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The effect of energy conservation strategies on fatigue, function, and quality of life in adults with motor neuron disease: Randomized controlled trial

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Keywords
Motor Neuron Disease; Fatigue; Conservation of Energy Resources; Amyotrophic Lateral Sclerosis; Occupational Therapy

Abstract

Background: Fatigue is one of the most frequent complaints in patients with motor neuron diseases (MNDs), with a significant impact on the quality of life (QOL). There is lack of enough evidence for current pharmacological or non-pharmacological treatments of fatigue in this population to be applied in clinical setting. Energy conservation strategies are one of the key interventions for fatigue management in chronic diseases. We aimed to investigate the effect of applying these techniques in the fatigue management of patients with MND.

Methods: This randomized controlled trial (RCT) study was carried out on 28 patients with MND. Participants were randomly assigned to either the intervention or control group. In addition to routine treatment, patients in the intervention group participated in 3 weekly 1-hour energy conservation programs provided by an experienced occupational therapist. The Fatigue Severity Scale (FSS) score, 36-Item Short Form Survey (SF-36), and Canadian Occupational Performance Measure (COPM) were measured at baseline, immediately after the last intervention session, and one month later.

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Results: FSS and COPM significantly changed after the course in the intervention group ($P < 0.001$ and $P = 0.001$, respectively). Both FSS and COPM improved significantly toward the final assessment only in the intervention group. The SF-36 changes were not significant in each of the groups.

Conclusion: According to the findings of the present study, using energy conservation strategies could lead to better mid-term fatigue management and occupational performance improvement, but it did not improve QOL in patients with MND.

Introduction

Motor neuron diseases (MNDs) include several rapidly deteriorating progressive neurodegenerative disorders involving the upper motor neurons (UMNs), lower motor neurons (LMNs), or a combination of both. MNDs are characterized by progressive degeneration and loss of motor neurons (MNs) in the spinal cord, brain stem, or motor cortex.[1-3] The MND has a worldwide incidence of approximately 2.16 per 100000 person-years.[4] The disease occurs throughout adult life, with the peak incidence between 50 and 75 years of age, and men are affected more.[5,6] Amyotrophic lateral sclerosis (ALS) manifests clinically as muscle weakness, atrophy, respiratory and swallowing dysfunction, fatigue, sleep disorders, pain, difficulty in performing activities of daily living (ADLs) and social-psychological problems.[1,7] The median survival time is approximately 3 years. An older age, onset in bulbar muscles, and lower pulmonary function tests are associated with shorter survival.[8]

Fatigue is one of the most frequent complaints in patients with MND reported in 44%-86% of cases.[9] Fatigue in the MND is multifactorial and partly related to impaired muscle activity. MND is defined as reversible motor weakness, lack of energy, and whole-body tiredness, partially relieved by rest.[10-12] Fatigue has a significant impact on the quality of life (QOL) in this population and is associated with disease progression, age, site of MND onset, severity, and depression.[13,14] Currently, several pharmacological or non-pharmacological treatments have been studied for fatigue in people with MND, with not enough evidence to make conclusions about either treatment.[4,15]

According to studies on fatigue management in chronic diseases, teaching energy conservation management (ECM) by a trained occupational therapist is one of the interventions to control this symptom.[16] Energy management (or energy conservation) strategies are a well-known intervention in the fatigue rehabilitation of patients with multiple sclerosis (MS).[17] The ECM has been defined as "the recognition and development of modifications in daily activities leading to a less fatigue impact through a systematic analysis of daily work, home, and leisure activities in all relevant environments".[17] The strategies include: (I) balance between rest and activity, (II) ability to communicate to others, (III) analyzing and modifying activities, (IV) delegating activities, (V) priority selection and modification, (VI) using the body parts efficiently, (VII) organizing work environment, and (VIII) using assistive devices.[18]

Although Jackson and Rosenfeld[15] suggested that the ECM might be valuable in reducing fatigue and improving performance in people with MND, the effectiveness of these strategies for MNDs has not been evaluated up to now. Given that limited studies are conducted on this subject, high-quality studies on intervention to improve fatigue in MND are much needed.[19] Hence, a randomized controlled trial (RCT) was conducted to investigate the effect of energy conservation techniques in patients with MND.

