Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

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

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 ± 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)

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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 to55 years Not taking amantadine and dalfira drugs EDSS score ≥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 univversity of birjand
Street address
End of University Boulevard - Shaukat Abad Campus - Central Organization of Birjand University
City
birjand
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South Khorasan
Postal code
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Approval date
2024-10-29, 1403/08/08
Ethics committee reference number

IR.BIRJAND.REC.1403.014

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
Pittsburgh Sleep Quality Index

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 aloneThe 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 8-Week Total Quinoa Powder 20 640 grams Methyl Paraben 18.0 mg 76.5 mg Propyl Paraben 2.0 mg 64.0 mg Sucrose 5 grams 160 grams Microcrystalline Cellulose 1 gram 32 grams Sodium Chloride 1.0 mg 2.3 mg Tween 80 0.5 mg 6.1 mg Total 35.26 g 2.843 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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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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