01, 1404/12/10

**Expected recruitment end date**

2026-07-06, 1405/04/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of whole body vibration training (Vibration Therapy) and Qavoot intake on physical performance and muscles electromyography characteristics involved at the Gait initiation in multiple sclerosis patients

**Public title**

The effect of vibration therapy and the use of Qavoot supplements on MS patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

1. Age range 20 to 55 years Not taking amantadine and dalfira drugs EDSS score  $\geq 5.4$  points (4.5-1) Patient approval from the doctor Not receiving other rehabilitation activities during the study period Completed the informed consent form Suffering from relapsing-remitting type No skin sensitivity or flushing due to the use of the ingredients in Qavoot

**Exclusion criteria:**

Personal dissatisfaction Injury while performing the exercise program Participation in organized exercise and rehabilitation programs other than the exercise program of the present study

**Age**From **20 years** old to **55 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**Target sample size: **64****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Main method: simple randomization (using random.org). Allocation was done individually Randomization was unstratified. Website www.random.org (online random number generator based on atmospheric noise) Sealed envelopes to store allocation sequence How to create a random sequence First draw the groups (possibly determine the order of the groups or choose the type of the first group) Then randomly select individuals to be allocated to the groups This process was done using www.random.org. The generated sequence was stored in sealed envelopes. Allocation concealment The random sequence was stored in sealed envelopes. Decryption was only possible in emergency situations (serious complications) and under the supervision of the

responsible physician. The evaluators and training instructors (implementation team and evaluation team) were unaware of the grouping code.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Those who were blinded to the allocation: Participants (MS patients) were blinded (participants did not know which group they were in). Reason: The intervention and placebo were designed and prepared in exactly the same way in terms of appearance (shape, color, taste) and method of administration. The study is single-blinded from the participants' perspective. The exercise trainers (the intervention team/those who performed the vibration exercise) were blinded. "The intervention team (the exercise trainers) ... were unaware of the allocation codes." The assessors/those who collected the data or evaluated the results were blinded. "The assessors (those who collected the data or evaluated the results) were unaware of the allocation codes." This includes assessors of functional tests (e.g. TUG, 7-meter walk), electromyography, and questionnaires. The principal investigator (and other members of the main research team) were blinded. The principal investigator was aware (open-label to the PI). The health-care personnel (neurologist, physician responsible for monitoring complications) Were aware (not blinded). The referring physician was the specialist. The responsible physician was authorized to decode the envelopes in emergency situations. At least one senior physician was aware or could have been aware of the allocation.

**Placebo**

Used

**Assignment**

Factorial

**Other design features**

Innovation in vibration therapy and the use of traditional Qavot supplements

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

research ethics of university of birjand

**Street address**

End of University Boulevard - Shaukat Abad Campus - Central Organization of Birjand University

**City**

birjand

**Province**

South Khorasan

**Postal code**

9717434765

**Approval date**

2024-10-29, 1403/08/08

**Ethics committee reference number**

## Health conditions studied

### 1

#### Description of health condition studied

Multiple sclerosis

#### ICD-10 code

G35

#### ICD-10 code description

Multiple sclerosis

## Primary outcomes

### 1

#### Description

Timed Up and Go

#### Timepoint

Before the start of the intervention and eight weeks after the intervention

#### Method of measurement

Measuring round trip time using a stopwatch

### 2

#### Description

Timed 25-Foot Walk - T25FW

#### Timepoint

Before the start of the intervention and eight weeks after the intervention

#### Method of measurement

Measuring round trip time using a stopwatch

### 3

#### Description

Muscle Synergy Index (Muscle Synergy Index or the number/structure of muscle synergies) calculated from electromyography (EMG) signals during walking

#### Timepoint

Before the start of the intervention and eight weeks after the intervention

#### Method of measurement

Extraction of muscle synergies using Non-negative Matrix Factorization (NMF) analysis or similar methods on sEMG data of muscles involved in the gait cycle (e.g. Quadriceps, Hamstrings, Gastrocnemius, Tibialis Anterior). The number of synergies, the contribution of each synergy (muscle weight per synergy), or the amount of variance explained (VAF) by the synergies using Matlab software.

