Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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

Kharazmi University

Country

Iran (Islamic Republic of)

Phone

+98 21 8888 2991

Email address

std_saharnazary@khu.ac.ir

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)
Street address
No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1587958711
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 questionaire

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

Street address
Taleghani Square, gohardasht

City
karaj

Province
Alborz

Postal code
3149779451

Phone
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Email
alborzms@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kharazmi University

Full name of responsible person
Mohammad Delnavaz

Street address
No. 43. South Mofatteh Ave., Tehran, Iran

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Tehran

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14911-15719

Phone
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Email
info@khu.ac.ir

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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KhU, No. 43. South Mofatteh Ave., Tehran, Iran
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Person responsible for updating data

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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 testsare 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