

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of the effectiveness of tele rehabilitation program with routine rehabilitation program on improving upper limb function in patients with multiple sclerosis: a pilot study

Protocol summary

Study aim

Determining the effect of telerehabilitation program on upper limb function in people with Multiple Sclerosis (MS)

Design

The present study is a pilot study in the form of a clinical trial. Sampling is available from the patients of the center. Before starting, the random allocation study is done through the software and they are divided into three groups. The number of 5 people in each group (15 people in total) is selected.

Settings and conduct

The study site is the adult occupational therapy ward of Rofideh Hospital in Tehran. The study population of patients with MS who are visited by a neurologist in the hospital and have the conditions to enter the study. No blinding was performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction of people to participate in the study; Diagnosis of MS by a specialist; Extensive Disability Status Scale (EDSS) score below 8; The person has access to the Internet; The person has the ability to work with a computer; The person has a score higher than 24 based on the MoCA scale. Non-inclusion criteria: The person has vision problems related to the disease; Recurrence of the disease

Intervention groups

Control group : receives routine occupational therapy interventions in the hospital; Intervention group 1: receives routine occupational therapy interventions with the use of Pressure MOLEB in the hospital; Intervention group 2: receives routine occupational therapy interventions with the use of Pressure MOLEB at home.

Main outcome variables

Upper limb tone; Upper limb function speed; Fatigue; Independence level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210627051725N1**

Registration date: **2021-09-07, 1400/06/16**

Registration timing: **prospective**

Last update: **2021-09-07, 1400/06/16**

Update count: **0**

Registration date

2021-09-07, 1400/06/16

Registrant information

Name

Tahmineh Marandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2247 6448

Email address

tahmineh.m9@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of tele rehabilitation program with routine rehabilitation program on improving upper limb function in patients with multiple sclerosis: a pilot study

Public title

Evaluation of the effectiveness of tele rehabilitation program on upper limb function in people with MS : Pilot study

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction of people to participate in the study
Diagnosis of MS by a specialist
Extensive Disability Status Scale (EDSS) score below 8
The person has access to the Internet
The person has the ability to work with a computer
The person has a score higher than 24 based on the MoCA scale

Exclusion criteria:

The person has vision problems related to the disease
Recurrence of the disease

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling is available from the patients of the center based on the demographic questionnaire and inclusion and exclusion criteria. Before starting the study, a list of random assignments of individuals to groups is prepared using R software and they are divided into three groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Rehabilitation Sciences and Social Health

Street address

Koodakyar deadend alley, Daneshju Blvd., Evin

City

Tehran

Province

Tehran

Postal code

1985713871

Approval date

2021-07-17, 1400/04/26

Ethics committee reference number

IR.USWR.REC.1400.100

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Upper limb tone

Timepoint

Before the meetings, after the meetings, one month later

Method of measurement

MASHworth test

2

Description

Upper limb function speed

Timepoint

Before the meetings, after the meetings, one month later

Method of measurement

9-Hole peg test

3

Description

Fatigue

Timepoint

Before the meetings, after the meetings, one month later

Method of measurement

FIS test

4

Description

Independence level

Timepoint

Before the meetings, after the meetings, one month later

Method of measurement

FIM test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Routine occupational therapy interventions with the use of motor biofeedback system (Pressure MOLEB) in the hospital

Category

Rehabilitation

2

Description

Control group: Routine occupational therapy interventions in the hospital

Category

Rehabilitation

3

Description

Intervention group 2: Routine occupational therapy interventions with the use of motor biofeedback system (Pressure MOLEB) for remote rehabilitation at home

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofideh Rehabilitation Hospital

Full name of responsible person

Tahmineh Marandi

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Ne'emati Alley, South Salimi Avenue, Andarzgoo Blvd, Qeytarie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khoram Khorshid

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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 social welfare and rehabilitation sciences

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 social welfare and rehabilitation sciences

Full name of responsible person

Tahmineh Marandi

Position

occupational therapist

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Person responsible for updating data

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Tahmineh Marandi

Position

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