

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the effect of dual task exercise versus combined exercise in water and land on balance and gait of patients with multiple sclerosis.

Protocol summary

Study aim

Comparison of the effect of dual-task exercise v.s combined exercise in water and land on balance and gait of patients with multiple sclerosis.

Design

RCT with the control group, the double-blinded factorial group on 78 patients. Participants will be randomized using block randomization at <http://randomizer.org/>.

Settings and conduct

This study focuses on exercise therapy on people with multiple sclerosis as pre-test and post-test. gait biomechanics analysis tests in the laboratory, cognitive and movement tests are evaluated pre and post twelve-week treatment. The movement biomechanics laboratory, swimming pool, and gym will be at the Khwarazmi University of Karaj. outcome assessor who does not know the hypothesis and study methods will be blinded to group allocation, also the data analysts will analyze the information of individuals in a code format. so he will be blinded too.

Participants/Inclusion and exclusion criteria

inclusion criteria: patients with relapsing-remitting type, The (EDSS) should be between 1.0 and 5.5. exclusion criteria: Inability to stand and walk without aids.

Intervention groups

1. Intervention group: dual-task exercise in water: dual-task exercise will be done in the swimming pool. 2. Intervention group: dual-task exercise on land: dual-task exercise will be done in the gym. 3. Intervention group: combined exercise in water: combined exercise will be done in the swimming pool. 4. Intervention group: combined exercise on land: combined exercise will be done in a gym 5. Control group: patients with multiple sclerosis walking in water. 6. Control group: patients with multiple sclerosis walking in land.

Main outcome variables

static and dynamic Balance rate; gait biomechanics.

General information

Reason for update

This study underwent changes after the time of registration due to the following reasons: 1. Because the type of study was changed from parallel to factorial, the researchers should have added another control group to the study so that the factorial type was 3-2-2 In this case, even the environmental factor was properly investigated in the study. so the participant number increased from 65 to 78. 2. Participants genders changed from only women to both 3. the primary and the secondary outcome exchanged, Because the statistical error will be reduced.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051581N1**
Registration date: **2023-01-25, 1401/11/05**
Registration timing: **prospective**

Last update: **2023-09-14, 1402/06/23**

Update count: **1**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

سحر Nazari

Name of organization / entity

Khwarazmi University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-28, 1401/11/08

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

2023-01-30, 1401/11/10

Actual recruitment end date

2023-02-15, 1401/11/26

Trial completion date

empty

Scientific title

Comparison of the effect of dual task exercise versus combined exercise in water and land on balance and gait of patients with multiple sclerosis.

Public title

effect of exercise treatment in patients with multiple sclerosis.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with relapsing remitting type of multiple sclerosis. No MS relapse occurred within eight weeks prior to the inclusion Status Scale (EDSS) score ranging from 1.0 to 5.5 lack of regular physical exercise

Exclusion criteria:

being unable to comply with the requirements of the protocol. Inability to stand and walk without aids and braces.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **78**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block randomization
Randomization unit: it is individual. Randomization type: Randomization will be online randomization using the website <http://randomizer.org/>. Patients who meet the inclusion criteria will be randomly assigned to the experimental group (exercise in water and exercise on land) and the control groups. In this site, first, the number of sets of random numbers that is needed is determined (six sets of numbers are needed; 1. experimental group A, 2. experimental group B, 3. experimental group C, 4. experimental group D, 5. group Control E, and 6. control group F). The numbers that Research Randomizer needs to generate in each set are determined (six sets of 13 numbers are needed for each group). We specify the minimum and maximum amount

of numbers that need to be produced (from 1 to 78).

Concealment: Concealment of random assignment using a block randomization table (blocks of 10) generated by computer (number 1 for experimental group 1, number 2 for experimental group 2, number 3 for experimental group 3 and number 4 for experimental group, number 5 for control group and number 6 for control group) will be done before the start of data collection by a researcher who will not participate in calling or treating patients. Randomization tool: Random numerical sequence is placed in non-transparent and sealed envelopes. Another investigator, blinded to the initial assessment, will open an envelope and proceed with treatment as assigned by the group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study, is doubled blinded, and the outcome assessor and the data analyst will be blind (uninformed) regarding the allocation of groups. Patients will be aware of the type of study. Outcome assessor : In this study, an independent evaluator who does not know the hypothesis and methods of the study will evaluate the results before the interventions and 12 weeks after the interventions. Data analyst: The data analyst is blinded. the collected data will be matched with the codes given to each patient. so, the data analyst will see each patient in the form of a code, and the grouping of patients will not be recognizable to him.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Sport Sciences Research Institute (SSRI)

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No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

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Approval date

2022-11-21, 1401/08/30

Ethics committee reference number

IR.SSRC.REC.1401.082

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

the brief repeated battery of neuropsychological tests

Timepoint

before and after intervention

Method of measurement

psychological and cognitive test

2

Description

dual task rate

Timepoint

before and after intervention

Method of measurement

dual task questionnaire

Secondary outcomes

1

Description

static and dynamic Balance rate

Timepoint

before intervention and after intervention

Method of measurement

force plate and motion analyze instrument

2

Description

biomechanic gait including movement angles and forces on the ground, which may change with intervention.