Materials and Methods

Study design: This two-arm RCT with allocation ratio of 1:1 was implemented in the Physical Medicine and Rehabilitation Clinic of Shariati Hospital, Tehran, Iran, from July to October 2021. 28 known cases of ALS (14 women and 14 men) entered the study. The MND diagnosis was determined by either an experienced neurologist or physiatrist according to Awaji criteria.[20] Based on Awaji criteria, the patients with the probable or definite diagnosis were enrolled. Other inclusion criteria were as ambulatory patients (with or without a cane), age of 18-65 years, Fatigue Severity Scale (FSS) score of > 4, Mini-Mental State Examination (MMSE) score of > 24, Pittsburgh Sleep Quality Index (PSQI) of < 5, Beck Depression Inventory (BDI) of < 17, and the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R) of > 30.

The exclusion criteria were the patients with significant pulmonary or cardiac problems and subjects who were reluctant to participate (Figure 1).

The study completely followed the principles of the Declaration of Helsinki. Moreover, all participants gave written informed consent.

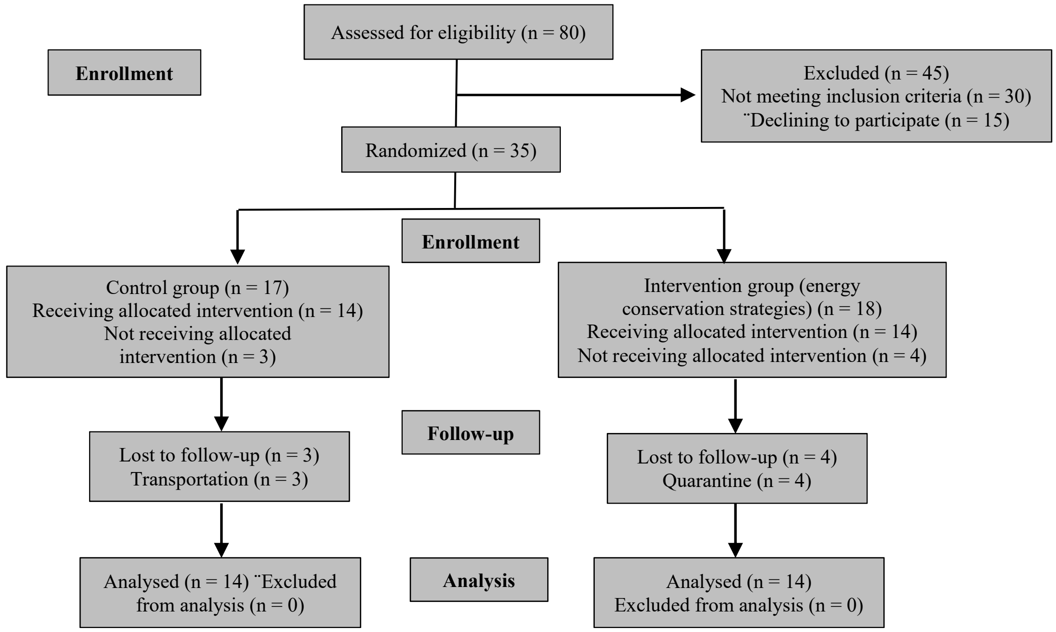

Figure 1: The flow diagram of the study

The RCT was approved by the Ethics Committee of the Institutional Review Board of Shahid Beheshti University of Medical Sciences, Tehran, with the approval code of "IR.SBMU.RETECH.REC.1398.191". Besides, it was registered at the Iranian Registry of Clinical Trials (IRCT) with the registration number of "IRCT20210505051194N1".

Intervention: Participants were randomly assigned into either intervention (n = 14) or control group (n = 14). Simple randomization, using a random number table, was applied as a randomized assignment method. The researcher (NM) selected the randomized number and assigned it to the specific group. Patients in either group received routine rehabilitation programs for three weeks, including occupational therapy (OT) sessions. Additionally, patients in the intervention group participated in 3 weekly 1-hour energy conservation programs provided by an experienced occupational therapist.