### 4

#### Description

Sleep Quality Index

#### Timepoint

Before the start of the intervention and eight weeks after the intervention

#### Method of measurement

### 5

#### Description

Quality of life index

#### Timepoint

Before the start of the intervention and eight weeks after the intervention

#### Method of measurement

(MSQoL-54)

## Secondary outcomes

### 1

#### Description

Quality of life score

#### Timepoint

Before the intervention and eight weeks later

#### Method of measurement

Quality of life questionnaire

### 2

#### Description

Sleep quality score

#### Timepoint

Before the intervention and eight weeks later

#### Method of measurement

sleep quality questionnaire

### 3

#### Description

25-foot and TUG test

#### Timepoint

Before the intervention and eight weeks later

#### Method of measurement

Measuring round trip time

## Intervention groups

### 1

#### Description

Control Group: Only placebo will be received! An active placebo with 5% coffee, essence, and chemicals, also prepared with a flavor similar to coffee, will be delivered to the placebo group.

#### Category

Placebo

### 2

#### Description

Intervention Group 1: Receiving vibration therapy alone; the exercise intervention will be implemented for 8 weeks with a frequency of 3 sessions per week (on even days to avoid excessive fatigue). Each session will last approximately 30-35 minutes, including warming up, vibration training, and cooling down. Standing on a

platform with a 30-degree knee bend but a straight torso, the vibration-to-rest ratio is 1:2. The exercise protocol is designed with innovation and progressive challenges to increase balance difficulties and bring it closer to environmental reality. Each week, specific conditions will be applied to reduce reliance on external support and increase reliance on proprioception and the vestibular system.

### Category

Treatment - Drugs

## 3

### Description

Intervention group 3: Receiving and consuming traditional Qavoot supplement alone. The quinoa was obtained from reputable pharmacies in Kerman, and to prevent oil spoilage and ensure the final mixture's stability, preservatives such as methyl paraben and propyl paraben will be added. The subjects consumed the prepared quinoa as a suspension, three teaspoons (equivalent to 300 milligrams per kilogram of body weight) every other day (four days a week; a total of 32 days) for eight weeks. To prepare the suspension, the daily dose was calculated based on each individual's weight and packaged in 250-milligram bottles for delivery to the subjects.

Ingredient	Amount/Gram
Total Quinoa Powder	20 640 grams
Methyl Paraben	18.0 mg
Propyl Paraben	2.0 mg
Sucrose	5 grams
Microcrystalline Cellulose	1 gram
Sodium Chloride	32 grams
Tween 80	0.5 mg
Total	35.26 g

### Category

Treatment - Drugs

## 4

### Description

Intervention group: Intervention group 4: Receiving vibration therapy and taking traditional Qavot supplement = Intervention 3+2

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Hazrat Valiasr Hospital

#### Full name of responsible person

Seyed Mohammad Mousavi Mirzaee

#### Street address

Ayatollah Ghaffari Street - Birjand University of Medical Sciences

#### City

Birjand

#### Province

South Khorasan

#### Postal code

9۷۱۷۸۵۳۰۷۶

#### Phone

+98 56 3239 5000

#### Fax

+98 56 3239 5000

#### Email

mousavim903@mums.ac.ir

#### Web page address

<https://www.bums.ac.ir/>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

University of Birjand

#### Full name of responsible person

Marziyeh Saghebjo

#### Street address

End of University Boulevard - Shaukat Abad Campus - Central Organization of Birjand University

#### City

birjand

#### Province

South Khorasan

#### Postal code

9717434765

#### Phone

+98 56 3102 0000

#### Fax

+98 56 3102 0000

#### Email

m.m.ahmadi2005@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

University of Birjand

#### Proportion provided by this source

50

#### 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

University of Birjand

#### Full name of responsible person

Seyyed mojtaba Hosseini

#### Position

Student

#### Latest degree

Master

**Other areas of specialty/work**

Physiology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

University of Birjand

**Full name of responsible person**

Mohsen Mohammadnia Ahmadi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Exercise physiology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

University of Birjand

**Full name of responsible person**

Seyyed mojtaba Hosseini

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiology

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

It is private and confidential.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

Not applicable

**Data Dictionary**

Not applicable