Timepoint

before intervention and after intervention

Method of measurement

force plate and motion analyze instrument

3

Description

evaluation of electromyography during tasks

Timepoint

before intervention and after intervention

Method of measurement

electromyography instrument

Intervention groups

1

Description

Intervention group: dual-task exercise in water Dual task exercises are exercises in which both cognitive and motor exercises are prescribed to the patient. For example, walking in water while deducting seven numbers from the number 129. Dual task exercises in water are first presented separately in the form of single cognitive exercises, then in the form of movement exercises and finally by combining both of these exercises, dual task exercises are presented to the subject. These exercises are performed in a swimming pool depth of 120 cm and at a water temperature of 30 to 31. The ambient temperature of the pool will be maintained around 26 to 28 degrees Celsius. These exercises last two days a week for 12 weeks (24 sessions) for one hour in each session.

Category

Rehabilitation

2

Description

Intervention group: dual task exercise on land These exercises are the same as the dual task exercises in the water, with the difference that they will be performed on land and in the gym. Dual task exercises are exercises in which both cognitive and motor exercises are prescribed to the patient. For example, walking in land while deducting seven numbers from the number 129. Dual task exercises inland are first presented separately in the form of single cognitive exercises, then in the form of movement exercises and finally by combining both of these exercises, dual task exercises are presented to the subject. These exercises last two days a week in a period of 12 weeks (24 sessions) for one hour in each session.

Category

Rehabilitation

3

Description

Intervention group: combined exercise in water These exercises will also be performed in water, with the difference that instead of performing dual task, combined exercises (including strength, endurance and stretching exercises) will be used. Therefore, it is not a repetitive intervention. These exercises will be performed in water depth of 120 cm and at a water temperature of 30 to 31 degrees Celsius, and the pool's ambient temperature is maintained at 26 to 28 degrees Celsius. These exercises last two days a week in a period of 12 weeks (24 sessions) for one hour in each session. The specialist considers existing muscle weaknesses and balance defects to prescribe sports exercises. These deficits are determined based on manual muscle testing to assess weakness based on participant observation. All sessions begin with a 10-minute warm-up and end with a 5-minute cool-down. Joint stretching of the muscles plus specific stretching is done according to the specific

needs of the participants. Combined exercises in the water include a strength, aerobic and balance training program.

Category

Rehabilitation

4**Description**

Intervention group: combined exercise on land In this group, combined exercises are performed in the gym and on land. Therefore, it will not be a repeated intervention. These exercises last two days a week in a period of 12 weeks (24 sessions) for one hour in each session. The specialist considers existing muscle weaknesses and balance defects to prescribe sports exercises. These deficits are determined based on manual muscle testing to assess weakness based on participant observation. All sessions begin with a 10-minute warm-up and end with a 5-minute cool-down. Joint stretching of the muscles plus specific stretching is done according to the specific needs of the participants. Combined exercises in the water include a strength, aerobic and balance training program.

Category

Rehabilitation

5**Description**

Control group: patients with multiple sclerosis walk in water. walking will also be performed in water, with no training protocole. walking in water will be performed in depth of 120 cm and at a water temperature of 30 to 31 degrees Celsius, and the pool's ambient temperature is maintained at 26 to 28 degrees Celsius. walking last two days a week in a period of 12 weeks (24 sessions) for one hour in each session.

Category

Rehabilitation

6**Description**

Control group: patients with multiple sclerosis walk on land. walking will also be performed on land, with no training protocole. walking on land last two days a week in a period of 12 weeks (24 sessions) for one hour in each session

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alborz MS NGO

Full name of responsible person

Hossein Ashrafian

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kharazmi University

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

Kharazmi University

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**

Kharazmi University

Full name of responsible person

Sahar Nazary soltan ahmad

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Corrective exercises and sport injuries

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

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data files such as files related to the biomechanics of walking and motion analysis and gait tests, files related to EMG of worked muscles, dual-task questionnaires Balance scores and battery tests are the data that are examined in this study. will be. Data can potentially be shared after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published in validate journals.

To whom data/document is available

Only researchers working in academic and scientific institutions

Under which criteria data/document could be used

1. if the originality of the work is preserved and the names and information of the authors of this study are mentioned. 2. After the original data are published by the main researchers in a valid journal, permission is given to use the documents.

From where data/document is obtainable

saharnazary1992@gmail.com

saharnazary1992@khu.ac.ir Sahar Nazary Soltan Ahmad

What processes are involved for a request to access data/document

After reading the email, the information will be sent to the researchers.

Comments