The principles used during the ECM program included adequate rest during the day, energy budgeting, setting rest periods during the day, administration of proper body mechanics and posture, separating each daily activity in several components, prioritizing activities, teaching ergonomic principles, analyzing and utilization of the way that ADLs were performed, and environmental change. The training sessions were based on the theory of psycho-educational group development. They included discussions about the nature of illness and fatigue, setting short-term and long-term goals, doing homework, and executing 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 encountered during activities.

Along with the OT, the patients rested in short 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 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, emphasizing performing hard and exhausting work at the beginning of the day, and the importance of ergonomics and environment modifications.[17,21-23]

Outcome measures: Patients were assessed by the FSS score, 36-Item Short Form Survey (SF-36), and Canadian Occupational Performance Measure (COPM). All outcome measures were assessed at baseline, week 3 (after the final treatment session), and one month after the final treatment session. Therapist performed all assessments to the group allocation.

FSS: It is a 9-item self-report scale that measures the severity of fatigue and its effect on a person's activity and lifestyle in patients with various disorders. Each item is scored on a 7-point Likert scale, where 1 = strongly disagree and 7 = strongly agree. The final score represents the mean value of the 9 items, ranging from 1 to 7. The Persian version of FSS is a reliable and valid instrument to measure fatigue status in Iranian patients with neurological disorders.[24]

SF-36: This questionnaire is a patient-reported measure of health and QOL. It measures health on eight multi-item dimensions, covering functional status [physical functioning (10 items), physical role functioning (4 items), social role functioning (2 items), emotional role functioning (3 items)], wellbeing [vitality (4 items), bodily pain (2 items), perceived mental health (5 items)], and overall evaluation of health [general health perceptions (5 items), health transition (an indication of perceived change in general health status over one year)]. Items in the SF-36 questionnaire are claimed to detect positive as well as negative states of health. In six of the eight dimensions, patients are asked to rate their responses on three or six-point Likert scales. For each dimension, item scores are transformed on a scale from 0 (worst health) to 100 (best health), and the final score represents the mean value of all eight dimensions. The SF-36 has been translated into Persian and tested successfully for validity and reliability.[25]

COPM: It is a semi-structured interview performed in a five-step process to identify and prioritize problems in participant's occupational performance. In the first step, the occupational therapist asks the caregivers to determine if they have any occupational performance problems. When the caregiver identifies a need and an inability to perform an activity satisfactorily, this performance area is recognized as a problem. In the second step, the caregiver is asked to rate the importance of each of these activities to him/her on a 1-10 scale (1 = not able at all, 10 = perfectly able). In the third step, the caregiver is asked to assess his/her capability to perform the five most urgent activities or tasks and how content he/she is with this ability using the same 1-10 scale. Step 4 is a reassessment and follows the intervention process.

The final step aims to plan for treatment continuation, follow-up, or discharge.[26] According to Dehghan et al.,[27] the Persian version of the COPM scale had acceptable reproducibility and validity and could be used as an appropriate tool in research and clinical setting.

Data analysis was performed using SPSS software (version 22, IBM Corporation, Armonk, NY, USA). A P-value of less than 0.05 was considered significant. The Kolmogorov-Smirnov test showed a normal distribution of the data. All analyses were performed on 14 patients per group. The repeated measures analysis of variance (ANOVA) was performed to analyze changes in fatigue, QOL, and function at both groups during the time intervals. Independent samples and paired samples t-tests were carried out to compare between groups and within groups, respectively.

Results

A total of 80 patients were assessed from the point of inclusion criteria; they were called for participation in this study and 35 persons were accepted and randomized into two groups. Seven patients left the study during sessions for reasons such as transportation problems and coronavirus disease 2019 (COVID-19)-related quarantine. Finally, data of 28 patients who completed all sessions and assessments were analyzed. The baseline demographics and characteristics of participants of either group are presented in table 1. Both groups included 7 men and 7 women, and the mean age was 49.6 ± 12.2 years in the intervention group and 53.7 ± 9.2 years in the control group. Baseline FSS, SF-36, and COPM mean values did not show any significant difference between the two groups at the baseline (Table 1).

