

# 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,

Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

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

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**Email**

niloofar.ot92@gmail.com

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Niloofar Shirzad

**Position**

Occupational therapist

**Latest degree**

Master

**Other areas of specialty/work**

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Niloofar Shirzad

**Position**

Occupational therapist

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Master

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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**