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The effectiveness of a self-management occupational therapy intervention on activity performance in people with MS-related fatigue: a randomized controlled trial

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List six to eight keywords (chosen from Index Medicus, Medical Subject Headings if possible): self-care, occupational therapy, fatigue, energy conservation, energy management, occupational balance, rehabilitation

Abstract

Objective: to evaluate the effectiveness of an individual self-management occupational therapy intervention program (SMOoTh) versus relaxation on the performance of and satisfaction with relevant daily activities in people with MS-related fatigue.

Design: single blind randomized controlled trial

Sample: 31 subjects with MS (SMOoTh: n=17, relaxation: n=14), randomly allocated to three individual sessions focusing on pacing, prioritizing, ergonomics and self-management (SMOoTh) or on stress management and relaxation (relaxation). Outcomes (blind assessor): Canadian Occupational Performance Measure (COPM) (primary), Modified Fatigue Impact Scale (MFIS), Checklist Individual Strength (CIS) and SF-36.

Results: COPM improved in SMOoTh and relaxation group, at post-intervention and three months later (COPM performance: F=13,1, p=0,001 and COPM satisfaction: F= 10,4, p=0,001); non-significant group differences showed a trend in favor of SMOoTh. MFIS, CIS and most of SF-36 subscales did not change. Clinically relevant changes in COPM performance scores were found in 71% and 27% in SMOoTh versus relaxation group.

Conclusion: Both interventions seem to be feasible approaches to improve performance of and satisfaction with relevant daily activities in people with MS, with a sustained effect after three months. Neither program was able to change fatigue (impact) or quality of life. Future studies with larger sample sizes are needed.

Introduction

Fatigue is one of the most common and bothersome symptoms in MS patients and is reported in 50% to 92% of the MS population. Pharmacological treatments are often unsatisfactory whereas rehabilitation strategies seem to have better effects.[1–7]

Energy management (or energy conservation) is a well-known strategy in fatigue rehabilitation for individuals with MS.[8] All available evidence is based on a group format, which could bias the net effect of energy management.[9] Therefore the aim of this study is to evaluate the effectiveness of an individual self-management occupational therapy intervention program (SMOoTh) versus relaxation on the performance of and satisfaction with relevant daily activities in people with MS-related fatigue

Methods

Sample

The study was approved by the ethical committees of the University Hospital of Antwerp and National MS Center of Melsbroek and all participants signed an informed consent. The study protocol was registered at ClinicalTrials.gov (Identifier: NCT01512329).

Participants were recruited in the National MS Center Melsbroek and University Hospital Antwerp (Belgium). Eligibility was screened on the following criteria: definite diagnosis of MS confirmed by the neurologist, age between 18 and 65 years, Dutch speaking, ambulatory (EDSS of 5 or lower) and high impact of fatigue (VAS score of at least 60).[10] Exclusion criteria: involved in rehabilitation program during the study period, pregnancy, relapse 3 months prior to the study or evere cognitive disorders (as judged by the neurologist).

Required sample size was calculated with the software G-power 3.1.7, using the change scores of the Canadian Occupational Performance Measure (performance scale) in a pilot sample of subjects with chronic fatigue syndrome.[11,12] With a significance level of 0.05 and a power of 0.8, the total sample size needed to be at least 20 subjects to detect a clinically relevant change in COPM scores of 2 or more.

Procedure

The study has a single blind randomized controlled trial design, with assessment at baseline, post intervention and at 3-months follow-up (Figure 1). Selected potential participants were informed about the study by one of the researchers or study nurse by telephone and received a study leaflet. One week later they were contacted to confirm willingness to participate. Informed consent was signed during their first visit prior to assessment.

<Insert Figure 1 Flowchart of the study>

All assessments were performed by a researcher blinded for treatment allocation. After the interview and scoring of the COPM, subjects completed the questionnaires in a random order to account for test order bias. To prevent administration bias, participants performed self-report assessment without input or feedback from the researcher.