No difference was observed between the two treatment groups regarding age, sex, and baseline values (all with $P > 0.05$). The descriptive statistics of FSS, SF-36, and COPM in both groups are presented in table 2.

The course of outcome measures during study follow-up is demonstrated in table 3 and figures 2-4. FSS improved toward the end of the study in either group, reaching 3.9 ± 0.5 and 4.8 ± 0.7 in intervention and control groups, respectively (Figure 2).

As demonstrated in figure 3, COPM increased in either intervention or control group toward the final assessment, reaching 5.8 ± 0.7 and 5.4 ± 1.9, respectively.

In the intervention group, SF-36 values improved throughout the study reaching to 50.6 ± 9.9 in the final assessment, while in the control group, after a decline in the period between first and second assessment (from a baseline value of 51.9 ± 10.8 to 51.9 ± 10.9) improved to 52.0 ± 10.8 in the third evaluation (Figure 4).

Table 1. Participants demographics and baseline evaluations

Characteristics	Intervention	Control	P
Number	14	14	
Sex [n (%)]			
Men	7 (50.0)	7 (50.0)	
Women	7 (50.0)	7 (50.0)	
Type of MND			
Probable ALS	9 (52.9)	8 (47.1)	
Definite ALS	5 (45.4)	6 (54.6)	
Onset of disease			
Upper limb	6 (54.6)	5 (45.4)	
Lower limb	6 (42.9)	8 (57.1)	
Bulbar	2 (66.7)	1 (33.3)	
ALSFRS-R			
Score: 30-39	9 (47.4)	10 (52.3)	
Score: 40-48	5 (55.6)	4 (44.4)	
Age (year) (mean ± SD)	49.57 ± 12.15	53.71 ± 9.16	0.318
FSS (mean ± SD)	5.24 ± 0.59	4.94 ± 0.72	0.227
SF-36 (mean ± SD)	49.81 ± 10.76	51.90 ± 10.82	0.614
COPM (mean ± SD)	4.61 ± 0.80	5.10 ± 1.52	0.301

MND: Motor neuron disease; ALS: Amyotrophic lateral sclerosis; ALSFRS-R: Revised Amyotrophic Lateral Sclerosis Functional Rating Scale; FSS: Fatigue Severity Scale; SF-36: 36-Item Short Form Survey; COPM: Canadian Occupational Performance Measure; SD: Standard deviation

Table 2. The descriptive findings of the study

	Mean ± SD	Min	Max
FSS (1st)			
Control	4.93 ± 0.71	4.0	6.0
Treatment	5.24 ± 0.58	4.1	6.2
FSS (2nd)			
Control	4.84 ± 0.70	4.0	6.0
Treatment	4.68 ± 0.82	3.5	6.0
FSS (3rd)			
Control	4.75 ± 0.72	4.0	6.0
Treatment	3.94 ± 0.52	3.0	5.0
SF-36 (1st)			
Control	51.89 ± 10.82	35.0	66.0
Treatment	49.80 ± 10.75	33.0	65.0
SF-36 (2nd)			
Control	51.85 ± 10.87	35.0	66.0
Treatment	50.24 ± 10.39	35.0	65.0
SF-36 (3rd)			
Control	52.03 ± 10.77	35.0	66.0
Treatment	50.60 ± 9.89	37.0	65.0
COPM (1st)			
Control	5.10 ± 1.52	3.0	8.0
Treatment	4.61 ± 0.79	3.5	6.0
COPM (2nd)			
Control	5.25 ± 1.47	3.0	8.0
Treatment	5.46 ± 0.74	4.5	7.0
COPM (3rd)			
Control	5.35 ± 1.48	3.0	8.0
Treatment	5.75 ± 0.67	5.0	7.0

FSS: Fatigue Severity Scale; SF-36: 36-Item Short Form Survey; COPM: Canadian Occupational Performance Measure; SD: Standard deviation

As is noted in table 3, a significant improvement was observed regarding FSS and COPM only in the intervention group (both with $P < 0.001$). There was a significant interaction between time and group in terms of FSS ($P < 0.001$) and COPM ($P = 0.001$), and not SF-36 ($P = 0.240$).

