Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of sensory-motor and virtual reality interventions on gait, balance and quality of life indicators of patients with multiple sclerosis.

Protocol summary

Study aim
Investigating the effectiveness of sensorimotor intervention (SN) compared to virtual reality (VR) intervention on the functional status and quality of life of MS patients.

Design
The clinical trial, two parallel intervention and control groups, single-blind, randomized with computer software and on 30 patients with MS.

Settings and conduct
Initially, 36 MS patients undergoing Rituximab treatment were selected after reviewing their medical records, and ultimately, 30 of them met the inclusion criteria. These 30 individuals were then randomly divided into three groups. Each group performed their specific exercises separately on different days at the Institute of Sports Science and Wellness at the University of Birjand.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Relapsing and relapsing MS patients between 18 and 65 years of age with an EDSS of 2 to 6 and the ability to walk at least 100 meters. Exclusion criteria: lack of personal desire of patients and absence in more than 3 sessions and not answering the phone

Intervention groups
VR training group: balance exercises based on virtual reality SN training group: Balance exercises based on sensory and motor integration Control (CON) group: usual care of MS patients

Main outcome variables
Timed Up and Go test or TUG to assess walking. Timed 25-Foot Walk test or T25FW to assess dynamic balance. Multiple Sclerosis Quality of Life 54 or MSQOL54

General information

Reason for update

Acronym
TUG, T25FW, SN,VR, MS

IRCT registration information
IRCT registration number: **IRCT20240926063172N1**
Registration date: **2024-11-02, 1403/08/12**
Registration timing: **prospective**

Last update: **2024-11-02, 1403/08/12**
Update count: **0**

Registration date
2024-11-02, 1403/08/12

Registrant information

Name
Hadi Asghari

Name of organization / entity
University OF Birjand

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-10, 1403/08/20

Expected recruitment end date
2024-11-20, 1403/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effectiveness of sensory-motor and virtual reality interventions on gait, balance and quality of life indicators of patients with multiple sclerosis.

Public title
Comparison of two types of balance interventions based on sensory integration in multiple sclerosis (MS) patients.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
MS patients between 18 and 65 years of age Relapsing and relapsing MS patients treated with rituximab with high disease activity Patients with an Extended Disability Status Scale (EDSS) of 2 to 6 Ability to walk without assistance and at least 100 meters
Exclusion criteria:
Patients' personal unwillingness to continue the exercises absence in more than 3 training sessions Failure to answer the phone call to continue the treatment
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each indicator will be measured 2 times, one in the pre-test and one in the post-test for each participant
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: random grouping through Randomizer Random Pick software Randomization Unit: Individual Randomization tool: Randomizer Random Pick software How to create randomization: Select Randomize List to create a randomization list About concealment: coding the patient and carrying out the entire process by someone who was not aware of the evaluation of the variables and the implementation of the exercises.
Blinding (investigator's opinion)
Single blinded
Blinding description
In general, the participants, clinical caregivers, and outcome evaluators will not have any modification of the nature of the study and study groups, and only the method of implementation for the participants, how to care for the patient, and how to evaluate the variables will be told to them.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University
Street address
Central Organization of Birjand University, Shaukatabad Campus, End of University Boulevard, Birjand, South Khorasan, Iran
City
Birjand
Province
South Khorasan
Postal code
9717434765
Approval date
2022-12-28, 1401/10/07
Ethics committee reference number
IR.BIRJAND.REC.1402.002

Health conditions studied

1

Description of health condition studied
Multiple sclerosis or MS
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Gait Indicator with T25FW
Timepoint
2 days before 8 weeks and 2 days after 8 weeks
Method of measurement
In this test, the participant travels 7.5 meters in a straight line without assistance in the shortest possible time. This test is repeated twice and the walking speed is calculated as the average of the two tests. During the test, the tester stays close to the patient to prevent falls or any other accidents.