Subjects were randomly allocated to the SMOoTh versus the relaxation group by blindly self-picking a folded paper out of a box and hand it over to an independent researcher (not involved in data collection or analyses). The latter informed subjects about the type of intervention they would receive. Subjects were informed that both interventions could be helpful for improving fatigue and were therefore quasi-blinded for treatment effects.

Treating therapists were not involved in any of the assessment procedures.

Subjects were asked not to change or initiate any new (pharmaceutical) interventions during the study period. Inevitable changes in medication were reported.

Intervention

Self-management occupational therapy

The self-management occupational therapy (SMOoTh) program is based on the recommendations of the MS Council, principles described in Packer et al. and the Energy Conservation/Envelope Theory.[13–15] The intervention includes strategies to support clients in taking control over the performance of activities within the limits of their available energy and therefore raise their self-efficacy in managing fatigue.[16] This process implies a behavioral change in clients and therefore the intervention also includes several techniques to support this behavioral change, e.g. “goal setting”, “self-monitoring” or “feedback”.[17]

The SMOoTH consists of three individual sessions of 60-90 minutes for 3 consecutive weeks and is provided by an experienced occupational therapist. Supplement 1 shows the structure and planning of the SMOoTH. The first session focuses on coaching the client how to balance daily activities within the limits of their available energy. Daily activities include all responsibilities and desired activities regarding personal and child care, domestic care, productivity and leisure. Prioritized problem activities were extracted from the Canadian Occupational Performance Measure (COPM) within baseline assessment.

To support education, participants received a booklet with evidence-based information on (possible factors influencing and maintaining) fatigue, strategies to cope with fatigue and pace activities. For seven consecutive days prior to the first session, participants registered hourly type of activity, level of fatigue, how important the activity is for the client and how satisfied he/she is with actual performance the importance in a fatigue diary.[13] Diaries were discussed in treatment sessions to support self-awareness and self-efficacy in balancing activities.

Relaxation therapy

Stress may play an important factor in the persistence of fatigue, therefore relaxation may be a crucial component in the treatment of MS-related fatigue.[18]

The relaxation program for this study includes education about the role of stress (management) in MS and practicing relaxation techniques like Jacobson, Schultz, visualization, etc. pending their individual preferences.[19] All information was assembled in an evidence-based information booklet, and participants completed a stress-reaction diary to register activities or events that evoke stress. This diary was used to coach clients in improving coping with similar future stress events. The mode, duration and frequency of the relaxation therapy were identical to the SMOoTh program.

Outcome measures

The *Canadian Occupational Performance Measure* (COPM) (primary outcome measure) assesses (changes in) the perceived ability to perform and satisfaction with relevant daily activities.[20] Using a semi-structured interview, the therapist explores problems in performing relevant daily activities in the domains of self-care, productivity and leisure. For performance and satisfaction subscales, the mean score for all activities is calculated (1-10). For follow-up assessment, COPM blind scores are used, i.e. previous COPM scores on performance and satisfaction are made invisible for both the researcher and the participant.[21] The COPM is a reliable, valid and responsive instrument and change scores of 1.4 for performance and 1.9 for satisfaction are considered clinically important.[21–24]

The *Modified Fatigue Impact Scale* (MFIS) assesses the impact of fatigue on physical, cognitive and psychosocial functioning (range 0-84).[13,25] The MFIS showed adequate reliability, validity and responsiveness in MS samples.[25–27]

The *Checklist Individual Strength* (CIS) is a self-report instrument to evaluate diverse aspects of fatigue (subjective experience of fatigue, reduction in concentration, motivation and activity).[28] The CIS has acceptable reliability and validity.[29,30]

The *Short-Form Health Measure* (SF-36) assesses functional status and well-being, or quality of life and has adequate reliability and validity in a wide variety of patient populations.[31–33]

Statistical analyses

Data were analysed with SPSS, version 21.0 (SPSS Inc; Chicago, Illinois). Shapiro-Wilk normality test showed a normal distribution for all variables.