This implies that the behavior of our treatment groups differed regarding the changes in these outcomes in the course of the trial in favor of the intervention group (Table 3).

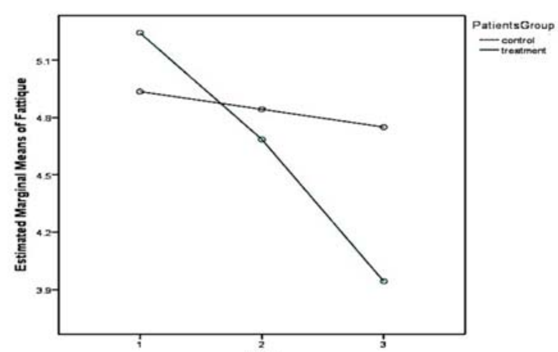

Figure 2. Fatigue Severity Scale (FSS) course in either group

Discussion

This study evaluated the effect of a three weekly 1-hour ECM programs on MND-related fatigue, performance, and QOL. The ECM program improved patients' fatigue (assessed by FSS) and occupational performance (evaluated by COPM) in the short- and mid-term.

Table 3. The between-group analysis of outcome measures by treatment group

Group	Before intervention	After intervention	1 month after intervention	P	Group and time interaction
FSS (mean ± SD)					
Intervention	5.24 ± 0.59	4.69 ± 0.82*	3.94 ± 0.53#	< 0.001	< 0.001
Control	4.94 ± 0.72	4.84 ± 0.70*	4.75 ± 0.73#	0.108	
SF-36 (mean ± SD)					
Intervention	49.81 ± 10.76	50.24 ± 10.39*	50.61 ± 9.90*	0.150	0.237
Control	51.90 ± 10.82	51.87 ± 10.88*	52.04 ± 10.77*	0.301	
COPM (mean ± SD)					
Intervention	4.61 ± 0.80	5.46 ± 0.75*	5.75 ± 0.67*	< 0.001	0.001
Control	5.10 ± 1.52	5.25 ± 1.48*	5.36 ± 1.49*	0.084	

*No statistical significance between intervention and control group ($P > 0.05$)
#Statistical significance between intervention and control group ($P \leq 0.05$)
FSS: Fatigue Severity Scale; SF-36: 36-Item Short Form Survey; COPM: Canadian Occupational Performance Measure; SD: Standard deviation

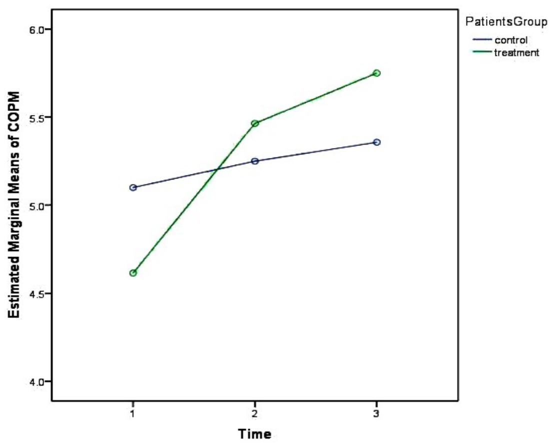

Figure 3. Canadian Occupational Performance Measure (COPM) course in either group

In contrast, patients in the control group reported significant improvement in neither of the measured outcomes.

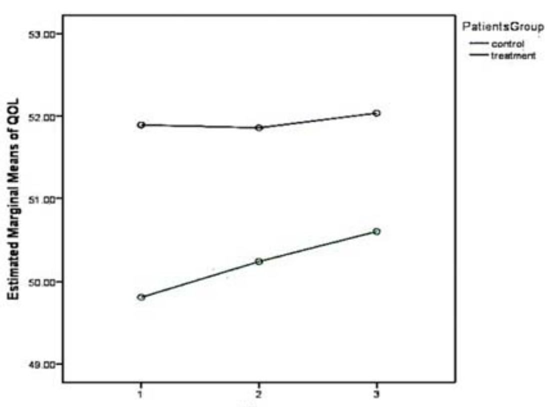

Figure 4. 36-Item Short Form Survey (SF-36) course in either group

We did not find a significant difference in QOL score after the course in treatment group. The observed improvement in the treatment group was preserved toward one month after the last ECM session. Even patients' performance further improved significantly in the period between post-intervention and 1-month evaluation. The sustained improvement in the interval between post-intervention and 1-month evaluation indicates that behavioral changes made as a result of the course became incorporated into daily routines and had a lasting effect on fatigue and everyday performance.

