Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Long-term effect of CoDuSe program on balance, fall risk, and gait in patients with multiple sclerosis

Protocol summary

Study aim
To evaluate the long-term effect of a group-based balance exercise program targeting core stability, dual tasking, and sensory strategies (CoDuSe) on balance, fall risk, and gait in patients with multiple sclerosis

Design
Pre and post-experimental study, designed as a randomized, controlled trial.

Settings and conduct
Data collection and intervention was carried out in the biomechanics lab of the Collage of Applied Medical Sciences, Prince Sattam bin Abdulaziz University

Participants/Inclusion and exclusion criteria
The inclusion criteria - The age ranged from 20 to 50 years - The body mass index (BMI) was 25 to 35 kg/m2 - The duration of illness not more than 10 years, with no relapses over the past three months - Walking ability not exceeding 200 m (with or without a walking aid), -Ability to transfer between a wheelchair and a plinth with only slight assistance The exclusion criteria - Patients with any difficulty to communicate or understand the program instructions - any other neurological deficits or orthopedic abnormalities or cardiovascular diseases - having participated in balance exercise administered by health care personnel during the past 30 days - or having started or changed medication with 4-aminopyridine during the past 30 days

Intervention groups
Patients were randomly assigned into two matched groups; The study group received CoDuSe program combined with the selected exercise program, whereas the control group received the selected exercise program. The rehabilitation program lasted for 8 weeks for both groups.

Main outcome variables
Static and dynamic balance, Fall risk index test, gait speed, and walking ability were assessed using the Berg Balance Test (BBT), the Biodex Balance System (BBS), the timed 25-foot walk test (T25FW), and the 12-Item MS walking scale (MSWS-12) respectively.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210909052421N4**
Registration date: **2023-04-23, 1402/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-23, 1402/02/03**
Update count: **0**

Registration date
2023-04-23, 1402/02/03

Registrant information

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Nadia Radwan

Name of organization / entity
Prince Sattam Bin Abdulaziz University

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-23, 1402/02/03

Expected recruitment end date
2023-06-30, 1402/04/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Long-term effect of CoDuSe program on balance, fall risk, and gait in patients with multiple sclerosis

Public title
Long-term effect of CoDuSe balance exercise program

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The age ranged from 20 to 50 years. The body mass index (BMI) was 25 to 35 kg/m2. The duration of illness not more than 10 years, with no relapses over the past three months. Walking ability not exceeding 200 m (with or without a walking aid). Ability to transfer between a wheelchair and a plinth with only slight assistance (in order to be able to participate in the intervention).

Exclusion criteria:
Patients with any difficulty to communicate or understand the program instructions. Any other neurological deficits or orthopedic abnormalities or cardiovascular diseases. Patients who have participated in balance exercise administered by health care personnel during the past 30 days. Patients who have started or changed medication with 4-aminopyridine during the past 30 days

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
A computer-based randomization program, by an independent researcher, allocated the patients randomly into two groups (study and control group) equally.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients were recruited and allocated randomly into on of the two groups. Based on the randomized block design,a drawing sealed non-transparent envelope with a specific code for each envelope was chosen by all participants for either group (group A and group B) under the supervision of a blinded independent assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Prince Sattam Bin Abulaziz university

Street address
ALmanifeia, Alraghi building

City
Alkharj

Postal code
00966

Approval date
2023-01-10, 1401/10/20

Ethics committee reference number
SCBR-003-2023

Health conditions studied

1

Description of health condition studied
multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Demyelinating diseases of the central nervous system-multiple sclerosis

Primary outcomes

1

Description
Static and dynamic balance

Timepoint
All patients were assessed four times, pretreatment, one-week post-treatment, after 6 and 12 months after the rehabilitation program. The rehabilitation program lasted for 8 weeks.

Method of measurement
The Berg Balance Test

2

Description
Fall risk index test

Timepoint
All patients were assessed four times, pretreatment, one-week post-treatment, after 6 and 12 months after the rehabilitation program. The rehabilitation program lasted for 8 weeks.

Method of measurement
the Biodex Balance System

3

Description
gait speed
Timepoint
All patients were assessed four times, pretreatment, one-week post-treatment, after 6 and 12 months after the rehabilitation program. The rehabilitation program lasted for 8 weeks.
Method of measurement
the timed 25-foot walk test

4

Description
walking ability
Timepoint
All patients were assessed four times, pretreatment, one-week post-treatment, after 6 and 12 months after the rehabilitation program. The rehabilitation program lasted for 8 weeks.
Method of measurement
12-Item MS walking scale

Secondary outcomes

empty

Intervention groups

1

Description
The study group received the CoDuSe balance training combined with the selected exercise program. The CoDuSe balance exercise was given in small groups (two to five people) with at least one physical therapy present. The first 15 min were primarily focused on core stability exercise, that is, controlled leg movements. The participants were then encouraged to maintain a focus on core stability while performing the remaining exercises, which included dual tasking and sensory strategies such as carrying something while walking or walking on an uneven surface.
Category
Rehabilitation

2

Description
Control group: The control group received the selected exercise program. The study group and the control group both received the conventional exercise program which included progressive static and dynamic balance exercises, that was presented by the ability to hold trunk against minimal then moderate push in unexpected directions from sitting then standing positions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Prince Sattam Bin Abdelaziz university hospital
Full name of responsible person
Mashael Alghamedi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Prince Sattam bin Abdul-Aziz university
Full name of responsible person
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ah.alshehri@psau.edu.sa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
self funding
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity

Prince Sattam bin Abdulaziz University
Full name of responsible person
Nadia Lotfy Radwan
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
patient information sheet , raw data , results
When the data will become available and for how long
after publication
To whom data/document is available
public
Under which criteria data/document could be used
statistical analysis
From where data/document is obtainable
n.radwan@psau.edu.sa
What processes are involved for a request to access data/document
via email. research gate
Comments