Parametric analyses include 2 (Group: SMOoTh & Relaxation) x 3 (Time: T0, T1 & T2) mixed model analysis of variance (ANOVA). Group is a between-subjects factor and time is a within-subjects factor. Both compliers and intention-to-treat (first observation carrier forward method) analyses were performed. Effect sizes are expressed as Cohen's d with 95% confidence interval and considered small when d= .20; moderate when d=.50 and values of .80 and more reflect large effect sizes.[34]

The proportion of subjects with a change score in COPM of 1,4 or more for performance and 1,9 or more for satisfaction is calculated to evaluate clinical relevance.[21]

Statistical significance is considered with alpha=0,05 and beta=0,20.

Results

The sample consisted of 31 subjects with MS (n=17 intervention group and n=14 control group) (Figure 1).

Mean age was 41 ± 9,2 years. The SMOoTh group was slightly older; all other variables were similar in both groups (Table 1). Dropouts (18% in the SMOoTh group and 21% in relaxation group) did not significantly differ from compliers for baseline variables, and the dropout rate was similar in both groups.

<Insert Table 1>

In compliers, COPM performance and satisfaction scores changed significantly over time in both groups without differences between groups (Table 2). SF-36 scores of "social functioning" and "physical pain" showed significant time effects; group effects were only found for the latter (effect

size T1: 0,47 [-0,31;1,3]; T2: 2,11 [0,73-2,55]). Similar results were found in the intention-to-treat analyses.

<Insert Table 2>

Clinical relevant changes in occupational performance and satisfaction were more obvious in SMOoTh group (Figure 2). At three months follow-up (T2), more than 70% of the SMOoTh group perceived better performance in desired activities, with a clinically relevant improved satisfaction score in 50% of cases.

<Insert Figure 2>

None of the participants reported initiation or alteration of other treatments during the study period, except for two drop-outs (who were admitted to hospital).

Discussion

The results of this pilot study suggest a beneficial effect of both individual face to face self-management occupational therapy program and a relaxation program on the performance of and satisfaction with desired and important activities in daily life in people with MS-related fatigue. Seventy one percent (71%) of participants in the self-management group showed clinically relevant changes in COPM performance scores three months following the program, compared to 27% of subjects in the relaxation group.

The effect of relaxation is somewhat surprising, although explicable. By using stress management techniques, people may also be more efficient in performing the scope of daily activities.[35] The

positive trend towards favoring the SMOoTh may be explained by the more practical focus on managing problem activities. Stress management may be one of the approaches within the overall self-management of fatigue.

Self-management nor relaxation was able to reduce feelings of (the impact of) fatigue. This is the first study in MS using COPM as a (primary) outcome, but most of the energy conservation programs and relaxation techniques showed a reduction of fatigue.[9,36,37] Energy conservation interventions all used a group format and were compared to wait list controls receiving no intervention. In MS, an individualized outpatient rehabilitation program including occupational therapy focusing on energy conservation did not show any changes in fatigue (impact) scores, which is in line with our findings.[38] However, a similar individual program did show improvements both in COPM and fatigue scores in people with chronic fatigue syndrome.[39] These results may suggest that group dynamics are highly important in reducing fatigue (impact) scores in people with MS, but no studies yet compared individual and group approaches.

The self-management program is based on behavior change theories, focusing on alterations in daily life activity performance (values), prioritizing, task duration, alternation between physical and mental activity etcetera. Several behavioral change techniques were used.[17] Although the individual approach was very useful to set and review personal and relevant goals and tailor-made graded tasks, the technique “comparison of behavior” with peers was not possible.[40] Using filmed peer experiences or including one or more group sessions in the program would make it possible for participants to compare their behavior with others and share strategies. Earlier work showed a decrease in fatigue impact in a multidisciplinary group-based education program not particularly focusing on fatigue (as a placebo intervention).[41] Future work could study a combination of individual and group sessions to facilitate sharing information and experiences.