In the recent decade, several studies have been conducted to evaluate the role of different rehabilitation interventions on the function and QOL improvement of patients with ALS, including self-management occupational therapy intervention program (SMOoTh),[17] structured home-based exercise,[28] inspiratory muscle training,[29,30] and aerobic exercise training (AET), and cognitive behavioral therapy (CBT).[2] But there is no established treatment for energy conservation strategies in ALS. A most recent Cochrane review article has indicated that due to the poor quality of available evidence, it is impossible to reach firm conclusions about the effectiveness of interventions regarding energy conservation strategies for people with ALS.[4]

Veenhuizen et al. revealed that the energetic self-management program combining aerobic training, ECM, and relapse prevention resulted in a significant improvement in social participation (COPM-performance) compared to usual care in a heterogeneous group of patients with neuromuscular diseases (NMDs), mainly facioscapulohumeral dystrophy (FSHD), mitochondrial myopathies, and inclusion body myositis (IBM) who were chronically fatigued.[31]

Lewis and Rushanan indicated that though ECM strategies were effective in MS, the generalization of applying these techniques for patients with ALS was debatable and required further studies.[32] Mathiowetz et al. reported that there were significant improvements in all three subscales of the Fatigue Impact Scale (FIS) and in four subscales of 1-year post-course compared with pre-course in the patient with MS.[23] Vanage et al.,[17] Kos et al.,[21] and Hersche et al.[33] in separate studies revealed that ECM courses were associated with improvement in FIS, COPM, and FFS, respectively, in individuals with MS. Moreover, Young described an educational program based on an energy conservation technique for the management of fatigue in patients with post-polio syndrome (PPS) with successful results.[34]

According to a systematic review and meta-analysis by Blikman et al.,[18] ECM techniques can be more effective than no treatment in reducing fatigue and improving some dimensions of QOL (i.e., physical role functioning, social role functioning, and perceived mental health) in fatigued patients with MS.

One of the advantages of ECM over CBT is that it is a proven method for managing patients with chronic pain,[35,36] and the other is that ECM can be performed with regular OT, while experienced psychologists should only teach CBT.[31] Hence, ECM is a more feasible approach.

Finally, as demonstrated in a recent meta-analysis,[37] in patients with common disabling disorders, only 11% of fatigue severity could be attributed to the underlying disorder, while other factors have vital impacts on the reported fatigue, including motivation and activity level. This finding further supports performing fatigue-management approaches like ECM that focus on patient characteristics rather than disease characteristics.

In summary, the present study showed that ECM techniques resulted in the short- and mid-term improvement of fatigue and occupational performance in patients with ALS.

The present study was the first RCT with a control arm to evaluate the feasibility and efficiency of the ECM program alone in patients with ALS. It provides promising data for further RCTs. Nevertheless, this study has some limitations that should be addressed. The main limitations were the small sample size and short follow-up. Additionally, neither the teaching OT nor other participants could be blinded to the group allocation due to the nature of the intervention. Further studies with a larger sample size and longer follow-up could provide a better understanding of ECM in ALS.

Conclusion

According to the findings of the present study, using energy conservation strategies could lead to better fatigue management and occupational performance improvement, but it could not improve QOL in patients with MND. These benefits seem to occur without any adverse effects to cause patients to drop out of the study. Clinicians might be encouraged to use energy conservation strategies in rehabilitation programs of patients with MND, which could be more influential due to better function in daily life activities.

Conflict of Interests

The authors declare no conflict of interest in this study.

Acknowledgments

None.

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