2

Description
Dynamic balance Indicator with TUG
Timepoint
2 days before 8 weeks and 2 days after 8 weeks
Method of measurement

A stopwatch is used in this test to measure the time it took the subject to stand up from the armchair and travel a distance of 3 meters as quickly as possible, then turn around and seat back in the chair and lean back. The examiner remains near the patient to keep them from falling

3

Description

Quality of life for MS patients with MSQOL54

Timepoint

2 days before 8 weeks and 2 days after 8 weeks

Method of measurement

The MSQoL-54 questionnaire is a health-related self-assessment tool with two components: physical health and mental health scores. Composite scores were calculated by converting item scores to a scale of zero to 100 where zero indicates the worst health condition and 100 indicates the best health condition. Also, the sum of two subscale scores of mental health and physical health was used to calculate the overall score of MSQoL-54

Secondary outcomes

1

Description

Sleep quality with PSQI

Timepoint

2 days before and after 8 weeks

Method of measurement

The Pittsburgh Sleep Quality Index (PSQI) was used to evaluate the sleep quality of MS patients. PSQI consists of 9 items that measure seven different aspects including sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disorders, use of sleeping pills and daytime dysfunction. The PSQI score ranges from 0 to 21, with higher scores indicating lower sleep quality. In general, a PSQI score more than 5 indicates poor quality sleep

Intervention groups

1

Description

Control group: The control group was not allowed to engage in any physical activity during the trial time, but were encouraged to conduct SN and VR activities after the study was completed

Category

Rehabilitation

2

Description

Intervention group 1: Sensorimotor training is a modified training protocol based on previous studies in which participants go through 18 training stations in a circuit in each session. The exercises were divided into static and dynamic categories. The static part includes 12 stations and the dynamic part (on foot) also includes 6 educational stations. Static exercises include external destabilization and self-destabilization patterns that are performed on the floor surface and cushion foam in three conditions: eyes open, closed, and with a helmet. During external stabilization exercises, the practitioner pushes (shifts) the patient's pelvis forward and to the side, during which the patient must quickly maintain their balance. In self-destabilizing activities, patients shift their weight from one leg to the other to intentionally shift their center of gravity. During walking exercises, the patient is given cognitive activities such as counting numbers, subtracting numbers, and remembering specific human or animal names. Each exercise session begins with a 10-minute warm-up. The last five minutes of each training session are devoted to cooling down. The duration of each station from the first to the sixth week is 30, 35, 40, 45, 50, 55 seconds and 60 seconds in the seventh and eighth weeks. The ratio of work to rest is also considered similar from the first to the eighth week.

Category

Rehabilitation

3

Description

Intervention virtual reality group : The virtual reality exercise in the present study was also a modified exercise protocol that was formed based on previous research. Virtual reality games consist of two components: dynamic and static. Dynamic games include one or more of the 12 walking patterns presented in Table 4. The primary priority for the VR dynamics component was to select games that employ 12 different walking patterns. Patterns during a VR training session. The virtual games considered for the dynamic component included Plank rich, Pistol whip, Boxing, Walking dead, Temple Run. Static VR games were also performed in such a way that 6 static movement patterns were used in a VR training session. This component also included Beat saber, Power beat saber, OHSHIP games. The duration of each VR station and the rest between stations were equivalent but different from the SN protocol. However, the total duration of a training session was similar to the SN protocol and was 18, 21, 24, 27, 30, 33 minutes for weeks 1 to 6 and 36 minutes for weeks 7 and 8, respectively. All virtual reality games were played in a 10x10 room. Comprehensive descriptions of dynamic and static movement patterns are shown in Table 4.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Specialized and Subspecialized Hospital, Birjand

Full name of responsible person

Dr. Seyed Mohammad Mousavi Mirzaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Birjand

Full name of responsible person

Dr. Saeed ilbeigi

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Faculty of Sports Sciences, Behavioral Sciences Campus, University of Birjand, End of University Boulevard, Shokatabad Campus, Birjand, South Khorasan, Iran

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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

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

University of birjand

Full name of responsible person

Seyed hadi asghari

Position

PHD student in sports physiology

Latest degree

Master

Other areas of specialty/work

Fitness and sports rehabilitation

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Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Birjand

Full name of responsible person

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Position

PHD student in sports physiology

Latest degree

Master

Other areas of specialty/work

Fitness and sports rehabilitation

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Person responsible for updating data

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Name of organization / entity

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Seyed hadi asghari

Position
PHD student in sports physiology
Latest degree
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available