Participants of the self-management group showed a significant improvement of the SF-36 pain subscale. Although the intervention did not focus on pain management, a similar occupation-based self-management approach is used in people with chronic pain.[42] Especially in chronic conditions, the

concept of Occupational Value may play a central role in coping with consequences of the disease. Occupational value encompasses three components: concrete value (the visible outcome of an occupation: finished products, improved skills or avoidance of negative consequences), symbolic value (the connotation of the occupation through which people can identify themselves within a subgroup, culture or ideology), and self-reward value (immediate reward of performance an occupation: enjoyment, getting in a flow state).[43] Within an individual approach, occupational therapists may be able to optimize not only activity performance itself, but also the perceived value of doing everyday activities.[44,45]

Limitations

In addition to the study strengths (balanced treatment groups, blinded assessors, randomized design and careful screening of eligible patients), some limitations require mentioning. The sample size was rather small, but met the requirements resulting from the a priori power calculation. This calculation was based on the primary outcome COPM which may have resulted in an overestimation of the effect on secondary outcomes. Future studies with larger samples are needed to confirm the findings.

The pacing self-management program was well tolerated in our sample. No adverse effects were reported and dropout rate was rather limited. However, subjects may have been highly motivated to participate in an intervention program because of the voluntary nature of recruitment. It is assumable that people already entered the first stage(s) of behavioral change, facilitating actual (sustained) behavioral change.[46] The time since diagnosis within the sample was quite divers (8.4 ± 5,2 years), which may imply distinct levels of coping with (consequences of) the disease and redesign of activities.[47] Conclusions may therefore not be valid for the entire MS population.

Although depression is common in people with MS and correlates with fatigue, we did not screen for depression.[48] We argue that, consistent with other studies, the behavioral approach provided here may also benefit depression, regardless of the origin, and therefore we did not want to exclude

depressed people.[49] To explore the net effects of the intervention(s) on primary fatigue, all potential causes of secondary fatigue should be excluded.[50] However, it is still unclear how all factors interact in the origin and persistence of fatigue in MS. Future research with large sample sizes may be able to reveal potential (combinations of) influences on the effects of behavioral interventions.

Participants needed to visit the center five times, which may have excluded those who are either not able to travel or were limited in spending time during office hours for this purpose. To encounter these barriers, therapist may provide the program at home, which is additionally beneficial in the possibility to perform/train/advice activities in the authentic situation. Future research may evaluate the feasibility, effectiveness and economic analysis of such home-delivered intervention.

Conclusion

Both interventions seem to be feasible approaches to improve performance of and satisfaction with desired daily activities in people with MS, with a sustained effect after three months. A trend favoring the SMOoTh was seen. Neither program was able to change fatigue (impact) or quality of life, but the self-management program resulted in more clinically meaningful improvements in performance and satisfaction with desired daily activities. Future studies with larger sample sizes are needed to confirm the results.

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Conflict of Interest Statement

The Authors declare that there is no conflict of interest.

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Table 1 Baseline characteristics of the sample

Variable	SMOOTh group	Relaxation group	p
n	17	14	
Age (mean ± SD)	37 ± 8.2	44 ± 8.9	0.023
EDSS (median, IQR)	3 (0.75)	3,5 (1.5)	0,565
COPM performance (mean ± SD)	3.9 ± 1.9	5.3 ± 2.1	0.091
COPM satisfaction (mean ± SD)	4.6 ± 1.6	5.1 ± 2.3	0.493
MFIS total score (mean ± SD)	43.8 ± 8.5	44.9 ± 14.2	0.744
CIS subjective fatigue (mean ± SD)	43.3 ± 5.9	42 ± 11.4	0.706

Table 2 Mean values and standard deviation (SD) of baseline (T0), postintervention (T1) and 3 months follow-up (T2) assessment of compliers in SmooTh (n=14) and relaxation group (n=11), including time effects and time*group effects

