

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of energy conservation strategies on fatigue, function and quality of life in adult with motor neuron disease

Protocol summary

Study aim

Effect of energy conservation strategies on fatigue, function and quality of life in adult with motor neuron disease

Design

Clinical trial with control group, with two parallel groups(control and intervention), double blind(patient and assessor), randomized

Settings and conduct

Energy conservation strategies will be held for 3 weeks and one hour per week in the rehabilitation department of Shariati hospital. After obtaining the inclusion criteria and completing the initial consent form, the information of the individuals is recorded. According to the parallel design, patients are randomly divided into two groups of control(B) and treatment(A). Both groups receive routine treatments, but in addition to routine treatment, the treatment group will also attend training sessions on energy conservation strategies. Assessments are completed three times in the first week before treatment, then in the third week after intervention, and finally one-month follow-up. Then all the information will be collected and handed over to the statistics consultant for analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-65 year; Mini mental status exam score more than 24; Beck depression inventory score less than 17; Pittsburgh Sleep Quality Index score less than 5; Fatigue severity scale more than 4; able to walk with or without crutches Exclusion criteria: cardiopulmonary problems; no interests in participation

Intervention groups

Intervention group(A): Patients in the intervention group participated in 3 weekly, 1-hour energy conservation programs provided by an experienced OT. Control group(B): Patients participated in 3 weekly, 1-hour occupational therapy sessions provided by an experienced OT in Shariati hospital.

Main outcome variables

Fatigue severity scale, SF36 questionnaire, Canadian occupational performance measure

General information

Reason for update

Record the actual sample size, the start and end date of the actual sampling and the end date of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20210505051194N1**

Registration date: **2021-06-03, 1400/03/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-14, 1400/08/23**

Update count: **1**

Registration date

2021-06-03, 1400/03/13

Registrant information

Name

Niloofer Shirzad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6659 6311

Email address

niloofer.ot92@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-19, 1400/02/29

Expected recruitment end date

2021-09-19, 1400/06/28

Actual recruitment start date

2021-05-22, 1400/03/01
Actual recruitment end date
2021-10-01, 1400/07/09
Trial completion date
2021-11-01, 1400/08/10

Scientific title
Effect of energy conservation strategies on fatigue, function and quality of life in adult with motor neuron disease

Public title
Effect of energy conservation strategies on fatigue, function and quality of life in adult with motor neuron disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

Age between 18-65 year Mini mental status exam score more than 24 Beck depression inventory score less than 17 Pittsburgh Sleep Quality Index score less than 5 Fatigue severity scale more than 4 Patients able to walk with or without crutches

Exclusion criteria:
Patients with cardiopulmonary problems Patients with no interests in participation in study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **28**
Actual sample size reached: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
After initial evaluation, samples will be assigned into one of the 2 groups A or B group using sealed envelopes, the patients have to pick up one the sealed envelopes, so their group will be defined randomly

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 Shahid beheshti University of Medical Sciences

Street address

Damavand street, across from Buali hospital, Tehran, Iran. SBMU School of Rehabilitation Sciences

City

Tehran

Province

Tehran

Postal code

1616913111

Approval date

2019-09-03, 1398/06/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.191

Health conditions studied

1

Description of health condition studied

Motor neuron disease

ICD-10 code

G12.2

ICD-10 code description

Motor neuron disease

Primary outcomes

1

Description

Function

Timepoint

Before, after and one months after treatment

Method of measurement

Canadian occupational performance measure

2

Description

Fatigue

Timepoint

Before, after and one months after treatment

Method of measurement

Fatigue severity scale

3

Description

Quality of life

Timepoint

Before, after and one months after treatment

Method of measurement

SF36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group(A): Patients in the intervention group participated in 3 weekly, 1-hour energy conservation programs provided by an experienced OT. The principles used during the ECM program include The importance of rest during the day, energy budgeting, setting rest periods during the day, administration of proper body mechanics and posture, separating of each daily activity to several components, prioritizing activities, teaching ergonomic principles, analyzing and utilization of the way that ADLs are performed, and environmental change. The training sessions were based on the theory of psychoeducational group development and included discussions about the nature of illness and fatigue, setting short-term and long-term goals, doing homework, and execution of strategies at home. In the first session, patients were taught about the MND nature, the effects of fatigue on ADL, and the importance of rest and adjusting rest periods during the day. Patients were asked to explain their daily routine and the barriers they encounter during activities. The patient, along with the OT, sets short rest periods between daily activities at certain times of the day. In the second session, the therapist spoke about the importance of correct body posturing and emphasized on the performing tasks in the sitting position rather than standing. Patients were taught to divide each activity into smaller, easier steps. The third session focused on prioritizing activities during the day, emphasizing on performing hard and exhausting work at the beginning of the day, and the importance of ergonomics and environment modifications

Category

Rehabilitation

2

Description

Control group(B): Patients participated in 3 weekly, 1-hour occupational therapy sessions provided by an experienced OT in shariati hospital.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Niloofer Shirzad

Street address

No. 25, Jalal Al-Ahmad Highway, North Kargar Street,

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City

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1418815516

Phone

+98 21 8490 2110

Email

niloofer.ot92@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niloofer Shirzad

Street address

No. 25, Jalal Al-Ahmad Highway, North Kargar Street,
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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

Shahid Beheshti University of Medical 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Niloofer Shirzad

Position

Occupational therapist

Latest degree

Master

Other areas of specialty/work

Occupational Therapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Niloofar Shirzad

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The findings of this study will be published as soon as possible.

When the data will become available and for how long

2023

To whom data/document is available

results will be available for journals readers data will be available for reasonable requests for example systematic reviews

Under which criteria data/document could be used

systematic review and meta analysis

From where data/document is obtainable

Shariati Hospital, Tehran, Rehabilitation Department

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

Through email; (niloofar.ot92@gmail.com)

Comments