Variable	Group	T0		T1		T2		Time effect		Time*group effect	
		Mean	SD	Mean	SD	Mean	SD	F	p	F	p
COPM_Performance	SMOoTh	3,9	1,9	6,2	1,5	6,4	1,6	13,1	**0,00**	1,5	0,23
	Relaxation	5,3	2,1	6,3	2,0	6,3	2,1				
COPM_Satisfaction	SMOoTh	4,6	1,6	6,1	2,1	6,7	1,6	10,4	**0,00**	0,9	0,39
	Relaxation	5,1	2,3	6,0	1,9	6,3	2,1				
MFIS_Total	SMOoTh	43,5	8,5	33,9	11,4	32,3	11,1	2,5	0,10	0,4	0,27
	Relaxation	44,9	14,3	39,3	13,1	41,9	15,4				
MFIS_Physical	SMOoTh	21,2	3,8	17,2	5,2	16,6	5,4	1,8	0,19	1,4	0,26
	Relaxation	22,2	6,7	20,0	5,8	20,4	7,5				
MFIS_Cognitive	SMOoTh	17,8	6,3	14,0	7,5	12,8	6,7	1,5	0,25	0,8	0,48
	Relaxation	18,7	7,2	16,1	6,5	17,7	8,3				
MFIS_Psychosocial	SMOoTh	4,4	3,9	2,8	1,7	2,9	1,0	2,4	0,11	1,4	0,26
	Relaxation	1,5	2,0	3,2	1,7	3,8	2,4				
CIS_Total	SMOoTh	91,6	12,9	76,9	17,3	77,0	14,6	1,3	0,29	0,8	0,47
	Relaxation	83,6	25,2	78,6	20,9	74,8	32,7				
CIS_Concentration	SMOoTh	20,9	6,4	17,8	7,9	18,6	8,5	0,3	0,75	0,2	0,74
	Relaxation	18,1	9,1	17,0	6,1	17,1	8,8				
CIS_Physical activity	SMOoTh	12,2	4,1	10,5	2,9	10,6	5,5	0,2	0,82	0,9	0,44
	Relaxation	9,6	5,8	10,5	5,6	9,4	5,5				
CIS_Motivation	SMOoTh	15,2	5,8	12,8	3,8	10,6	5,5	0,7	0,50	0,1	0,95
	Relaxation	14,0	7,0	13,2	5,7	9,4	5,5				

CIS_Subjective fatigue	SMOoTh	43,3	5,9	35,8	9,4	37,9	8,0	2,5	0,10	1,1	0,34
	Relaxation	42,0	11,4	37,9	9,5	36,6	16,0				
SF36_Physical functioning	SMOoTh	63,2	20,2	67,4	23,9	66,9	16,9	1,4	0,27	0,2	0,84
	Relaxation	51,4	23,2	58,5	21,8	58,3	24,1				
SF36_Role physical funct	SMOoTh	35,3	36,5	30,9	27,3	59,4	40,0	3,0	0,07	0,4	0,70
	Relaxation	39,3	32,1	42,3	43,8	66,7	35,4				
SF36_Physical pain	SMOoTh	62,9	25,7	73,5	19,4	83,3	11,4	5,9	**0,01**	4,1	**0,03**
	Relaxation	56,3	22,8	64,5	15,0	59,2	17,2				
SF36_General health	SMOoTh	47,9	15,5	49,7	20,9	48,8	16,9	0,3	0,72	0,2	0,84
	Relaxation	45,0	20,0	41,9	17,5	47,6	14,2				
SF36_Vitality	SMOoTh	48,5	15,0	52,9	14,9	54,4	16,8	0,3	0,77	0,1	0,94
	Relaxation	46,1	16,9	52,7	12,8	48,9	16,4				
SF36_Social functioning	SMOoTh	47,8	16,1	61,8	22,7	71,9	17,4	5,9	**0,01**	1,9	0,18
	Relaxation	58,9	22,2	65,4	18,5	68,1	16,7				
SF36_Role emotional funct	SMOoTh	60,8	35,8	76,5	34,9	79,2	35,4	0,6	0,56	0,6	0,56
	Relaxation	76,2	33,2	82,1	29,2	85,2	33,8				
SF36_Mental health	SMOoTh	65,2	14,0	67,8	12,5	64,0	11,7	0,2	0,81	1,3	0,28
	Relaxation	65,4	16,3	64,9	11,4	70,7	17,8				
SF36_Health change	SMOoTh	49,1	28,7	50,0	28,3	43,8	25,9	0,9	0,43	0,1	0,93
	Relaxation	56,1	27,0	66,7	22,2	58,3	17,7				

Figure legends

Figure 1 Flow chart of the study, based on [51]

Figure 2 Clinically relevant changes in primary outcome Canadian Occupational Performance Measure (COPM)